SOUTH AFRICAN NATIONAL CAUSE-OF-DEATH VALIDATION STUDY

TRAINING MANUAL FOR MEDICAL DOCTOR REVIEWERS

SAMRC Burden of Disease Research Unit | July 2020

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Department of Home Affairs
Centers for Disease Control and Prevention
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National Funeral Directors Association

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FUNDING

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DISCLAIMER

The contents of the guidelines are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention, the CDC Foundation or the Bloomberg Philanthropies Data for Health Initiative.

A copy of this resource is available at:
www.mrc.ac.za/intramural-research-untis/BurdenofDisease-resource-materials

Programme for training in physician coding of Verbal Autopsy

Day 1	**09h00 – 17h00**
09h00– 09h45	Importance of mortality data Death registration in SA Orientation to the National cause-of-death validation project
10h00-12h45	Underlying cause of death (COD) and certification of COD ICD-10 mortality coding *Practical: Certification of cause of death for case scenarios*
13h15-17h00	Orientation to Verbal Autopsy (VA) and experience in South Africa VA questionnaire structure Physician coding of VAs Introduction to data capture tool and tablets Public Health Research Ethics *Practical: Physician coding of VAs (10)*
Homework	Evaluation: Certification of cause of death – 20 clinical scenarios Evaluation: Physician coded VAs 10
Day 2	**09h00 – 13h00**
	Recap training of previous week Work through homework case scenarios and VA reviews Practical – 5 VA reviews Competency test (online submission)

Programme for training in physician coding of Medical and Forensic Records

Day 1	**09h00 – 17h00**
09h00– 09h45	Importance of mortality data Death registration in SA. Orientation to the National cause-of-death validation project
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13h15-17h00	Medical record abstraction and medical certification of cause of death Levels of certainty of diagnoses of COD Introduction to data capture tool and tablets Public Health Research Ethics *Practical: Medical Record reviews and certification of cause of death (10)*
Homework	Evaluation: Certification of cause of death – 20 clinical scenarios Evaluation: Medical Record Reviews (5)
Day 2	**09h00 – 13h00**
	Recap training of previous week Work through homework case scenarios and 5 Medical Record reviews Practical – 5 medical record reviews Competency test (online submission)

Contents

1. National cause-of-death validation project team

1.1 Principal Investigators

Professor Debbie Bradshaw, Director: Burden of Disease Research Unit, South African Medical Research Council is the principal investigator (PI). Dr Jané Joubert and Dr Pam Groenewald, Burden of Disease Research Unit, SAMRC, are co-principal investigators.

1.2 Project funding

This project falls under the Funding Opportunity Announcement CDC-RFA-GH13-1340: "Strengthening strategic information, program implementation and capacity building in order to reduce morbidity and mortality in the Republic of South Africa (SA) under the President's Emergency Plan for AIDS Relief (PEPFAR)". It has been funded through the Cooperative Agreement between the CDC and the SAMRC number 1U2GGH01150-01. In addition, some of the project activities have received funding support from the Data for Health: Civil Registration and Vital Statistics project administer by the CDC Foundation.

1.3 Project collaborators

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Dr Tshilidzi Muthivhi, Health Research Division, National Department of Health.

1.4 Fieldwork partners

Epicentre was the implementing partner in Phase 1 of the project, facilitating the recruitment of next-of-kin. GeoSpace International was the implementing partner of Phase 2 of the project with collection of medical and forensic records and the follow-up of next-of-kin to conduct verbal autopsies.

1.5 Project co-ordination and support

Dr Monique Maqungo, Project Co-ordinator and Data Manager
Ms Noluntu Funani, Project Manager (Stakeholders)
Administrative support:

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Ms Monique Fourie
Mr Riyaadh Fredericks
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1.6 Ethics and permissions

This project has:

- SAMRC ethics approval: EC004-2/2017
- Clearance from the CDC Centre for Global Health Associate Director of Science, (ADS): 27-231
- Permissions from all 9 Provincial Departments of Health and 27 health districts
- Permission from all collaborating hospitals and forensic pathology services

The project has the support of the National Department of Health, the Department of Home Affairs, Stats SA, the National Funeral Directors Association (NFDA) and South African Funeral Practitioners Association (SAFPA) who all serve on the Project's Steering Committee.

2. About this manual

This manual has been compiled specifically for the training of medical doctors who will assist with verbal autopsy (VA) and medical and forensic record reviews, and certification of the cause of death for study decedents from the National Cause of Death study. It provides the background and rationale for the study, international guidelines on the medical certification of cause of death from the World Health Organisation (WHO) International Classification of Diseases and Related Health Problems, Tenth revision (ICD-10), as well as a description of the 2016 WHO VA instrument. The latter is a tool intended to allow for simple and inexpensive identification of causes of death in places where no other routine system is in place, and for non-medically certified deaths. The training will cover the following:

- the importance of mortality data
- South African (SA) civil registration and vital statistics system (CRVS)
- challenges with the quality of SA mortality data
- background and motivation for the national cause of death validation study
- ICD-10 guidelines for medical certification of cause of death
- ICD-10 guidelines for coding causes of death
- statistical presentation of causes of death data (tabulation lists)
- development and history of VA
- history of VA in SA
- the importance of VA for assigning causes of death for non-medically certified deaths
- description of the VA questionnaire
- physician review of VA and medical certification of cause of death
- use of Kobotools to capture medical certificate of cause of death
- research ethics for public health research

3. The importance of mortality data

Mortality statistics form an integral part of civil registration and vital statistics systems. They are one of the basic inputs for evaluation of population growth and health. Further, cause-specific mortality rates are key indicators of health trends in populations. Statistics on causes of death are required by health planners, administrators, and medical professionals, and are useful to:

- Explain the trends and differentials in overall mortality
- Decide priorities for allocation of resources to and within the health sector
- Decide priorities for intervention programs
- Monitor public health programs
- Decide priorities for biomedical and sociomedical research
- Raise questions for epidemiological research
- Compare South African mortality profiles with those of other low- and middle-income countries, as well as high income countries

Mortality statistics, as compared to morbidity, are advantageous for these purposes, as they can be collected efficiently on a routine basis through civil registration systems. Also, statistical analysis of mortality data is facilitated by the fact that death is a unique, clearly defined and final event, resulting in one count per individual as compared to episodes of morbidity. Hence, collection and analysis of mortality data at the population or national level is more feasible and elegant. From an epidemiological perspective though, it is important to understand that mortality, specifically cause of death, informs about health status based on past exposures and experiences, while morbidity data informs of what the health situation is at the current time and portends for the future. A complete health information system would include both types of data.

Data on causes of death is collected most efficiently through civil registration systems, in which every death is legally required to be registered with a medical opinion as to cause. Complete civil registration and vital statistics systems require vast resources, both in terms of financial inputs as well as trained manpower. These systems may therefore be unequally distributed or implemented across the country resulting in some bias in national statistics e.g. urban better reported than rural. A viable alternative lies in conducting efficient mortality registration in a sample of nationally representative population clusters, which has been demonstrated to provide reliable information on levels and trends in overall mortality in a

population. However, the absence of medical attention at death hinders authentic certification as to the cause.

To fill the existing data gap, verbal autopsy methods hold much promise as an interim measure until vital registration systems are built up to full efficiency. These methods have been developed to ascertain the cause of death when the event occurs at home, in the absence of medical attention. By definition, verbal autopsy is a structured interview with relatives or close care giver of the deceased, to obtain information on the on the clinical symptoms, signs and events during the illness leading to death. This is followed by a review of the collected information, in order to assign a probable cause of death, either by medical practitioners using standard diagnostic guidelines for specific conditions, combined with clinical judgment; or using computer software specially developed for standardised assessment of verbal autopsy data.

The accuracy of cause of death ascertainment by this method is highly dependent on the verbal autopsy tool, quality of the interview, and procedures used to assign causes of death. The quality of the interview can be affected by a range of factors related to the interviewer, respondent, or both. The method has been proved to work reasonably for ascertaining causes of death in infancy, or due to specific conditions such as injuries or maternal causes. However, medical causes of adult deaths are not so straightforward, when based solely on symptom description by relatives. This is because a number of such causes have common symptom complexes, and it is sometimes difficult to distinguish between different causes of death from such descriptions.

The family of the deceased in some instances does possess some medical evidence on the illness preceding death, either verbal or documentary, based on visits to health facilities prior to death. For adult deaths, such information can include vital details, especially about non-communicable diseases such as cancers, diabetes, cardiovascular conditions among others. This has enhanced the scope and applicability of the verbal autopsy interview, by seeking and collecting such information in addition to that on symptoms and events.

Studies in Tanzania,[i] China,[ii] India,[iii] Indonesia,[iv] Vietnam[v], and Malaysia[vi] have successfully tested a combination of demographic and mortality surveillance using verbal autopsy in a representative sample of population clusters, leading to the development of a framework for measuring population level cause-specific mortality using verbal autopsy methods. Verbal

autopsy has been validated in rural South Africa as a means of establishing biological cause of death.[vii]

While mortality data by age and sex strictly adhere to the principle of one death-one count, the situation becomes more complex when extended to the recording of the cause of death. Frequently there are multiple conditions that could have caused the death, which could be

- sequential stages in the natural history of one disease,
- complications arising from one of the intermediate conditions, or
- different diseases existing simultaneously at the time of death.

To overcome this problem, the World Health Organisation (WHO) recommends the use of a standard 'Medical Certificate of Cause of Death', which enables the recording of several causes.[viii] The definitions, concepts and guidelines regarding the certification of causes of death are discussed in detail in Chapter 7, which includes a description of the duties and responsibilities of certifying medical practitioners in filling in the certificate.

From an analytical perspective however, the WHO also developed the concept of the underlying cause of death, to enable uniform statistical presentation and interpretation for international comparison. The WHO recommends that all primary tabulations on causes of death should be based on the underlying cause of death. Therefore, a complete understanding of the concepts of underlying cause of death is critical for personnel responsible for coding causes of death.[viii] This topic is discussed in more detail in Chapter 7.

The usability of aggregated cause specific mortality statistics is significantly influenced by the accuracy of cause of death assignment and coding at the individual level, and Chapter 8 provides details on these aspects. Certain specific principles related to statistical tabulations are described in Chapter 9, and this includes a brief description of a 'short' list of causes that are amenable to identification using verbal autopsy methods, for most of which specific diagnostic guidelines are provided in Chapters 12 and 13.

4. The Civil Registration and Vital statistics System in South Africa (CRVS)

Accurate complete mortality data are essential for national health planning. In addition, accurate mortality data at sub-national level are essential to gauge inequalities in health status and indicate differences in access to and quality of health services so that these can be addressed. A well-functioning national CRVS system which covers the whole country and records all deaths as they occur, is required to achieve this.

4.1 Civil registration and vital statistics in SA

SA has a reasonably well functioning CRVS system with the legal framework provided by the Births and Deaths Registration Act (Act no 51 of 1992). The Act requires that all deaths are notified to the Department of Home Affairs (DHA) on the official death notification form (DHA-1663) which includes the medical certification of the cause-of-death. An example can be found in Appendix 1. A medical doctor is required to complete this form, except in the case of stillbirths which may be certified by a professional nurse.

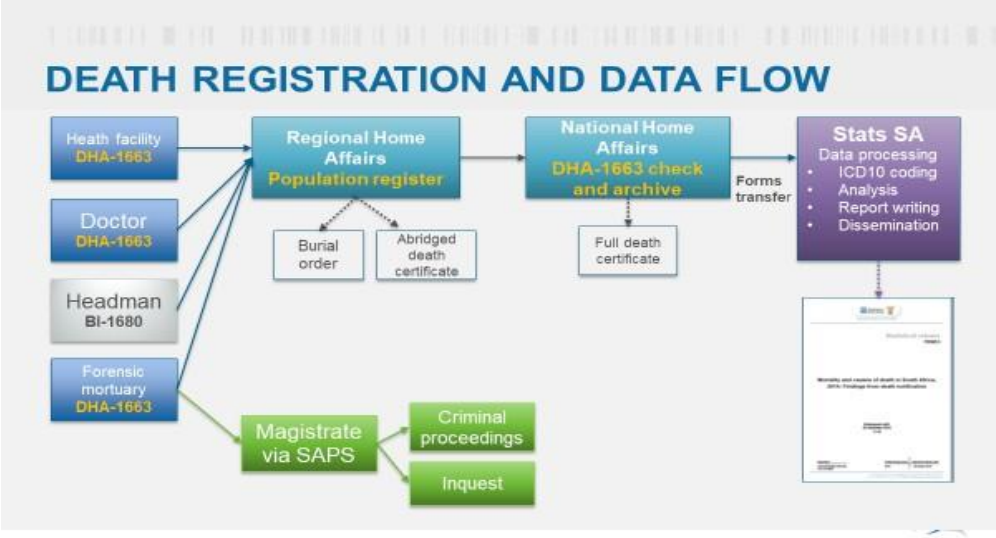
In some areas, where access to medical doctors is poor, a traditional leader may complete the notice of death (DHA-1680) for deaths due to natural causes. Once the death notification form (DHA-1663) has been completed, the funeral undertaker or family member will register the death at the nearest DHA office. The forms are then sent to the national DHA office in Pretoria where they are collated and collected by Statistics South Africa (Stats SA). At Stats SA, the causes of death and underlying cause-of-death (UCOD) are coded according to the International Statistical Classification of Diseases and Related Health Problems (ICD-10) guidelines.[viii] The UCOD is used for further analysis, and annual cause-of-death reports are produced by Stats SA. A diagram of the death registration system is shown in Figure 1.

4.2 Data quality challenges

South Africa has made great strides in improving the coverage and completeness of civil registration over the past 20 years. Prior to 1994 during apartheid the country was divided into 4 provinces and 14 “homelands” and there was complete fragmentation of administrative systems. At that stage registration of white, coloured and Indian deaths was fairly good, however only 50% of African deaths were registered and the situation was particularly poor in rural areas. Given the legal requirement for all deaths in SA to be notified since 1992, coverage has improved and is now satisfactory, and completeness is currently estimated to

be more than 90% for adults. Completeness is less certain for children. Despite these improvements, major challenges remain with the quality of COD information. These include a high proportion of deaths with ill-defined causes,[ix] under-reporting and misclassification of HIV deaths,[x] an inaccurate profile of injury deaths,[xi] and variable quality data at district and sub-district level.[xii]

Figure 1: Diagram of the civil registration and vital statistics system in South Africa



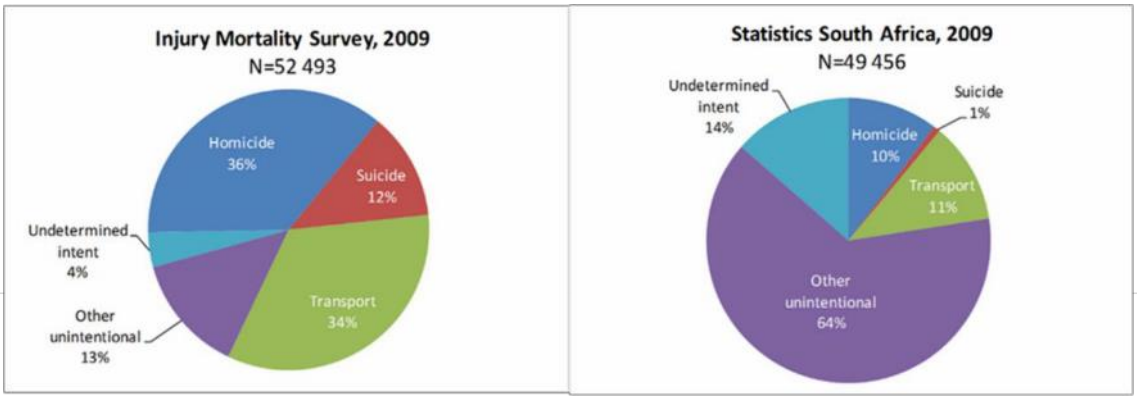
The leading causes of death in South Africa in 2012 are shown in Table 1 below. The unaltered cause-of-death data as reported by Statistics SA is compared with best estimates of the true cause-of-death profile from the 2nd National Burden of Disease study.[xiii]

For various reasons the external cause of death for injury deaths is not reported on the death notification form. As a result, the cause-of-death profile for injuries in the vital statistics is inaccurate. In 2009, a national survey of the causes of death for injuries was conducted at forensic mortuaries.[xi] The cause-of-death profile from the survey is compared with the cause-of-death profile reported in the official statistics in Figure 2 below.

Table 1: Estimated versus reported leading causes of death in South Africa, 2012

SA NATIONAL BURDEN OF DISEASE				STATISTICS SOUTH AFRICA 2012			
Rank	**Cause of death**	**Number**	**% of all deaths**	**Rank**	**Cause of death**	**Number**	**% of all deaths**
1	HIV/AIDS	153 661	29.1	1	Ill-defined and unknown causes	65 033	13.5
2	Cerebrovascular disease	39 830	7.5	2	Tuberculosis	47 472	9.9
3	Lower respiratory infections	25 977	4.9	3	Influenza and pneumonia	26 385	5.5
4	Ischaemic heart disease	24 969	4.7	4	Cerebrovascular disease	23 994	5.0
5	Tuberculosis	23 817	4.5	5	Other forms of heart disease	21 612	4.5
6	Diabetes mellitus	18 894	3.6	6	Diabetes mellitus	21 230	4.4
7	Hypertensive heart disease	18 755	3.5	7	HIV/AIDS	18 663	3.9
8	Interpersonal violence	18 741	3.5	8	Hypertensive diseases	16 195	3.4
9	Road injuries	17 597	3.3	9	Other viral diseases	15 057	3.1
10	Diarrhoeal diseases	16 349	3.1	10	Intestinal infections	14 948	3.1
Top 10 causes		358 590	67.8	**Top 10 causes**		270 859	56.3
Total		528 947	100.0	Total		480 476	100.0

Figure 2: Injury cause-of-death profile from the 2009 Injury Mortality Survey[xi] compared with official reported statistics



5. What is the South African National Cause-of-Death Validation Project?

5.1. Background to the National Cause-of-Death Validation Project

In South Africa, the civil registration and vital statistics system is well established, and completeness of death registration is more than 90%. However, challenges remain with the quality of cause-of-death data, which is essential for health planning and monitoring. Three main challenges are:

- The misclassification of HIV deaths to HIV/AIDS related conditions such as TB, pneumonia and diarrhoea. Factors contributing to the misclassification of HIV deaths are fear of stigma or losing health insurance benefits. These factors, together with concerns regarding the confidentiality of death certificates, often result in an underreporting of deaths from HIV/AIDS.
- A large proportion of deaths with ill-defined causes (due to poor certification, poor access to medical records by certifying the certifying doctor; certification by tribal headman in areas where there is no access to medical doctors)
- Inaccurate causes of injury deaths (forensic pathologists cannot report the manner of death (homicide, suicide or accident) as this is determined by inquest.

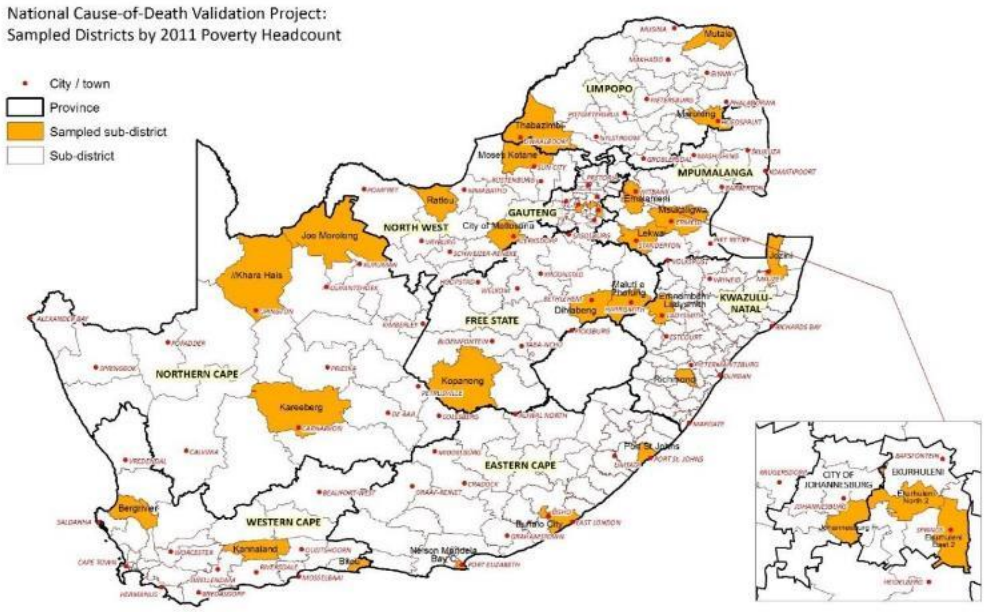
5.2. Aim

This study aims to validate the cause of death reported on the official death notification form (certified by a medical doctor and coded by Stats SA) for each decedent against the cause of death obtained from medical or forensic records where available. Where deaths occurred at home and medical records are not available, the official cause of death will be compared with the cause reported in the verbal autopsy.

5.3. Sampling

It is important that data collected by the study is representative of the whole of South Africa so that the results are applicable to the South African population. For this reason, a nationally representative sample of 27 health sub-districts, 3 per province (stratified by socioeconomic status) were selected. The study includes decedents who were resident in the sampled areas – even if they died at a hospital outside the area. A map highlighting the 27 sampled sub-districts is shown in Figure 3 below.

Figure 3: National Cause-of-Death Validation project: 27 sampled sub-districts.



5.4. Data collection

During Phase 1 of the study, data on deaths that occurred between 1 September 2017 and 13 April 2018 data were collected in the 27 districts. Deaths were recorded at Home Affairs offices and funeral parlors, to enable the project to contact next-of-kin of study decedents. Initial consent was obtained from the next-of-kin, for the project to contact them to arrange a verbal autopsy interview at a later stage. Demographic information on the deceased was captured in a booklet. This included place of death and hospital and forensic mortuary information, if available. Where possible, a copy of pages 1 and 2 of the DNF of the deceased was attached to the booklet information. In addition, for next-of-kin who consented to be contacted, their name and contact details were recorded.

Phase 2 of the study involves following up with the next-of-kin who consented to be contacted and to obtain informed consent to conduct a verbal autopsy interview about the signs, symptoms, and circumstances leading up to the death of their relative. The interview is conducted during a face-to-face individual interview, using one of the three 2016 WHO Verbal Autopsy structured questionnaires, which is captured into an electronic form created with the software programme KoBoToolbox, using an Android tablet, and uploaded to a secure server.

This phase also involves getting access to hospitals, where study decedents died, to make copies of the medical records pertaining to the last admission before death. The records are scanned using the ClearScanner application on a tablet and uploaded as a multiple page pdf document. For study decedents whose death was subjected to a forensic investigation, access is obtained to the forensic pathology services facility to make copies of the relevant post-mortem investigation, as for the medical records.

5.5. Data processing

To enable comparison of the cause of death, as reported on the DHA-1663, with the cause of death from medical records and verbal autopsies, it is necessary to establish an underlying cause of death from the information in the VA and or medical and forensic records. In addition, to enable comparability, the cause of death identified in the medical records and or verbal autopsy needs to be certified according to the international guidelines for medical certification of cause of death.

A panel of medical doctors trained in the international guidelines on medical certification of cause of death will review the medical records from the last admission before death and abstract the relevant information to certify the cause of death. The abstracted data and certificate of cause of death with be captured in a medical record abstraction form, created with Kobotoolbox, using a tablet. The forensic records will be reviewed by a panel of forensic pathologists for the cause and manner of death. These will be captured on the forensic record abstraction form using a tablet.

A panel of medical doctors trained in the international guidelines on medical certification of cause of death will review the verbal autopsy interviews and certify a cause of death using the verbal autopsy COD form on Kobotoolbox using a tablet. Each verbal autopsy interview will be reviewed by two doctors and where a different underlying cause of death is selected, a third doctor will resolve the difference.

After the causes of death have been allocated these will be coded to ICD-10 using the automated coding software IRIS. Rejects from IRIS will be coded manually by two investigators who have received training in mortality coding.

5.6. Data linking and analysis

Once the underlying cause-of-death data from the various sources have been coded, the study data will be linked to decedent data from the official mortality data in a data enclave at Stats SA. The linked data will be anonymized before further data analysis is conducted. Agreement between the causes of death reported in official statistics and that from medical or forensic records and verbal autopsy data will be measured. Correction factors will be calculated to adjust the national cause-of-death profile. The national cause-of-death profile will be adjusted to reflect the best estimates of cause of death. Where a case has the cause of death from medical records and verbal autopsy, the cause of death from medical records will be assumed to be the “best” or most accurate cause of death. Where a case has the cause of death from both hospital and forensic records, the forensic records will be assumed to be the ‘best’ or most accurate cause of death.

6. Research Ethics

6.1. Why Research is important

Medicine is not an exact science. It is often described as an art because even though it is based upon universal scientific principles established treatment is not always effective, indicated, or accessible to all patients. This implies that established treatments need to be evaluated and monitored for efficacy, the search for new treatments is ongoing, medicine is inherently experimental and new diseases and conditions are emerging. Research is thus a central and indispensable component of improving health. Whilst much new knowledge has been generated over the past century, gaps remain. The knowledge and tools available are not always adequate to tackle existing health problems and there is a never-ending need to develop more effective ways of promoting health and reducing disease in human populations. There is a need to expand research on the health problems of poorer countries and marginalized populations with the full involvement of local researchers, with the goal of improving health services and alleviating suffering.

6.2. The evolution of research ethics

Research involving humans has been part of medicine for centuries, however, when animal experimentation became current practice scientists began to question the need for experimentation on humans. Medical Research has involved some highly questionable practices across the world: infectious agents were injected into orphans, mentally disabled, and prisoners in North America and Europe without their consent or knowledge; during the colonial period in Africa, many people were subjected to isolation, quarantine, segregation, and other constraints for surveillance purposes. The Nuremberg trials in 1946 highlighted the inhumane treatment of thousands of concentration camp prisoners who died during and after horrific experiments. This led to the development of 10 principles to be followed in conducting research on humans – the Nuremberg code (1947). The first principle is that the voluntary consent of the human participant is absolutely essential.

In 1953, the United States developed a federal funding requirement for institutional review of proposed research involving humans by an independent committee. Shortly after this the WHO published **the Declaration of Helsinki (1964**) – the first international statement on the concept of independent review of research. However, questionable research practices continued during latter half of the 20th Century in many different parts of the world. Some of these prompted concrete actions, such as the Tuskegee syphilis study (US, 1932–1972)

observed the effects of untreated syphilis in black men over 40 years, despite penicillin becoming the treatment of choice for syphilis in 1947.[xiv] The revelations about the unethical practices in this study led to the US **National Research Act, 1974** which requires research institutions to establish independent, local, multidisciplinary review boards (IRBs) to protect human research participants.

In 1979, a presidential commission in the USA published the **Belmont report** which identified three basic principles of research involving humans;

> **Respect for persons**, requiring respect for a person's autonomy, and protection of persons with diminished autonomy – Consent
>
> **Beneficence**, which requires minimizing harms and maximizing benefits (appropriate risk benefit ratio)
>
> **Justice**, requiring fairness in the distribution of the benefits and burden of research (equitable selection of research participants)

International harmonization of requirements for clinical drug trials resulted in the **Good Clinical Practice (GCP) Guidelines** which aim at avoiding unnecessary duplication of studies by making data generated in trials in one country admissible in others and accelerating the drug development process. Despite these regulations, recent unethical practices highlight the need for continued vigilance (vanTx trial in Switzerland; Low dose of AZT; Trovan trial).

6.3. Core values of ethics for research on humans

The core values and concepts for ethics for research involving humans are based upon the protection of human rights and dignity. The following list of principles of ethics facilitate the protection of human rights and dignity:

- Justify the inclusion of humans in research: social value (potential benefits to society as a whole)
- Ensure scientific value and validity (reproducible observations – sound methodology)
- Bring about more good than harm (minimize risks; risk benefit ratio)
- Promote the interests of humans who participate in the research before the interests of science and society
- Ensure voluntary participation – choosing to take on the risks of research (informed

consent)

- Distribute the risks and benefits of research fairly (those who share in the burden of research should share in potential benefits)
- Show ongoing respect for persons (ongoing informed consent; maintaining confidentiality of personal information; consideration of what will happen once trial is over – if experimental product is efficacious will control arm receive it etc.)
- Uphold transparency during the research process (requiring that a trial be included in a registry of clinical trials to ensure that with negative results are not suppressed)

There are various international ethical guidelines for medical research involving human participants and many countries have enacted legislation, guidelines, or rules to regulate research involving humans. In addition, institutions where biomedical research is conducted bear responsibility for the ethical conduct of research involving humans.

6.4. Research Ethics evaluation

This is a process whereby a group of people representing different perspectives meet to review the ethical acceptability of a research project. This involves two steps: ethical deliberation and decision-making. This is important to ensure that a given project is ethically acceptable and properly protects participants. This includes a review of the scientific validity of the study. The primary role of a Research Ethics Committee (REC) or Institutional Review Board (IRB) is to ensure the well-being, safety, and protection of research participants. This involves working with the researchers to ensure that the research meets the highest standards through the following activities:

- Prior ethics evaluation and approval of projects
- Continuing review of ongoing research
- Active promotion of principles of ethics through education and training

The REC may decide that a given project

- Is acceptable as presented
- Needs to be modified as per REC's comments before it can be accepted
- Requires more information before a decision can be made, or
- Is unacceptable in current form

Usually this is the first step in the approval process before the study can be conducted.

6.5. Research Ethics in Public Health Research

Public health is the physical, mental, and social well-being of a **specific population** as opposed to an individual.

6.5.1. Public health research

- Focuses on the health of a specific population as a single entity rather than an individual
- Focus on disease prevention and health promotion (healthy living conditions and behaviours)
- Aims to reduce health inequity by prioritizing populations with above average health needs
- Employs a broad range of research methods (quantitative and qualitative)
- Often does not involve physical interventions therefore posing a low risk of harm for the physical integrity of individual
- Participants may be providers rather than recipients of health care
- Not as dependent on funding from industry as clinical trials or drug development

Many of these features pose challenges for RECs who are more used to dealing with the well-established ethical principles for research on individual participants, where the interests of the individual are paramount. In public health research the interests of the population are equally if not more important than that of the individual.[xv] [xvi] They may lack confidence in assessing the scientific rigor of the study methods. Whilst risk of physical harm is low, other forms of harm may exist – invasion of privacy, psychological distress and criminal liability as well as possible discrimination against a specific population identified as having a high rate of a communicable disease.

6.5.2. Ethical considerations for public health research

- Freedom (autonomy) is the most important value in individual health care, but in public health, individual autonomy can be subordinate to another value, the public good. For example, prohibiting smoking in public places to protect non-smokers from exposure to cigarette smoke. (The Siracusa principle: public health may be used as grounds for limiting certain individual rights if these constitute a serious threat to the health of a population or individuals)
- Privacy and confidentiality is another important individual right, but public health ethics sometimes permits breaches of confidentiality in collection and use of data.

- Justice or fairness is not a traditional value in individual health care where the individual patient is still considered to be most important and justice for others considered secondary. For public health ethics, justice is predominant with the health of all members of the population being equally important, and there should be no discrimination against sub-populations. Justice does not mean equal treatment for all, as sub-populations with above average health needs should receive priority in the provision of services.
- Trust is an important value for both individual and public health care.

Criteria for dealing with conflicts between individual rights and public health objectives

- Effective in achieving its goal to justify restrictions on individual liberty.
- Proportionality in this context means that the public health benefits of an intervention must outweigh the inconvenience or harms to individuals or sub-populations resulting from the intervention.
- Necessity for achieving an important, not just a minor, public health benefit.
- Least infringement of individual liberty should be chosen, for example, an educational program rather than a coercive law.
- Public justification the proposed intervention, seek feedback from those who will be affected and keep them informed about how the intervention is proceeding.

6.6. Ethical considerations for Public Health Research

1. Balancing the rights of individuals and the needs of the public
    a. Randomisation of interventions: research participants should receive best standard care that is available as well as any benefits of the research.
2. Risk assessment
    a. Likelihood of harm from non-existent to minimal to likely to certain.
    b. Severity of potential harm that are minimal, moderate, serious, life-threatening.
    c. Type of harm (physical, mental, emotional, spiritual, financial, reputational, cultural)
    d. Potential victims are those undergoing an intervention, those in a control group, those ineligible for participation, the affected community, those providing the intervention, the public at large).
3. Stigmatisation of a group that is affected by a specific health problem, most often one that is considered to be self-inflicted and/or morally suspect (e.g., tobacco, alcohol or

drug addiction, sexually transmitted diseases, some mental health conditions).

4. Consent
    a. When is individual consent not required?
        i. Large scale epidemiology studies on data and samples, particularly if the data or samples are anonymized, although care must be taken to avoid stigmatization of affected populations;
        ii. Population level interventions (e.g. a comparative study of the effects of fluoridation of the water supply in two locations, only one of which is provided with fluoridation), for which individual consent from all community members would be virtually impossible to request and those who object to the intervention could not be separated from other community members;
        iii. Disaster situations (epidemics, earthquakes, wars, etc.) in which individual consent to participate in public health research cannot be sought because of the destruction of public health infrastructure and the urgency of testing interventions.
        iv. Exceptions:
            1. Physical interventions such as the collection of blood or tissue samples or vaccinations;
            2. Interviews with individuals or focus group discussions, especially where sensitive information is being sought (for example, about child, spousal or elder abuse or illegal drug use);
            3. Small scale population studies (e.g., of an isolated indigenous group or an extended family).
    b. When is group consent required? - many public health interventions that involve individuals do not require their consent. Their implementation can be decided by public health officials working within their legal mandate or by political authorities responsible for the public good, including health departments.
5. Confidentiality: Anticipate potential breaches of confidentiality and implement measures to prevent this.
    a. Who will have access? – in a single research study an individual's data can be viewed by many members of the research team. Although data storage and transmission are supposed to be secure, there are many opportunities for

breaches to occur, whether due to technical failure or to human error. Even when data are anonymized, it is often possible to identify individuals or populations by combining databases.

   b. In what format the data will be preserved, how secure they will be, how long they will be kept and how they will be destroyed?
   c. Security measures - When planning a study, researchers should anticipate potential breaches of confidentiality and state how they can prevent or at least minimize their occurrence. Among other safeguards, they must explain who will have access to the data.
   d. When disseminating results of the research researchers need to respect the privacy of individuals. Some details of the study may need to be suppressed to avoid identifying participants.

6. Access to results
   a. Post-trial access to intervention may not be feasible in public health trials but needs to be considered before the study.
7. Disclosure of research results need to be considered: the researcher has an obligation to report the findings of the study even if the findings are negative.

7. International guidelines on the medical certification of cause of death

The purpose of the International Classification of Diseases (ICD) is to permit the systematic recording, analysis, interpretation, and comparison of mortality data collected in different geographic areas and at different times.[viii] It was originally developed to classify the causes of mortality recorded at the registration of death, but its scope has been extended to include diagnoses in morbidity. The ICD is a variable-axis classification which groups statistical data on diseases in the following structure:

- Epidemic diseases
- Constitutional or general diseases
- Local diseases arranged by site
- Developmental diseases
- Injuries

The basic ICD is a single coded list of three-character categories which can each be divided up into ten four-character subcategories using a decimal point system. It uses an alphanumeric code with a letter in the first position and numbers in the rest. The 10th revision of ICD (ICD-10) comprises three volumes: Volume 1 contains the main classifications; Volume 2 contains instructions on how to use the classification; and Volume 3 contains an alphabetical index to the classification and should always be used with Volume 1 when coding, as it contains many terms that are not included in Volume 1.

The World Health Assembly in 1967 defined the causes of death to be entered on the medical certificate of causes of death as *"all those diseases, morbid conditions or injuries which either resulted in or contributed to death and the circumstances of the accident or violence which produced any such injuries."* The international form of medical certificate of cause of death is designed to indicate the sequence of morbid events leading to the immediate cause of death, and thus facilitates the selection of the underlying cause of death when more than one cause of death is listed. Public health interventions can thus be implemented to prevent the underlying causes of death. However, in practice, certifiers often do not follow the ICD guidelines for medical certification of the cause of death.

Thus, the ICD has a set of selection and modification rules to guide coding and the selection of a single underlying cause of death from the causes of death entered on a death certificate. This underlying cause of death is then assigned an ICD-10 code according to standard

procedures or coding rules which are described in Volume 2. In addition to the underlying cause, multiple causes of death are useful for evaluating the frequencies of co-morbidities and/or sequential combinations of causes for epidemiological research.

Causes of death have been defined as all those diseases, morbid conditions or injuries that either resulted in or contributed to death and the circumstances of the accident or violence that produced any such injuries. A death often results from the combined effect of two or more conditions. These conditions may be completely unrelated but present simultaneously; or they may be causally related to each other in a patho-physiological sequence. Where there is a sequence, it is important to ascertain the **underlying cause of death** (defined below), which is the cause that is selected for the purpose of tabulation, for reasons mentioned above.

The underlying cause of death is defined as

- **the disease or injury which initiated the train of events leading directly to death**

OR

- **the circumstances of the accident or violence which produced the fatal injury**

When a number of conditions have been identified to have occurred in the deceased, it is the responsibility of the reviewer to construct a chain of events that place the various conditions in sequence, i.e. one leading to the second to the third etc. (see example below). Once the chain has been constructed, then the reviewer can select the underlying cause, as defined above, and illustrated below.

Example 1:

Massive upper gastro intestinal haemorrhage

caused by

Bleeding esophageal varices

caused by

Cirrhosis of the liver

caused by

Chronic Hepatitis B infection

It is evident from this case that **Chronic Hepatitis B infection** initiated the chain of events that resulted in the upper gastrointestinal haemorrhage and death, and hence Chronic Hepatitis B infection is selected as the underlying cause.

Example 2:

Aspiration bronchopneumonia

due to (or as a consequence of)

Prolonged coma

due to (or as a consequence of)

Cerebrovascular infarction

Cerebrovascular infarction is adjudged as the underlying cause.

Example 3:

Pulmonary embolism

due to

Pathological fracture of femur

due to

Secondary carcinoma of femur

due to

Carcinoma of breast

Carcinoma of breast is adjudged as the underlying cause.

Example 4:

Cerebral haemorrhage

due to

Hypertension

due to

Chronic pyelonephritis

due to

Prostatic adenoma

Prostatic adenoma is adjudged as the underlying cause.

Example 5:

Traumatic shock

due to

Multiple fractures of lower limbs and hip

due to

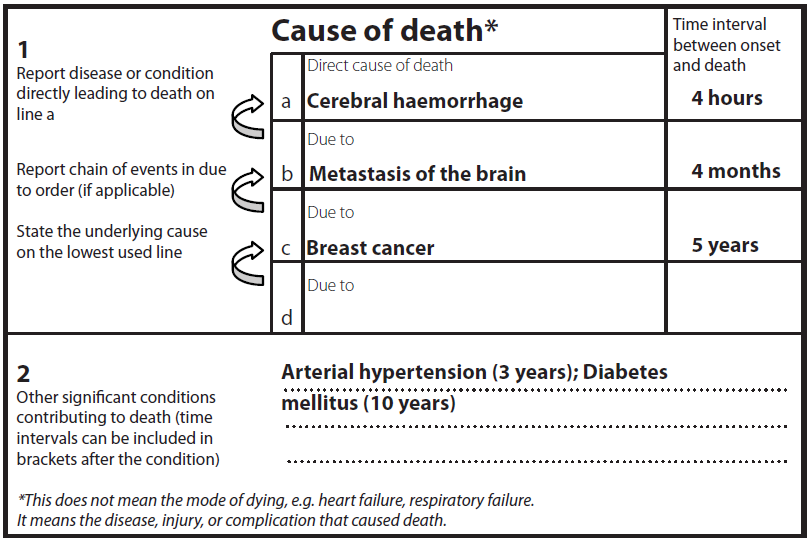
Pedestrian hit by truck (traffic accident)

Pedestrian hit by truck is adjudged as the underlying cause

In each of the above examples, there is a clear sequence of events (**causal sequence**) that

can be constructed from detailed information available in most situations of hospital deaths or those occurring with medical attention. Similar detail of information is not available from VA interviews. In many instances, **only one cause** can be identified from the history and symptom duration checklist. In that case, only the identified cause needs to be listed on the certificate. When more than one cause is identified, they should be listed in the pathophysiological sequence of events, on the standard death certificate in Figure 4. In case there are causes present, which do not fall directly in the pathophysiological sequence, they should be listed in Part II of the certificate.

Figure 4: International form of medical certificate of cause of death (2016)



Cause of death*			Time interval between onset and death
1 Report disease or condition directly leading to death on line a	a	Direct cause of death: **Cerebral haemorrhage**	**4 hours**
Report chain of events in due to order (if applicable)	b	Due to: **Metastasis of the brain**	**4 months**
State the underlying cause on the lowest used line	c	Due to: **Breast cancer**	**5 years**
	d	Due to:	
2 Other significant conditions contributing to death (time intervals can be included in brackets after the condition)		**Arterial hypertension (3 years); Diabetes mellitus (10 years)**	

**This does not mean the mode of dying, e.g. heart failure, respiratory failure. It means the disease, injury, or complication that caused death.*

Where there is a clear sequence of events on the certificate, the cause of death listed on the lowermost line of the sequence in part 1, which initiated the train of events leading to death is defined as the **underlying cause of death**.

For practical purposes, the cause listed on the topmost line of the sequence is referred to as the **immediate cause of death**, since it is the terminal event that occurred, leading to the death. While constructing the chain of events, it is essential to note that modes of death such as respiratory failure, heart failure, or brain death etc., should not be considered as immediate causes of death.

All other causes listed on lines in between the underlying cause of death (on the lowermost line), and the immediate cause (on the topmost line) are referred to as **antecedent causes of death**.

Sometimes (notably among adults) there are other significant medical conditions present in

the deceased, which do not fit into any defined sequence of events, but may contribute, in an indirect manner, to the final event of death. For instance, in the first example, if the deceased also happened to suffer from COPD, then during the verbal autopsy, relatives of the deceased may also provide information about the symptoms and signs of COPD. Or, in the second example, the deceased may have been suffering from Diabetes, which may be elicited in the history. In such situations, those diseases or conditions that are independent of the causal chain of events (which originated in the underlying cause and terminated in the immediate cause) are defined as **contributory causes of death.**

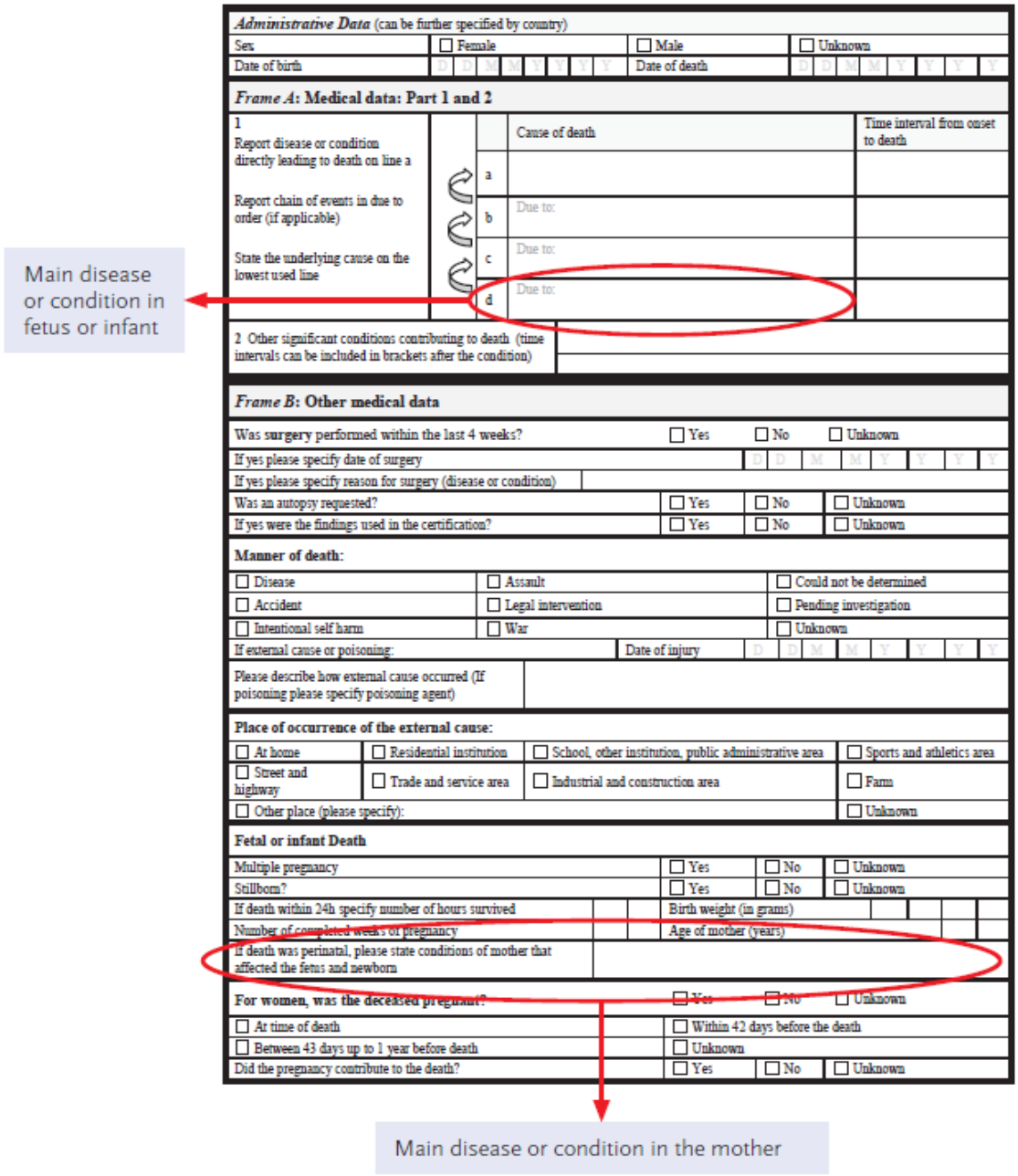
Whilst Figure 4 shows the basic medical certificate of cause of death form, in some instances additional information is required to code the cause of death accurately using the ICD-10 classification. These include:

- **perinatal deaths** where conditions in the mother could have affected the fetus or infant
- **maternal deaths** where it is important to know the pregnancy status of the woman
- **injuries** – where the manner of death is important

For this reason, the WHO 2016 international form for the medical certificate of cause of death includes additional sections for the required information, see Frame B in Figure 5 below. Previously, the WHO had a separate perinatal death certificate which captures the same information but in a different format, see box below.

Causes of death
(a) Main disease or condition in fetus or infant
(b) Other diseases of conditions in fetus or infant
(c) Main maternal disease or condition affecting fetus or infant
(d) Other maternal diseases or conditions affecting fetus or infant

Figure 5. WHO death certificate for all ages



Administrative Data (can be further specified by country)

Sex	☐ Female	☐ Male	☐ Unknown
Date of birth	D D M M Y Y Y Y	Date of death	D D M M Y Y Y Y

***Frame A*: Medical data: Part 1 and 2**

		Cause of death	Time interval from onset to death
1 Report disease or condition directly leading to death on line a	a		
Report chain of events in due to order (if applicable)	b	Due to:	
State the underlying cause on the lowest used line	c	Due to:	
	d	Due to:	
2 Other significant conditions contributing to death (time intervals can be included in brackets after the condition)			

***Frame B*: Other medical data**

Was **surgery** performed within the last 4 weeks?	☐ Yes	☐ No	☐ Unknown
If yes please specify date of surgery	D D M M Y Y Y Y		
If yes please specify reason for surgery (disease or condition)			
Was an autopsy requested?	☐ Yes	☐ No	☐ Unknown
If yes were the findings used in the certification?	☐ Yes	☐ No	☐ Unknown

Manner of death:

☐ Disease	☐ Assault	☐ Could not be determined
☐ Accident	☐ Legal intervention	☐ Pending investigation
☐ Intentional self harm	☐ War	☐ Unknown
If external cause or poisoning:	Date of injury	D D M M Y Y Y Y
Please describe how external cause occurred (If poisoning please specify poisoning agent)		

Place of occurrence of the external cause:

☐ At home	☐ Residential institution	☐ School, other institution, public administrative area	☐ Sports and athletics area
☐ Street and highway	☐ Trade and service area	☐ Industrial and construction area	☐ Farm
☐ Other place (please specify):			☐ Unknown

Fetal or infant Death

Multiple pregnancy	☐ Yes	☐ No	☐ Unknown
Stillborn?	☐ Yes	☐ No	☐ Unknown
If death within 24h specify number of hours survived		Birth weight (in grams)	
Number of completed weeks of pregnancy		Age of mother (years)	
If death was perinatal, please state conditions of mother that affected the fetus and newborn			

For women, was the deceased pregnant?	☐ Yes	☐ No	☐ Unknown
☐ At time of death	☐ Within 42 days before the death		
☐ Between 43 days up to 1 year before death	☐ Unknown		
Did the pregnancy contribute to the death?	☐ Yes	☐ No	☐ Unknown

8. ICD-10 mortality coding overview

In order to ensure comparability of data across time and place, the ICD has a set of rules to guide multiple cause coding and the selection of a single underlying cause of death (classification of underlying causes) from the causes of death entered on a death certificate. Multiple cause coding refers to the assigning of an ICD-10 code to every condition listed on the death certificate. The ICD-10 selection and modification rules are then applied to classify and code the underlying cause of death which is used for statistical purposes.

8.1. Multiple cause coding

When coding and classifying causes of death, you must first assign ICD codes to all the conditions mentioned on the death certificate. Many coding instructions are based on specific ICD codes and, to determine whether any of the instructions apply, you need to know the ICD codes for all conditions on the certificate.

Simplified instructions for assigning a code to a disease or injury are set out below.

1. Identify the **type of statement** to be coded and refer to the appropriate section of the **Alphabetical index (Volume 3)**.
2. Locate the **lead term**. For diseases and injuries, this is usually a noun for the pathological condition. However, some conditions expressed as adjectives or eponyms are included in the Alphabetical index as lead terms.
3. Read and be guided by any **note** that appears under the lead term in Alphabetical index.
4. Read any **terms enclosed in parentheses** after the lead term (these modifiers do not affect the code number), as well as any terms indented under the lead term (these modifiers may affect the code number), until all the words in the diagnostic expression have been accounted for.
5. Follow carefully any **cross-references** (‘see’ and ‘see also’) found in the Alphabetical index.
6. Refer to the **Tabular list (Volume 1)** to verify the suitability of the code number selected
7. Be guided by any **inclusion or exclusion terms** under the selected code, or under the chapter, block or category heading.
8. Assign the code.

8.2. Selection of underlying cause

There are two steps to selecting the underlying causes: firstly, to identify the starting point of the causal sequence (tentative underlying cause), and then to check if any special instructions apply to the starting point identified. If so, the initial starting point is modified, and the process repeats until a starting point which has no special instructions is identified.

8.2.1. Finding the starting point (Steps SP1 – SP8)

SP1 - Single cause on certificate in Part I or 11:

- select as starting point and then go to Step M4

SP2 – Only one line used in Part 1:

- if more than one condition in a line, select first mentioned as tentative SP then go to Step SP6
- if only 1 condition in Part 1 and 1 or more in Part 2, select condition in Part 1 as tentative SP then go to Step SP6

SP3 – More than 1 line in Part I; first cause on lowest line explains all entries on lines above

- select lowest line cause as tentative SP and then go to Step SP6

SP4 - First cause on lowest used line does not explain all entries above, but a sequence ends with the terminal condition

- if only one sequence ending in terminal condition, select originating cause in sequence as the tentative SP then go to Step SP6
- if more than one sequence ending in a terminal condition, select the starting point of first mentioned sequence as tentative SP then go to Step SP6

SP5 – No sequence in Part 1

- If there is no sequence ending in the terminal condition, select the terminal condition as tentative SP then go to Step SP6

SP6 – Obvious cause

Check whether the tentative starting point you selected in Steps SP1 to SP5 was obviously caused by another condition on the certificate.

- If the tentative starting point is in Part 1, then this other condition must be either on the same line, further down in Part 1, or in Part 2.
- If the tentative starting point is in Part 2, this other condition must also be in Part 2.
- Repeat this process with new tentative SP until SP has no obvious cause further down on certificate then go to step SP7.

If there is no condition mentioned on the certificate that obviously caused the tentative starting point you selected in Steps SP1 to SP5, go to Step SP7.

SP7 – Ill-defined conditions

Now check whether the tentative starting point is listed in the table of ill-defined conditions. If it is, the tentative starting point is considered ill-defined. Then do as follows:

- If there are other conditions reported on the certificate, check whether they are all ill-defined. If all other conditions are ill-defined, go to Step M1.
- If there is at least one condition that is not ill-defined, then disregard the ill-defined condition and go to Step SP1 and select another starting point, as if the ill-defined condition had not been mentioned on the certificate.

If the tentative starting point is not ill-defined, go to Step SP8.

SP8 – Conditions unlikely to cause death

Next, check whether the tentative starting point is listed in the table of conditions unlikely to cause death. If it is, do as follows:

- If there are other conditions reported on the certificate, check whether they are all ill-defined or unlikely to cause death. If they are all ill-defined or unlikely to cause death, go to Step M1.
- If there are other conditions reported that are not ill-defined or unlikely to cause death, first check whether the death was caused by a reaction to treatment of the condition unlikely to cause death that you selected as the tentative starting point. If it was, then select the reaction to treatment as the starting point. Next, go to Step M1.

- If the death was not caused by a reaction to treatment of the condition unlikely to cause death, check whether the condition was the cause of another condition that is not on the list of conditions unlikely to cause death and that is not ill-defined. If it was, then the condition unlikely to cause death is still the tentative starting point. Next, go to Step M1.
- If there was no reaction to treatment and no complication of the condition unlikely to cause death, then disregard the condition unlikely to cause death. Go to Step SP1 and select another starting point, as if the condition unlikely to cause death had not been mentioned on the certificate. If the starting point is not a condition unlikely to cause death, then go to Step M1.

8.2.2. Checking for modifications of tentative starting point (Steps M1 – M4)

Step M1 – Special instructions

Check whether special coding instructions apply to the tentative underlying cause. If a special coding instruction applies, assign a new tentative underlying cause according to the instruction.

Next, check whether any special instructions apply to this new tentative underlying cause. That is, reapply Step M1. Repeat until you have found a tentative underlying cause that is not affected by any further special coding instruction. Next, go to Step M2.

If no special coding instruction applies, then the starting point you found using Steps SP1 to SP8 is the tentative underlying cause. Next, go to Step M2.

Step M2 – Specificity

If the tentative underlying cause describes a condition in general terms and a term that provides more precise information about the site or nature of this condition is reported on the certificate, this more informative term is the new tentative underlying cause.

Next, check whether this new tentative underlying cause can be specified even further by other terms on the death certificate. That is, reapply Step M2. Repeat until you have found a tentative underlying cause that cannot be specified further.

Step M3 – Recheck Steps SP6, M1 and M2

If, at this point, the tentative underlying cause is not the same as the starting point you selected using Steps SP1 to SP8, then go back to Step SP6. Repeat the procedures described in Steps SP6, M1 and M2.

When you have found a cause of death that is not further changed in either Step SP6 or Steps M1 to M3, you have arrived at the underlying cause of death.

Step M4 – Special instructions on maternal mortality and surgery and other medical procedures

If SP1-8 and M1-3 point to an underlying cause being surgery or a medical procedure, apply instructions from section 4.2.9 in Volume 2; or due to poisoning or injury, code the external cause of death. If the decedent is a woman and pregnancy, childbirth or puerperium is reported; apply instructions on maternal mortality in section 4.2.8 in Volume 2.

9. Tabulation and statistical presentation

The ICD prescribes a set of guidelines on data presentation of ICD coded causes of death by age groups and gender, to facilitate statistical and epidemiological interpretation. In principle, the degree of detail in cross-classification by cause, age, gender, and geographical area will depend on the purpose(s) for developing the statistics, as well as the practical limits to their tabulation. This chapter discusses some relevant aspects of age groupings, and more importantly, aggregations of deaths by cause for statistical tabulation.

The determination of age at death is important in communities where verbal autopsy procedures are implemented, as people may not be aware about birth dates, and the Gregorian calendar may not be implemented locally. It is recommended that verbal autopsy interviewers are appropriately training in recording as accurately as possible the age at death. From both demographic and epidemiological perspectives, correct age reporting is important, and the compilation of statistics is recommended according to standard age-groupings as follows:

1. For deaths below one year, reporting should be according to the following categories:
    a. 0–6 days (early neonatal deaths)
    b. 7–27 days (late neonatal deaths)
    c. 28–364 days (post neonatal deaths)
    d. 0–364 days (infant deaths)
2. 1– 4 years
3. Five year age groups from 5 to 84 years (i.e. 5–9, 10–14, …..80–84, 85+)

In terms of tabulations by cause, the ICD recommends that primary tabulations should be according to the detailed list of three-character ICD categories. In general, the hierarchical structure of the ICD allows considerable flexibility for possible groupings of the three-character categories (over 2000 in all), to produce a tabulation which is epidemiologically meaningful, at the same time with as few empty cells as possible. The ICD recommends several special tabulation lists for mortality statistics, which are provided in Volume 1, and these lists could be used in preparing statistics for the monitoring and analysis of population health status and mortality-related health concerns at both national and international level. Of these, the first list including 103 cause categories, is practical and convenient for most publication purposes, especially as it provides for residual elements within each ICD chapter, which enables the derivation of chapter specific sub totals for comparisons across populations and over time.

The use of these ICD lists implies that the source of data on causes of death is from medical certificates issued by the attending physician. The ICD also stipulates that deaths that are not medically certified should be published separately. More details regarding these guidelines and recommendations on tabulation are available in the chapter titled 'Statistical Presentation' in Volume 2 of the ICD.

Based on these guiding principles in tabulation, there is potential to use a special **selected mortality list,** to tabulate cause of death statistics derived through verbal autopsy methods. This list has been designed in accordance to the following principles:

- Structured according to the ICD-10 chapters
- Includes causes of epidemiological and public health relevance for developing countries
- Of these, specific causes that have clearly distinguishable symptom complexes have been listed separately (expert algorithms for diagnosing these causes available)
- Some specific symptoms, which may be the only information gleaned from the verbal autopsy, have been listed as individual causes, to serve as clues to the possible underlying pathology
- Residual cause categories have been provided for some of the chapters where it is considered necessary to have a chapter total e.g. maternal causes, perinatal causes, infectious and parasitic diseases etc.
- The cause categories enable evaluation of individual health programs for specific infectious diseases, Integrated Management of Childhood Illnesses (IMCI), maternal health, injury prevention, chronic disease control etc.
- An overall residual category has been provided, to complete the tabulation of all possible causes

The list consists of 64 causes of death **(Appendix 2)** and provides information about many important diseases and external causes of death that can be identified by verbal autopsy methods, as well as some other significant conditions of public health importance that require supporting diagnostic information (e.g. cancers). Primary tabulation of deaths by age and sex and cause according to this list are recommended, for comparability of data collected by these VA methods in different populations. Such tabulations facilitate comparison over time and observation of shifts in relative frequencies of individual causes as local health programs take effect.

It also permits comparisons between sub national areas and population subgroups. Further,

it enables the comparison between statistics derived from VA methods with statistics from vital registration systems or health facilities, where causes of death are medically certified. Tabulations according to this list can be collapsed into broader cause categories, depending on further research or policy interests. Collapsing results to broader cause groups is also useful for assessing validity of data. If individual deaths were coded to specific ICD codes, tabulations based on such codes would be amenable to different ICD code groupings, based on specific research interests.

10. Background to the 2016 Verbal Autopsy WHO VA Instrument

10.1 Principles of verbal autopsy

The practice of verbal autopsy methods has been adopted to obtain the best evidence available to identify the probable cause of death for deaths occurring at home, in the absence of medical attention, or as is often the case in South Africa, where Western medical care was sought during the terminal illness but the death occurred at home, or where the certified cause of death is not reliable.

By definition, verbal autopsy involves an interview with a close caregiver of the deceased to elicit details of symptoms, signs, clinical events or circumstances during the illness preceding death, and an assessment of the collected information by physician reviewers or using specially developed computer software, to determine a probable cause of death. Cause of death ascertainment using verbal autopsy was principally developed to provide information in settings with limited access to health care and poor CRVS, and is based on three key assumptions:

- The symptom complex for each disease of interest is unique (e.g. neonatal tetanus or motor vehicle accidents)
- Family members or other caregivers can accurately recall symptoms and their timing
- Caregivers are willing to disclose this information (important where a death is stigmatized)

These assumptions have been successfully validated for causes of infant deaths[xvii] [xviii] and a few clearly demarcated causes of adult deaths such as injuries[xix] and pregnancy-related[xx] deaths. Certain common causes of adult mortality are easy to recognize by the community, based upon their cardinal symptoms e.g. cerebrovascular disease-causing one-sided paralysis, chronic breathlessness and cough in COPD. However, other common communicable (tuberculosis, malaria, HIV) and non-communicable diseases (cancers, diabetes, renal, digestive tract disorders etc.) have overlapping symptomatology, which makes it difficult to clearly distinguish one from another even for clinical diagnosis, let alone verbal autopsy. Also, as described earlier, there could be multiple illnesses or conditions in an individual, either sequentially or simultaneously. This is particularly so in the case of adult deaths.

It is now recognized that while many adult deaths still occur at home or outside registered clinical facilities, the deceased could have accessed some health care in the period preceding death or may even have died within a health facility. For these reasons, the VA interview includes the collection of relevant health facility access and health care data. This could include details from available medical documents, or any information on the illness or death conveyed to the family by the consulted health professional. If possible, the health facility could be contacted to obtain more detailed information, provided consent for this is obtained from family members.

The WHO2016 VA tool has three different forms for deaths in different age groups; one to capture data on stillbirth, perinatal, and neonatal deaths; one for childhood deaths; and another for adult deaths. The principal causes of death in each of these age groups differ, and by developing a separate form for each group, the scope and duration of the interview is effectively limited. The layout and question flow in the forms is structured using skip patterns, which allow the recording of only pertinent data depending on the nature of the case. The forms have the same general structure but include specific sections and or questions pertaining to the age of the deceased and the circumstances of the death. This is described in more detail later in this chapter.

The key component of the verbal autopsy interview is the symptom duration checklist, which includes questions intended to provide sufficient information to arrive at a valid cause of death, and to exclude differential diagnoses. There are several key factors in judging the quality of the information made available from these questions to construct a diagnosis; these distinguish between clinical histories used regularly by medical practitioners, and verbal autopsies.

A verbal autopsy relates to a clinical event/series of related clinical events that occurred at a time prior to the interview. The respondent did not experience the illness, but observed, or was told about, the symptoms and signs in the deceased. This fundamental difference between the two results is evident in the somewhat ‘lay’ design of the symptom duration checklist, in terms of terminology used, and level of clinical detail sought. Medical practitioners would prefer to review information similar to a clinical history record, which includes questions on specific details and characteristics of individual symptoms – e.g. number of diarrhoeal episodes per day; consistency, colour and odour of faeces, number of

vomiting episodes, specific symptoms and signs of circulatory failure. They consider these questions important to verify the diagnosis, since their treatment plans hinge on such verification of the diagnosis. However, these are not feasible in the verbal autopsy setting, where respondents can be expected to remember only some major symptoms or grossly visible signs, e.g. presence of diarrhoea, and presence of blood, and a reasonable estimate of the duration. Table 2 highlights some conceptual differences between design characteristics of a clinical history and a verbal autopsy interview, and it is useful for medical practitioners to consider these while evaluating verbal autopsies to determine probable causes of death. Details of the actual process of cause-of-death certification from verbal autopsies are provided in later chapters.

Table 2: Differences between clinical histories and verbal autopsies

Design characteristic	**Patient history**	**Verbal autopsy**
Motive	Preliminary step in search for exact diagnosis to plan treatment	Retrospective questioning to identify underlying cause of death with reasonable certainty
Respondent	Patient in person	Relative, who should not be expected to remember or know about anything more than gross details
Procedure	Interview followed by physical examination, and possibly investigations	One-off interview, no follow up
Recall period	Usually a few days, since onset of symptoms	Weeks / months after death
Interviewer	Physicians / other health workers whose notes are reviewed by examining	Usually lay interviewers
Instrument	Narrative written after completing interview, and composing thoughts, requires much training and practice to become skilled	Short narrative to start the interview, followed by a structured questionnaire, including questions about health facility visits
Disease classification	Any possible disease	Search for a **limited number of causes**, which □ are important causes of death in the population □ are characterized by symptoms easily recognized by the community □ can be uniquely identified from these symptoms

Given this background, verbal autopsy is an imperfect method to arrive at a probable cause of death, applicable only in settings where there is no reliable data on cause-specific mortality based on medical assessment. Despite its limitations, however, verbal autopsy can serve as an interim measure to derive such information, until adequate health care systems are set up to provide wider coverage of medical attention, leading to availability of expert opinion on the cause of death as part of vital registration.

10.2 General structure of the VA instrument

The 2016 version of the WHO verbal autopsy (VA) data collection instrument – WHO 2016 – is being used for data collection. The instrument is administered digitally on tablets using Computer-Assisted Personal Interviewing (CAPI). Data are uploaded electronically to a central server located at GeoSpace HQ. The instrument is designed to cover deaths for all age groups, including maternal and perinatal deaths, as well as deaths caused by injuries.

The WHO 2016 version of VA questionnaires are organized in three separate forms:
WHO VA Questionnaire 1 —for neonatal and perinatal deaths, and stillbirths (deaths of infants aged less than four weeks).

WHO VA Questionnaire 2 —for post-neonatal and child deaths up to 11 years (deaths of children aged four weeks to 11 years).

WHO VA Questionnaire 3 —for adolescent and adult deaths (death from 12 years and above).

Note that these three different forms are part of the same digital questionnaire and are activated or deactivated using specific skip patterns and questions (the response to one or more age questions in the beginning of the questionnaire activates the applicable form). Skip patterns are also built into each form. A skip pattern or skip logic is a question or series of questions associated with a conditional response. Hence some questions pertain only to certain respondents, depending on earlier responses. Skip patterns therefore change what question a respondent must answer next, based on how they answered the current or previous question.

The three forms share several common modules on **identity, socio-economic characteristics, and health services utilisation**, but include specific modules on the **history, symptoms and clinical events** during the terminal illness preceding death. Such separation is necessary as each questionnaire targets certain common causes of death within the specific age group. For instance, the first form is designed to identify stillbirths, and deaths from prematurity (incomplete pregnancy); low birth weight; birth asphyxia; birth injuries; hypothermia, new-born bacterial sepsis, and congenital malformations, among other rarer causes. The post-neonatal and child death questionnaire addresses the above causes (except for stillbirths), as well as the common infectious diseases such as pneumonia, diarrhoea, malaria, vaccine preventable diseases such as measles and pertussis, and injuries, among others. Finally, the adolescent and adult questionnaire addresses common adult causes of death such as tuberculosis, HIV/AIDS, malaria, maternal causes, major non-communicable diseases and injuries.

The questionnaire items are largely in the form of Yes/No response choices; with a few items that collect information either in categories (e.g. durations in days/weeks/months); or in grades of severity (e.g. fever –mild/moderate/severe). There are also some items in which an open text response is to be recorded (e.g. the cause of death mentioned by a health worker).

In the symptoms sections, there are several modules with detailed skip patterns. For instance, the module on fever starts with an initial question about fever, and if there is a positive response, goes on to elicit more details about duration, severity, pattern etc.

In each form, in addition to the main sections that collect information on symptoms and clinical events, there are three additional sections that collect allied information.

- information on a history of medical conditions, as known to the family members in the form of diagnostic opinion conveyed by health professionals. This section provides important clues towards the potential causes of death. The information on past medical conditions may or may not be directly related to the terminal illness but provides additional evidence to ascertain the diagnosis.
- details from any available health records of the deceased, for example from hospital discharge notes, medical prescriptions, laboratory or X- ray or scan reports, among others. Often such information relates to chronic conditions such as diabetes, cardiovascular diseases, cancers, or TB. Such information could be of useful in making the diagnosis of the cause of death.

- **The open narrative text section -** an open text narrative section which requests the respondent to provide a brief description of the illness and terminal events in her/his own words. This sometimes provides critical information that may not be captured in any of the other sections or items of the questionnaire.

10.3 Verbal Autopsy Ethical aspects

10.3.1 Informed consent

Informed consent must be provided by the respondent before an interview takes place.

10.3.2 Privacy and confidentiality

Information obtained during VA interviews remains strictly CONFIDENTIAL. VA materials are not to be left in an unsecured location, where unauthorized people may have access to them. Electronic data should be password protected.

10.3.3 Timing of VA interviews

The time period between the date of death and the date of the VA interview has important implications for the quality of information collected. Long recall periods are likely to impair a respondent's ability to remember and report relevant information, whereas if a VA interview is conducted too close to the death, it may cause distress and impact the willingness and ability to engage in an interview and facilitate accurate information for VA. Therefore, the time period between death and VA interview should be long enough to provide time for mourning, and short enough for people to recall details on the circumstances leading to death. The usual mourning period is 1–3 months in most cultures and people generally can recall the events leading to death up to 12 months. So, it is recommended that a VA interview should be completed within six weeks – 12 months after a death.

10.3.4 Identification of an appropriate respondent.

The interviewer must identify the primary care giver (usually a family member) who was with the deceased in the period leading to death. This is the individual most likely to know about the deceased person's signs and symptoms during the period just before death. The educational status and communication skills of potential respondents may also be considered while identifying the most appropriate respondent. The respondent who provides information about the deceased can also be a witness to a sudden death or accident.

The VA interviewer must determine who was with the deceased and caring for the person in the period leading to death. For deaths of infants and children, the mother is usually the best respondent unless she is working away, in which case it may be another close family member, often a grandmother or aunt. Acceptable respondents are:

- head of the household or that person's spouse
- either parent (preferably the mother), or grandmother/other female relative in a neonatal or child's death
- sister or adult female relative in case of potential maternal death
- responsible family member or close relative of the deceased (at least 18 years)
- mature non-relative permanent resident of the deceased person's household (at least 18 years of age).

Generally, a good respondent is a person who:

- was present during the illness and around the time of death;
- was involved in any type of care for the deceased during the illness and around the time of death;
- knew the deceased very well and over a long period of time;
- knew the habits and lifestyle of the deceased.

11. Completion of the 2016 WHO verbal autopsy questionnaires

11.1 Detailed structure of the verbal autopsy questionnaires

The layout and questions' flow of all three questionnaires is guided by two basic principles:

- all three questionnaires follow the same general structure;
- "skip patterns" (when an answer to a specific question results in bypassing or "skipping" other irrelevant questions) are employed to facilitate the use of the questionnaires.

The skip patterns are driven by:

- age
- sex
- maternal or perinatal death
- symptoms/signs
- other relevant features of symptoms and signs requiring more detailed information (e.g. duration, timing, severity, and location)

11.2. Sections of the VA questionnaire

Introductory Section (Team information, GPS, and HH outcome)

e-consent

1. Preset HIV and Malaria mortality levels and season (wet or dry)
2. Information on the respondent
3. Information about the deceased
    a. Socio-demographic information
    b. Civil registration information
4. History and details of injury/accidents
5. Medical history associated with the final illness
    a. Duration of final illness
    b. History of diseases likely to be associated with or the cause of death
    c. General signs and symptoms associated with final illness
    d. Signs and symptoms associated relevant to maternal deaths
    e. Signs and symptoms relevant to neonatal and child deaths
    f. Health service and contextual factors

g. Death certificate with cause of death

6. Open narrative (text field). This is an embedded image in the SA data.
7. Check list of key indicators from the narrative description

The Introductory Section collects information on the team and interviewer identification, as well capturing the decedent's unique identification number. A subsection recording whether access to the household was successful and, if not, the reasons why, enabling an estimate of household response rate. This section also captures the GPS coordinates for the corresponding household.

The e-consent section includes the administration of digital consent. An interview cannot continue without the respondent providing written consent on both the digital platform and on a hard copy form.

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 programmes 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 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.

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.

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, to complete the checklist of some indicators (section 6a) that are required for assigning causes of death using Tariff 2.0.

11.3. The importance of the VA narrative

The open narrative section is extremely important, since the respondent might disclose information relevant to the cause of death of the decedent that has not been recorded as part of the standard questions. The open narrative also provides an informal recall of the circumstances of death which can provide a more holistic picture than the structured information provided in the rest of the questionnaire. The interviewer must make sure that the narrative does not contradict information captured as part of the structured questions, by making as accurate notes as possible. Close to the beginning of the questionnaire, the interviewer will be required to ask the respondent about the general cause and circumstances of death for the first time. This information is recorded in the fieldworker's notebook and images of their notes recorded at the end of the questionnaire. Once the respondent has completed the initial response, interviewers prompt for additional information as relevant:

- Symptom recognition (when were first symptoms recognised, what other symptoms did s(he) have, what were the sequence of symptoms, when did the respondent realise illness was severe)
- Timing (how long it took from first symptoms to realising it was severe)
- Actions taken inside and outside the home (how long after first symptom(s) and severe symptom(s) was any action taken, what actions, was there any treatment given, what treatment, what was the response to treatment, who made the decision to seek or not to seek care, reason for this action, if care outside the home was not sought – why?)

Note, depending on the type of questionnaire completed (neonate, child, adult), a checklist regarding specific medical conditions is completed, according to the information collected for the open narrative. This checklist will automatically appear on the digital questionnaire after the interview has been concluded and the narrative itself captured.

12. Guidelines for physician cause-of-death certification from Verbal Autopsy

Reliability and validity of cause-of-death assignment from verbal autopsy data are the key elements in determining their usefulness. Physician review of completed VA instruments was the most common method for cause-of-death assignment. However, a standard approach to assigning causes of death is essential. This requires adequate training on cause-of-death certification and verbal autopsy review, as well as the use of standard disease / condition specific diagnostic guidelines to increase reliability and reduce inter-observer bias. Chapter 13 provides a set of standard disease descriptions and criteria for some of the common causes of deaths, based on previous epidemiological observations and experience. It is important to rely on the presence of key words or cardinal symptoms of the disease (e.g. sudden onset chest pain for diagnosing myocardial infarction, recurrent bouts of cough with breathlessness for COPD), as well as associated symptoms (e.g. radiation of pain, associated sweating etc. for MI, clinical features of cor pulmonale for COPD), as is usually done while making a clinical diagnosis. This is because relatives may not know or be able to recall specific details, especially when they are mostly subjective in nature.

Reviewers are expected to provide an opinion on the probable cause of death based on the information available in the VA, and with the assurance that these data are collected purely for generating health statistics for policy formulation and program evaluation, and not for any legal purposes.

Reviewers are encouraged to assign, wherever possible, specific disease/condition as causes of death, rather than ill-defined conditions such as senility, abdominal pain, fevers etc. Diagnostic criteria are provided in Table 3, to assist and guide the selection of specific causes of death. Also, wherever available, information on the illness before death – from medical documents available at the home of the deceased, or as told to the relatives by health personnel – should be considered and corroborated with the evidence provided in the symptom section of the verbal autopsy.

In summary, if there is only once cause identified, it should be entered on line I (a) of the certificate. If there is more than one cause, the immediate (or terminal) cause is entered at (a) and the underlying cause is entered last, with any intervening (or antecedent) causes listed in between. Any other significant condition that contributed to the fatal outcome, but was not related to the sequence of events causing death should be listed in part II as a contributory cause.

12.1. Special features of non-communicable diseases

Multiple causes of death have special relevance in the case of adult deaths from chronic diseases. For example, it is possible that an underlying cause of death, e.g. cerebrovascular disease (stroke), could pass through different pathophysiological sequences of events to terminate in bronchopneumonia, infected bed sores, or urinary tract infection as the immediate cause of death. Similarly, bronchopneumonia could be an immediate cause of death secondary to cerebrovascular disease, various cancers, or COPD, among other underlying causes. Hence, the sequence of events would have to be determined on a case- by-case evaluation of available information.

Non-communicable diseases can have symptoms and signs that may or may not be organ / system specific, as illustrated in the following examples:

- diabetes can manifest as renal failure, peripheral vascular disease, skin infections, or ketoacidosis and coma
- cancers may present only at the time of metastases, with symptoms and signs related to an organ (e.g. liver or lung) which is the not the primary site
- pathology in individual intra-abdominal organs present with similar symptoms and signs and cannot be differentiated based on clinical observations alone.

Non-communicable diseases commonly terminate in an infectious disease complication (pneumonia, urinary tract infection, septicaemia, etc.) that is the immediate cause of death. Therefore, the identification of such infectious causes, especially among adults, should stimulate a careful examination of the data from the VA interview to identify any possible non-communicable underlying causes of death.

The longstanding nature of non-communicable diseases means that individuals may have a history of visiting multiple health care facilities, with varying accounts of diagnostic and treatment services provided, and this could also complicate certification of the cause of death. Hence, it is important to take into account the response to each symptom, along with its duration, when constructing the sequence of events. In addition, details about past history, previous hospitalizations, or information conveyed by health professionals need to be considered.

12.2. Childhood infectious diseases

Acute febrile illnesses among children pose a particular problem when identifying a specific disease as the underlying cause of death, because multiple conditions commonly present at the time of death. Also, the relatively short interval between onset of symptoms and severe illness marked by lethargy, drowsiness and even unconsciousness, compounds the problem of identifying the initial symptom, which could point to the underlying cause.

For instance, children with either malaria or measles are prone to develop pneumonia at some stage in their illness. Similarly, meningitis could be confused with malaria, and convulsions could occur in both; and meningitis can also be preceded by pneumonia. Nevertheless, a careful interview could reveal the chronology of one cardinal symptom apart from fever, which could aid in the diagnosis of the underlying condition. For example, fast breathing early in the illness could indicate pneumonia as the underlying condition, especially in regions with low risk of malaria. On the other hand, presence of fever with convulsions or loss of consciousness in the absence of (or before) respiratory symptoms, would suggest malaria in an endemic or epidemic area.

Fever with rashes anytime within about a month before death is suggestive of measles as underlying condition, irrespective of the development of other organ-specific symptoms later in the course of the illness. With a history of diarrhoea, it is important to establish the presence of features of dehydration before death, to determine diarrhoea as the underlying cause. Finally, the presence of fever with neck stiffness (a particularly difficult sign to pick up in a VA interview) and or bulging fontanelle could guide the selection of meningitis as underlying cause in infants.

Given the uncertainties in determining specific underlying causes, reviewers should exercise judgment in applying diagnostic guidelines, and certifying multiple causes on the death certificate. The underlying cause is provided on the lowermost line on Part I of the death certificate. Significant contributory conditions co-existing with any of the above infectious diseases are noted on Part II.

12.3. Infectious diseases in adulthood

HIV/AIDS is a condition that requires careful attention, both for inclusion as well as exclusion as an underlying cause of death. Of course, the availability of serological evidence on HIV status is sufficient for labelling it as the underlying cause, but care should be taken to identify any specific co-existing infections (TB, fungal infections, diarrhoea, or opportunistic pneumonia), which should be listed as the immediate cause of death. In the absence of serological evidence, any clinical record of Kaposi's sarcoma, cryptococcal meningitis, or pneumocystis carinii pneumonia could be used to make a presumptive diagnosis of HIV/AIDS.

Several epidemiological studies which employ VA methods to measure HIV/AIDS mortality have adapted clinical features and signs from the WHO guidelines for the provisional clinical case definition for AIDS where diagnostic resources are limited, and either used them to construct specific diagnostic algorithms for the same, or categorised them into major and minor signs that help identify the diagnosis. For instance, major signs include chronic diarrhoea for more than one month, prolonged fever for more than one month, and weight loss of more than 10% body weight (inferred from a history of weight loss over one month). Minor signs that assist diagnosis include the presence of prolonged cough with difficulty in breathing, oral candidiasis, generalized swellings in groin, neck, armpits (suggestive of lymphadenopathy), and recurrent skin infections (herpes zoster). In general, judicious clinical judgment on the part of the physician certifier should be applied to ascertaining the diagnosis, using these major and minor signs as guide.

Tuberculosis is another infectious disease that may co-exist with HIV/AIDS, or manifest by itself. Wherever possible, the above criteria could be used to identify TB associated with HIV/AIDS, which could also be inferred from a relatively short interval between onset of TB-like symptoms and death (less than 3 months). A positive sputum smear is confirmatory of tuberculosis, either by itself or as co-existing with HIV/AIDS. In the absence of such evidence, a prolonged duration of symptoms of tuberculosis (fever, night sweats, cough, bloody sputum etc.) punctuated by periods of treatment and relapses, with terminal respiratory symptoms, could guide clinical judgment of TB.

12.4. Maternal causes of death

Death of a woman in the reproductive age group (12 to 50 years) should prompt a detailed investigation into whether it was associated with pregnancy, childbirth or within six weeks of childbirth (some definitions extend this period to one year after delivery). To ascertain this accurately, previous experience suggests that the respondent for the VA interview should be with a female relative of the deceased, and wherever possible, a sister.

The VA questionnaire has relatively straightforward questions in the 'maternal' module to identify pregnancy status, and conditions such as ante / postpartum haemorrhage, obstructed labour, and abortion. To identify eclampsia and other hypertensive disorders of pregnancy, the reviewer would have to integrate responses to the 'maternal' module with responses to other items in the questionnaire such as history of hypertension, presence of ankle swelling, and presence and nature of convulsions. Similarly, a diagnosis of puerperal sepsis would need positive responses to questions on fever, foul vaginal discharge, and lower abdominal pain, located in other sections of the questionnaire. Finally, occurrence of other medical conditions (e.g. hepatitis, rheumatic heart disease, malaria, diabetes etc.) while the deceased is pregnant requires their mention on the death certificate, which will lead to their coding as indirect maternal causes of death.

12.5. Stillbirths, and perinatal causes of death

Distinguishing between a live and stillbirth is crucial to accurately measure early age mortality i.e. perinatal, neonatal and infant mortality rates. In settings where births often occur without skilled attendance, identifying signs of life at birth is difficult' While a gold standard assessment of life at birth is based on an Apgar score measured by a trained clinician, VA information to differentiate live from stillbirths would be observation by the mother or birth attendant of a cry, breathing, or voluntary muscle movement at birth. Other signs such as presence of heartbeat or umbilical cord pulsation are generally too technical for family or traditional birth attendants to observe, record and finally report to the bereaved mother. Also, the mother (the best respondent for such events) would probably be too exhausted at the end of labour to notice such specific details and would rely on information conveyed to her by those present at the birth.

Finally, in many societies, deaths occurring within a few hours of birth are often not reported or are regarded as stillbirths. To obtain the best information possible, the questionnaire includes an item on the mother's appreciation of foetal movement prior to labour, a specific question on breathing at birth, followed by a general question on life at birth (which takes into account the crying, breathing and movement at birth).

Interviewer training programs stress the need for careful interviewing and recording of responses to these questions. Similar attention is required from physician reviewers in interpreting these responses and distinguishing between live births and stillbirths as well as possible. To assist such interpretation, specific validation studies are being conducted, to assess the predictive values of responses to each of these specific questions in arriving at the correct diagnoses.

For those live births that do not survive the first week of life, the duration of gestation and weight or size at birth are important to assess the cause of death. The questionnaire contains several items to identify the common causes of neonatal death, details of which are provided in Chapter 13. An algorithm to assist in diagnosing the cause of an infant death with respiratory symptoms is set out in Figure 6 in Chapter 13.

The WHO prescribes a detailed special certificate for recording the causes of perinatal death, which includes information regarding the mother's obstetric history and clinical conditions during the current pregnancy, circumstances of the delivery, and the diseases / conditions in the child. However, for diagnoses from verbal autopsy, the standard medical cause of death certificate for all ages is recommended. In this regard, as per current convention, the condition of 'low birth weight' is to be listed as a 'contributory' cause, with the direct pathological condition (sepsis, trauma, asphyxia, etc) listed in Part I of the certificate.

12.6. Injuries

Intuitively, external causes of death should be readily identified in verbal autopsy settings, given the relatively straightforward circumstances and events of the accident or violence resulting in death. However, in the absence of an adequate medico-legal system that requires accurate identification and registration of these details, a range of sociological factors come into play that could mask the true cause of death in many cases.

While these may not be that significant for transport accidents or falls, they could be so in the case of suicides, cases of assault, and poisoning. Even in the former, while the event may be obvious (traffic accident), it is important to record the actual circumstances on the death certificate (motor cycle rider hit by car OR pedestrian hit by truck etc.), as this would permit detailed coding of the underlying cause according to the ICD. The VA questionnaire permits the recording of these details in the open narrative section, and interviewers have been trained to do so. Similar details are required for all external causes of death.

12.7. Guidelines for cause-of-death certification for verbal autopsy

Before certifying causes of death, the physician reviewer should do the following:

- in general, **precedence should be given to available medical opinion** on the cause of illness / death**, if it can be corroborated** with the details of symptoms and events described by the relatives.
- carefully screen all modules of the completed instrument for relevant information
- make a separate record of all the positive evidence
- use clinical judgment and diagnostic guidelines (Table 3) to identify specific causes of death.
- in some instances, the absence of a particular symptom / sign etc. might be helpful in judging cause.
- Place identified clinical conditions / events into chronological and pathophysiological sequence.
- Do not imagine the sequential events which are not documented in VA forms; be careful to adhere to the information provided in the VA forms only.
- After assessing all the available information, the reviewer can attempt to record the identified sequence of causes as immediate, antecedent, underlying, and contributory causes, in the form of a standard death certificate described above.

Common Do's and Don'ts in Assigning Cause of Death

Do's

1. Use common sense and best clinical judgement – based on the information in the VA form. There is no substitute.

2. Read the narrative, history and any other information very carefully. You can avoid going down blind alleys and false diagnosis by a careful read.

3. Corroborate what a health care provider may have said on the form with some other symptom or signs in the checklist.

4. Do look for important negatives in the history. These can narrow down several possible causes to one or two.

5. Do think from a public health perspective- common causes are common.

6. Do not be afraid to state that no cause can be assigned. This is reality.

7. Write only one cause of death on each line of the death certificate.

8. Do not use any abbreviations or acronyms.

Don'ts

1. Do not make a random diagnosis if no evidence is found in the VA interview.

2. Do not try to make a pathological diagnosis. It is very difficult from the Verbal Autopsy report to make a pathological diagnosis (e.g., various types of myocardial infarction). Moreover, while such pathological diagnosis is appropriate for clinical and hospital care, getting right the overall categories of causes of death is far more important for public health.

3. Do not rely on the respondent's education level, or other characteristics, only use them as supporting information. Misconceptions abound across education or income levels of respondents.

4. Do not rely on the **risk factors** alone for making a diagnosis. For example, cirrhosis occurs not only among alcohol drinkers but also among non-drinkers. Similarly, lung cancer can happen among smokers and non-smokers. Although this is common clinical and epidemiological knowledge, the mention of these examples here is merely to serve as a reminder for physicians at the time of certification of cause of death.

13. Guidelines for certifying common causes of death from verbal autopsy interviews

Detailed instructions and guidelines on the certification of cause of death, using the standard international certificate are provided in Chapter 7. While this is adequately accomplished when detailed medical records are available that provide documented empirical evidence as to the medical diagnosis of the illness(es) present at the time of death, the same is not the case from a verbal autopsy questionnaire. Several critical issues that govern data quality from verbal autopsy questionnaires have been discussed in Chapter 10. These can result in the recording of a multitude of symptoms, signs and other evidence, which could create uncertainty as to the cause(s) operating at the time of death.

For these reasons, Table 3 has been included in the manual to provide a set of general diagnostic guidelines for specific common causes of death that can generally be identified from verbal autopsy data. **These guidelines are not specific diagnostic algorithms or criteria** for selection of the individual causes that have been described here, but for differentiating one cause from other competing causes, in case of overlapping symptomatology or any confusion arising from the verbal autopsy data. Also, **these guidelines are to be used to support clinical judgment** in the adjudication of cause of death and should be used in conjunction with the ‘do’s’ and ‘don’ts’ listed above.

Table 3: General diagnostic guidelines for specific causes of death from VA data

CAUSE OF DEATH	CRITERIA
INFECTIOUS DISEASES	
Diarrhoea / Gastroenteritis / Dysentery	Frequent/liquid/water loose or soft stools **AND** Any of the following: □ Low/nil urine content □ Restricted fluid intake □ Vomiting □ Eyes sunken or depressed fontanelle □ Blood or mucus in stool
Pulmonary Tuberculosis	Chronic cough of long duration with fever AND Any one of the following signs or symptoms: □ Blood in sputum □ Chest pain □ Breathlessness □ Loss of appetite □ Chronic weight loss □ Treatment history of TB
Tetanus, Neonatal	Baby able to suck after birth **AND** Stopped sucking after 3 days **AND** Baby's body became rigid with or without convulsions **Possibly With** Umbilical cord inflammation **OR** Fever
Measles	Rash all over body after an attack of fever > 3 days **AND** Red or watery eyes or cough, running nose – Coryza
Viral Hepatitis	Marked acute jaundice with abdominal pain; progressive yellowness of eyes and skin **AND** Any of the following signs or symptoms: □ Fever □ Headache □ Nausea □ Vomiting □ Loss of appetite □ Urine is yellow in colour □ Hepatitis B/C serology **AND** No other obvious cause
Meningitis	Continuous fever until death **AND** Neck stiffness OR Vomiting **OR** bulging fontanelle **OR** ear discharge **Possibly With** Loss of consciousness **OR** No symptoms of ARI, diarrhoea **OR** Photophobia

CAUSE OF DEATH	CRITERIA
Encephalitis	Convulsion of body/body parts or asymmetrical weakness or paralysis **AND** Fever until death **AND** Any of the following: □ Vomiting □ Unconsciousness □ Stiff neck **Possibly With** Confusions, altered sensorium
HIV/AIDS	H/o severe weight loss in less than 3 months **AND** History of prolonged unexplained fever **or** diarrhoea **or** persistent cough for more than 1 month (intermittent or continuous) **OR** HIV +ve serology
	Possibly With □ Mouth sores / white patches in mouth □ Skin rash □ Generalized swelling of nodes in armpits, neck, groin □ History of spouse/partner with similar illness/death of spouse/partner from illness
Malaria	Acute onset of high grade fever, with chills and rigor. Fever may be intermittent **AND** Blood test positive for malaria **AND** Any one of the following: □ Jaundice □ Breathlessness □ Decreased urine output □ Convulsion/Unconscious □ Headache PRESENCE OF SYMPTOMS OF □ ARI □ Diarrhoea □ Burning during micturition could be suggestive of immediate or contributory causes
Pneumonia	Acute cough (dry or productive) **AND** High fever **AND** Any of the following: □ Shortness of breath/fast breathing □ Chest pain □ Blood in sputum **AND** Any of the following: □ No Wheezing □ No swelling of legs □ No distension of abdomen
Acute Lower Respiratory Tract Infection	Cough **OR** Fever **AND** Rapid breathing **OR** Difficult breathing with in-drawing of chest (often local term)

CAUSE OF DEATH	CRITERIA
Neoplasms	
Oral Cancer (mouth)	Lump or mass or swelling on tongue/ cheek/ mouth cavity/ gum/ palate, usually progressive **AND** Any one of the following: □ Non healing sore or ulcer □ Bleeding on touch □ Restriction/difficulty in opening mouth □ Weight loss **OR** Diagnosed as mouth cancer
Throat cancer (Pharynx C10-C11, larynx C32, Trachea C33)	Growth in throat / neck or hoarseness of voice **AND** Weight loss over several months **OR** Diagnosed as throat cancer
Oesophageal Cancer	Progressive difficulty in taking foods **AND w**eight loss over several months **OR d**iagnosed as oesophageal cancer
Stomach Cancer	Vomiting/ Vomiting of blood. Difficulty in swallowing **AND** Mass in upper abdomen **AND** Any of the following: □ Pain in abdomen □ Weight loss □ Enlarged liver □ Black stools **OR** Diagnosed as stomach cancer
Colon/ Rectal Cancer	Bleeding from anal opening **AND** Any of the following: □ Constipation alt with loose stools or constipation alone □ Weight loss □ Painful abdominal distension □ Lump in lower part of abdomen **OR** Diagnosed as colorectal cancer
Liver Cancer	Enlargement of liver **AND** Abdominal distension (Ascites) within weeks **AND** weight loss **AND** H/o hepatitis or jaundice. **AND** no regular fever **OR** Diagnosed as liver cancer
Breast Cancer	Painless lump in one or both breasts **AND** Any of the following: □ Discharge from nipple □ Skin ulceration over breast □ Enlarged glands in the neck/axilla **OR** Diagnosed as breast cancer
Bronchus and Lung Cancer	Chronic cough and blood streaked sputum eventually leading to haemoptysis, and not responding to antibiotics and antitubercular drugs **AND** Any of the following: □ Breathlessness □ Chest pain □ Hoarseness of voice □ Recurrent history of Pneumonia □ Rapid loss of weight towards end **AND** No h/o Tuberculosis (no fever) **OR** Diagnosed as lung cancer

CAUSE OF DEATH	CRITERIA
Anaemia	Marked paleness of body **AND** Any of the following: □ Weight loss □ Fatigue or weakness or breathlessness on exertion □ Giddiness □ History of bleeding anywhere □ **AND** □ None of the following: □ Jaundice □ Enlarged lymph glands □ Features of chronic cough □ Chest pain □ Fever **OR** Diagnosed as Anaemia
	Possibly With Pallor of fingers **OR** Ankle swelling **OR** Swelling of the whole body **OR** Health professional's remarks about need for blood transfusions
Malnutrition	Not growing properly or losing weight and becoming very thin over months **AND** Any of the following: □ Recurrent febrile illness □ Reddish brown discoloration of hair □ Flaking of skin □ Pallor □ Abnormality distended abdomen □ Swelling of feet □ Night-blindness
Diabetes Mellitus	Frequent urination or increased thirst or and increased hunger **AND** Any of the following: □ Recurrent infection (particularly respiratory) and Septicaemia □ Ulcers/foot sores or wounds not healing properly/gangrene □ Neuropathy □ Renal complications □ Septicaemia □ Vascular complications
Myocardial Infarction	Severe chest pain lasting for more than ½ hour but less than 24 hours, within the last month before death **AND** Any of the following: □ Shortness of breath □ Vomiting □ Anxiousness □ Pain radiating to left arm □ Sweating □ Sudden death **OR** Diagnosed heart attack/Myocardial infarction

CAUSE OF DEATH	CRITERIA
Congestive Heart Failure	Progressive shortness of breath on lying down or at night, improving on sitting up **AND** Any of the following signs or symptoms: □ Swelling of feet □ Distension of abdomen □ Progressive cough H/o previous MI/hypertension \ heart disease, which should be listed as the underlying cause of death
Stroke (cerebrovascular disease)	Sudden onset of paralysis of one or more limbs in the month preceding death **AND** Any of the following: □ Unconsciousness □ Loss of vision □ Urinary incontinence □ Loss of sensations on any part of body □ Altered speech □ Sudden onset of headache with altered sensorium In long standing cases, commonly leading to development of bed sores with septicaemia, or features of pneumonia as the immediate cause of death
Chronic Obstructive Pulmonary Disease	Recurrent episodes of productive cough >2yrs **AND** Breathlessness, initially episodic (more in winter) later progressive or ankle swelling late in disease **AND** Exclude TB
Cirrhosis of Liver	Abdominal distension (fluid in abdomen) ascites gradually **AND** Swelling of lower limbs **AND** Any of the following signs or symptoms: □ Early progressive jaundice □ Painless liver □ Vomiting of blood □ Passing of blood in stool □ Drowsiness or coma □ H/o chronic alcoholism **AND** No fever
Renal Failure	Progressive or acute onset of decreasing urinary output for more than 1 day **AND** Any of the following signs or symptoms: □ Progressive loss of appetite □ Hiccups □ Drowsiness □ Confusion □ Unconsciousness □ Swelling of eyelids/face/body in the morning **OR** History of dialysis

CAUSE OF DEATH	CRITERIA
Pregnancy	
Abortion	Abortion (termination before 28 weeks of pregnancy) in less than 42 days before death **AND** Any of the following: □ Lower abdominal pain □ Excessive vaginal bleeding □ Abnormal vaginal discharge □ Fever till death
Eclampsia	History of convulsions for first time in pregnancy **OR** Doctors report of very high blood pressure with convulsions **Possibly with** Ankle swelling and/or Hypertension
Ante-Partum Haemorrhage	Acute excessive bleeding in pregnancy after 28 weeks of gestation but before birth of baby
Post-Partum Haemorrhage	Excessive bleeding after delivery of baby, for example, blood completely covering the floor or used many garments to soak blood **Possibly with** retained placenta
Obstructed Labour	Abnormal presentation (breech, shoulder, hand or transverse) **AND** Baby not delivered **OR** Difficulty in delivering baby, Forceps/vacuum delivery **AND** Prolonged labour >24 hours Prim> 12 hr
Puerperal Sepsis	High fever persisting till death **AND** Any of the following: □ Foul smelling vaginal discharge with or without blood □ Lower abdominal pain/distention □ Vomiting **AND** No cough, no burning, micturition, no yellowness of eyes
Perinatal	
Low-Birth-Weight (Full term pregnancy)	Smaller than average size baby. If weighed, birth weight below 2.5 kilograms **AND** No other obvious causes of death **AND** Full-term pregnancy
	Possibly With Poor sucking after birth **OR** Death at 3-7 days
Prematurity (Not full term)	Born between 28 and 36 but before 37 weeks of gestation **AND No other** obvious causes of death
Birth Trauma	Bruises at birth, or elongation/swelling/blood clots over skull **OR** Any limb broken at birth **OR** Convulsions in first 72 hours of birth
	Possibly With Instrument delivery **OR** Complicated delivery
Asphyxia At Birth	Delayed or poor breathing or no breathing at birth **OR** Delayed or no cry at birth **AND** Any sign of life present at birth (i.e. exclude stillbirths) **OR** convulsions in first 72 hours
	Possibly With Prolonged or difficult labour **OR** Death at 3-7 days **OR** Cold to touch
Bacterial Sepsis of New-born	Fever **AND** No other obvious causes of death (like ARI, diarrhoea)
	Possibly With Postulant cord **OR** Poor sucking **OR** Limp
Congenital Malformations	Abnormality of head (small, flat, swelling), spine, body, arms or legs reported at birth For specific diagnoses refer to codes Q65-Q88

CAUSE OF DEATH	CRITERIA
Acute Abdomen (Not elsewhere classified)	Severe acute abdominal pain; Vomiting of blood; Abdominal distension **AND** Any of the following signs or symptoms: □ Fever □ Constipation □ Collapse/Unconsciousness History of peptic ulcer
Epilepsy/Seizures	History of convulsions of body or parts of body over years, with fit on the day of death **AND** Loss of consciousness following fits **AND** No H/o injury to head or fever or neck stiffness
Hyperplasia of Prostrate	Difficulty in passing urine with frequent urging in elderly man >60 years **AND** Lower abdominal pain **AND** Any of the following signs or symptoms: Patient becomes dull and drowsy □ Hiccups □ Vomiting □ Face is swollen □ Delirium or coma **AND** Rule out Prostrate Cancer
Pyrexia of unknown origin	Fever of long duration (more than 4 weeks) **AND** No possible reason found **OR** Diagnosed pyrexia of unknown origin by a doctor
Jaundice (Not elsewhere classified)	Progressive yellowness of eyes and skin **AND** Any of the following signs and symptoms: □ Fever □ Headache □ Nausea □ Vomiting □ Loss of appetite □ Urine is yellow in colour **AND** No other obvious cause (exclude viral hepatitis)

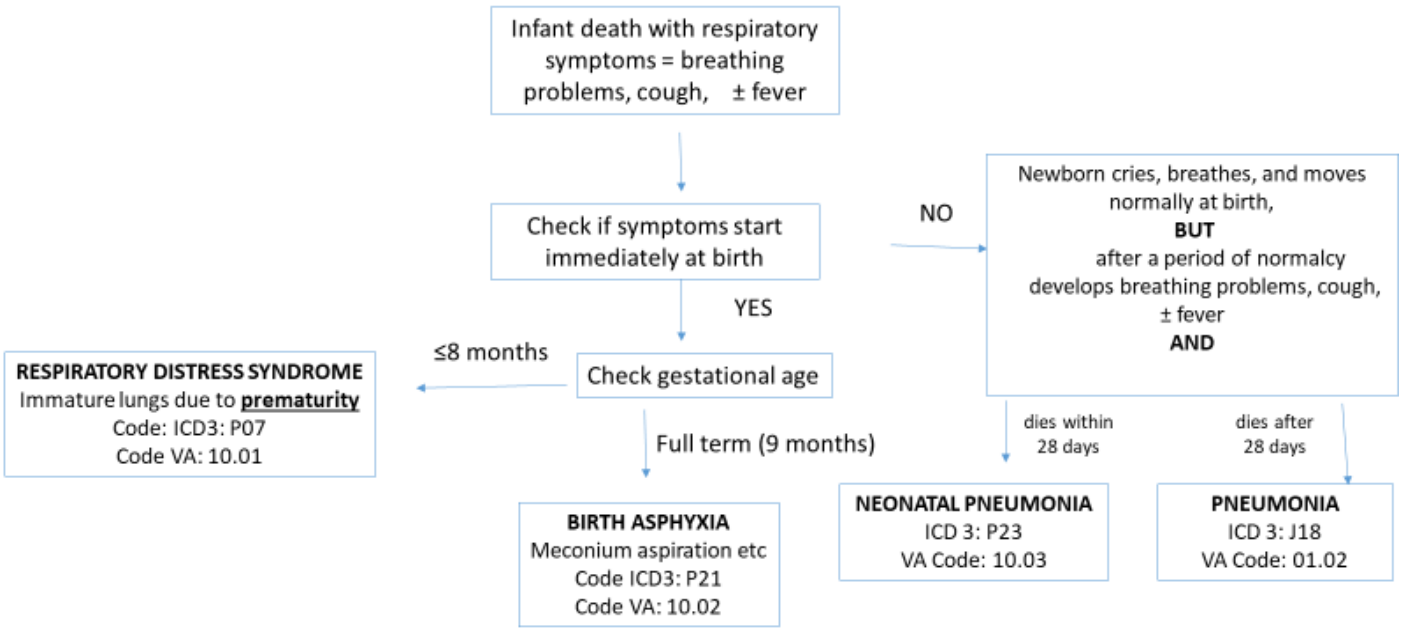
In list, but NO criteria

□ Leishmaniasis
□ External causes

WITH criteria, but not in list

□ Dengue Fever (usually as epidemic outbreak)
□ Epilepsy/Seizures
□ Stroke
□ Hyperplasia of Prostrate
□ Jaundice (not elsewhere classified)

Figure 6: Algorithm for diagnosing an infant death with respiratory symptoms



14. Guidelines for medical record reviews

Medical records for 19 000 decedents from our sampled districts, who died in hospital are anonymized, labelled with a unique study identifier and scanned by fieldworkers before being uploaded as multi-page pdf documents. Fieldworkers have been instructed to look for and copy certain sections of the medical records pertaining to the last admission before death. These sections include

1. Admission notes (Casualty / Emergency notes or Emergency medical services)
2. Birth record for babies
3. Doctor's progress notes in ward
4. Prescription charts
5. Observation charts
6. Special investigations
7. Referral letters
8. Road to health cards for children
9. Discharge forms

Reviewing doctors are expected to download the pdfs allocated to them on a laptop or pc, read through the available notes, summarise the sequence of events leading to the death, and certify the causes of death according to ICD-10 guidelines, along with an indication of the quality of information available for the diagnosis of each of the reported conditions. These include whether the information is based upon the medical history, clinical findings, special investigations, histopathology, imaging etc. In addition, doctors will be required to give a subjective opinion on the quality of the medical records in terms of whether it provided the information required to certify the causes of death.

The summary of events and the certification of causes of death need to be captured on Kobotools using a tablet that will be provided to each of the reviewing doctors. A copy of the data capture form and instructions on how to use the tool are provided in Chapter 15.

Please note that the name of the facility and the medical and nursing staff have not been hidden. Please note that this information may not be shared with anyone other than the PI or used to contact the facilities or the medical staff named in these documents. Should you find any information about a facility or medical staff that concerns you, please communicate this directly to the PI so that a decision can be made on an appropriate response.

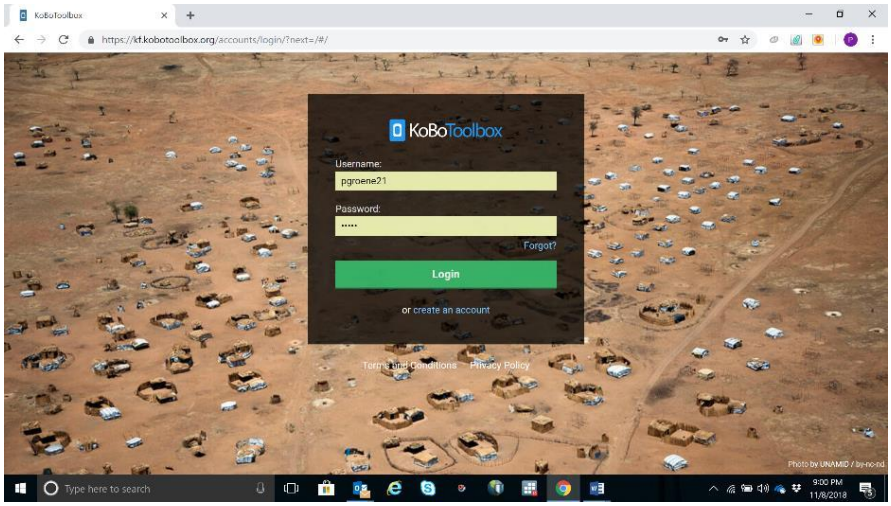
15. Instructions for use of KoboToolBox data capture instrument

1. **GO TO THE FOLLOWING SITE**:

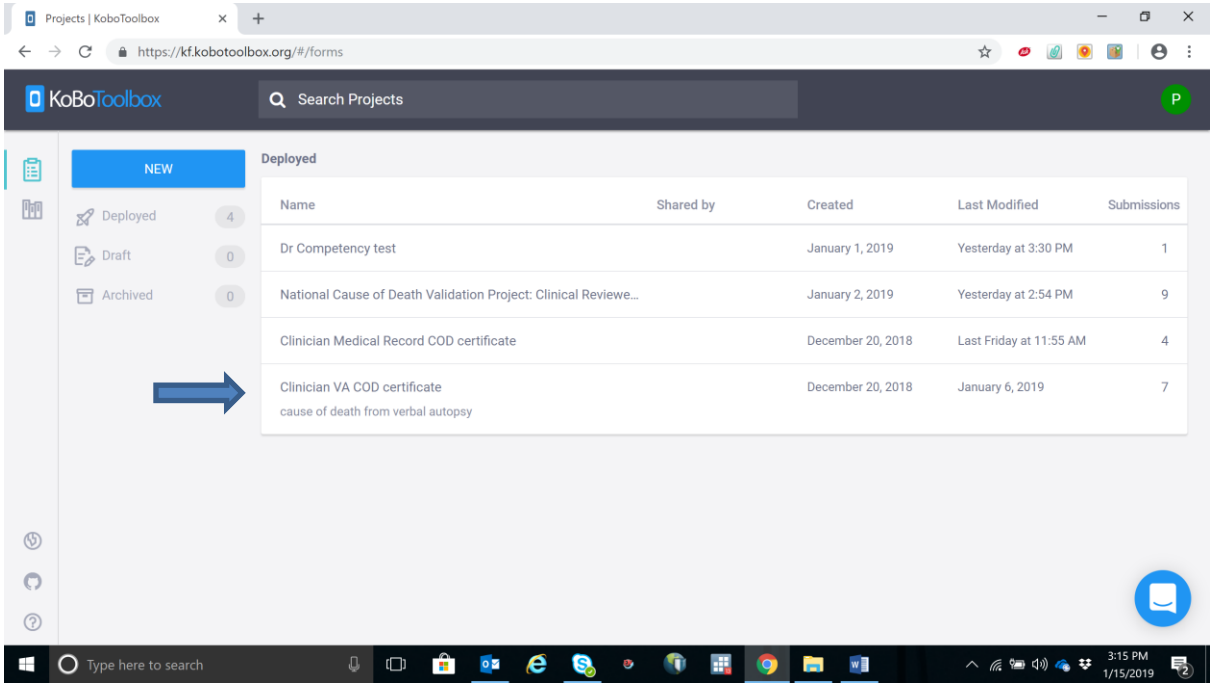
https://kf.kobotoolbox.org/#/forms/aWLgQn3bnwPntLdSyet7Xb

2. **ACCESS KOBOTOOLBOX**

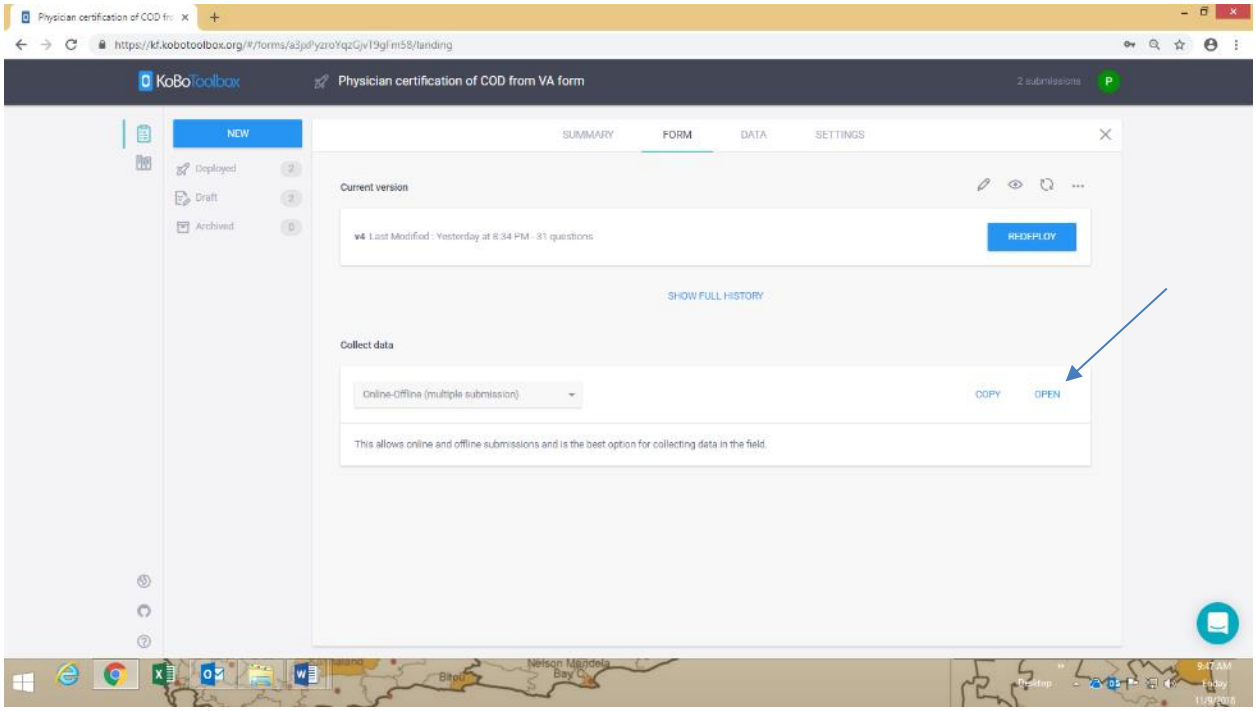
Username: pgroene21 Password: NCODV



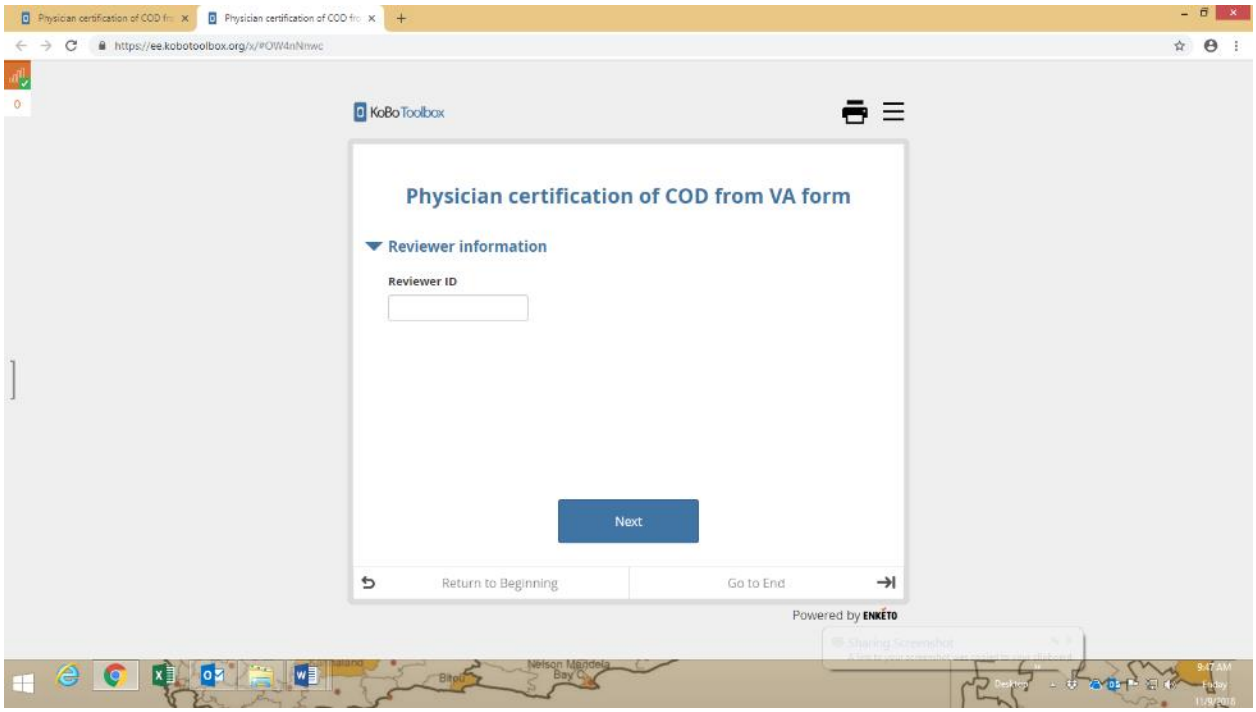
3. **SELECT THE FORM**

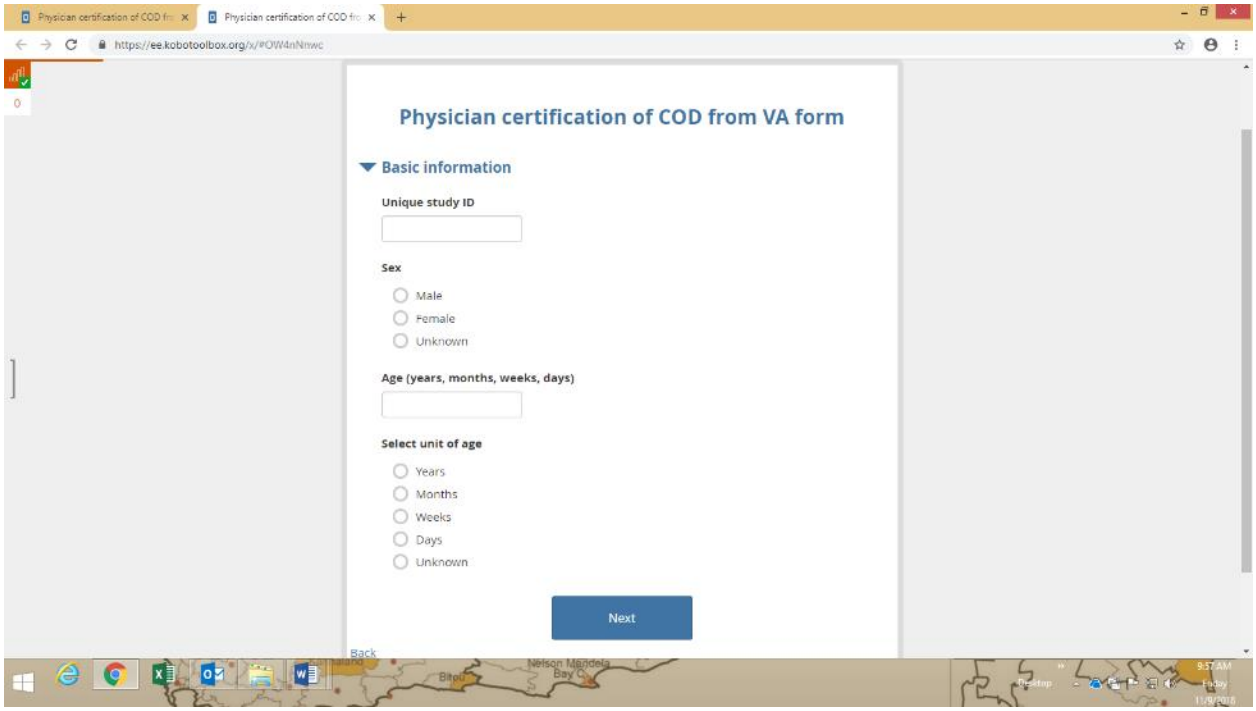


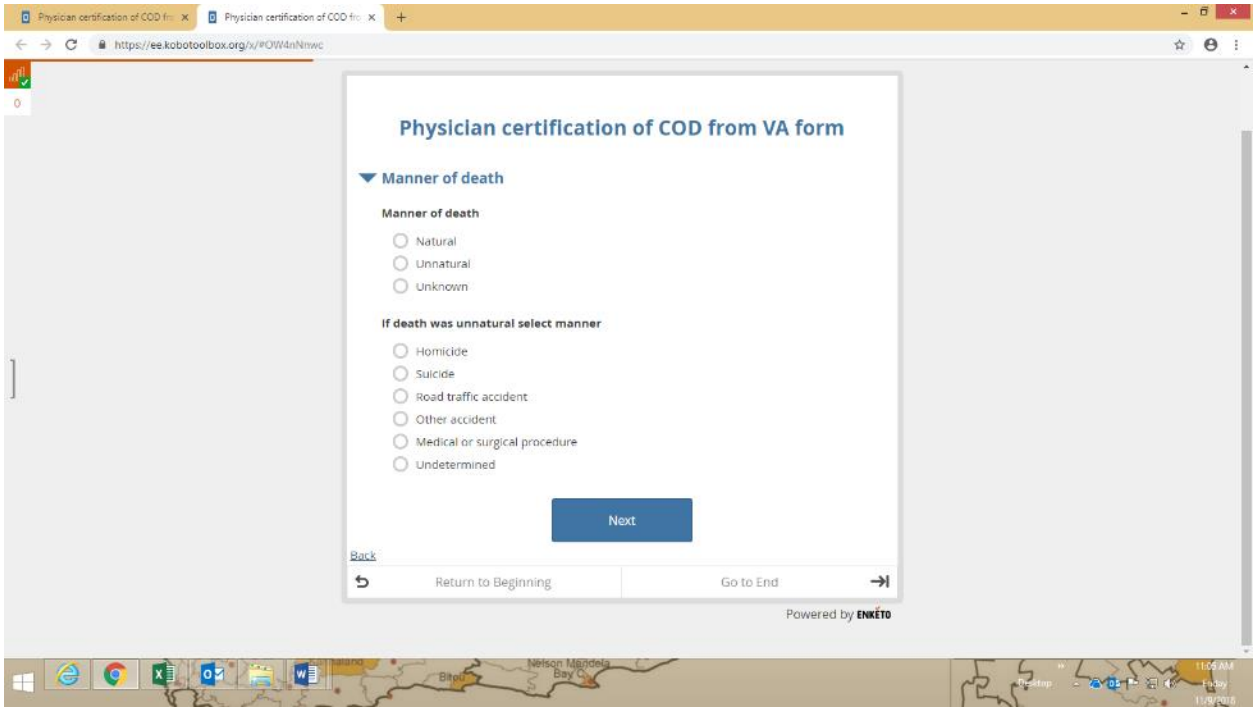
4. OPEN THE FORM

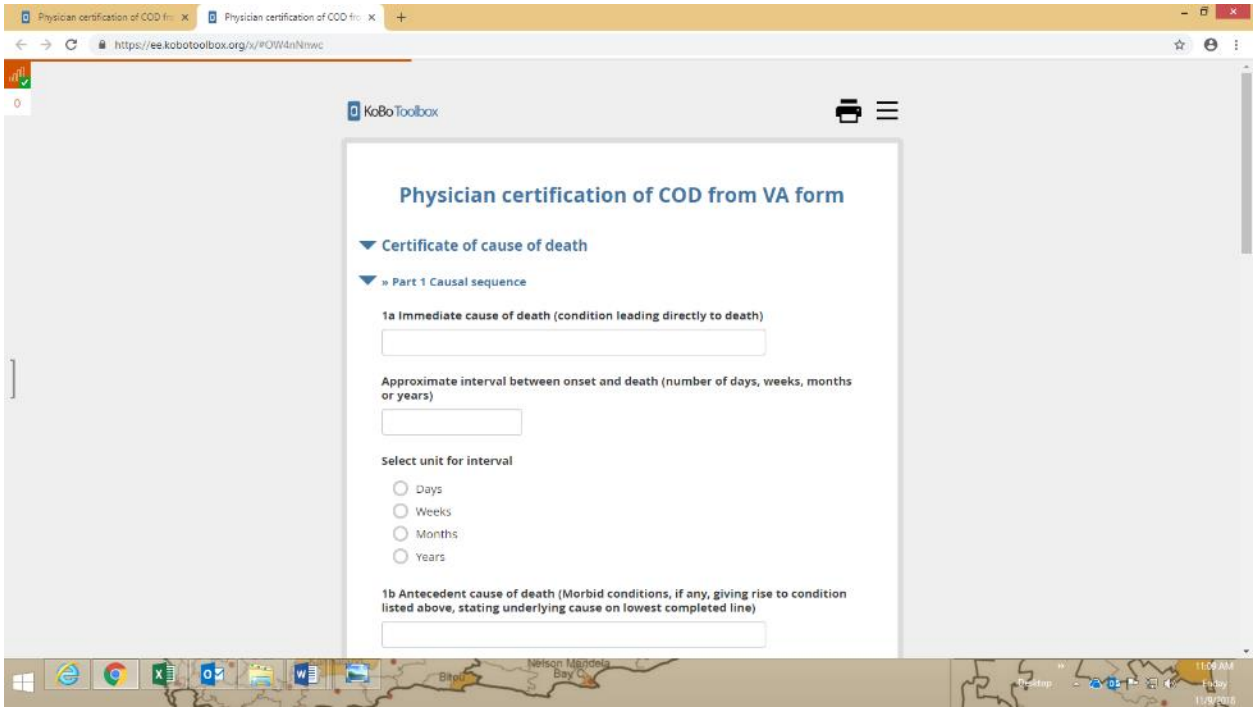


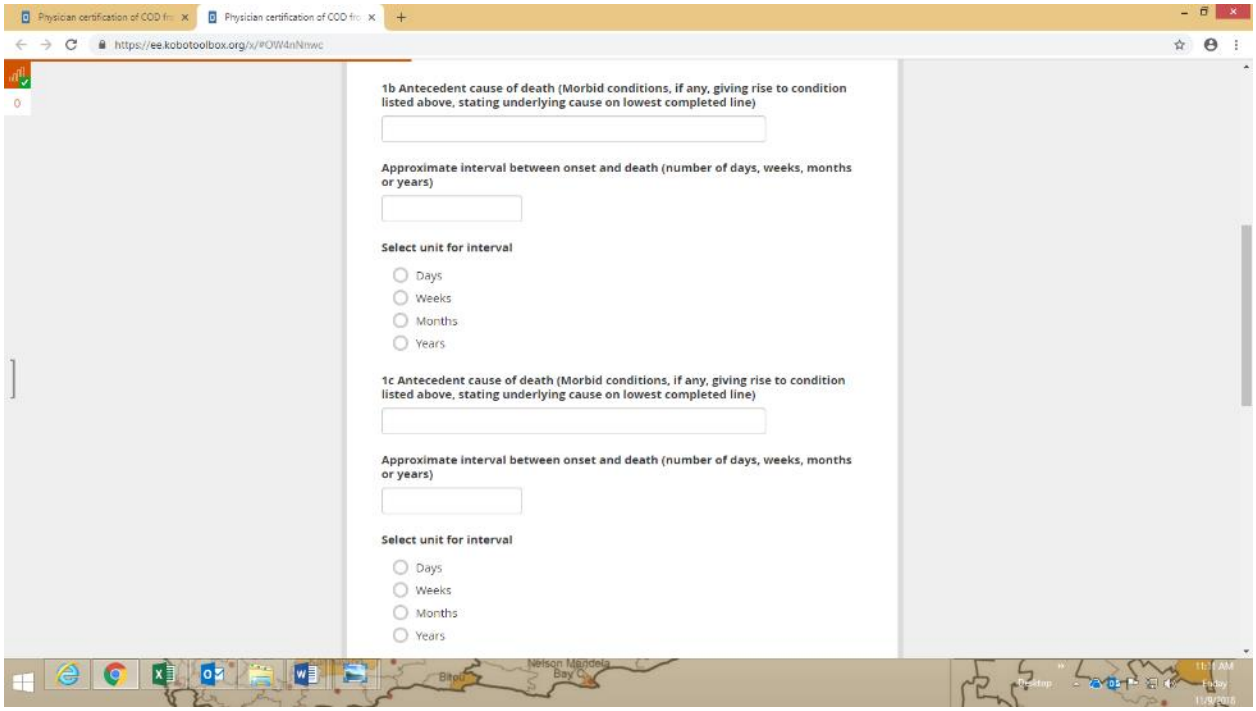
5. COMPLETE THE FORM

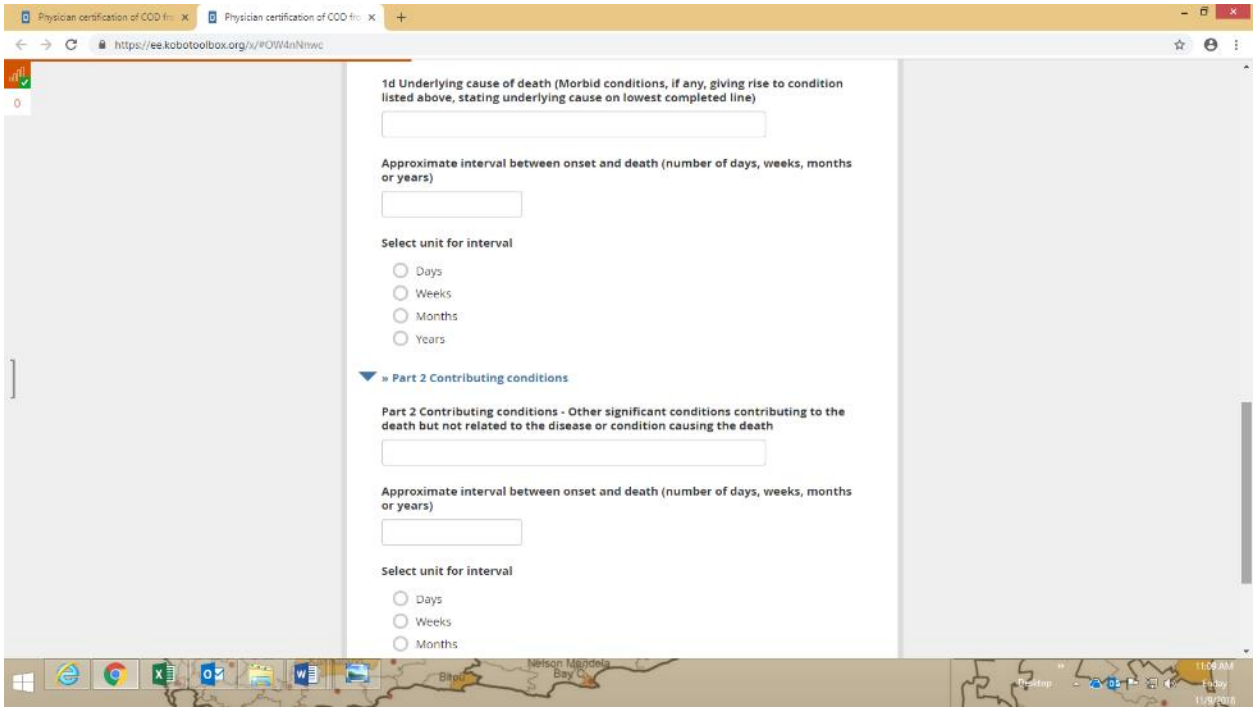


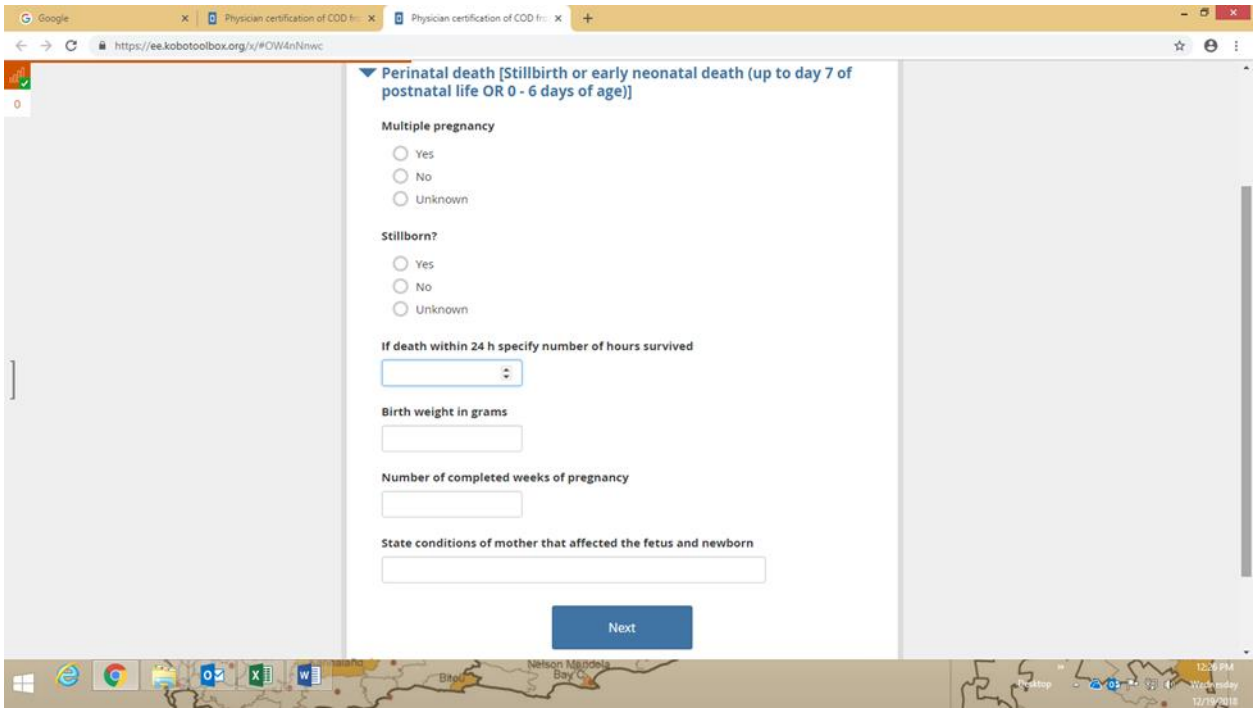

Physician certification of COD from VA form
Basic information
Unique study ID
Sex
Male
Female
Unknown
Age (years, months, weeks, days)
Select unit of age
Years
Months
Weeks
Days
Unknown
Next
Back


Physician certification of COD from VA form
Manner of death
Manner of death
Natural
Unnatural
Unknown
If death was unnatural select manner
Homicide
Suicide
Road traffic accident
Other accident
Medical or surgical procedure
Undetermined
Next
Back
Return to Beginning
Go to End
Powered by ENKETO

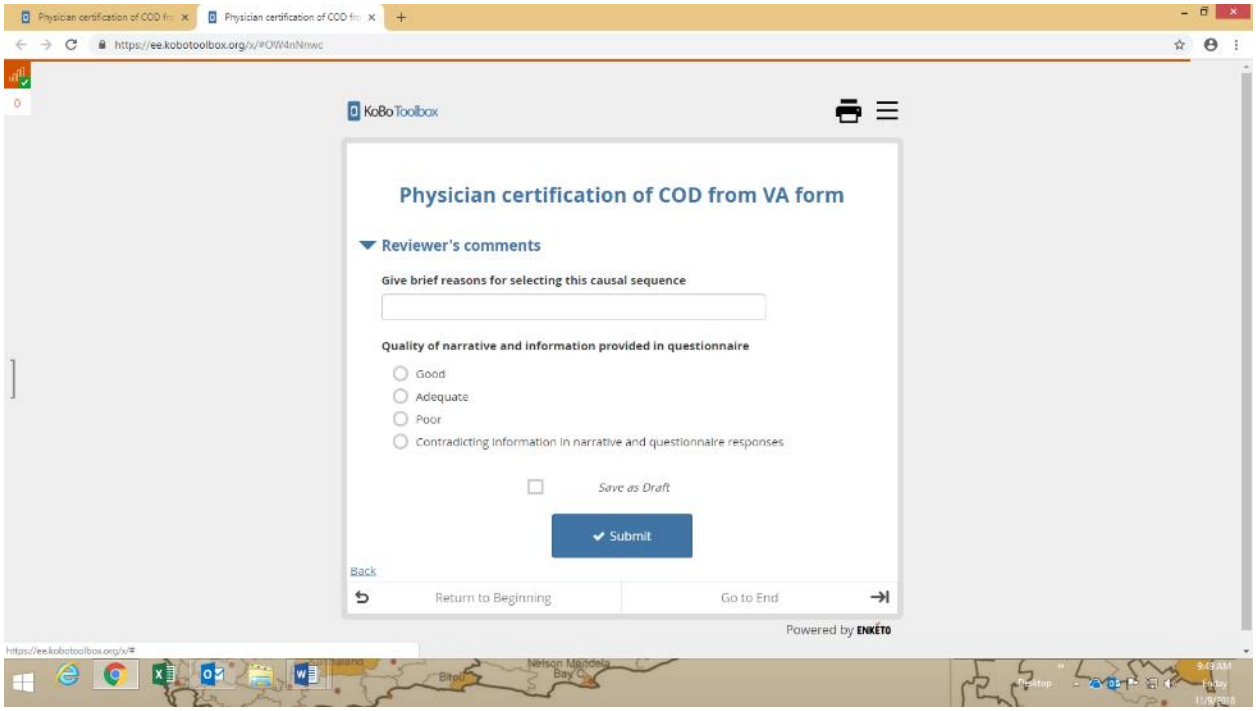

KoBoToolbox
Physician certification of COD from VA form
Certificate of cause of death
» Part 1 Causal sequence
1a Immediate cause of death (condition leading directly to death)
Approximate interval between onset and death (number of days, weeks, months or years)
Select unit for interval
Days
Weeks
Months
Years
1b Antecedent cause of death (Morbid conditions, if any, giving rise to condition listed above, stating underlying cause on lowest completed line)


1b Antecedent cause of death (Morbid conditions, if any, giving rise to condition listed above, stating underlying cause on lowest completed line)
Approximate interval between onset and death (number of days, weeks, months or years)
Select unit for interval
Days
Weeks
Months
Years
1c Antecedent cause of death (Morbid conditions, if any, giving rise to condition listed above, stating underlying cause on lowest completed line)
Approximate interval between onset and death (number of days, weeks, months or years)
Select unit for interval
Days
Weeks
Months
Years

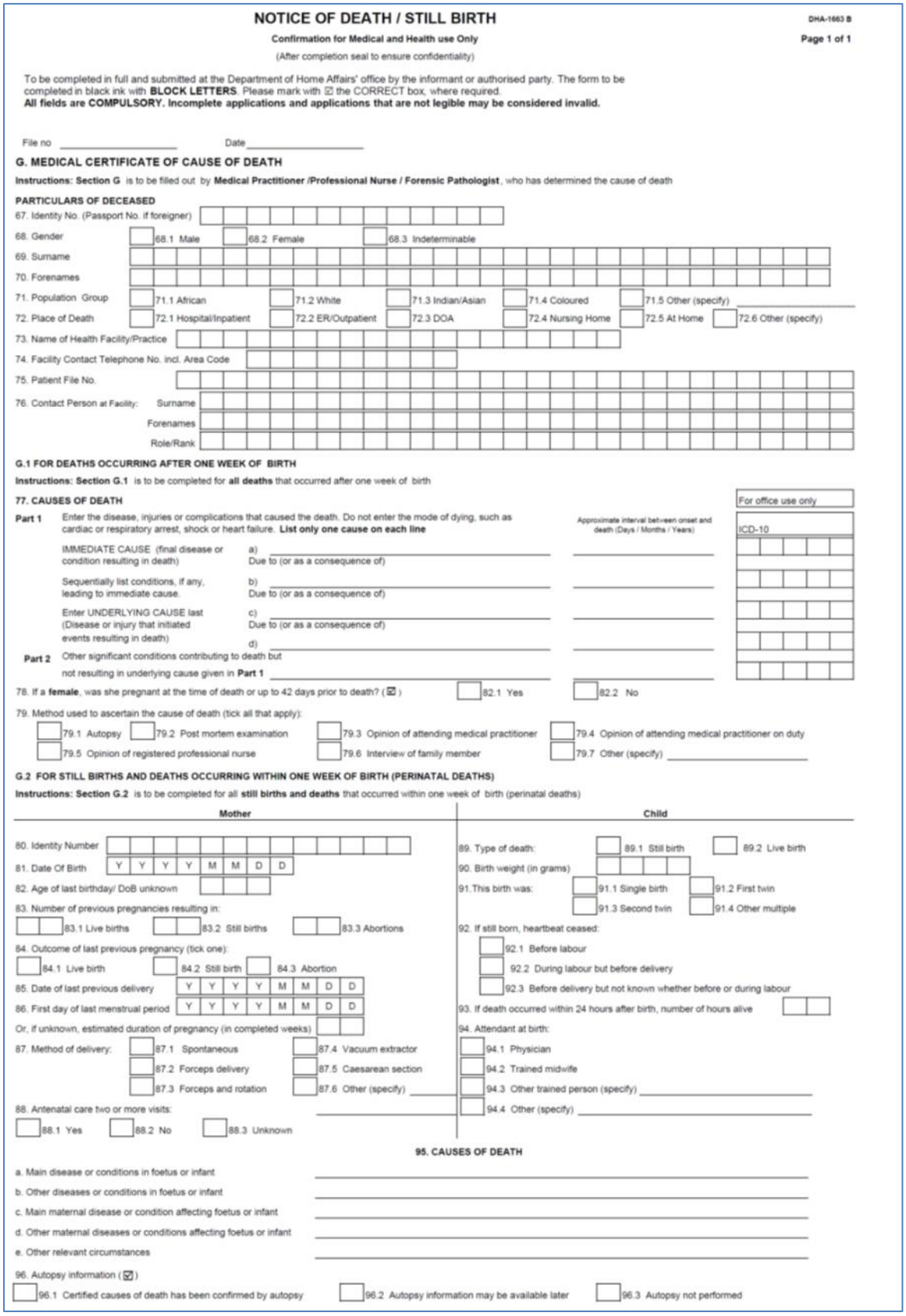

1d Underlying cause of death (Morbid conditions, if any, giving rise to condition listed above, stating underlying cause on lowest completed line)
Approximate interval between onset and death (number of days, weeks, months or years)
Select unit for interval
Days
Weeks
Months
Years
» Part 2 Contributing conditions
Part 2 Contributing conditions - Other significant conditions contributing to the death but not related to the disease or condition causing the death
Approximate interval between onset and death (number of days, weeks, months or years)
Select unit for interval
Days
Weeks
Months


Perinatal death [Stillbirth or early neonatal death (up to day 7 of postnatal life OR 0 - 6 days of age)]
Multiple pregnancy
Yes
No
Unknown
Stillborn?
Yes
No
Unknown
If death within 24 h specify number of hours survived
Birth weight in grams
Number of completed weeks of pregnancy
State conditions of mother that affected the fetus and newborn
Next

6. END OF FORM


KoBoToolbox
Physician certification of COD from VA form
Reviewer's comments
Give brief reasons for selecting this causal sequence
Quality of narrative and information provided in questionnaire
Good
Adequate
Poor
Contradicting information in narrative and questionnaire responses
Save as Draft
Submit
Back
Return to Beginning
Go to End
Powered by ENKETO

Appendix 1. South African Death Notification Form



NOTICE OF DEATH / STILL BIRTH

DHA-1663 B

Confirmation for Medical and Health use Only

Page 1 of 1

(After completion seal to ensure confidentiality)

To be completed in full and submitted at the Department of Home Affairs' office by the informant or authorised party. The form to be completed in black ink with **BLOCK LETTERS**. Please mark with ☑ the CORRECT box, where required.
All fields are COMPULSORY. Incomplete applications and applications that are not legible may be considered invalid.

File no _____ Date _____

G. MEDICAL CERTIFICATE OF CAUSE OF DEATH

Instructions: Section G is to be filled out by **Medical Practitioner /Professional Nurse / Forensic Pathologist**, who has determined the cause of death

PARTICULARS OF DECEASED

67. Identity No. (Passport No. if foreigner)

68. Gender ☐ 68.1 Male ☐ 68.2 Female ☐ 68.3 Indeterminable

69. Surname

70. Forenames

71. Population Group ☐ 71.1 African ☐ 71.2 White ☐ 71.3 Indian/Asian ☐ 71.4 Coloured ☐ 71.5 Other (specify) _____

72. Place of Death ☐ 72.1 Hospital/Inpatient ☐ 72.2 ER/Outpatient ☐ 72.3 DOA ☐ 72.4 Nursing Home ☐ 72.5 At Home ☐ 72.6 Other (specify)

73. Name of Health Facility/Practice

74. Facility Contact Telephone No. incl. Area Code

75. Patient File No.

76. Contact Person at Facility: Surname

Forenames

Role/Rank

G.1 FOR DEATHS OCCURRING AFTER ONE WEEK OF BIRTH

Instructions: Section G.1 is to be completed for **all deaths** that occurred after one week of birth

77. CAUSES OF DEATH

For office use only

Part 1 Enter the disease, injuries or complications that caused the death. Do not enter the mode of dying, such as cardiac or respiratory arrest, shock or heart failure. **List only one cause on each line**

Approximate interval between onset and death (Days / Months / Years)

ICD-10

IMMEDIATE CAUSE (final disease or condition resulting in death) a) _____ Due to (or as a consequence of)

Sequentially list conditions, if any, leading to immediate cause. b) _____ Due to (or as a consequence of)

Enter UNDERLYING CAUSE last (Disease or injury that initiated events resulting in death) c) _____ Due to (or as a consequence of)

d) _____

Part 2 Other significant conditions contributing to death but not resulting in underlying cause given in **Part 1** _____

78. If a **female**, was she pregnant at the time of death or up to 42 days prior to death? (☑) ☐ 82.1 Yes ☐ 82.2 No

79. Method used to ascertain the cause of death (tick all that apply):

☐ 79.1 Autopsy ☐ 79.2 Post mortem examination ☐ 79.3 Opinion of attending medical practitioner ☐ 79.4 Opinion of attending medical practitioner on duty

☐ 79.5 Opinion of registered professional nurse ☐ 79.6 Interview of family member ☐ 79.7 Other (specify) _____

G.2 FOR STILL BIRTHS AND DEATHS OCCURRING WITHIN ONE WEEK OF BIRTH (PERINATAL DEATHS)

Instructions: Section G.2 is to be completed for all **still births and deaths** that occurred within one week of birth (perinatal deaths)

Mother

80. Identity Number

81. Date Of Birth Y Y Y Y M M D D

82. Age of last birthday/ DoB unknown

83. Number of previous pregnancies resulting in:

☐☐ 83.1 Live births ☐☐ 83.2 Still births ☐☐ 83.3 Abortions

84. Outcome of last previous pregnancy (tick one):

☐ 84.1 Live birth ☐ 84.2 Still birth ☐ 84.3 Abortion

85. Date of last previous delivery Y Y Y Y M M D D

86. First day of last menstrual period Y Y Y Y M M D D

Or, if unknown, estimated duration of pregnancy (in completed weeks) ☐☐

87. Method of delivery: ☐ 87.1 Spontaneous ☐ 87.4 Vacuum extractor

☐ 87.2 Forceps delivery ☐ 87.5 Caesarean section

☐ 87.3 Forceps and rotation ☐ 87.6 Other (specify) _____

88. Antenatal care two or more visits:

☐ 88.1 Yes ☐ 88.2 No ☐ 88.3 Unknown

Child

89. Type of death: ☐ 89.1 Still birth ☐ 89.2 Live birth

90. Birth weight (in grams)

91. This birth was: ☐ 91.1 Single birth ☐ 91.2 First twin

☐ 91.3 Second twin ☐ 91.4 Other multiple

92. If still born, heartbeat ceased:

☐ 92.1 Before labour

☐ 92.2 During labour but before delivery

☐ 92.3 Before delivery but not known whether before or during labour

93. If death occurred within 24 hours after birth, number of hours alive ☐☐

94. Attendant at birth:

☐ 94.1 Physician

☐ 94.2 Trained midwife

☐ 94.3 Other trained person (specify) _____

☐ 94.4 Other (specify) _____

95. CAUSES OF DEATH

a. Main disease or conditions in foetus or infant _____

b. Other diseases or conditions in foetus or infant _____

c. Main maternal disease or condition affecting foetus or infant _____

d. Other maternal diseases or conditions affecting foetus or infant _____

e. Other relevant circumstances _____

96. Autopsy information (☑)

☐ 96.1 Certified causes of death has been confirmed by autopsy ☐ 96.2 Autopsy information may be available later ☐ 96.3 Autopsy not performed

Appendix 2: 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 **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

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