

Kenya Verbal Autopsy Standards & Guidelines

June 2019

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ABBREVIATIONS & ACRONYMS

| CDC | - Centre for Disease control | | | |
|-------|---|--|--|--|
| CHV | - Community Health Volunteer | | | |
| CHWs | -Community health workers | | | |
| CRS | - Civil Registration Service | | | |
| CRVSS | - Civil registration and Vital Statistic System | | | |
| DHIS | - District Health Information Software | | | |
| HDC | - Health Data Collaborative | | | |
| ICD | -International Classification of disease | | | |
| KeVA | - Kenya Verbal Autopsy | | | |
| KNBS | - Kenya National Bureau of Statistics | | | |
| MCCD | -Medical Certification of cause of death | | | |
| VA | - Verbal Autopsy | | | |
| WHO | - World Health Organization | | | |
| | | | | |

Foreword

The scarcity of reliable data on the levels and causes of mortality in Kenya continues to limit efforts to build a solid evidence base for health policy, planning, and monitoring and evaluation. In settings where the majority of deaths still occur at home and where other routine data systems (e.g. civil registration, vital statistics, and medical certification of cause of death) do not function optimally, there is little chance that a death occurring away from health facilities will be recorded at all, let alone certified with a cause of death. In these settings, verbal autopsy (VA), a process recommended by the World Health Organization (WHO), can be used to allow for simple and inexpensive identification of causes of death; independently, it can also be used in research and disease-specific programmes.

The past two decades have seen a proliferation of interest, as well as research and development, in all aspects of the verbal autopsy process, including data collection systems where VA is applied (e.g. demographic surveillance sites, sample or sentinel registration systems, census or household surveys); questionnaire content and format; application to different age groups; cause-of-death assignment processes; coding and tabulation of causes of death according to ICD rules; and the vexing issue of validation.

As Kenya's systems for Civil Registration and Vital Statistics (CRVS) and medical certification of cause of death undergo parallel strengthening efforts, VA can be used to derive credible mortality data with an improved coverage. Accordingly, the health investment area of the Kenya Health Strategic Plan has guided the development of the Kenya Verbal Autopsy (KeVA 2019) Standards as a model for the application of VA throughout Kenya. Application of the KeVA 2019 Standards, and the accompanying Kenya VA Implementation Guidelines, will support all stakeholders in understanding cause of death at the community level in Kenya. It is my hope that these Standards and Guidelines will assist in addressing the challenges of under-reporting and quality of vital statistics in the county.

The KeVA 2019 Standards are an adaptation of the international WHO VA standards that are designed for all age groups, including maternal and perinatal deaths, and deaths caused by injuries. While a set of paper forms by age group shows the design of the instrument, it is recommended to use electronic data collection methods, based on the electronic format of the published instrument. It is envisaged that the KeVA 2019 Standards will be used by all stakeholders that carry out VA in Kenya, including all partners of the Health Data Collaborative (HDC).

The KeVA 2019 Standards mark the outcome of a partnership led by the Ministry of Health and an expert group of researchers, data users, and other stakeholders under the sponsorship of the World Health Organization (WHO). The Standards are intended to serve the needs of various users and producers of mortality information, including researchers, policy-makers, programme managers and evaluators. In order to make these Standards as easily and widely accessible as possible, they will be published on the MOH web site health.go.ke and in printed form, as part of a forthcoming resource kit for strengthening national vital statistics systems.

It is envisaged that the KeVA 2019 Standards, as a function of strengthening CRVS systems to establish cause of death at community level, will form the basis for informed policy formulation which will assist in the implementation of changes needed to improve quality of care. I therefore call upon all the stakeholders to continually be committed in the pursuit of an effective performance-based management system, and to play their part in the implementation of this standard at respective counties. My office will endeavor to ensure that the requisite support is provided.

Dr J Wekesa Masasabi Ag. Director General for Health MINISTRY OF HEALTH

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Finally, the Ministry would like to thank all those who we have not enumerated who were either consulted during the development and review of the standards or who in one way or another contributed to this process. Without their contributions this work would not have been possible and we are greatly indebted.

Dr. Charles M. Nzioka Ag. Director, Directorate of Health policy, Research, Monitoring & Evaluation

10 INTRODUCTION

There is global shift for real-time and accurate statistics on mortality and cause of death as an ingredient for the improvement of national and local health and population policies, for proper planning and budgeting. There is therefore a growing global momentum to strengthen civil registration and vital statistics (CRVS) systems especially in low-income countries, given the dynamics of the demographic and health transitions occur- ring around the world and the need to document progress towards the Sustainable Development Goals.

The World Health Organization (WHO) sets the international standards for monitoring levels and causes of death, including its endorsement in 1948 of the international classification of diseases and injuries (ICD) as well as a standard medical certificate of cause of death with rules for classifying the causes of death. WHO recommends the use of the underlying cause of death, derived from medical certification of cause of death (MCCD) using a uniform set of rules, for measuring and monitoring burden of mortality. However, where routine systems for civil registration and MCCD are lacking.

WHO recommends verbal autopsy (VA) as a source of information for simple and inexpensive identification of causes of death. VA ascertains probable causes of a death based on an interview with family, relatives, or caregivers, using a questionnaire to elicit information on signs and symptoms experienced by the deceased before death and the circumstances preceding that death. To support consistent, high-quality VA implementation globally, WHO has developed international VA standards and implementation guidance. In recent years, these standards have shifted to support routine (i.e., non-research) application of VA, which requires a simplified and practical VA approach.

At 41.2%, national death registration coverage is still significantly low in Kenya, with some counties recording as low as 4.1% (KVSR 2017). Most statistics available are often biased, since they derive cause of death information only from health facilities, especially in urban settings, and they are not representative of the experience of the general population. In settings where most of deaths occur at home and where civil registration systems do not function routinely, there is little chance that deaths occurring away from health facilities will be recorded and the cause of death certified. As a result, CRVS systems are unable to generate data that is sufficiently reliable and representative for public health policy and planning purposes. Accordingly, the Ministry of Health recommends use of VA as a complement to MCCD, to provide critical vital statistics information where routine systems are otherwise lacking.

1.2Background: Death registration and cause of death in Kenya

In Kenya, civil registration is the mandate of the Ministry of Interior and Coordination of National Government, under the State Department of Immigration, Border Control and Registration of Persons. The Civil Registration Services (CRS) is mandated to register all births and deaths occurring in Kenya, and births and deaths of Kenyans occurring abroad as provided in the Births and Deaths Registration Act Cap 149 laws of Kenya. The national level department works with the sub county registration offices to register events that are notified by community-based informants who serve as a legal witness to an event. In Kenya, these legally designated informants, or local registration agents, include both health workers and assistant chiefs of sub-locations.

Deaths that take place in health facilities are notified by the health facilities using Form D1, which includes the medical certificate of cause of death. With some exceptions, deaths at home or in the community are notified using Form D2, which is filled by the local registration agent, usually the assistant chief. In the event of a death in a family/community, a member may:

- 1. Report to the assistant chief seeking notification of death. The assistant chief may notify the death using Form D2 or refer the family member(s) to the police for further investigation; or
- 2. Report to a Community Health Volunteer (CHV) who informs the assistant chief for notification using Form D2; or
- 3. Report to the police who in turn take the body to the mortuary for preservation and investigation of the possible cause of death. Once certified the death is notified by the pathologist using Form D1 and the information is registered with the CRS. Alternatively, if no inquest exists, the family may obtain an affidavit for a natural cause of death from the commissioner of oaths. The death is then notified by the assistant chief using Form D2.

As noted above, Form D1 includes the medical certificate of cause of death, which is completed by the health facility. The deaths on Form D2 are generally not medically certified; the assistant chief, a lay person who is not trained in ascertaining cause of death, selects the most probable cause of death among a list of 14 natural causes. For accidents, the proper authority, such as the coroner, selects one among the seven unnatural causes listed.

While CRS and MOH collect the cause of death information from both Forms D1 and D2, inadequate training for completing Form D1 and lack of medical knowledge for completing Form D2, in addition to a number of insufficiencies in the data aggregation and ICD coding processes, yield cause of death data that is not useful for planning and monitoring purposes. Kenya has undertaken a number of initiatives to strengthen their system for MCCD and ICD coding. However, given that an estimated 40-50% (BSAR, 2013) of registered deaths take place outside of a health facility, VA is necessary to supplement statistics on cause of death for the foreseeable future.

It is therefore recommended that VA be completed for at least a sample of community deaths for which a D2 is completed.

To standardize the application of VA in the various settings in which it is used, and to support expanded use of VA in Kenya, the Ministry of Health has developed the Kenya Verbal Autopsy (KeVA) 2019 Standards. Their application will contribute to a more robust, comparable, and high-quality pool of mortality data that can support "evidence-based" planning, monitoring, and priority setting, both at national and subnational levels.

1.2Goal of the KeVA 2019 Standards

The overall goal of KeVA 2019 Standards is to enhance the resilience of Kenya's health systems through informed policy development for universal health care. The KeVA 2019 Standards can support this goal by ensuring better design, planning, piloting, demonstration, integration and implementation of VA as a system-wide intervention to improve population-level estimates for causes of death.

1.3 Purpose and content of the KeVA 2019 Standards

The KeVA 2019 Standards provide an overview of the structure, content, and scientific basis for the recommended model of VA application in Kenya. Their application will contribute to a more robust, comparable, and high-quality pool of mortality data that can support "evidence-based" planning, monitoring, and priority setting, both at national and subnational levels. The Standards include:

- A description of VA uses
- An orientation to the standard VA instrument, which includes:
 - Age-specific questionnaires in both electronic and paper forms;
 - o Cause of death list for VA with associated ICD-10/11 codes; and
 - Cause of death assignment resources;
- Description of the legal and ethical basis for VA;
- Recommendations for local adaptation of VA methods; and
- Description of the recommended infrastructure to support VA implementation, including:
 - The data collection and management platform;
 - Hardware and software requirements; and
 - o Integration with a system for reporting community-based deaths; and
- Recommendations on the use of VA-generated data.

An accompanying set of country-specific guidelines is available upon request to support VA implementation in Kenya. Additional information is available from WHO and the WHO Verbal Autopsy Reference Group at https://www.who.int/healthinfo/statistics/verbalautopsystandards/en/.

Collectively, this guidance provides recommended strategies, procedures, and tools for implementing the KeVA 2019 standards and includes materials to support planning, system design, and set-up; data collection; supervisor and interviewer training; quality control; and analysis, interpretation, and use of VA data.

2.0 USES AND USERS OF VA DATA

2.1 General applications of VA

VA was originally developed for research purposes, to provide information on causes of death in longitudinal population studies, intervention research, or epidemiologic studies. However, its use and application has expanded in recent years, and common VA applications now include:

- 1. As the only feasible alternative to comprehensive medical certification of deaths, providing information used in policy, planning, priority setting and benchmarking, for settings with no or unreliable vital registration systems;
- 2. As a source of supplementary information for determining cause of death in hospital settings where there is uncertainty as to the cause of death for a patient, where a patient is brought to the hospital after the death has taken place (e.g., "Dead on Arrival" or "Brought in Dead"), or as an aid to physicians who need to certify a death for a patient they have not seen; and
- 3. As a tool to validate and adjust causes of death reported within a country's civil registration systems.

2.2Application of VA in Kenya

In Kenya, VA has been used in the research context through a series of surveillance systems that were designed to respond to the lack of capacity to medically certify cause of death. For the last two decades, multiple Health and Demographic Surveillance System (HDSS) sites, including in Nairobi, Kilifi, Kisumu, and Homa Bay, have used VA to understand mortality patterns in their populations under surveillance and to provide critical information on mortality, especially for major causes of deaths such as malaria, TB, HIV, and for reproductive health challenges.

Various program-specific surveillance efforts in Kenya have also used VA as a tool to better understand patterns of death. To list a few: UNICEF has supported VA for better understanding maternal mortality patterns; KEMRI/CDC has used VA, along with minimally invasive tissue sampling (MITS) as a gold-standard method to validate cause of death findings, as part of the Bill and Melinda Gates Foundation's Child Health and Mortality Prevention Surveillance (CHAMPS) program in the Kisumu area; and VA has been used to measure all-cause mortality in support of a WHO- and GAVI-sponsored RTS,S Malaria Vaccine Implementation Pilot in Western Kenya.

Shifting from research and surveillance applications, the MOH and CRS in Homa Bay have tested community-based VA implementation in Homa Bay County through the Homa Bay CRVS

Improvement Project, with support from the Kenya Medical Research Institution (KEMRI)/ U.S. Centers for Disease Control and Prevention (CDC), the CDC's National Center for Health Statistics, and the Bloomberg Data for Health Initiative.

Implementation testing began with all community health units in Rachuonyo North Sub-county in November, 2016. Testing has shown to be that the community-based application of VA is acceptable and feasible, as demonstrated by a low refusal rate among respondents, a high VA completion rate among eligible, reported deaths, and a high percentage of VAs being successfully analyzed by the automated software. However, it should be noted that such routine implementation of community-based VA is nascent, and guidance and standards for integrating VA processes into Kenya's CRVS system are still emerging. Accordingly, future implementation and scale up should be based on flexible platforms that are readily able to adapt to evolving tools, resources, and support structures (HBMOH, 2019).

2.3 Integration of Kenyan VA and CRVS processes

The basis of VA within the official CRVS processes of death notification and registration is a basic principle of routine VA application; all deaths should be officially notified to civil registration authorities before a VA is conducted. As noted above and as depicted in Figure 1 below, official notification of community deaths through the KeVA Standards can occur in one of three ways:

- 1. Via report to the assistant chief, seeking notification of death. The assistant chief may notify the death using Form D2 or refer the family member(s) to the police for further investigation; or
- 2. Via report to a Community Health Volunteer (CHV), who informs the assistant chief for notification using Form D2; or
- 3. Via report to the police who in turn take the body to the mortuary for preservation and investigation of the possible cause of death. Once certified the death is notified by the pathologist using Form D1, and the information is registered with the CRS. Alternatively, if no inquest exists, the family may obtain an affidavit for a natural cause of death from the commissioner of oaths. The death is then notified by the assistant chief using Form D2.

The assistant chief submits Forms D2 to the CRS via a CRS server. To supplement the available cause of death information of Form D2 for national vital statistics information, it is recommended that VA be conducted on at least a sample of deaths for which a Form D2 was completed. Accordingly, after harmonizing their list of deaths with the assistant chief, the CHV informs their Community Health Extension Worker (CHEW) supervisor of the relevant community deaths, and the CHEW schedules a VA session with the family. Unique Personal Identifiers (UPIs) and/or Form D2 serial numbers can be used to link the relevant Form D2 data elements from the CRS server to the VA automated questionnaire via the MOH VA database. Once the CHEW completes the VA, the information is relayed to the MOH VA database, which also captures the probable cause of death.

The MOH VA database and the comprehensive CRD databases shall be interoperable and should be sharable amongst the Integrated Population Registration System (IPRS), Kenya National Bureau of Statistics (KNBS), KEMRI and other stakeholders as needed.

It should be noted that the specific manner in which VA is applied determines the way in which the resulting cause of death information should be used (e.g., for legal, administrative, and/or statistical purposes). The WHO 2016 VA instrument was designed to support data collection and cause of death assignment in the absence of physicians. In such applications, the context and method of information gathering to assign cause of death from VA is different from the medical certification of cause of death by a physician; with VA, the certainty of the cause of death is generally lower, and some causes of death cannot be ascertained reliably. Thus, while the probable COD from such applications of VA is a valuable statistical product, it should not be considered legally valid at the individual level.



Figure 1: Integration of VA within Kenya's CRVS system

2.4 Users of data generated using VA

Researchers and epidemiologists use VA data to estimate the burden of disease by comparison of local and national differences in mortality ratios, monitoring of trends over time, and evaluation of interventions and health programs. While the design of data collection for these uses is program specific, information compiled can also be informative for purposes beyond the original research effort.

National and sub-national decision-makers and health system managers require comprehensive cause of death data for planning, budgeting and resource allocation and for monitoring and reporting to donors. While it is best that this information be collected from a routine, standardized system, the absence of such systems (e.g., well-functioning civil registration and MCCD systems) should not restrict the compilation and use of information available from alternative (e.g., research) sources. In order that the general population might benefit from all available information, HDSS sites and other surveillance programs should follow the KeVA standards, and resulting data should be compiled. The MOH therefore recommends a regular meeting (e.g., quarterly) to convene relevant stakeholders to jointly review VA practices and collected vital statistics and cause of death data and to determine if and how findings may be extrapolated to the national level and made available for broader public health decision making.

3.0 KENYA VERBAL AUTOPSY 2019 INSTRUMENT

The KeVA 2019 instrument includes the following standard components:

- 1. VA data collection tool for three age groups (under four weeks; four weeks through 11 years; and 12 years and above);
- 2. A cause-of-death list for VA mapped according to the ICD-10/11; and
- 3. Diagnostic criteria for assigning causes of death.

Each of these components is described in more detail below.

3.1 Standard VA data collection tool

The KeVA 2019 data collection tool comprises three age-specific questionnaires that have been adapted from the WHO 2016 VA standards, following implementation testing in Homa Bay County. The tool is designed for electronic data collection and contains sections common to all ages, as well as specific sections appropriate to the age and sex of the deceased. Within sections and subgroups of the instrument, skip patterns are driven by the age and sex of the deceased and whether it was a maternal or a perinatal death. The same age categories may apply to those interested only in particular age categories of death, such as perinatal, maternal, child or adult deaths. In this case, the

relevant subset of questions can be extracted from the list of indicators of the 2019 KeVA instrument.

Where data are captured electronically, the embedded skip patterns will ensure that only the relevant subset of questions is applied for different age group. Where interviews are conducted for all age categories of deaths, it is recommended that data be captured electronically to ensure correct functioning of the embedded skip patterns.

The KeVA 2019 questionnaire is structured into six sections as follows:

Section 1 contains key identifying and socio-demographic information and data fields necessary for the management of completed forms. This section also includes information related to death notification and registration to support VA and CRVS integration.

Section 2 collects information about the respondent, consent if required in certain contexts and time the VA interview was started.

Section 3 collects information about the prevalence of malaria and HIV in the area where the deceased lived and whether death occurred in rainy or dry season. This information is essential for selecting the appropriate algorithm used by some software for assigning the cause of death. In most settings this information will be pre-completed by study staff or supervisors.

Section 4 provides essential information for assigning the cause of death due to accidental and intentional injuries.

Section 5 contains several sub-sections that collect information required for assigning causes of death.

5a) includes questions to determine the duration of the final illness;

5b) includes questions on the history of known past or present diseases that would give clues to the causes of death;

- 5c) contains symptoms and sings that are relevant for all deaths;
- 5d) contains symptoms and signs specific to maternal deaths;
- 5e) contains symptoms and sings relevant for neonatal and child deaths;

5f) contains questions about the utilization of health services and contextual factors;

5g) includes fields for recording information from a medical certificate of cause of death, if this information is available (e.g., if VAs were also conducted on hospital deaths).

Section 6 is an open narrative text field that allows for comments and adding additional information for quality control and for providing additional information for physician assessment of the cause of death if needed.

For feasibility, electronic data collection is recommended for routine applications of VA in Kenya. Tools to support electronic data collection using Open Data Kit (ODK)1, along with paper questionnaires for each of the three age groups, are available and are further described in Section 4.

3.2 Standard cause of death list

The KeVA 2019 standard list of causes of death for VA has been adopted from the WHO 2016 VA list, which includes causes of death of public health importance that 1) can be ascertained with reasonable accuracy from a well-administered VA interview and 2) are amenable to automated assignment of cause of death using analytical software. The list is presented in Appendix 1 and includes a mapping of the causes to corresponding ICD-10/11 codes. The use of a minimum set of causes of death facilitates comparison of data from VA at sub-national, national, and international levels. Additional information about the cause selection process is available in the WHO VA standards documentation2.

3.3 Standard diagnostic criteria for assigning causes of death

Adapted from the WHO 2016 VA instrument, the KeVA 2019 questionnaire is specifically developed to ascertain cause of death through automated methods. The KeVA standards recommend the use of automated methods for cause of death identification to facilitate routine application, as a more cost-effective and feasible alternative to physician-coded VA. While there is not currently a single, standard recommended method for assigning cause of death from VA, and currently available methods are rapidly evolving, where VA results are used for official statistics, a single cause assignment method that best suits user needs should be selected a priori. The various automated cause of death assignment methods are described on the WHO VA website.2

4.0APPLICATIONS AND IMPLEMENTATION OF THE KEVA 2019 INSTRUMENT

This section provides recommendations to support standardized application and implementation of the KeVA 2019 instrument, in alignment with the 2016 WHO VA standards. The section is divided into three subsections on application of the data collection tool, VA system and infrastructure, and analysis and use of VA data.

4.1 Application of the VA data collection tool

The KeVA 2019 data collection tool contains both common sections and specific sections appropriate to both the age and sex of the deceased. NOTE: Age, sex, information about the season,

¹ https://opendatakit.org/

² https://www.who.int/healthinfo/statistics/verbalautopsystandards/en/

the local prevalence of HIV and malaria, section 3, 4, and 5 are essential information for the analytical software that assigns causes of death. No questions may be removed from these sections, and the numbering of the questions must remain unchanged. Questions added locally will not be used by the currently available analytical software. Other components of the personal information and the respondent can be adjusted to the local legal requirements. While the open narrative is not currently used by the analytical software in its written form, it is a critical component for physician coding of VA (PCVA) for cause of death assignment or validation purposes. The VA standards can change based on any changes in the legal framework in the country. The KeVA 2019 instrument instituted select amendments on the 2016 WHO VA questionnaires; these amendments are described in Appendix 2.

4.2 Technical description and use of the Table of Indicators (ODK XLS)

The 2019 KeVA data collection tool is designed for use with an electronic data collection platform. Excel- and XML-files with the required instructions and electronic programming are posted on the MOH website at: http://www.health.go.ke/resources/guidelines-and-manuals/. The Excel file includes a Table of Indicators of the 2019 KeVA instrument containing all indicators for all age groups with relevant details describing each indicator. The questions are grouped by sections, as is described above, and are programmed with embedded skip patterns that automatically navigate the various combinations of age-, sex-, maternal- and perinatal-specific indicators within a single, comprehensive instrument. Questions, hints, skip instructions, and other details, including the variable ID, the data type, threshold values to categorize numeric values, notes for translators and interviewers, are defined for each indicator in the "survey" sheet; a brief description of the columns of this sheet is provided in Table 1 below. Selectable values are listed in the "choices" sheet.

| type | Describes the type of question, e.g. yes/no, multiple choice, integer, continuous or text. | |
|----------------|--|--|
| name | Language independent identifier of the question. Describes | |
| | the variable naming that will represent the column head | |
| | names in the database. | |
| label::English | Describes how a question will appear on the tablet i.e | |
| | the specified language, when the language is selected during | |
| | the interview. | |
| hint::English | Hints give a little more information and description of a | |
| | question to aid the interviewer on how to ask/answer the | |
| | question. | |
| relevant | Conditions for check the applicability of a question. | |

| Table 1: | Quick | overview | of the | columns | in the | sheet | "survey" |
|----------|-------|----------|--------|---------|--------|-------|----------|
|----------|-------|----------|--------|---------|--------|-------|----------|

| required | Determines whether the question must be answered, if asked. | | | |
|-------------|---|--|--|--|
| appearance | Describes how the question(s) will appear in the tablets/phones. | | | |
| calculation | Specifies formula using the values of preceding questions. It is used to determine the age group default. | | | |
| constraint | Add restriction (s) to the data fields. | | | |
| constraint | Used to display a message when the restriction/constraint is | | | |
| message | violated. | | | |

4.2.1 Printable questionnaires

A printable/paper version of the KeVA 2019 standard data collection tool, in the form of three agespecific (under four weeks; 4weeks-11 years, 12 years and above) questionnaires, is also available in both English and Swahili languages. These questionnaires demonstrate the layout of the questions and can be used to support training and orientation to the VA data collection tool; they can also be used as a backup method of data collection if necessary. If the printable/paper version is used for data collection, responses must be entered into a database that retains the variable IDs as defined in the Table of Indicators to facilitate the use of automated analytical software for the assignment of of The found cause death. following questionnaires can be at http://www.health.go.ke/resources/guidelines-and-manuals/:

VA questionnaire 1: death of a child aged under four weeks

Sample VA questionnaire 1 is designed to determine causes of early neonatal deaths, late neonatal deaths, perinatal deaths and stillbirths. In addition to "signs and symptoms noted during the final illness" list, the questionnaire contains questions concerning the history of the pregnancy, delivery, the condition of the baby soon after birth, and the mother's health and contextual factors.

VA questionnaire 2: death of a child aged four weeks through 11 years

Sample VA questionnaire 2 is designed to ascertain the major causes of post- neonatal child mortality (i.e. starting from the fourth week of life), as well as causes of death that may be seen through 11 years of age. Questionnaire 2 includes all the common sections and questions described above, as well as questions related to causes of death in children aged four weeks to 11 months. The skip pattern is indicated by references to the next question.

VA questionnaire 3: death of a person aged 12 years and above

Sample VA questionnaire 3 is designed to identify all major causes of death among adolescents and adults (i.e. starting at age 12), including deaths related to pregnancy and childbirth. Questionnaire 3 includes a section for all female deaths, in addition to the above-mentioned common sections and questions.

4.2.2 Guidelines on augmentation, local adaptation, and translation

The KeVA 2019 data collection tool by design allows for evolution and local adaptation of the instrument. The KeVA 2019 instrument instituted select amendments on the 2016 WHO VA questionnaires; these amendments are described in Appendix 2 and include recommendations on the use of Unique Personal Identifiers (UPIs)/serial numbers to facilitate integration of data from VA into civil registration database.

However, for any changes made to the KeVA 2019 data collection tool, it is critical to note that changes may affect the comparability of the resulting data. Such modifications that may affect the comparability of results include:

Changing or adding to response categories in the checklist of "signs and symptoms noted during the final illness;"

Adding new questions about diseases of particular interest (e.g. malaria, HIV/AIDS, diarrhoeal disease).

Examples of modifications that are unlikely to affect the comparability of results include:

Adding questions or sections about household characteristics or environmental or behavioural risk factors;

Adding or changing questions about usage of a particular health context.

Changes may also compromise the usability of analytical software for assigning cause of death. Specifically, age, sex, information about the season, the local prevalence of HIV and malaria, and questions in sections 3, 4, and 5 are essential information for the analytical software that assigns causes of death. No questions may be removed from these sections, and the numbering of the questions must remain unchanged.

Changes to the KeVA 2019 data collection tool should only be undertaken when there is a complete understanding of the purpose of the VA instrument and technical knowledge of the data collection platform (e.g., Open Data Kit); all changes should be fully tested to ensure that the desired changes have been applied correctly and that implemented changes have not yielded any unintended consequences. It should also be noted that questions added locally will not be used by the analytical software.

If modifications are necessary for the KeVA 2019, they should be carefully documented and distinguished from the 2019 standard sections and indicators. In general, only changes to the wording of existing indicators for the purposes of enhancing local comprehension or ensuring cultural acceptability of questions are recommended. The definitions in the KeVA 2019 instrument may provide some guidance about the meaning that needs to be preserved in such changes.

Any need for modification KeVA 2019 should be shared with National Office together with the rationale for modification. The reporting of modifications made to the National Office will inform future revisions of this instrument.

Adding or changing questions: It is acknowledged that there may be a desire to expand the data collection tool to address locally relevant conditions. Modifications may be necessary if there are emerging or locally important causes of death for which there are no questions in the current data collection tool. However, the addition of new questions about particular diseases of interest may bias results if a disproportionate amount of information about only one condition is available in the cause of death assignment process. The impact of augmentation on the total length of the questionnaire should also be considered when adding questions. Advice may be sought from the National Office for making such modifications.

With regard to changes to the existing questions, in general, only changes to the wording of existing indicators for the purposes of enhancing local comprehension or ensuring cultural acceptability of questions are to be undertaken. The definitions in the VA Field Interviewer Manual provide guidance about the intended meaning of each question. It is acknowledged that some teams may wish to alter the order of the questionnaire elements. While a sequence change may not directly affect the comparability or usability of analytical software, it should be noted that the provided sequence is a result of expert consultation and empirical review; changing the order may cause an unknown degree of variability in results. Furthermore, as the questionnaire structure includes a complex and dynamic series of skip patterns, the process to relocate questionnaire items requires utmost care to ensure that the correct pathways remain and unintended consequences in questionnaire flow do note emerge. For these reasons, it is recommended that changes to the question sequence be avoided.

Translation: The KeVA instrument should be translated and administered in the language of the The electronic English and Swahili translation available respondent. is at http://www.health.go.ke/resources/guidelines-and-manuals/. The specific terminology used for indicators and interviewer and translator notes (in the Table of Indicators) aims to convey the highest level of clarity and conciseness about the intent of a question. Indicators, instructions and data collection tools need to be translated or adapted according to the language of the interviewers and to ensure local understanding; local adaptation of terminology may be required even use (even if administered in British English and Swahili). The notes in the Table of Indicators are intended to guide translators in the translation process; both the questions in the instrument and the hints in the Table of Indicators should be translated, as the notes will also provide guidance to interviewers. Translators may need to adapt the wording of the questions to the local terminology used in the locations where interviews will be conducted. For quality assurance, a second translator should carry out a back-translation to English. Cognitive testing to ensure that respondents understand the questions as they are intended, after translation has been completed, is also recommended. Such

testing was conducted in Western Kenya in 2013 with a Dholuo translation of an earlier version of the WHO VA instrument; a comprehensive report is available for reference.³

4.3 VA system and infrastructure

All KeVA applications should be structured in a way that 1) contributes to a national mortality profile and 2) synergizes with and links to other existing national health information mechanisms, including civil registration services, disease control programmes, and other health initiatives. Specifically, community-based VA can support CRS services through universal death reporting and notification, and it can support universal health care by providing more complete information on cause of death for health planning and evaluation. While specific system designs will vary, all KeVA applications should aim to support these principal functions. A cornerstone for such integration is a business process design that enables all relevant stakeholders across various levels to access the appropriate information to support their processes. In other words, data collection should complement existing personnel structures, and data collected should be stored in a centralized location and in an accessible manner that that facilitates the necessary queries.

A description of system-level considerations for integrating community-based VA into CRVS systems is available elsewhere, covering broadly the domains of governance, design, operations, human resources, financing, infrastructure, logistics, information technologies and data quality assurance.⁴ Below are specific considerations and recommendations for the Kenya context.

4.3.1 Governance

KeVA applications should be undertaken in coordination with key stakeholders at both the national and local levels. At the national level, the Mortality Statistics Subcommittee, which is led by the CRVS Unit of the Kenya Ministry of Health, is responsible for coordinating VA in Kenya. KeVA plans and results should be shared with this Subcommittee. Key stakeholders at the local level will vary, but they are likely to include the CRS county and/or subcounty registrars, assistant chiefs, MOH lead officers, Community Health Unit and Health Management Team personnel, and leads of programs involving mortality surveillance (e.g., maternal death surveillance and response). KeVA applications should be planned and coordinated with these stakeholders.

³ Scanlon P, Nichols EK. Results of the cognitive interviewing study of the 2012 WHO verbal autopsy instrument in Nyanza Province, Kenya. Hyattsville: National Center for Health Statistics, Centers for Disease Control and Prevention; 2013.

⁴ Don de Savigny, Ian Riley, Daniel Chandramohan, Frank Odhiambo, Erin Nichols, Sam Notzon, Carla AbouZahr, Raj Mitra, Daniel Cobos Muñoz, Sonja Firth, Nicolas Maire, Osman Sankoh, Gay Bronson, Philip Setel, Peter Byass, Robert Jakob, Ties Boerma & Alan D. Lopez (2017) Integrating community-based verbal autopsy into civil registration and vital statistics (CRVS): system-level considerations, Global Health Action, 10:1, DOI: 10.1080/16549716.2017.1272882

4.3.2Design and operations

Process map example: A critical early step in designing KeVA applications is to prepare a detailed process map that describes the process flow for the application and specifically details the integration of VA with CRS processes. A general flow is described in section 2.3 and Figure 1 above. A specific process map example is provided in Appendix 3. The process for reported deaths to be officially notified to civil registration authorities should be clearly defined in the process map.

Sampling: A broad goal of KeVA is to estimate the cause of death in out-of-facility deaths where there is no medical certification. At a national level, a representative sample of all deaths or in a selection of registration administrative areas (e.g., Wards) will yield statistically reliable results with cost savings. However, specific VA applications may have more targeted surveillance or monitoring goals. Given Kenya's decentralized health system, there may be an interest or need to target all out-of-facility deaths in a particular area for VA. Where funds are limited, a phased approach to implementation, involving a representative and/or strategic selection of health areas that are also meaningful to both registration and statistical authorities (e.g., Wards) is recommended.

Death reporting and notification: Guidelines provided in Section 2.3 describe an active means through Kenya's Community Health Unit (CHU) structure for identifying deaths via household visitation and ensuring that all identified deaths are officially notified to civil registration authorities. Death reporting is a core function of Community Health Volunteers. Accordingly, KeVA applications should coordinate with and support the relevant CHU structures and avoid compromising CHU operations by overtasking or tasking outside of CHU protocols. It should be noted that as death notification is an official process of Kenya's civil registration system, verification of a death event must be completed by a designated registration official, which includes assistant chiefs, community health extension workers, and other government health workers, but *not* community health volunteers.

A standard, electronic system for reporting community deaths is currently under consideration (e.g., via SMS). Until such a system is routinely available, for death reporting and notification, partners planning KeVA applications should capture the data elements required for death notification in Kenya; an example death reporting form is included in Appendix 4 for reference.

Informed consent: KeVA standards call for informed consent to be obtained from the respondent before a VA interview is completed. The consent process should be guided and documented using a standard consent form that includes the following elements at minimum:

- purpose of the VA;
- description of the VA process;
- what is required of the respondent, including time commitment;
- benefits and risks of participating;
- actions to be taken in the case of adverse events; and

• contact information for a primary point of contact in case the respondent has questions.

An example consent form is provided in Appendix 5. Documentation of consent via the electronic data collection platform is acceptable.

VA interview: Not including introductions and consent procedures, the VA interview take approximately 30-40 minutes, depending on the specific age, sex, and conditions of the decedent. VA interviews should be conducted as soon as practically possible after the report of the event is received, but after any culturally prescribed mourning period has passed. The mourning period in Kenya varies from one ethnic community and/or religion to another and should be determined in consultation with local authorities and stakeholders. However, 30-40 days after the death can be used as a general guideline. Interviews should be conducted no more than one year after the death, as recalls of more than one year should be interpreted with caution.

The respondent who provides information about the deceased and allows the interviewer to complete the VA questionnaire should be the primary caregiver (usually a family member) who was with the deceased in the period leading to death or a witness to a sudden death or accident. This individual is likely to provide the most reliable and accurate account of the signs and symptoms of importance. It is not uncommon for a VA respondent to require assistance from other household or family members in answering the VA questions. However, the verbal autopsy interviews should be conducted in privacy, in a safe and comfortable space.

Assigning cause of death: As a more cost-effective and feasible alternative to physician-coded VA, the KeVA 2019 instrument was specifically developed to ascertain cause of death through automated methods. The use of automated VA cause of death assignment methods also ensures that causes of death are determined in a standard fashion, removing the variability inherent with physician coding of VA.

Analytical software tools compatible with the KeVA 2019 instrument for cause of death assignment without the use of physicians include InterVA (University Umea)⁵, SmartVA (PHMRC/IHME)⁶ and InsilicoVA (University of Washington)⁷. The intended possible use of these software will allow to assess both against the same database of indicators and contribute to further development of this VA instrument as well as of the software.

Where VA results are used for official statistics, a single cause assignment method that best suits user needs should be selected *a priori*. KeVA standards recommend the use of InterVA or InSilicoVA using the InterVA probability matrix due to the WHO standards-based composition of the corresponding COD list and the inclusion of specific maternal causes in the COD list. The use of

⁵ http://www.interva.net/

⁶ https://github.com/ihmeuw/SmartVA-Analyze; http://www.healthdata.org/verbalautopsy/tools;

⁷ http://openva.net/

more than one cause assignment method, particularly including independent physician review, allows for quality control and the investigation and characterization of sources of variation among COD diagnoses. Resulting knowledge can help focus efforts to standardize COD analysis and improve the performance of automated algorithms; however, as noted above, for official statistics, a single method should be used.

Where physicians assess the cause of death, WHO guidelines for PCVA should be followed.

4.3 Human resources

Cadres: Basing VA applications within Kenya's CHU structure will minimize the need for new cadres of personnel. As previously noted, death reporting is a current function of CHVs, who provide a recommended cadre for identifying and reporting deaths. Given their training and familiarity with the community setting, CHEWs are ideal candidates to serve as VA interviewers. However, other cadres of interviewers, such as mortality surveillance officers, could also be considered. Interviewers involved in the application of VA should have the following minimum qualifications:

- i. Have completed at least secondary school and have good working knowledge in the relevant local language(s);
- ii. Be acceptable to the local community; where possible, selected by the local community;
- iii. Have good training in conducting VA interviews and know very well the content and uses of the VA instrument; and
- iv. If the interviewer is to also validate a death notification form (e.g., D2), be a government of Kenya employee designated to serve as a registration agent.

Supervisors should be proficient with all processes of the VA system and should be assigned with a direct line of supervision over designated VA interviewers and associated community death reporters.

The table below is adapted from de Savigny et. al. and provides suggestions for human resources cadres needed for a VA system in Kenya. The number of informants for death reporting is consistent with Kenya's CHU guidelines for one CHV per 100 households. As a low frequency of deaths in an interviewer's catchment area is expected, interviewer work will likely not be full time. An alternative approach would be to assign broader catchment areas for a fewer number of interviewers who are deployed full time for mortality surveillance services. Regardless of arrangement, interviewers should be given enough time to prepare and carry out VA interviews, and it is proposed that each VA interviewer conduct at least two to three VA interviews per month to retain their proficiency.

| Cadre | Number/1,000,000 Level | |
|-------|------------------------|--|
| | population (for 9,000 | |
| | deaths per year, where | |

Table 2. Suggestions for human resource cadres needed to operate VA in a CRVS system, adapted for Kenya from de Savigny, et. al.

| | crude death rate = 9 per | | |
|---------------------------|-----------------------------|------------------------------|--|
| | 1,000) | | |
| Community key informants | at least 1,000 | Unpaid or minimally paid | |
| or community health | (or 1 per 1,000 population) | volunteer, part time | |
| volunteers (CHVs) for | | | |
| death reporting | | | |
| VA interviewers | 250 | Paid, part time or full time | |
| VA regional supervisors | 25 | Paid, part time | |
| VA physician coders or | 6 | Paid, per event, part time | |
| signers (optional) | | | |
| VA IT, logistics and help | 2 per country (MOH) | Paid, full or part time | |
| desk | | | |
| VA analyst | 1 per country (MOH) | Paid, full or part time | |
| VA national coordinator | 1 per country (MOH) | Paid, part time | |

Job descriptions, training plans, and training materials must be developed for the new functions of these cadres. Examples are being compiled and will be available upon request.

Training: The goal of training is to produce a competent survey implementation team with appropriate supervisory structures. VA experts associated with the various VA applications already underway in Kenya, e.g., the CDC/KEMRI Field Research Station and other HDSS platforms, can be consulted for training support. More detailed training resources, including an interviewer guide that explains the meaning and importance of each indicator and how to ask each question, are available on the WHO and MOH websites. General training parameters are described below.

Two levels of training are to be conducted for VA interviewers. First, a training of trainers (ToTs) who are later used to train and possibly supervise the survey implementation team. Interviewers should be trained on using the instrument and on conducting interviews with persons who may still be in mourning and may become upset during the interview. For new interviewers, classroom training is expected to take approximately 5 days with an additional 3-5 days of field practice. Below is a brief summary of key points included in VA interviewer training:

- i. Orientation to the specific VA application/project;
- ii. Basic interview techniques, ethics, and confidentiality;
- iii. Death identification, reporting, and notification;
- iv. Identification of the respondents and building rapport;
- v. Understanding and filling the KeVa 2019 instrument;
- vi. Use of electronic data collection devices (if applicable);
- vii. Role play of introductions and consent;
- viii. Mock interviews for different age groups of the deceased (e.g., maternal, perinatal, child, adult);

- ix. Self care, compassionate interviewing, and grief management; and
- x. Field practice (at least five supervised VA interviews are recommended to build sufficient VA interviewer skills).

Given the vast numbers of community-based death reporters (e.g., CHVs) who are likely to be involved in a KeVA application, a ToT-style training is recommended for these functions. If the death reporters are in some way assigned to the VA interviewers, the VA interviewer training can include this topic, and the interviewers can subsequently roll out training to their assigned death reporters. The death identification and reporting roll out training can be expected to be completed in 1-2 hours, and therefore, for cost savings, can likely be tacked on to another event for which the death reporters are convened.

Refresher trainings should be provided for interviewers every 6-12 months, or more frequently if significant problems are identified during routine supervision and/or during data quality reviews. Given the steady turn-over of staff within Kenya's CHU structure, a full training for new interviewers is likely to be needed once a year.

4.3.4Financing

Experience from the community-based VA demonstration in Homa Bay County, together with emerging findings from the application of a CRVS VA costing and budgeting tool,⁸ has provided insight on the expected costs for such VA applications. Costs should be factored for the following activities/expenses:

- Start-up activities, including initial trainings, sensitization meetings, and planning workshops;
- Governance activities, including workshops/trainings for county officers and project management staff and coordination meetings;
- Recurrent training and workshops, including transportation, per diem, venue, and facilitation fees for recurrent trainings and workshops, such as interviewer and death reporting trainings and analysis/results review workshops;
- Program management, including full- or part-time salary and/or allowances for staff involved in VA program management;
- Supervision, including travel, accommodation, and subsistence for remote supportive supervision; and
- VA delivery and analysis, including costs for communications; maintenance; field personnel; supplies, utilities, and other recurrent operational costs; vehicles; and consultants.

An expected budget for a given KeVA application should be prepared during planning; funding plans should factor in complementary or concurrent activities, such as mortality surveillance programs, where there is a potential for coordination and cost reduction. Payment for CHU

⁸ Verbal autopsy costing and budgeting tool. https://crvsgateway.info/Verbal-autopsy-costing-and-budgeting-tool~489.

personnel, including volunteer CHV stipends, CHEW payment, and other health officer salaries should be carefully coordinated with local health leadership to complement and support the existing structures, rather than overtasking, complicating, or distracting from existing priorities. Funding gaps that cannot be covered by the annual government workplan should be discussed with the broader stakeholder group to identify opportunities for additional funding, support, or other cost saving measures.

4.3.5 Infrastructure and logistics issues

Once process maps have been drafted and personnel and IT needs have been determined, an assessment of the infrastructure needed to support the work should be completed. Opportunities to leverage synergies with existing infrastructure available to support the work (e.g., available office space and computer/IT resources) should be considered. The ministry will partnerships with mobile phone carriers, offices that can be readily used to provide support during VA implementation though pull rapid SMS and data transmission.

4.3.6 Data and information technology systems

The KeVA 2019 instrument is compatible with electronic data collection platforms and automated analytical software to assign cause of death; software is also available to integrate VA results into Kenya's health information and vital registration systems. The sections below outline the software, hardware, and technical requirements.

Data collection: Data collection for the KeVA 2019 is designed to be Computer Assisted Personal Interviewing (CAPI) with a mobile platform. The Excel- and XML-files with the electronic programming for the 2019 KeVA instrument are designed for use with the Open Data Kit (ODK) suite of tools, which support electronic data collection, data use, and data management. Additional details on the use of ODK are available online at http://xlsform.org/ and https://opendatakit.org. However, any robust electronic data collection software (e.g., KoboToolbox or REDCap), or a custom-designed program, can be programmed for data collection using this instrument, as long as all answers to all questions, assigned cause of death and method of assigning cause of death are recorded in a database. Due to the complexity of the programming, it is highly recommended that the programming of the KeVA core electronic questionnaire (Excel/XML files) be used as the base for implementation, in order to avoid programming errors.

Each interviewer and supervisor may be issued with an Android tablet or smartphone, which should be installed with the data collection application from a dedicated server. The application will provide the interfaces to conduct interviews and upload final data to the server. Where the cadre of interviewers and supervisors are using similar mobile devices for other programs, efforts should be made to coordinate VA-related data collection with that of the other programs for cost savings and to minimize equipment loss. Staff issue with any equipment will be responsible in taking care within any laydown policies and regulations. The organization may insure the equipment for any loss or damage as part of risk management. **Data management and automated cause of death assignment:** Regardless of the data collection method (electronic or paper), answers to all questions, including the full, verbatim narrative, and the cause of death assigned to each case, should be recorded in a database with ministry warehouse/data service layer platform. The compilation of this information into a database shall facilitate quality assurance and case review, sharing results with MOH and other stakeholders, and enabling further improvements to this instrument. The database should retain the cause of death together with a variable that identifies the method of assigning the cause of death. The name of the interviewer and date, time and duration of the interview should also be retained in the database. If data are reported electronically this information can be generated automatically. If physician review is used to assign the cause or causes of death, then all assigned causes and the identity of the physician who assigned each cause should be recorded.

The selected electronic data collection software will need to link to servers, either locally or centrally, according to the data flow design outlined during business process mapping. The ministry will continue to strengthen ICT infrastructure with engagement of multi-agency on areas of servers, e-governance, data security, confidentiality and data encryption issues. Cloud-based servers, servers located at government facilities, and/or servers hosted by research collaborators may be considered. Where mobile and wireless connectivity is unreliable, provisions must be made for the mobile devices to be brought to a central location for manual download of VA data on a regular basis. In order to use the available automated cause of death assignment software, the data collected with the KeVA 2019 instrument need to be converted into the formats that can be processed by the respective software. Most questions in the VA questionnaires follow a simple yes/no pattern. However, some questions use a continuous variable to capture a time interval or a frequency. All continuous variables should be recorded as continuous variables in the database and should be categorized in a second step using a recommended threshold value according to guidance of the chosen method for assigning cause of death.

Health information systems: Through health system strengthening for Universal health coverage may want to adopt feed results into or via their digital health information infrastructure, such as OpenSRP⁹ or DHIS2¹⁰. Both can handle ODK standard instruments and have the ability to conduct batch processing and output of results. Data is output in a table format and is at any time ready for analysis. The IT systems could have dedicated customized dashboards with controlled level access for various managers and implementers.

VA data pipeline: Work is underway by the WHO VA Reference Group to develop the openVA pipeline, an interoperable pipeline system to transfer data from the ODK electronic data collection platform, through automated cause assignment, and into an electronic health information system. A version link to the demo for testing and download is available at https://www.health.gov.ke/guidelines/verbalautopsystandards. Further guidance can be provided from the National Office.

⁹ https://www.smartregister.org

¹⁰ https://www.dhis2.org/

4.3.7 Data quality assurance

Given the complex nature of a community-based VA system, quality assurance must be applied at multiple levels for the system to yield informative findings. Guidance and tools to support quality assurance throughout the VA data cycle are emerging, but standard practices for monitoring, evaluation, and quality control in field data collection apply.

VA supervision and management. Well-trained VA supervisors should be readily engaged in planning, coordination, and implementation processes to provide them with a complete understanding of the system. Data managers should follow a routine practice of data cleaning and checking, and data that does not meet the standards should be sent back to the field for call-backs, verification, and correction. Data managers should share data quality issues with VA supervisors who should remain in regular contact with death reporters and VA interviewers to provide supportive supervision, retraining, and corrective action as needed. Appendix 6 provides an example VA supervisor checklist to support such duties. Electronic VA management platforms are being developed to support data quality assurance processes; contact the National Office for more information on the status of the various VA quality assurance resources.

External validation: Methods are also emerging for providing locally relevant gold-standard data sets to assess the external validity of VA as a diagnostic tool. Physician coding of VA (PCVA) theoretically represents a direct, clinically plausible, and readily understood and directly verifiable method for ascertaining causes of death from VA. However, standardization of physician review protocols, rigorous training programs, data quality control mechanisms, and regular assessment of reliability and validity of physician cause attribution from VA are needed to assure data quality. All of these elements have resource implications for implementation in a routine program for assessment of causes of death in a population. In the interim, physician review is expected to remain a core element of VA development, and PCVA of approximately 10% of VAs conducted is recommended for quality control purposes. Standardized guidelines for PCVA are in development; contact the National Office for more information.

4.4 Tabulation, interpretation, and use of verbal autopsy-generated data

Tabulation: Once cause of death has been assigned, results should be compiled, interpreted or reviewed for plausibility, and presented to support public health decision-making. VA results are classically presented in aggregate as cause-specific mortality fractions (CSMFs), a measure of the relative frequency of different CODs in a defined population, stratified by sex and if possible, by ICD-recommended age groups: < 1 year, aged 1-4 years, and then in 5-year groups from age 5 years to 84 years, followed by a group for those aged 85 years or older. If there are insufficient cases for

this level of age disaggregation, then broad age categories should be used (e.g. neonates, under-fives, adolescents, younger adults and elderly).

Because VA draws on diagnostic procedures that differ significantly from those used by physicians in hospitals, with less clinical information available, the VA cause list includes fewer causes organized into broader groups than medical certification. The KeVA 2019 instrument is designed for use with the WHO VA standard cause list that is included in Appendix 1. This list includes ICD codes that can be used for tabulation purposes.

Interpretation:

After tabulation, VA data must be interpreted to evaluate the plausibility of the mortality data and to understand the strengths and limitations of the data. *Guidelines for Interpreting VA Data*, supported by a tool to analyse verbal autopsy data—Verbal Autopsy Interpretation, Performance and Evaluation Resource (VIPER)—have recently been developed.¹¹ The guidelines provide a five-step process for interpreting VA results, including understanding the VA population, estimating the completeness of death reporting for VA data, assessing the plausibility of the age-sex distribution of death from VA, conducting a plausibility analysis on the CSMFs from VA data, and presenting the main findings of VA data for policy action. While standard demographic patterns and expected epidemiologic trends can be referenced across these steps, a locally and temporally relevant comparator dataset is recommended. Options include:

- population statistics from the CRVS system
- cause-of-death information from medical certification of cause of death (MCCOD) or health management information systems
- cause-of-death distributions from ongoing HDSS sites
- morbidity data from hospitals that provide information on the diseases presenting at hospitals; specific mortality surveillance and program data such as from maternal/perinatal death notifications, and registries for cancers, malaria, HIV/AIDS and tuberculosis
- periodic household surveys such as Demographic and Health Surveys (DHSs) or maternal mortality surveys
- Global Burden of Disease (GBD) Compare / GHDx website for GBD data¹²

Unexplainable deviations from expected patterns in the VA data may point to weaknesses in the data. Efforts should be taken to identify sources of possible error and corrective actions applied where possible. Where data are presented with known issues, corresponding limitations should be included in accompanying text.

¹¹ https://crvsgateway.info/Implementing-verbal-autopsy~41

¹² https://vizhub.healthdata.org/gbd-compare/

VA data use and sharing: Findings should be shared and discussed regularly with program managers and stakeholders to support quality assurance, corrective action, and timely response to emerging trends of public health concern. Step 5 in the *Guidelines for Interpreting VA Data*¹³ can otherwise be referenced for recommendations on presenting VA data for various target audiences, including compiling a policy brief and visualizing data. The VA data results also will be presented/share through community dialogue days by use of chalkboard on what is actual ailing/affecting the community for action. Nonetheless, the result on VA on cause of death will be envisage to be integrated with medical certification of cause of death for statistical purpose and the results shared with CRS and KNBS for generation of National vital. statistic report. The National Office also, aims to compile all available sources of mortality data, in order to produce an overall national mortality profile and to be able to track national and international targets. The quality, completeness and accuracy of the various datasets (e.g. VA, MCCOD) must be examined and adjusted based on known biases.

VA information used for statistical purposes does not required identifiable information. Thus, where data are shared for such purposes, to protect confidentiality, the datasets should be properly deidentified and anonymized before they are shared as may apply to country laws. Personal data—in particular name, geographical information, and contact information about the respondent—should be kept separate from the epidemiologic data (e.g., reported signs and symptoms) and assigned cause of death. A common case-ID is necessary to allow linkage across the epidemiologic, narrative, and diagnostic datasets; to maintain confidentiality, an ID structure that cannot otherwise identify decedents should be used. Additional guidance for anonymizing VA datasets, following recommendations adapted from the U.S. Health Insurance Portability and Accountability Act of 1996 (HIPPA) Privacy Rule's Safe Harbor de-identification standard, is provided in Appendix 7.

VA methods are still being actively developed and the anonymized data can be used to improve the current methods. Accordingly, the National Office encourages the sharing of anonymized data with the WHO VA Reference Group and other trusted authorities to advance knowledge of this data source. Please contact the National Office for more information on the process for sharing data in this capacity.

¹³ https://crvsgateway.info/Implementing-verbal-autopsy~41

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1 Appendices

Appendix 1: 2016 cause of death list for verbal autopsy with corresponding ICD-10 codes (

This list is current as of April, 2019. Users should check the WHO website for the latest standards: https://www.who.int/healthinfo/statistics/verbalautopsystandards/en/.

2016 cause of death list for verbal autopsy with corresponding ICD-10 codes.

Column 1 contains the code for the verbal autopsy entity. Column 2 lists the related titles. Column 3 lists the ICD-10 codes that would be used if the condition labelled by column 2 were coded to ICD-10. Column 4 lists the ICD-10 categories that need to be grouped to match the content of the relevant VA entity.

| Verbal autopsy code | Verbal autopsy title | ICD-10 code (to ICD) | ICD-10 codes (from ICD) |
|------------------------|---|-----------------------------|--|
| VAs-01 Infec | tious and parasitic diseases | | |
| VAs-01.01 | Sepsis | A41 | A40-A41 |
| VAs-01.02 | Acute respiratory infection, including pneumonia | J22/J18 | J00-J22 |
| VAs-01.03 | HIV/AIDS related death | B24 | B20-B24 |
| VAs-01.04 | Diarrheal diseases | A09 | A00-A09 |
| VAs-01.05 | Malaria | B54 | B50-B54 |
| VAs-01.06 | Measles | B05 | B05 |
| VAs-01.07 | Meningitis and encephalitis | G03; G04 | A39; G00- G05 |
| VAs-01.08 | Tetanus Excludes: Neonatal tetanus VAs-10.05 | A35 (obstetrical A34) | A33-A35 |
| VAs-01.09 | Pulmonary tuberculosis | A16 | A15-A16 |
| VAs-01.10 | Pertussis | A37 | A37 |
| VAs-01.11 | Haemorrhagic fever | A99 | A92-A99 |
| VAs-01.12 | Dengue fever | A90; A91 | A90-A91 |
| VAs-01.99 | Unspecified infectious disease | B99 | A17-A19 A20-A38; A42-A89; B00-B19; B25-B49; B55-B99 |

Non-communicable diseases

Note:

This group covers all non-communicable conditions. Any infection of the systems that are listed in this section should be assigned to the suitable infectious disease category. Any maternal and perinatal condition should be assigned to the maternal and perinatal causes below.

| VAs-98 | Other and unspecified non- communicable disease Note: This group covers all non-communicable conditions that could not be assigned to another category in this section. There is a separate category for cases where the cause of death is unknown. | R99 | D55-D89; E00-E07; E15-E35; E50-E90; F00-F99; G06-G09 G10-G37; G50-G99; H00-H95; J30-J39; J47-J99; K00-K31; K35-K38 K40-K93; L00-L99; M00-M99; N00-N16; N20-N99; R00-R09 R11-R94 |
|------------|--|-----------|--|
| VAs-02 Neo | | | |
| VAs-02.01 | Oral neoplasms | C06 | C00-C06 |
| VAs-02.02 | Digestive neoplasms | C26 | C15-C26 |
| VAs-02.03 | Respiratory neoplasms | C39 | C30-C39 |
| VAs-02.04 | Breast neoplasms | C50 | C50 |
| VAS-02.04 | | C57 | C51-C58 |
| VAs-02.04 | Female reproductive neoplasms | Constants | |
| | Male reproductive neoplasms | C63 | C60-C63 |

| VAs-03.01 | Severe anaemia | D64 | D50-D64 |
|---|--|-------------------------|--|
| VAs-03.02 | Severe malnutrition | E46 | E40-E46 |
| VAs-03.03 | Diabetes mellitus | E14 | E10-E14 |
| VAs-04 Dise | eases of the circulatory system | | |
| VAs-04.01 | Acute cardiac disease | I24 (acute ischemic) | 120-125 |
| VAs-04.02 | Stroke | 164 | 160-169 |
| VAs-04.03 | Sickle cell with crisis | D57 | D57 |
| VAs-04.99 | Other and unspecified cardiac disease | 199 | 100-109 110-115 126-152 170-199 |
| | | | |
| VAs-05 Res | piratory disorders | | |
| VAs-05 Res VAs-05.01 | Chronic obstructive pulmonary disease (COPD) | J44 | J40-J44 |
| VAs-05.01 | Chronic obstructive pulmonary | J44 J45 (J46) | J40-J44 J45-J46 |
| VAs-05.01 VAs-05.02 | Chronic obstructive pulmonary disease (COPD) | 18-000 | |
| VAs-05.01 VAs-05.02 VAs-06 Gas | Chronic obstructive pulmonary disease (COPD) Asthma | 18-000 | |
| VAs-05.01 VAs-05.02 VAs-06 Gas VAs-06.01 | Chronic obstructive pulmonary disease (COPD) Asthma trointestinal disorders | J45 (J46) | J45-J46 |
| VAs-05.01 VAs-05.02 VAs-06 Gas VAs-06.01 VAs-06.02 | Chronic obstructive pulmonary disease (COPD) Asthma trointestinal disorders Acute abdomen Liver cirrhosis | J45 (J46) | J45-J46 |
| VAs-05.01 VAs-05.02 VAs-06 Gas VAs-06.01 VAs-06.02 VAs-07 Ren | Chronic obstructive pulmonary disease (COPD) Asthma trointestinal disorders Acute abdomen Liver cirrhosis | J45 (J46) | J45-J46 |
| VAs-05.01 VAs-05.02 VAs-06 Gas VAs-06.01 VAs-06.02 VAs-07 Ren VAs-07.01 | Chronic obstructive pulmonary disease (COPD) Asthma trointestinal disorders Acute abdomen Liver cirrhosis al disorders | J45 (J46) R10 K74 | J45-J46 R10 K70-K76 |

| VAs-09.01 | Ectopic pregnancy | O00 | O00 | |
|------------|--|--|---|--|
| VAs-09.02 | Abortion-related death | O06 | O03-O08 | |
| VAs-09.03 | As-09.03 Pregnancy-induced hypertension | | O10-O16 | |
| VAs-09.04 | Obstetric haemorrhage | O46 (ante partum) O72 (post partum) | O46; O67; O72 | |
| VAs-09.05 | Obstructed labour | O66 | 063-066 | |
| VAs-09.06 | Pregnancy-related sepsis | O75.3 (ante partum) O85 (post partum) | 085; 075.3 | |
| VAs-09.07 | Anaemia of pregnancy | 099 | O99.0 | |
| VAs-09.08 | Ruptured uterus | 071 | 071 | |
| VAs-09.99 | Other and unspecified maternal cause | 005 | O01-O02; O20-O45; O47-O62; O68-O70; O73-O84; O86-O99 | |
| VAc 10 Non | natal causes of death | | | |
| VAs-10 Neo | Prematurity | P07 | P05-P07 | |
| VAs-10.02 | Birth asphyxia | P21 | P20-P22 | |
| VAs-10.03 | Neonatal pneumonia | P23 | P23-P25 | |
| VAs-10.04 | Neonatal sepsis | P63 | P36 | |
| VAs-10.05 | Neonatal tetanus | A33 | A33 | |
| VAs-10.06 | Congenital malformation | Q89 | Q00-Q99 | |
| VAs-10.99 | Other and unspecified perinatal cause of death | P96 | P00-P04; P08-P15; P26-P35; P37-P94; P96 | |

| VAs-11.01 | Fresh stillbirth | P95 | P95 |
|-------------|--|-----|---|
| VAs-11.02 | Macerated stillbirth | P95 | P95 |
| VAs-12 Exte | rnal causes of death Note: The list of questions contains sub questions that allow for more specificity for accidents. | | |
| VAs-12.01 | Road traffic accident | V89 | V01-V89 |
| VAs-12.02 | Other transport accident | V99 | V90-V99 |
| VAs-12.03 | Accidental fall | W19 | W00-W19 |
| VAs-12.04 | Accidental drowning and submersion | W74 | W65-W74 |
| VAs-12.05 | Accidental exposure to smoke, fire and flames | X09 | X00-X19 |
| VAs-12.06 | Contact with venomous animals and plants | X29 | X20-X29 |
| VAs-12.07 | Accidental poisoning and exposure to noxious substance | X49 | X40-X49 |
| VAs-12.08 | Intentional self-harm | X84 | X60-X84 |
| VAs-12.09 | Assault | Y09 | X85-Y09 |
| VAs-12.10 | Exposure to force of nature | X39 | X30-X39 |
| VAs-12.99 | Other and unspecified external cause of death | X59 | S00-T99; W20-W64; W75-W99; X50-X59; Y10-Y98 |
| VAs-99 | Cause of death unknown | R99 | R95-R99 |

Appendix 2: KeVA 2019 amendments to the 2016 WHO VA Questionnaires

- 1. General information section:
 - Id10010 Name of the interviewer moved up
 - Id10011-Id10012 Time and date moved up and preset
 - Id10013 Consent; if "No Consent" given, End interview
 - Inclusion criteria added: Was post mortem done? If Yes, (a) Where was it done/Place?; (b) If No, End the interview
- 2. Information on the respondent and background about interview: Response options modified for Id10008 What is the relationship of the respondent to the deceased?
 - a) Spouse (**Option retained**)
 - b) Son or Daughter (Option added)
 - c) Sister/Brother (**Option added**)
 - d) Son or Daughter in-law (**Option added**)
 - e) Grandchild (Option added)
 - f) Parent (Option retained)
 - g) Parent in-law (**Option added**)
 - h) Adopted/Foster/Stepchild (Option added)
 - i) Not related (Friend, health worker, public official etc) (**Option added**)
 - j) Other (specify) (**Option added**)
 - k) Ref (**Option removed**)
 - 1) Child (**Option removed**)
 - m) family_member (Option removed)
 - n) friend (**Option removed**)
 - o) spouse (**Option removed**)
 - p) health_worker (**Option removed**)
 - q) public_official (**Option removed**)
 - r) another_relationship (**Option removed**)
- 3. Information on the deceased and location:
 - Id10055 County and Sub County (Place of Event Occurrence and Native Place of residence) usual residence=more than 3 months
 - Id10058 Where did the deceased die, remove "Don't know" response
 - Id10051 to be made "Yes" by default
 - Id10057 to be preset and moved up
 - Id10060 on Marriage: if married, add approximate years in marriage
 - Id10063 What is deceased highest level of education reached, response options modified:

- a. None
- b. Pre-primary
- c. Primary
- d. Secondary
- e. College (middle level)
- f. University
- g. Vocational
- h. Informal (e.g. Madrassa)
- i. Don't Know
- Preset HIV-Malaria mortality and season: Since seasons and HIV-Malaria prevalence are different across the country, it is advisable that the project specify values across different regions yearly and distribute seasonal calendars and mortality documentations to VA interviewers before VA interviews begins. (The project office may make this question hidden to the interviewers in the electronic format).
- 4. Information about vital registration:
 - Id10069 up to Id10073: Change registration numbers to notification numbers (Note: these items can be automatically filled if an electronic data collection platform is used and the information is available from a previous data collection step.)
 - Change Id10069 from "Id10069_a Do you have a death registration certificate?" to "Id10069_a Do you have a burial permit?"

5. History of injury/accidents section:

Id10080 What was her/his role in the road traffic accident?: change option "driver or passenger on a motorcycle" to "rider or pillion on a motorcycle (bodaboda)."

6. Death certificate with cause of death section:

Id10462 to Id10476: Since this group refers to information provided on the medical certificate of cause-of-death, it should be skipped if the medical certificate is not available. This is likely to be the case for VA deaths that took place outside of a health facility. To skip this group of questions, add 1=2 in the *relevant* column of the group name.



Appendix 3: Example process map for integration of VA with CRS processes

Appendix 4: Example death reporting form

| | O FORM D1 | OF | ORM | D2 | Ser | ial Nu | umbei | r: [| | | | | |
|--|--|------------|-----------------|--------|---------------|--------|-----------|-------|-------|--------|---------|--------|-----|
| The Community Health Worker should | _ complete a locato | or form fo | or <u>eac</u> i | h dea | th oc | curin | g in as | ssign | ned h | ousel | olds | . Recc | ord |
| responses in the column on the right. | | | | | | | | | | | | | |
| . Date of report: (Tarik ma indike form) | | | / | |] / | 2 | 0 | | | | | | |
| Name of Community Unit: (Nying Community Unit Mari) | | | | | | | | | | | | | |
| Community Health Volunteer name (Nyingi mar tich) | : [| | | | | | | | | | | | |
| Name of Village: (Gweng ma dala nitie) | | | | | | | | | | | | | |
| . Contact number of homestead/com (Namba mar simu mar dala/landi) | pound: | | | | | | | | | | | | |
| Names of Head of Compound/h | nomestead (Nyi | nge wud | on dal | a/land | di) | | | | | | | | |
| . Christian/First name: (Nying mokuongo mar wuon dala/landi | , [| | | | | | | | | | | | |
| Middle name: (Nyingi madiere/Juok mar wuon dala/la | andi) | | | | | | | | | | | | |
| Last Family name: | | | | | | | | | | | | | |
| (Nying mogik mar wuon dala/landi) . Clan name: (Nying anyuola/dhot/nonro mar wuon c | | | | | | | | | | | | | |
| Christian/First name of the deceas (Nying mokuongo mar ng'at/nyathi mos 1. Juok/Middle name of the decease (Nying madiere mar ng'at/nyathi moser | senindo) L d: r | | | | | | | | | | | | |
| 2. Last name of the deceased: (<i>Nying mogik mar ng'at/nyathi mosenin</i> 3. Sex of the deceased: | | | | | | | | | | | | | |
| (Ngat/nyathi mosenindo ne en wuowi/d 4. Date of birth of deceased (Tarik mar nyuol mar ng'at/nyathi mose | | (miyo) | ⊖ Ma | | nwo | /wuo | ~) / | | -ema | le(mi | yo/ny | /ako) | |
| (Tank mar ny dor mar ny avny ani mose | | | | | /[| | / | | | | | | |
| | | | | | | | _ | _ | - | | | | |
| (Tarik mar donjo e dala) 5. Date of death: (Tarik mar tho) | | | | | / [| | 1 | 2.6 | | 1 1 | | | |
| Date of death: (<i>Tarik mar tho</i>) Where did the deceased die: O H (<i>Kama ne ng'at/nyathi otho e</i>) | lealth Facility(kar Dthers(mamoko) | thieth) | 0 | Home | / [e/In t | ransi | t(dala | /e wi | uoth) | | | | |
| (Tarik mar donjo e dala) 5. Date of death: (Tarik mar tho) 7. Where did the deceased die: (Kama ne ng'at/nyathi otho e) | Dthers(mamoko) old at the time of d | leath, red | cord ti | he pai | rents | /careg | giver's | s nan | | otherv | vise, | leave | |
| (Tarik mar donjo e dala) Date of death: (Tarik mar tho) Where did the deceased die: (Kama ne ng'at/nyathi otho e) C If deceased was less than 18 years of blank:(ka nyathi motho ne hike tin m Christian/First name of the parent/ | Others(mamoko) old at the time of d na ok no chopo hi <u>c</u> 'caregiver: | leath, red | cord ti | he pai | rents | /careg | giver's | s nan | | otherv | vise, | leave | |
| (Tarik mar donjo e dala) Date of death: (Tarik mar tho) Where did the deceased die: (Kama ne ng'at/nyathi otho e) If deceased was less than 18 years of blank:(ka nyathi motho ne hike tin m Christian/First name of the parent/ (Nying mokuongo mar janyuol kata jarit | Others(mamoko) old at the time of d ha ok no chopo hig caregiver: nyathi) ver: | leath, red | cord ti | he pai | rents | /careg | giver's | s nan | | otherv | vise, | leave | |
| (Tarik mar donjo e dala) Date of death: (Tarik mar tho) Where did the deceased die: (Kama ne ng'at/nyathi otho e) If deceased was less than 18 years of blank:(ka nyathi motho ne hike tin m Christian/First name of the parent/ (Nying mokuongo mar janyuol kata jarit) Middle name of the parent/careging | Others(mamoko) old at the time of d na ok no chopo hig (caregiver: nyathi) ver: arit nyathi) regiver: | leath, red | cord ti | he pai | rents | /careg | giver's | s nan | | otherv | vise, / | | |

| Today's date | | Village/Compound, House | ,_ |
|--------------|-----------|----------------------------|----|
| Name of fan | nily head | Filenum: | |

DETERMINATION OF SPECIFIC CAUSES OF DEATH USING VERBAL AUTOPSY IN A COMMUNITY SETTING IN HOMA BAY, KENYA

CONSENT FOR PARTICIPATION IN VERBAL AUTOPSY INTERVIEW

PURPOSE

Information on cause of death is important for public health planning—globally, nationally, and for regional development. However, most deaths that take place in Kenya are not registered, and for deaths that do not take place in a hospital, the cause of the death is not known. For these deaths, a verbal autopsy—or an interview about signs and symptoms that the deceased experienced prior to his/her death—is a way of getting cause of death information to help the Ministry of Health to develop programs to prevent such deaths in the future.

PROCEDURES

We would like to invite you to participate in this project to help us understand causes of death and to improve the health of the people in Homa Bay. If you agree to participate, we will ask you questions about the death of [INSERT NAME OF DECEASED]. The interview will last approximately 30 minutes. Your participation is completely voluntary and you may choose not to answer any question for any reason. If you do not want to answer a question, you can say so and we will move on to the next one. Again, all of the information you provide will be kept confidential.

BENEFITS & RISKS

The people of Homa Bay will benefit from health programs—like HIV/AIDS and malaria interventions—that are developed using information that is provided from this project. There is little or no risk to participating in this project, but some questions may be about sensitive or emotional issues. If the questions are upsetting or difficult to answer, we can skip those questions or we can end the interview at any time. You may refuse participation in this study at any point, and this will not involve any penalty or loss of benefits. We do not believe there are any serious risks involved in this study. However, you may experience emotional distress if you are asked questions about the death of a family member or a sick child or HIV/AIDS related questions. In this case, we'll offer counseling services at no cost to you.

Should any further questions arise, please <u>contact</u> Aduda Jacob 0791575691 You may also contact the Director of KEMRI/CDC Research and Public Health Collaboration or the Chief of DSS at the KEMRI/CDC Kisian field station offices in Kisumu, at 057 20 22902. If you have any questions about your rights as a participant, please contact the Secretary, KEMRI Ethics Review Committee, P.O. Box 54840-00200, Nairobi; Telephone numbers: 020-2722541, 0722205901, 0733400003; Email address: ERCadmin@kemri.org.

Would you allow me to interview you as part of this project?

HAVE RESPONDENT 1) SIGN TO INDICATE THEIR CONSENT OR 2) MAKE A MARK AND HAVE HIS/HER CONSENT CONFIRMED BY THE SIGNATURE OF A WITNESS:

_____ AGREES TO AN INTERVIEW

| DOES NOT AGREE TO PARTICIPA' |
|------------------------------|
|------------------------------|

| NAME OF STAFF OBTAINING CONSENT: | | | |
|----------------------------------|-------|---|---|
| STAFF SIGNATURE: | DATE: | / | / |

1

Appendix 6: Supervisor Checklist

CHECKLIST FOR THE SUPERVISOR

For the tasks described below, the Supervisor should attempt to address any issues identified with the Verbal Autopsy interviewers (CHEWs) and CHVs. Any unresolved issues should be referred to the Verbal Autopsy Coordinator.

A. Attending monthly CHU meetings between CHEWs and CHVs

- 1. Confirm that Locator Forms are complete, including D1/D2 number; for incomplete forms, review and troubleshoot issues with relevant CHV. Special effort should be made to ensure that each death reported through the Locator Form is registered and therefore has a D1/D2 number. Discuss any remaining issues with VA Coordinator.
- _____ 2. Identify "community deaths" for which a Verbal Autopsy should be scheduled.
 - 3. Assign interviews to the interviewers. Interviews are ideally assigned to the CHEW who supervises the CHV that visited the household and recorded the death. However, interviews may be reassigned as needed to ensure all are completed in an efficient and timely manner.
- 4. Check that interviewers update their Interview Tracking Form to indicate which interviews have been assigned to them.

B. Visiting CHEW stations regularly (e.g., every 2 weeks)

_____1. Review Interview Tracking Forms to ensure progress in completing interviews:

____ Check that an interview has been scheduled for each Locator Form received (Columns C/D).

____ For scheduled interviews, check that they have been completed as scheduled (Columns E/F).

____ For completed interviews, check that the data has been submitted/uploaded

(Column G).

____ Address any comments or issues noted in Column H.

- 2. For scheduled interviews, check that interviewers know how to locate the household. If not, work with the interviewer (CHEW) and CHV to locate the household. If the interviewer does not know the family, recommend that the CHV attend the interview with the CHEW.
- 3. Ensure that interviewers (CHEWs) are able to arrange transportation to households for interviews, piggybacking off of other planned travel as available; discuss any problems that cannot be resolved with the VA Coordinator.
- 4. Discuss any other issues with the interviewer (CHEW). Consult the Verbal Autopsy Coordinator as needed.

C. Observing Verbal Autopsy interviews

Supervisors should aim to accompany each Verbal Autopsy interviewer on interviews at least once a month (twice a month, if possible, in the early phases of implementation). Copies of this checklist should be printed, completed, shared, and discussed with the interviewer after the observation visit.

Mark each item completed by the interviewer. For any issues observed, record comments and suggestions to the interviewer in the box below and discuss with the interviewer.

- _____ 1. The interviewer identified the **best respondent** (an adult knowledgeable about the deceased).
- _____ 2. Consent process; the interviewer:
 - ____ **Described the interview process** to the respondent.
 - ____ Explained that **participation is voluntary**.
 - ____ Explained that all information will be kept **confidential**.
 - ____ Gave the respondent a chance to ask questions and **answered all questions**.
 - ____ Recorded the **respondent's signature**, indicating participation (or not).
 - _____ 3. Interview process (behaviour); during the interview, the interviewer:
 - ____ Requested a private location to conduct the interview.
 - ____ Maintained **direct engagement and/or eye contact** regularly with the respondent.
 - ____ Respected the **sensitive nature** of the interview questions.
 - ____ **Answered all questions** raised by the respondent during the interview.
 - _____ Use of **mobile device did not stall interview process** (if it did, estimated length of delay:_____)
 - 4. Interview process (questionnaire); during the interview, the interviewer:
 - _____ Asked and documented responses for all appropriate questions.
 - ____ **Did not lead** or guide respondents to responses.
 - _____Recorded the **narrative** so as to minimize the burden and wait time for the respondent (e.g., recorded written notes and completed the checklist during the interview and entered the information into the mobile device after concluding the interview).
 - _____ 5. IT considerations

- ____ Interviewer uses mobile device case and carries mobile device in protective bag.
- ____ Mobile device was more than 75% charged prior to the start of the interview.
- ____ Interview was completed prior to the depletion of battery charge.
- 6. After the interview; the interviewer:
 - _____Addressed any remaining questions or concerns of the respondent.
 - ____ Reviewed the questionnaire to make sure it is complete.

_____ Uploaded the interview data to the server.

COMMENTS & SUGGESTIONS FOR CORRECTIVE ACTION:

Appendix 7: De-identification / Anonymization Procedures

DE-IDENTIFICATION / ANONYMIZATION PROCESS FOR DATA FILES:

The table below lists data elements that could potentially identify an individual. In order to de-identify and anonymize the data files, these data elements should be removed from the individual records in the raw data file before data files are shared. Recommendations to de-identify the data file(s) are provided below; these recommendations are adapted from the U.S. Health Insurance Portability and Accountability Act of 1996 (HIPPA) Privacy Rule's Safe Harbor de-identification standard.¹⁴

- Keep all columns in the original data file, but change the data within the relevant individual cell to an anonymized descriptor consistent with the field type. Other strategies may be more appropriate, but for general guidance: "anonymous" may be entered for text fields.
- Maintain the expected format for all columns of the verbal autopsy data file(s) (e.g., keep text fields as text and date fields as dates).
- Year is permitted in the de-identified file; enter "01/01/YYYY" for date fields, where YYYY represents the year entered in the actual data.
- A unique ID is needed for each record; while and identifying numbers/IDs that can be used to identify a person should be removed from the dataset (e.g., a national ID number), please include a unique ID for each record that is only meaningful for the purposes of the data collection.
- *Regarding narratives: Narratives provide valuable information for evaluating VA data and advancing methods development. However, identifiable information, including the data elements listed in the table below, should be removed before narratives are submitted. Anonymization processes for narratives will vary based on file type. If assistance is needed, send an email to <u>verbalautopsy@who.int before</u> uploading narratives with potentially identifiable information.

| | Identifier Description | Relevant WHO 2016 VA | Comment |
|---|-------------------------|---------------------------|--------------------------|
| | | Indicator | |
| Α | Names | 10007 Name of VA | |
| | | respondent | |
| | | 10017 First name of | |
| | | deceased | |
| | | 10018 Surname of deceased | |
| | | 10061 Name of father | |
| | | 10062 Name of mother | |
| В | Geographic subdivisions | Below district level for: | Detail at district level |
| | | 10054 Place of birth | is acceptable. |

¹⁴ Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html

| | Identifier Description | Relevant WHO 2016 VA Indicator | Comment |
|---|--|--|---|
| | | 10055 Place of usual residence (most of the year) 10056 Place of usual residence (1-5 years before death) 10057 Where death occurred 10072 Place of death registration 10434 Name/address of health center where care sought? GPS coordinates | |
| С | Dates (except year) directly related to individual | 10020 Date of birth (month, day) 10022 Date of death (month, day) 10060 Date of marriage (month, day) 10071 Date of death registration (month, day) 10439, 10440, 10441 Dates of recent health visits/notes | "01/01/YYYY" for date fields, where YYYY represents the year entered in the actual data |
| D | Telephone numbers | N/A | May need to be removed if collected with other tracking processes |
| E | FAX numbers | N/A | May need to be removed if collected with other tracking processes |
| F | Electronic mail addresses | N/A | May need to be removed if collected with other tracking processes |
| G | Social security (national identification) numbers | 10073 National identification number of deceased | |
| Н | Medical record numbers | N/A | May need to be removed if collected with other tracking processes |
| Ι | Health plan beneficiary numbers | N/A | May need to be removed if collected with other tracking processes |

| | Identifier Description | Relevant WHO 2016 VA Indicator | Comment |
|---|---|---|---|
| J | Account numbers | N/A | May need to be removed if collected with other tracking processes |
| K | Certificate/license numbers | 10070 Death registration number/certificate | |
| L | Vehicle identifiers and serial numbers | N/A | |
| М | Device identifiers and serial numbers | N/A | |
| Ν | Web Universal Resource Locators (URLs) | N/A | |
| 0 | Internet Protocol (IP) address numbers | N/A | |
| Р | Biometric identifiers, including finger and voice prints | Any audio recordings | |
| Q | Full face photographic images and any comparable images | N/A | |
| R | Any other unique identifying number, characteristic, or code (except code to permit re- identification) | Possibly local program or project IDs that can be traced back to the individual | *NOTE: A unique ID for each record that is only meaningful for the purposes of the data collection is needed for analysis. |

For more information, contact

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