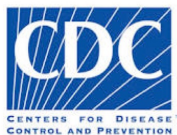


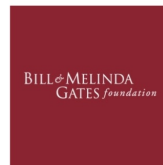
Verbal autopsy standards:

The 2016 WHO verbal autopsy instrument

V1.5



INDEPTH Network
Better Health Information for Better Health Policy



Australian National University

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1 Purpose and content

The 2016 version of the WHO verbal autopsy instrument is suitable for routine use. Based on the 2012 instrument, experiences with the interim 2014 version, and in collaboration with the authors of the different analytical software for assigning the cause of death, questions have been added or edited to facilitate the use of the publicly available analytical software (InterVA, SmartVA previously known as Tariff – simplified PHMRC, and InsilicoVA). Also, the skip pattern has been edited based on the information obtained from field testing and cognitive reviews of the 2012 instrument, and the 2014 interim version.

All materials (questionnaires, table of indicators with skip patterns, crosswalks, and this manual) are available separately for download at <http://www.who.int/healthinfo/statistics/verbalautopsystandards>.

The questions allow for responses with a simple yes or no answer, multiple choice, or a duration in some instances. This approach makes the instrument usable with analytical software that assigns causes of death. Some very few free text fields are included to allow adding information that may be used in reviews but they are not used by the analytical software.

The instrument is designed for all age groups, including maternal and perinatal deaths, and also deaths caused by injuries. A set of paper forms by age group shows the design of the instrument. It is however recommended to use electronic data collection methods, based on the electronic format of the published instrument.

Sets of questions address information relevant to vital registration and information relevant to assessment of the cause of death and the context.

The 2016 instrument is based on the 2012 version of the WHO verbal autopsy instrument that had been designed to become suitable for routine use. Compared to the 2007 instrument, numbers of conditions and questions had been reduced, based on evidence from the field and expert reviews. This document contains some references to the development of the 2012 instrument, because its development is the basis for this new version of the WHO instrument.

This manual informs users on how to use the 2016 WHO verbal autopsy (VA) instrument. The components of this manual include:

- Background on VA;
- The full matrix of questions, definitions and related skip patterns;
- Instructions on how to use the matrix of questions;
- ODK compatible form for all ages, including skip patterns and calculated fields
- Paper forms for illustration and data collection - where necessary
- Information about available analytical software for assigning cause of death, including crosswalks for publicly available analytical software: InterVA5, Smart VA (IHME) and InsilicoVA (Washington University);
- Criteria for setting up a data collection infrastructure and the related databases;
- Instructions on how to adapt questionnaires for local use;
- General cause of death certification and coding guidelines for applying the International Statistical Classification of Diseases and Related Health Problems, tenth revision (ICD-10)¹ to VA; and

Purpose and content

- A simplified cause of death list for VA with corresponding ICD-10 codes.
- Crosswalks for InterVA4 and SmartVA are available for download separately

This manual and its resources are the products of the first one-year effort by an expert group led by the World Health Organization (WHO), consisting of researchers, data users, and government agencies, for the 2012 VA instrument, and an additional year of work of the WHO Working Group on Verbal Autopsy (subgroup of the WHO Reference Group for Health Statistics). The 2016 WHO VA instrument is intended to allow for simple and inexpensive identification of causes of death in places where no other routine system is in place and will serve the needs of countries' civil registration and vital statistics (CRVS) systems. Independently, this instrument can also be used in research and disease specific programmes. All materials are easily and widely accessible on the WHO web site, in print, and will be incorporated into diverse resource kits, intended for strengthening national vital statistics systems. Additional language versions will be made available through similar channels.

Experience from the field and publications on the most widely used and validated VA instruments and procedures (WHO VA standards, InterVA and Population Health Metrics Research Consortium -PHMRC VA instrument)¹⁻³ were systematically reviewed and also assessed against experience in using analytical software for cause of death assignment (InterVA and SmartVA). The utility of each VA question was discussed with VA users. Experiences from field testing and cognitive reviews of the 2012 instrument, and the results of a simplification of the PHMRC Tariff method also contributed to the development of 2016 WHO VA instrument. These reviews and assessments have resulted in a simplified instrument with a reduced number of questions and causes of death, compared to 2007. However, the number of questions has slightly increased compared to the 2012 instrument, because some questions were added, and some complex questions were split into two thus making sure they ask about only one indicator at a time. Furthermore, the 2016 WHO VA instrument also facilitates the use of publicly available analytical software for assigning the cause of death, including InterVA and SmartVA.

The systematic application of the 2016 WHO VA instrument will facilitate the application of VA in routine surveillance of vital events and introduce more consistency and cross-comparability of VA-derived mortality data. The correspondence table (Appendix 1) allows for easy conversion to and from ICD-10.

The application of the 2016 Instrument in routine use and research with its standardized international set of questions will facilitate the compilation of larger databases that finally would provide the evidence for stepwise improvement of VA questionnaires internationally, and become a basis for continuous development of analytical methods.

2 VA 2016 Implementation Kit

This manual provides an overview of structure, content and scientific background to the WHO VA 2016 Instrument.

It is accompanied by

- A set of **sample questionnaires** - in case some setting wants to use paper questionnaires. The design can be adapted, but the sequence and skip patterns need to be preserved
- **VA Field Interviewer Manual** - with instructions for every question and some more general information
- **Manual for Training of Interviewers** - to conduct a full training for interviewers
- **Manual for the Training of Master Trainers and Supervisors**
- **Training curricula and template agendas for training of interviewers, master trainers and interviewers**

3 Introduction to verbal autopsy

Reliable data on the levels and causes of mortality are cornerstones for building a solid evidence base for health policy, planning, monitoring and evaluation.

The main objective of VA is to describe the causes of death at the community level or population level where civil registration and death certification systems are weak and where most people die at home without having had contact with the health system.

In settings where the majority of deaths occur at home and where civil registration systems do not function, there is little chance that deaths occurring away from health facilities will be recorded and the cause of death certified. As a partial solution to this problem, VA has become a primary source of information about causes of death in populations lacking vital registration and medical certification. VA has become an essential public health tool for obtaining a reasonable direct estimation of the cause structure of mortality at population level, although it may not be an accurate method for attributing causes of death at the individual level.

Verbal autopsy is a method used to ascertain the cause of a death based on an interview with next of kin or other caregivers. The interview is done using a standardized questionnaire that elicits information on signs, symptoms, medical history and circumstances preceding death. The cause of death, or the sequence of causes that led to death, are assigned based on the data collected using the VA questionnaire and any other available information. Rules and guidelines, algorithms or computer programs, may assist in interpreting the information collected using the VA questionnaire to determine the cause of death¹¹.

A standard VA instrument comprises a VA questionnaire, a list of causes of death or mortality classification system, and sets of diagnostic criteria (either expert or data derived algorithms) for assigning causes of death. The VA process consists of several steps, and many factors can influence the cause specific mortality fractions estimated through this process.⁴

3.1 Historical background

In Europe, before the 19th century when modern systems of death registration were implemented, designated death searchers visited the households of deceased people to assess the nature of deaths. The need for lay reporting of causes of death remained in low and middle income countries where there was a lack of medical capacity to produce death certificates for the population. As an alternative, in the 1950s and 60s in Asia and Africa, systematic interviews by physicians were used to determine causes of death. Workers at the Narangwal project in India labelled this new technique “verbal autopsy”^{5,6}.

The interest of WHO in VA (formerly “lay reporting”) of health data was first demonstrated in a publication by Dr. Yves Biraud in 1956. During the 1970s, WHO encouraged the use of lay reporting of health information by people with no medical training, leading to development in 1975 of lay reporting forms (WHO 1978). Since the late 1970s and early 80s when the Reproductive Age Mortality Studies (RAMOS), Matlab (Bangladesh) and Niakhar (Senegal) questionnaires first emerged, several other questionnaires have been developed for use in research settings and in national or large-scale regional surveys.⁵

The past two decades have seen a proliferation of interest, research and development in all aspects of the VA process, including VA data-collection systems, VA questionnaires’ content and format, cause of death assignment process, coding and tabulation of causes of death, and validation of VA instruments.

In 2007, needs and demands for standardization led to the development and publication of the WHO_2007 VA standard tools, which many researchers have adopted.⁷ The standards tools included:⁸

- Verbal autopsy questionnaires for three age groups (under four weeks; four weeks to 14 years; and 15 years and above);
- Cause of death certification and coding resources consistent with the International Classification of Diseases and Related Health Problems, tenth revision (ICD-10); and
- A cause-of-death list for VA mapped according to the ICD-10.

The WHO_2007 VA questionnaire has been modified in several projects to accommodate the local needs. In 2011, evidence from use of the WHO instrument and related VA instruments was reviewed to formulate the 2012_WHO_VA tools. Besides elimination of unreported causes and focus on useful questions, it was designed to facilitate VA use in routine vital registration systems to improve national cause-specific mortality data.

Over the past years, efforts have been made to develop and implement software programs for automated interpretation of VA data to generate computer-based diagnosis of causes of death. Currently, the two most commonly used programs are the InterVA method developed by the Umea University (Sweden) and the Tariff method (SmartVA) developed by the Institute of Health Metrics and Evaluation (USA). However, these two programs are based on slightly different versions of VA questionnaires. So far, it is not clear which of these two methods perform better and whether they complement each other, despite several comparative studies⁹⁻¹². In order to facilitate the application of the two commonly used and publicly available automated methods for interpreting VA and to allow comparison the causes of death data determined by these methods comparative analysis of these commonly used automated

methods of VA interpretation, the WHO VA instrument was updated in 2016 to include all input variables required for the optimum performance of these two software programs. Experience from the field in using the 2012_WHO VA tools and the interim 2014_WHO VA tools, and cognitive testing¹³ provided further inputs in the refinement of the 2016_WHO VA instrument.

This version of the WHO instrument is recommended for field implementation in conjunction with vital registration to enable use of automated VA interpretation programs as well as by physician coders of verbal autopsies.

3.2 Uses and users of VA data

VA is used in three main ways. First, it has been primarily used as a research tool in the context of longitudinal population studies, intervention research or epidemiological studies. Second, it has become a source of cause of death statistics to meet the demand for population-level cause-specific mortality data to be used in policy, planning, priority setting and benchmarking. Third, VA data are gaining acceptance as a source of cause of death statistics to be used for monitoring progress and evaluating what works and what does not. Because vital registration coverage has not significantly improved in developing countries, VA methods have been mainly applied in the following data collection systems: clinical trials and large-scale epidemiological studies; demographic surveillance systems; national sample surveillance systems; and household surveys.⁶

Over the past decade, due to the growing demand for robust estimates of vital events and determinants of health, the primary objective of health and demographic surveillance system (HDSS) sites evolved to encompass: 1) the production of population-based health information to support evidence-based health policies and 2) the monitoring and evaluation of health interventions in settings where routine health information and vital registration systems are incomplete. Most HDSS sites collect VA data and provide population level cause specific mortality data. However, HDSS sites may not provide representative data for national estimates of cause-specific mortality. Application of VA in large cross sectional surveys or in sample vital registration systems have been used to obtain national and sub-national level mortality estimates.,

Potential users of data generated using VA include communities, health care planners and managers, researchers, global decision-makers and donors. While there is a degree of overlap, these users have different perspectives on the uses of mortality data, which have an impact on the desirable characteristics of VA instruments. Researchers, epidemiologists and global-level decision-makers want VA data to inform burden of disease estimation and program evaluation, implying that cause of death estimates must meet high accuracy standards and be comparable over time and across countries.⁷ National and sub-national decision-makers and health system managers require cause of death data for planning, budgeting and resource allocation and for monitoring and reporting to donors, implying that VA data needs to be actionable and program relevant.

There have been a few instances where VA has been administered on a large scale as an explicit part of the development of national statistics.⁸ Users of VA have identified the need for simpler data collection instruments coupled with convenient IT-based solutions (e.g. mobile phones or hand-held devices). These large scale users of VA have a perspective different from that of

Introduction to verbal autopsy

researchers, giving priority to the VA instrument's simplicity, feasibility and adaptability to local contexts, cost-effectiveness and program relevance.⁷ A simplified VA instrument coupled with automated methods to ascertain causes of death can be a stepping-stone to increase the coverage of operational and representative civil and vital registration systems.

4 The development of the 2016_WHO verbal autopsy instrument

The simplified instrument (2016_WHO VA instrument) comprises a short list of causes of death of public health importance that can be ascertained from a limited number of questions suitable for use in VA interviews and amenable to automated assignment of cause of death using analytical software. The design of the VA questionnaire allows for addition of a narrative section where so desired and addition of locally relevant questions and diagnoses. The 2016_WHO VA instrument has been informed by field testing and cognitive reviews¹³ of the 2012_WHO instrument, and the results of a simplification of the PHMRC Tariff method.

The WHO standard VA instrument published in 2007 has been successfully applied in many research settings since then. In recent years, there has been growing interest in strengthening countries' CRVS systems, which has led to the demand for a more simplified and practical VA instrument that is associated with IT applications for data collection and analysis.

To produce a simplified 2012 VA instrument, WHO carried out a systematic review of the use of VA and led an expert group of researchers, data users and other stakeholders, in collaboration with HMN, the University of Queensland (UQ) and the INDEPTH Network. Based on the compiled experience and evidence from the most widely-used and validated VA procedures (WHO VA standards, InterVA and PHMRC VA instrument),^{1-3,14} consensus was reached on a simplified VA instrument for routine use as part of civil registration and vital statistics systems in settings where many deaths are not medically certified.

4.1 2016 List of causes of death for VA

VA cannot ascertain all causes of death and, as many validation studies have shown, VA does not perform equally well for all causes that it can ascertain. Taking these limitations into account, the 2007_list of causes of death for VA was revised to develop the 2016 list that includes all causes of death that could be ascertained with reasonable accuracy from a well-administered VA interview (Appendix 1). In developing the 2016 WHO VA instrument, a review was undertaken to compile evidence for the revision and simplification of the 2007 WHO VA standard cause of death list. The review included VA research studies that used either physician certified VA (PCVA) or automated analytical software to assign the cause of death¹⁵. In addition to research studies, a review of the materials and inputs from VA experts provided evidence on the feasibility and relevance of causes of death that can be reliably ascertained by VA.

The revision and simplification of the 2007 standard WHO VA cause of death list was based on:

- The frequency of a given cause of death being reported in VA; the importance and relevance of a given cause of death to global mortality levels¹;
- The cause of death can be addressed by public health interventions; and

¹ In the simplification of the list of diagnoses, attention has been given to the Global Burden of Disease (GBD) groupings. In view of the ongoing edits of the GBD, the correspondence table does not include GBD references. The mentioned ICD-10 codes may serve to distribute cases to the relevant GBD groups.

- The feasibility of the cause of death being ascertained through VA.

The list of causes of death resulting from the above process is presented in Appendix 1.

Using a minimum set of causes of death facilitates the merging and comparison of data from VA on an international scale. The mapping of the list of causes of death using ICD-10 codes shown in Appendix 1 allow comparison of mortality data determined by VA with ICD-10 coded causes of death data ascertained using the international certificate of causes of death.

4.2 List of indicators and their definitions, relevant age and sex groups and sample questions

The 2016_WHO VA questionnaire cause of death related indicators for all age groups in one sheet, but only subsets are used for the different age groups. The list of indicators is subdivided into 4 sections and 118 subgroups (Appendix 2). 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 perinatal death. The indicators were selected by reviewing the 2007_WHO VA questionnaire; identifying unused and uninformative indicators from the field experience of VA experts; and with input from cause of death assignment results using analytical software (InterVA and Tariff), and cognitive assessment of the WHO 2012 Instrument. Field testing with the interim 2014 Version and a final expert review and consolidation of the results led to the formulation of the present list of indicators.

The table shows the distribution of questions by age group and bread section of the questionnaire.

The levels refer to the skip questions. The 'entry level' questions will always have to be asked.

Questions for CRVS are a set recommended by the UN Statistical Division. They may not be necessary in all settings.

The questions asking for content of a medical certificate of cause of death may provide helpful information in certain settings and in case such a certificate has been issued.

Segment/ depth	Neonate	Child	Adult (incl. maternal)
Personal	19	21	20
Entry level	15	17	16
Level 2	4	4	4
CRVS	13	18	18
Entry level	2	2	3
Level 2	11	16	15
CoD	122	161	184
Entry level	38	86	66
Level 2	65	72	96
Level 3	19	3	22
Context	23	23	19
Entry level	7	12	10
Level 2	10	10	8
Level 3	6	1	1
DeathCert	12	12	12
Entry level	1	1	1
Level 2	1	1	1
Level 3	10	10	10
Grand Total	189	235	253
Entry level	63	118	96

The full set of indicators that were considered and the rationale for inclusion or exclusion of each indicator in the 2016 VA instrument is available for download at www.who.int/healthinfo/statistics/verbalautopsystandards. The list of indicators is further described in Section 4.2.

The instrument allows for the addition of indicators of topical interest such as risk factors where necessary. However, such augmentation of the 2016 instrument is not encouraged (see Section 4.4 “Guidelines on augmentation, and local adaptation”), because the 2016_instrument is comprehensive and if correct cause of death certification and coding procedures are used, it should be possible to generate comparable data over time across populations. Any addition of indicators should be done in consultation with WHO in order to ensure operability of the analytical software for assigning cause of death and comparability of results. See Section 4.4 for further guidance.

5 Application and implementation of the 2016 WHO VA instrument

This section describes the application and implementation of the 2016 WHO VA instrument. The 2016 WHO VA instrument and supporting documentation for implementation include the following components:

- 2016 Cause of Death List with ICD Codes (Appendix 1, described in Section 3.1, identical with the 2014 version)
- Table of Indicators (Appendix 2, described in Section 4.2): For each indicator, describes the variable ID and the data type, defines threshold values to categorize numeric values, defines skip patterns, and includes notes for translators and interviewers.
- 2016 WHO VA instrument
 - Excel- and XML-files and references to data collection platforms (posted on WHO website at: www.who.int/healthinfo/statistics/verbalautopsystandards)
 - 3 Sample (Paper) Questionnaires (Appendices 3-5)
- Tools and guidance for remote data collection and storage in a database (described in Section 4.8.2; will be posted on WHO website at: www.who.int/healthinfo/statistics/verbalautopsystandards)
- Instrument translation tables (described in Section 4.5, available for download at www.who.int/healthinfo/statistics/verbalautopsystandards)
- 2016 WHO VA instrument training manuals (are posted on WHO website at: www.who.int/healthinfo/statistics/verbalautopsystandards)
- Analytical tools for cause of death assignment are available at:
 - InterVA : <http://www.interva-4.net/>
 - Tariff : <http://www.healthdata.org/verbal-autopsy/tools>

Details for application and implementation described in this section include: a description of the structure and indicators included in the 2016 WHO VA instrument; guidelines for local adaptation and translation of the instrument; guidelines for data collection, management, and storage; and guidelines for cause of death assignment and use of VA data.

5.1 Sections of the 2016 WHO VA instrument

The 2016 VA instrument contains both common sections and specific sections appropriate to both the age and sex of the deceased.

NOTE: Age, sex, information about the season, 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 must be removed from these sections. 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.

The instrument consists of the following sections:

1. Preset HIV-Malaria mortality and season (the project office may make this question hidden to the interviewers in the electronic format);
2. Information on the respondent and background about interview;
3. Information about the deceased and vital registration;
 - a. Information on the deceased
 - b. Civil registration numbers.
4. History of injury/accidents;
5. Health history;
 - a. Duration of illness
 - b. Medical history associated with final illness
 - c. General signs and symptoms associated with final illness
 - d. Signs and symptoms associated with pregnancy and women
 - e. Neonatal and child history, signs and symptoms
 - f. Health service utilization
 - g. Background and context
 - h. Death certificate with cause of death.
6. Open narrative (text field).
 - a. Check list of additional items to record in the narrative open space.

Section 1 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 2 collects information about the respondent, consent if required in certain contexts and time the VA interview was started.

Section 3 contains key identifying and socio-demographic information and data fields necessary for the management of completed forms.

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. Section 5a) has questions to determine the duration of the final illness; 5b) history known past or present diseases that would give clues to the causes of death; 5c) contains symptoms and signs that are relevant for all deaths; 5d) contains symptoms and signs specific to maternal deaths; 5e) contains symptoms and signs relevant for neonatal and child deaths; and 5f) contains questions about the utilisation of health services and contextual factors. Section 5g has fields for recording information from a medical certificate of cause of death if this is available.

Section 6 is an open narrative text field that allows for comments and adding additional information. This section is particularly useful for quality control and for providing additional information for physician assessment of the cause of death if needed. While its use is optional, it is recommended that this question be asked, even if it is not recorded, in order to complete the checklist of some indicators (section 6a) that are required for assigning causes of death using Tariff 2.0.

5.2 Technical description of the Table of Indicators (ODK XLS)

The Table of Indicators of the 2016 WHO VA instrument (separate file mentioned in Appendix 2) consists of one table containing all indicators for all age groups with relevant details describing each indicator. The questions are grouped by sections, as is described above. Relevant skip patterns by age and sex are defined for each indicator.

Questions, hints and skip instructions are listed in the sheet “survey”. Selectable values are listed in sheet “choices”.

Quick overview of the columns in the sheet “survey”

type	Describes the kind of question, e.g. yes/no, multiple choice, integer, or text
name	language independent identifier of the question
label::English	question in a specified language: here English. You may add a column with the title “label:: <i>mylanguage</i> ” for the language of your choice. Having several language columns active allows to create multilingual forms.
hint::English	hint for the question in the specified language. You may add a column with the title “hint:: <i>mylanguage</i> ” for the language of your choice. Having several language columns active allows to create multilingual forms.
relevant	here you have the information for the skip patterns.
required	determines whether the question must be answered, if asked
appearance	describes appearance of questions in the form
calculation	specifies calculations using the values of preceding questions. It is used to determine the age group
default	

constraint add constraints to the data fields;
constraint message used to display a message why the entry is not accepted

Details about the format are available online at <http://xlsform.org/> and more generally at <https://opendatakit.org>.

5.3 Sample questionnaires

The 2016 WHO VA instrument is designed for use with an electronic data collection platform. Excel- and XML-files with the required instructions are posted on the WHO website at: www.who.int/healthinfo/statistics/verbalautopsystandards. A set of sample/paper questionnaires that demonstrate the layout of the questions, as described in the Table of Indicators (Appendix 2), are also provided as a guide to the user.

The sample questionnaires may also serve as a guide for data collection using paper-based questionnaires. However, to facilitate 1) the use of automated analytical software for the assignment of cause of death, and 2) the comparison of the responses across VA studies, all data (regardless of data collection method) should be entered into a database following the instructions provided in Section 4.8.2. It is especially important to retain the variable IDs as defined in the Table of Indicators in Appendix 2 review and.

Sample questionnaires are provided for three age groups (under four weeks; 4weeks-11 years, 12 years and above), as shown in the Appendices 3-5.

5.3.1 Sample 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 a “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.

5.3.2 Sample VA questionnaire 2: death of a child aged four weeks to 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.

5.3.3 Sample 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.

5.4 Guidelines on augmentation and local adaptation

The indicators contained in the 2016 WHO VA instrument address the most relevant causes of death in most populations where the use of VA is a necessary means to obtain cause of death information. The 2016 WHO VA instrument by design allows for evolution of the instrument. Users may add questions but under no circumstances should questions be removed from the list because of the resulting impact on the comparability of the causes of death information and the further data based evolution of the instrument.

NOTE: Age, sex, information about the season, 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 must be removed from these sections. The numbering of the questions must remain unchanged. Questions added locally will not be used by the analytical software.

It is acknowledged that there may be a desire to expand the instrument to address locally relevant conditions. However, adding signs and symptoms to the 2016 WHO VA instrument needs to be carried out with much caution because alteration can compromise the comparability of VA data between populations. In particular, 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. Modifications may be necessary if there are emerging or locally important causes of death for which there are no questions on the 2016 VA questionnaires. In these circumstances, advice may be sought from WHO for making such modifications. If modifications are necessary, they should be carefully documented and distinguished from the 2016 questionnaire sections and variables. In general, only changes to the wording of existing variables for the purposes of enhancing local comprehension or ensuring cultural acceptability of questions are to be undertaken. The definitions in the 2016 WHO VA instrument may provide some guidance about the meaning that needs to be preserved in such changes. Any need for modification should be shared with WHO together with the rationale for modification. The reporting of modifications made to WHO will inform future revisions of this instrument.

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.

Examples of 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).

Adding and removing questions will impact the comparability of the data **but also may compromise the usability of analytical software** for assigning cause of death. It may either not be possible to use the existing analytical software for assigning the newly added causes of death at all, or the outputs from the software become unreliable.

5.5 Translation

The specific terminology used for indicators and interviewer and translator notes (in the Table of Indicators) aims to convey the highest level of clarity about the intent of a question. Indicators, instructions and data collection tool need to be translated or adapted for local use (even if administered in English, as lay language differs across English speaking regions). 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.

For any translations, please use the XLS form for the 2016 WHO VA instrument that you can download at www.who.int/healthinfo/statistics/verbalautopsystandards. Fill in your translations in the sheets “survey” and “choices” adding columns and do it the same way it was done for the existing translations. The given identifiers and the resulting multilingual file will allow users to 1. re-use a translation as necessary for other projects, and 2. load translations into the WHO software for immediate use, if so desired.

5.6 Vital registration

For use of the 2016 WHO VA instrument in routine vital registration, two options are possible:

- 1) A death has been reported and notified, and an interviewer is sent to query the cause of death. In this case, the personal data are known and the interview will be conducted only to identify the cause of death. The “information on the deceased” section will be prefilled before the interview based on information from the death notification form, and a death registration number (or a similar identifier) will allow the user to link the VA outcome with the related entry in the death registration registry.
- 2) A death is reported and the certification and interview are conducted at the same time. In this case, the personal data are not known, or are known only in part, and need to be recorded at the time of the interview, using the “information on the deceased” section. A registration number will be required to ensure the vital registration linkage between the death registry and the VA data.

5.7 Age categories of death

Some projects may be 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 2016 WHO VA instrument. The three age-group specific questionnaires in the appendices for three age groups (under four weeks; 4weeks-11 years, 12 years and above) may serve as examples here. Where data are captured electronically, the embedded skip patterns will ensure that only the relevant subset of questions is applied.

Where interviews are conducted for all age categories of deaths, ideally the interview data should be captured electronically using the embedded skip patterns. Otherwise (eventually using paper if there is no other way), the interviewers should always be sure to have questionnaires available for all three age group during house visits for VA interviews.

5.8 Infrastructure

In routine surveillance contexts, information needs to be timely and linked to a response that involves effective dissemination mechanisms, appropriate use of data, and periodic evaluation of the surveillance system. The latter can trigger formulation of recommendations for a revision of the components of the 2016 WHO VA instrument to WHO and local workflows of the VA system in use. Thus, use of VA in routine surveillance involves monitoring, accountability, planning and programming.

To develop an adequate instrument for application in large-scale surveillance, the VA instrument needs to have a system that synergizes with other national mechanisms that are already in place. A permanent team that conducts Verbal autopsies on a representative sample of deaths is likely the most feasible way.

The infrastructure will depend largely on the given setting. Data should ideally be stored in a centralized location but at a level that facilitates necessary queries. Usually this is likely to be at the district level. All verified district data would then be forwarded to a central database at the national level.

Arrangements regarding collection, storage and handling of the vital registration and cause of death data should be made between the offices that are involved. Depending on the national infrastructure these offices are most frequently the Statistical Office, Ministry of Health, Ministry of Justice and Ministry of Interior.

Different arrangements may be necessary where VA is conducted in another context, as for research or disease specific programmes.

5.8.1 Interviewers

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. Interviewers should be given enough time to prepare and carry out VA interviews. It is proposed that at least one VA interview per month should be conducted by each VA interviewer to retain their proficiency in conducting VA interviews. Interviewers involved in the application of the VA should have the following minimum qualifications:

- Have completed at least secondary school and have good working knowledge in the relevant local language(s);
- Be acceptable to the local community; where possible, selected by the local community;
- Have good training in conducting VA interviews;
- Know very well the content and uses of the VA instrument.

The following steps are recommended to train VA interviewers. First the trainee interviewer should review all elements and the flow of questions with the help of an expert VA trainer. After discussing any questions that need clarification with the VA trainer, the interviewer can role play a VA interview using the VA trainer as proxy VA respondent. For this role play the VA trainer should have different case scenarios. Such scenarios would include the different age groups of the deceased (maternal, perinatal, child, adult) and thus varying relationship of the respondent to the deceased and also probable local behaviour on the interview per se, and on sensitive questions. In the next step, the interviewer would conduct real VA interviews in the presence of the expert trainer. The number of VA interviews to be conducted in the presence of the VA trainer required to certify proficiency of individual trainee VA interviewer will vary depending on the skills and abilities. Nevertheless typically it would take at least five VA interviews to become confident in doing VA interviews.

The interviewer guide that explains the meaning and importance of each indicator and how to ask each question included in the 2016 WHO VA instrument is posted on the WHO website at www.who.int/healthinfo/statistics/verbalautopsystandards.

5.8.2 Data collection software, database, technology and staff

The 2016 WHO VA instrument is designed to be compatible with electronic data collection platforms and automated analytical software to assign cause of death.

The 2016 Instrument form is provided in a format that is fully compatible with the Open Data Kit (ODK - <http://opendatakit.org>). This allows one to quickly start collecting data using Internet cloud-based services as well as local servers. Data is output in a table format and at any time ready for analysis. A link to the demo version for testing and download is available at www.who.int/healthinfo/statistics/verbalautopsystandards. The electronic data collection form includes embedded skip patterns that automatically navigate the various combinations of age-, sex-, maternal- and perinatal-specific indicators within a single, comprehensive instrument.

Any software 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. Further, any tool for assigning the cause of death can be used, as long as the data collected are what is required for the specific analytical tool.

The ODK format has been adopted by several data collection software systems. Software with wide implementation are OpenSRP and DHIS2. Both can handle ODK standard instruments and have the ability to conduct batch processing and output of results. For DHIS, this requires setting up a separate server that feeds the data into the DHIS server.

Regardless of the data collection method (electronic or paper), answers to all questions and the cause of death assigned to each case should be recorded in a database. 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 should be recorded.

In order to facilitate the use of data collection and analytical software and to simplify the interviews, most questions follow a simple yes/no pattern. However some questions address a time interval or a frequency. All continuous variables should be recorded as continuous variables in the database and will be categorized in a second step using a recommended threshold value. Categorization depends on the analytical software that is used to identify the cause of death. The converter tool will include the necessary algorithms.

The compilation of the information above into a database will provide a tool for reviewing cases as well as enable sharing of results with WHO to facilitate further improvements to this instrument.

In addition to the questions, a narrative can be helpful if physician assessment is a possibility, for quality assurance, and for later review. The full *verbatim* narrative should be stored in the database as well.

In order to use the existing analytical software, the data collected with the WHO VA Instrument need to be converted into the formats that can be processed by the analytical software that determines the cause of death. WHO makes available conversion algorithms in collaboration with the University of Washington and the Swiss TPH. These include a simple conversion

(programmed in R) and an all-in-one R package (openVA - <https://cran.r-project.org/web/packages/openVA/index.html>) that does the conversion and runs the analytical software and outputs the cause of death. Links to the packages are also available from the WHO website www.who.int/healthinfo/statistics/verbalautopsystandards.

VA, using ODK or other electronic data collection methods, requires at a minimum a central server, and mobile devices for data collection. The data will be stored on the central server as soon as a mobile or wired internet connection to the server is available. Sufficient maintenance staff with IT administration skills is necessary in order to set up and maintain the technical infrastructure. Data and software staff will ensure that data collection is complete and workflows work. Statistical and epidemiological staff will use the outputs from the system for tabulation and analysis.

5.8.3 Methods for determining causes of death

In the past decade, methodological developments in automated methods for assigning cause of death for VA have emerged with significant potential for future application in routine national and research data collection platforms. These methods create new opportunities for reliable, timely, and useful cause-specific mortality measurement. These developments have created a shift away from limited individual-level and clinical paradigms towards population-based epidemiological thinking and public health.¹⁶

The 2016 WHO VA instrument contains information on diseases, signs and symptoms, the age and sex of the deceased as well as his or her medical history (if available). Additional information may be recorded in the open text field at the end of the interview. To facilitate application in routine surveillance systems, the 2016 WHO VA instrument was specifically developed to ascertain cause of death through automated methods. As a more cost-effective and feasible alternative to physician-coded VA, the WHO recommends the use of automated methods for cause of death identification. 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 2016 WHO VA instrument for cause of death assignment without the use of physicians are listed on the WHO VA website (www.who.int/healthinfo/statistics/verbalautopsystandards). At present (2014) InterVA4 (University Umea), SmartVA (PHMRC/IHME) and InsilicoVA (University of Washington) are fully compliant with the 2016 WHO VA instrument and can be linked for batch processing to the data collection software.

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 Verbal Autopsy instrument as well as of the software.

In case physicians assess the cause of death, ideally two physicians will review the outcome of an interview and formulate a cause of death independently. If there were a discrepancy, a third physician would arbitrate the result. The opinion of each physician involved should be separately recorded in the database, as well as the consensus finding.

5.8.4 Legal requirements, privacy, confidentiality, informed consent

Ideally, informed consent should be sought from the respondent. Where the legislation or local regulations require that VA be conducted, informed consent may not always be necessary.

Personal data, in particular name, geographical information and contact information about the respondent, should be kept separate from the epidemiological data and ideally be encrypted to protect privacy and ensure confidentiality. Additional measures to anonymize the individual record may be subject to the legislation in force. A common case-ID in the person identifiable VA dataset and the diagnostic VA dataset will allow data linkage between personal and diagnostic data upon formal request in line with national and international regulations.

5.9 Appropriate respondents and recall period

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. The 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. Recalls of more than one year should be interpreted with caution. In general, shorter recall periods are preferable.

5.10 Use of verbal autopsy-generated data

The purpose of VA is to describe the causes of death at the community level or population level in instances where no better alternative sources of mortality data exist. Therefore, VA serves as a limited but essential substitute for medical certification. The quality of information of the assigned cause of death varies depending on the skills of the interviewer and the ability of the respondents to recognise, recall and report key indicators.

The 2016 WHO VA cause of death list (Appendix 1) is a core mortality classification system, specifying the most important causes of death in low-income and middle-income countries where it is deemed feasible to certify cause of death using VA. Coding causes of death using the ICD coding system facilitates the comparison of data and the retention of as much detail as needed in local settings.

The context and method of information gathering to assign cause of death from VA is different from the medical certification of cause of deaths by a physician. The certainty of the cause of death is much lower in VA, and VA cannot reliably ascertain some causes of death. Thus, causes of death data obtained from these two systems should not be merged, as it would conceal differences that may result from these methods and lead to misinterpretation of the results.

ICD-10 provides tabulation lists for mortality and morbidity in volume 1. Other professional groups have made different lists for grouping diseases and presenting mortality statistics. Regardless of the list used, deaths should be classified by sex and into the following age groups: aged < 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. Volume 2, section 5.6.1 of ICD-10, contains a full set of instructions for tabulation.

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Appendix 1: 2016 cause of death list for verbal autopsy with corresponding ICD-10 codes (identical with 2014)

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 Infectious 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 Neoplasms			
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-02.05	Female reproductive neoplasms	C57	C51-C58
VAs-02.06	Male reproductive neoplasms	C63	C60-C63
VAs-02.99	Other and unspecified neoplasms	C80	C07-C14 C40-C49 C60-D48

VAs-03 Nutritional and endocrine disorders			
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 Diseases of the circulatory system			
VAs-04.01	Acute cardiac disease	I24 (acute ischemic)	I20-I25
VAs-04.02	Stroke	I64	I60-I69
VAs-04.03	Sickle cell with crisis	D57	D57
VAs-04.99	Other and unspecified cardiac disease	I99	I00-I09 I10-I15 I26-I52 I70-I99
VAs-05 Respiratory disorders			
VAs-05.01	Chronic obstructive pulmonary disease (COPD)	J44	J40-J44
VAs-05.02	Asthma	J45 (J46)	J45-J46
VAs-06 Gastrointestinal disorders			
VAs-06.01	Acute abdomen	R10	R10
VAs-06.02	Liver cirrhosis	K74	K70-K76
VAs-07 Renal disorders			
VAs-07.01	Renal failure	N19	N17-N19
VAs-08 Mental and nervous system disorders			
VAs-08.01	Epilepsy	G40	G40-G41

VAs-09 Pregnancy-, childbirth and puerperium-related disorders			
VAs-09.01	Ectopic pregnancy	O00	O00
VAs-09.02	Abortion-related death	O06	O03-O08
VAs-09.03	Pregnancy-induced hypertension	O13 (or O15 for eclampsia)	O10-O16
VAs-09.04	Obstetric haemorrhage	O46 (ante partum) O72 (post partum)	O46; O67; O72
VAs-09.05	Obstructed labour	O66	O63-O66
VAs-09.06	Pregnancy-related sepsis	O75.3 (ante partum) O85 (post partum)	O85; O75.3
VAs-09.07	Anaemia of pregnancy	O99	O99.0
VAs-09.08	Ruptured uterus	O71	O71
VAs-09.99	Other and unspecified maternal cause	O05	O01-O02; O20-O45; O47-O62; O68-O70; O73-O84; O86-O99
VAs-10 Neonatal causes of death			
VAs-10.01	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 Stillbirths			
VAs-11.01	Fresh stillbirth	P95	P95
VAs-11.02	Macerated stillbirth	P95	P95
VAs-12 External causes of death			
<p>Note: The list of questions contains sub questions that allow for more specificity for accidents.</p>			
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			
VAs-99	Cause of death unknown	R99	R95-R99

Read carefully the explanations given in section 4.1 of this manual, and the instructions in the remaining sub-sections of section 4.

The sample questionnaires and the excel file for translation and production of ODK forms are provided as separate files.