

Theme: Strengthening vital statistics and cause-of-death data

Assessing the reliability of hospital-based cause-of-death statistics: evidence-based guidelines for country application

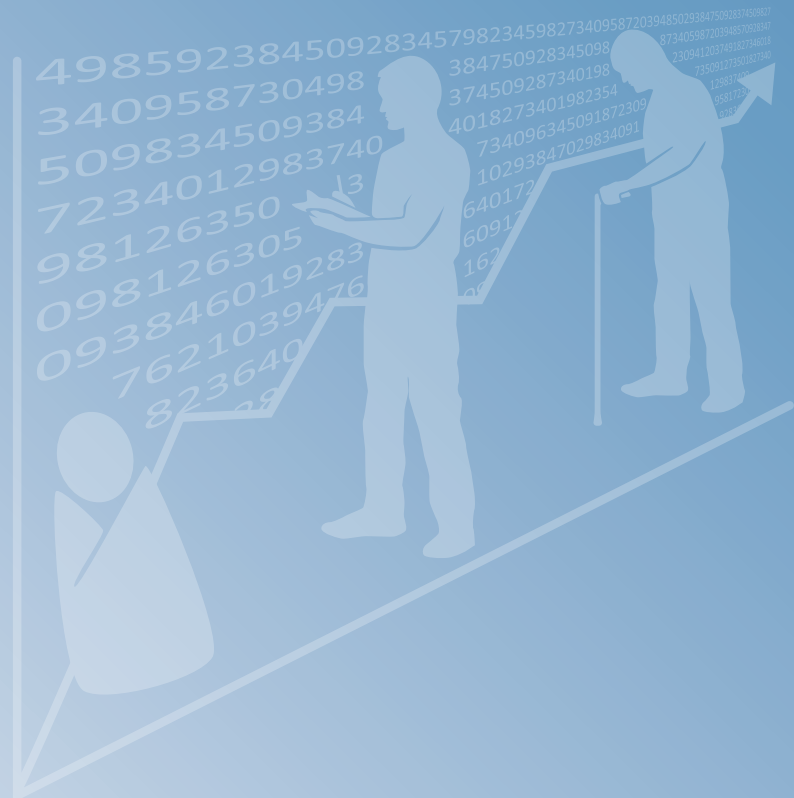
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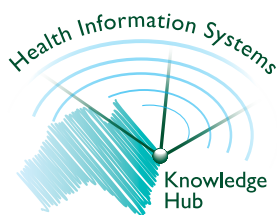
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Working Paper Series • Number 37 • October 2013 • WORKING PAPER



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*Strengthening health systems
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This research has been funded by AusAID. The views represented are not necessarily those of AusAID or the Australian Government.

© Health Information Systems Knowledge Hub 2013
Published by the Health Information Systems
Knowledge Hub, School of Population Health

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Acronyms and abbreviations

AMI	acute myocardial infarction
BVS	Biblioteca Virtual de la Salud
COD	cause of death
COPD	chronic obstructive pulmonary disease
HIS	health information systems
IHD	ischaemic heart disease
UCOD	underlying cause of death
WHO	World Health Organization

Summary

Accurate and timely data on cause of death (COD) are critical for guiding health programs and policies. Although COD certified by physicians is considered 'gold standard', accuracy of death certification by physicians does depend on many factors, including training on correct death certification practices. However, many physicians in the world do not get adequate opportunities to learn standard death certification guidelines as part of their medical curriculum and training or as postgraduate or professional development. The concept of underlying cause of death (UCOD), the sequence of events leading to death, how to correctly fill in a death certificate and the public health importance of accurate COD information are rarely introduced or emphasised to training physicians. This situation has led to poor quality COD data in many countries. The objective of this study is to synthesise the findings from a large number of studies that have used medical record reviews to validate the COD reported on the death certificate or through the vital registration system. Based on an analysis of a core set of these studies, we developed a methodological framework for medical record reviews for countries to follow for routinely validating their CODs.

The scope was limited to articles published in the period between 1983 and 2013 and to studies published in English, Spanish and Portuguese languages. The search for English articles was primarily conducted through the Medline/PubMed electronic database and Google Scholar, and Spanish or Portuguese articles were found based on a search conducted in the Medline/PubMed and LILACS-WHO/PAHO Biblioteca Virtual de la Salud (BVS). References quoted in original articles were manually searched for additional studies.

Articles identified from the initial search were screened (124 in English language and 75 in Spanish or Portuguese) for specific content and inclusion and exclusion criteria. After the detailed screening, 12 English articles, 10 Spanish and 7 Portuguese articles remained for the review. The selected articles were reviewed in detail using the pre-determined criteria, which had been developed by a panel of experts with experience in conducting medical record review studies.

The studies that were finally included in this review span the period 1986–2013, with the highest number of studies (n=9, 31.0%) conducted after 2005. Categorising the studies geographically showed that the highest percentage of studies came from the American

continent. The large majority of studies looked at deaths of all ages (n=22, 75.9%). Thirteen studies (44.8%) examined the COD patterns at the population level and hence aimed to correct the cause-specific mortality fraction. The rest of the studies (n=16, 55.2%), identified the discrepancies between the medical record diagnosis before and after the review at the individual level. Nineteen studies (65.5%) mentioned that they used physicians for the review; of these, only 15 studies (51.7%) stated that the physicians had received special training on standard death certification.

The term "standard diagnostic criteria" refers to a set of guidelines developed in advance for each disease to ensure all cases are diagnosed in a standard manner and are not subjected to reviewer bias. In our review, six studies (21%) used standard diagnostic criteria to arrive at a COD and two others used broad diagnostic criteria only. We also looked at how the studies have handled competing COD. Fourteen studies (48.3%) included in the review do not provide information about how the final diagnosis was determined when COD is not clear. In five studies (17.2%) consensus was reached through discussion within the panel.

Although the availability of diagnostic facilities can influence the ability to diagnose certain cases correctly, only one study specifically mentions that urban hospitals were selected to include hospitals with adequate diagnostic facilities. All the other studies reviewed do not refer to or discuss the specific diagnostic capacity of the hospital(s) before inclusion in the study.

Most of the included studies assessed the concordance between the original COD diagnosis and COD derived from the death certification review. The studies used various metrics to quantify the misclassification. These matrices varied from simple concordance, sensitivity and specificity, to Kappa statistics and chance-corrected concordance.

These medical record review studies have varied widely in the exact methodologies used, which makes it difficult to compare their findings. Many studies used a very basic approach to validate the quality of the COD assignment. We do not recommend this approach, as it omits important methodological steps that are likely to influence the quality of the reported CODs.

This literature review shows that little previous research has been concerned with developing and testing a robust framework for medical record reviews, hence

there is very little guidance for health professionals in countries where medical record reviews might be conducted. The value of all the studies included in our review should be recognised as they deal with the quality of the reported COD, an area that is sometimes neglected, and aim to improve medical certification and vital statistics. However, our detailed review has shown that, apart from similarities in the basic steps, there is no standard framework for medical record reviews. Many of the studies do not describe in sufficient detail the methodologies used to carry out the medical record reviews. There is substantial variation in approaches, and many studies seem to miss some important methodological steps. Building on this and our own empirical experience, we developed a methodological framework outlining a process with some additional steps that can guide future studies to better validate COD reported in routine systems in countries.

We recommended that all countries, particularly those that have incomplete and deficient COD statistics, undertake studies to validate the quality of their hospital COD data. The framework proposed is applicable for validation studies using medical records, from nationally representative samples of all CODs to studies of one specific cause from one hospital or municipality. The framework outlines a clear process to follow and explains the diagnostic criteria to be used for diagnosing the COD, as well as for evaluating the quality of the available medical records. Finally, it also assesses the quality of the hospital environment, be it diagnostic ability or quality of the current International Classification of Diseases practices.

Without the evidence from a medical record review study of the recorded CODs, no country should trust medical certification in hospitals is of sufficient quality. For countries where collection systems and practices need to be improved, there are several free, useful tools and training materials available that can help improve the reliability of COD statistics needed for public health planning and disease prevention.

Introduction

Health systems worldwide are struggling to respond effectively to a rapidly changing epidemiological environment, where largely avoidable causes of non-communicable diseases increasingly cause substantial health loss. At the same time that the burden of communicable diseases has decreased, health systems have had to face new threats and pandemics, often coming from outside national borders. Some of the main challenges and rate-limiting factors to achieving better health outcomes in many countries revolve around the need to improve health information systems (HIS) to deliver more useful and better quality data (Health Metrics Network & World Health Organization 2008). Within a HIS, accurate and timely data on cause of death (COD) are perhaps the most critical for guiding health programs and policies (Shibuya et al. 2005) and for measuring how health conditions are changing, both with respect to magnitude and distribution in populations (Ruzicka & Lopez 1990).

Some insight into the quality of COD and mortality statistics worldwide can be ascertained from a study based on the World Health Organization (WHO) Mortality Database (Mahapatra et al. 2007). For the period 1996–2003, Mahapatra and colleagues found that 118 countries had reported COD statistics for at least one year to WHO; of these, 31 countries were assessed to have high quality data, 24 as having medium-high quality data, 26 had medium-low quality data, 26 had low quality data and the remainder had data of only limited use, according to the quality criteria proposed by the authors. It is therefore not surprising that more recent and detailed assessments of vital registration systems have found significant weaknesses in the generation of COD statistics (Health Information Systems Knowledge Hub 2012a).

Reliable population-based COD statistics rely heavily on information provided in death certificates for individuals. The ‘gold standard’ for COD reporting is to have a medically qualified person certify the COD based on the rules and procedures of the *International Classification of Diseases and Related Health Problems* 10th revision (hereafter ICD-10) (World Health Organization 2010). However, the accuracy of death certification by physicians depends on many factors, including the certifiers’ knowledge and skills in correctly identifying the underlying cause of death (UCOD) (Maudsley & Williams 1994). Current standard guidelines for correctly certifying COD are given in volume 2 of ICD-10 (World Health Organization 2010). Although the majority of countries in the world use the ICD classification for

coding CODs, many physicians are not aware of the ICD-compliant standard death certification guidelines and have not been taught to apply these guidelines correctly in certifying the COD, either as part of their medical curriculum or as postgraduate professional development. As a result, an unknown but likely substantial fraction of physicians do not adequately understand the concept of UCOD, the sequence of events leading to death, and how to complete a death certificate correctly. Moreover, the public health importance of accurate COD information is even less well taught to physicians, and as a result many physicians consider death certification an unwelcome burden. It is hardly surprising, therefore, that the quality of medical certification, where it has been formally evaluated, is found to be low, which is reflected in the generally poor state of COD statistics in many countries.

Information about the COD distribution in a country is derived from vital registration systems where death declarations are, or should be, certified and written by physicians. The bulk of physician-certified deaths are reported from hospitals and are automatically assumed to be correct. Yet given the concerns about physician training in death certification, and the widespread lack of understanding among physicians of the public health importance of aggregate statistics based on individual death certificates, which they certify, this assumption is highly unlikely to be true, with potentially very grave consequences for the evidence base, often the only one, to inform health policy debates. In this paper, we systematically assess available evidence on the extent of misclassification of CODs in hospital statistics. Countries rarely undertake evaluations of the quality of these routine data from hospital systems, yet without doing so they have no assurance that the information base for their policies and planning is reliable and useable (Khosravi et al. 2008; Rampatige et al. 2013). At the same time, the value of and need for evidence-based public health policy and planning in countries has been long recognised (Moryama 1989).

Validation studies of COD data require a gold standard against which to compare the COD recorded by the vital registration system, which in turn compiles data on CODs from hospitals. The ideal gold standard for COD is to carry out autopsies, but this approach is prohibitively expensive, likely to be based on a biased sample of deaths of interest to coroners, and is not practical to do for all deaths occurring in a country, or even in all hospitals in a country (Shojania et al. 2003). Instead of using autopsy as the gold standard for large samples of

deaths, medical records, provided they are of sufficient quality, might be used as a reasonable alternative against which to compare CODs for validation. This use of medical record reviews has been applied in a number of studies in different countries, and many have found significant misclassification of COD reporting from hospitals (Rao et al. 2007; Pattaraarchachai et al. 2010; Hernandez et al. 2011; Rampatige et al. 2013).

A principal objective of this study is to encourage health professionals to challenge the belief that medically certified data in the vital registration system are always correct. By carrying out medical record reviews using the guidelines proposed in Part II of this paper, they can identify the need and scope of targeted interventions in hospitals to improve death certification practices. We first review and synthesise the methods and results from a large number of studies that have used medical record reviews to validate the COD reported on the medical death certificate using data either from hospitals or the vital registration system. Next, we select a subset of studies for more in-depth analysis of differences or commonalities in the methodological approaches used. Based on these findings, in Part II we propose a best practice methodological framework for medical record review. Countries interested in understanding the quality of their routinely reported COD data can adapt the framework to suit their particular needs and possibilities. In all cases, it is strongly recommended that countries use the findings to strengthen physician skills in proper COD certification.

Part I: Systematic review of evidence about cause-of-death accuracy in hospitals

Search strategy

From July 2012 to February 2013, we conducted a comprehensive literature search to identify published articles that used medical record reviews to validate routinely reported COD from hospitals. The scope of our study was limited to articles published between 1983 and 2013 (30 years) and to studies in English, Spanish and Portuguese languages. The key words/phrases used in the search included i) validity of COD reporting, ii) accuracy of hospital death reporting, iii) quality of UCOD certification, iv) validation of death certification, v) medical record review to validate COD, vi) validating COD reported in hospitals and vii) quality of hospital COD.

The search for English articles was primarily conducted through the Medline/PubMed electronic database and Google Scholar. References quoted in original articles were manually searched for additional studies. The initial search for English articles yielded 112 studies, and the manual search—using the references listed in the selected articles—enabled us to retrieve a further 12 articles, bringing the total number of articles to 124. The review of studies written in Spanish or Portuguese was based on a search conducted in the Medline/PubMed, and LILACS-WHO/PAHO Biblioteca Virtual de la Salud (BVS) and covered the same 30-year period, using similar key words and phrases to the English search. From this review, we identified a further 32 articles from Medline/PubMed and 31 from BVS on the assessment of the quality of death certification through a comparison with medical records or autopsy. The reference lists from the articles were also reviewed and allowed us to identify a further 12 studies of interest, bringing the total number of articles to 75.

Screening and selection

All 199 studies identified from the initial search were further screened (124 in English language and 75 in Spanish or Portuguese) for specific content and inclusion criteria. The inclusion criteria we selected allowed us to identify articles of special interest for the review. For a paper to be included in this review it needed to meet the following criteria: i) primary research (not a review), ii) published after 1983 in a peer reviewed journal, and iii) CODs reported from hospitals validated against a reference COD obtained through independent medical record review.

After this second screening, only 29 studies (12 English articles, 10 Spanish and 7 Portuguese) remained for the detailed review (Appendix 1). The selected articles were then subjected to further scrutiny using a set of

pre-determined criteria, shown in Box 1. The first broad set of criteria (Description of study) categorises studies according to timing, geographic location and basic study features, including scope, age groups and range of CODs that were validated.

The remaining criteria are more analytical and enquire about what might be considered essential criteria for a medical record review, such as characteristics of the reviewers, assessment of the quality of records to support the diagnosis, the reproducibility of the COD selection, and diagnostic facilities available at the hospitals.

Box 1 Criteria used for extracting information from included articles

1. Description of study
<ul style="list-style-type: none"> • Year of review • Continent • Sample size • Scope of the study • Age groups included • CODs that were validated
2. Characteristics of reviewers
<ul style="list-style-type: none"> • Personnel who did the review • Skills and experience of the reviewers • Number of physicians involved in the study
3. Assessment of quality of medical records to support COD diagnosis
<ul style="list-style-type: none"> • Was the quality of the medical records assessed for availability of information for conclusive COD diagnosis? • If assessed, what was the number of categories used in the assessment?
4. Reproducibility of the COD
<ul style="list-style-type: none"> • Use of diagnostic criteria for diagnosis • Method used to resolve disparities in diagnosis
5. Capacity of hospitals to diagnose COD
<ul style="list-style-type: none"> • Assessment of diagnostic capacity of the hospitals included in the study • Types of hospitals included • Quality of patient diagnosis and management in these hospitals

Description of the studies included in the review

Of these 29 studies, nine were published after 2005. In instances where the review had been ongoing for more than one year, we used the last year of the review to date the study. The number of deaths included in the review ranged from 23 in a study in Mexico (González-Medina & Martínez-Natera 2001) to 3316¹ deaths in a nationally representative study of COD accuracy in Thai hospitals (Pattaraarchchai et al. 2010).

The highest number of studies came from the American continent (18). Mexico had three studies and Brazil had six. There was only one study from the Pacific, namely Tonga (Carter et al. 2012), and one from Africa (Moussa et al. 1990). Eighteen of the studies included in the review considered all CODs, while the rest of the studies (11) were limited to investigating a sub-selection of causes. The large majority of studies (24) looked at deaths across all ages; two studies included only adult deaths; one study focused entirely on elderly deaths, and another on infants less than one year. Table 1 provides a summary of the key characteristics of the studies included in this review.

¹ The number of deaths should read 3274, not 3316. This error was in the original study, as cited. In this paper, we have chosen to use the total number of 3316.

Table 1 Key characteristics of the final 29 studies selected for inclusion in the review

	No. of studies	Percentage	Study reference (see Appendix 1)
Year of review			
After 2005	9	31.0%	2, 3, 4, 6, 9, 14, 17, 19, 22
2000–2004	8	27.6%	1, 5, 7, 10, 11, 20, 25, 29
1990–2003	11	38.0%	8, 13, 15, 16, 18, 21, 23, 24, 26, 27, 28
Earlier than 1990	1	3.4%	12
Sub-continent			
America	18	62.1%	3, 4, 10, 13, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29
Europe	4	13.8%	7, 8, 14, 15
Asia	3	10.3%	1, 2, 6
Pacific	1	3.4%	9
Africa	1	3.4%	11
Middle East	2	7.0%	5, 12
Sample size			
0–99	3	10.3%	14, 21, 27
100–499	14	48.3%	4, 8, 10, 11, 12, 15, 16, 17, 18, 19, 20, 22, 28, 29
500–1499	8	27.6%	5, 6, 7, 9, 13, 23, 24, 25
1500–4999	4	13.8%	1, 2, 3, 26
Scope of the study			
All conditions	18	62.2%	1, 2, 3, 6, 7, 8, 9, 11, 12, 13, 17, 18, 19, 20, 21, 24, 25, 26
Cardiovascular conditions and/or diabetes	3	10.3%	10, 16, 22
All non-accidental deaths	1	3.4%	4
Ill-defined and vague causes	1	3.4%	5
Deaths with legal implications	2	7%	14, 15
Neonatal causes	1	3.4%	23
Cancer	3	10.3%	27, 28, 29
Age groups included in the study			
All ages	24	82.8%	1, 2, 3, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 21, 22, 24, 25, 27, 28, 29
Adult deaths (age not defined)	2	7%	4, 20
Elderly patients (age not defined)	1	3.4%	7
Infants less than one year	1	3.4%	26
Neonatal period	1	3.4%	23

Purpose of medical review studies

Medical record reviews can and have been carried out to serve different purposes. Perhaps the most common reason is to independently assess the reliability of hospital COD data, reflecting a lack of confidence in the COD information from the vital registration system. In this case, the specific goal of the study is typically to establish a misclassification matrix of diagnoses from the two sources: cases reported from hospitals to the vital registration system, and the same cases independently assessed based on a review of medical records. Typically, countries (or hospitals or medical associations) would want to use these misclassification matrices to identify common misclassification errors and take urgent steps to address them through improved training of resident physicians in hospitals. Some examples of misclassification matrices based on empirical research carried out in China, Thailand, Iran and Sri Lanka are shown in Appendix 2.

The kinds of misclassification shown in the matrices can be seen in these example studies:

- The findings from the China study show that ischaemic heart disease (IHD) was undercounted by 31% in the official statistics because of systematic misclassification of true cases of IHD to stroke, diabetes, pneumonia and other forms of heart diseases. Hepatitis deaths were found to be frequently misclassified to other liver diseases, and pneumonia was found to be excessively and often incorrectly selected as the UCOD from among respiratory diseases.
- The study in Iran reported that the true COD pattern of the population was considerably different from the pattern of causes reported by the vital registration system in the country. In this study, ill-defined causes reported by the routine death registration system for many deaths among young and middle aged adults were primarily reclassified after review to IHD, cerebrovascular disease and injuries. Iranian health authorities would vastly underestimate the true importance of these CODs in Iran based on the recorded COD pattern from vital statistics. One interesting finding of the study was that half of the study sample injury deaths had been classified as senility or unknown in the vital registration system, thus greatly underestimating the importance of external CODs in Iran. In the same

study, ill-defined causes for the 70 or above age group were largely reclassified after review to IHD and stroke.

- The medical record review study in Thailand also reported massive misclassification of major CODs. Cases of septicaemia, commonly reported in the vital registration system, were reassigned to cerebrovascular disease, HIV/AIDS and pneumonia, and ill-defined causes were identified as true cases of IHD, other heart disease, chronic obstructive pulmonary disease (COPD) and stroke. The study also found gross under-diagnosis of diabetes by the vital registration system in Thailand.
- Similar to the above studies, recently published findings from a study in Sri Lanka confirmed major misclassification errors in identifying deaths due to vascular diseases and diabetes. Thirty per cent of deaths due to IHD (the leading COD) had been misclassified to diabetes and other heart diseases, and 25% of deaths due to diabetes mellitus (the third leading COD) had been misclassified as various diseases of the circulatory system (see Appendix 2 for details).

The primary purpose of medical records reviews is to identify the degree of misclassification of COD at the individual level, by comparing the medical record diagnosis with the reference diagnosis. This was the case for the majority of studies (1–7, 9, 10, 14, 18, 22–29). Some studies had very specific aims, for example, investigating whether the unusually high mortality rates from uterine cervical cancer in one local area were due to misdiagnosis or whether they were real (29). Another study (26) focused on correctly certifying the causes of infant mortality in order to heighten understanding among physicians about the value of correctly certified death certificates for health programs to reduce infant mortality.

In some cases, for example the Thai study, these misclassification matrices have been used to derive a series of “correction factors” to apply to routine COD data from vital registration systems to better understand national COD patterns. If the misclassification matrix is based on a reasonably representative sample of hospital deaths in the country, the correction factors can be applied to the vital registration data on CODs in hospitals to estimate the most likely true UCOD pattern at the population level, that is, the set of cause-specific

mortality fractions (CSMF). CSMFs are critical input into policy debates about the leading CODs in populations, and it is clearly of great importance to correctly specify these to guide policy responses and resource allocation. Fifteen studies (1–7, 9, 10, 14, 18, 22–25) were conducted to correct the CSMFs based on vital registration where these records were known or suspected to be incorrect.

Skills of study reviewers

The certification skills of the people reviewing the studies were also investigated, as the quality of the medical record review would largely depend on their ability to identify the UCOD correctly. Nineteen studies mentioned that physicians were used for the review; of these, 15 studies stated that the physicians had received special training on how to correctly certify the COD. One study mentioned the use of “professionals” to do the review, while the remaining nine studies provided no information about the qualifications of

the reviewers. One study from Brazil (Monteiro et al. 1997) used both a physician and a researcher, which we have classified under Physicians (see Table 2). The number of people reviewing the medical records in these studies ranged from one physician in four studies to 84 physicians in the Thai study (Pattaraarchachai et al. 2010); this high number was due to the size of the nationally representative sample (n=3316) drawn from nine provinces (Pattaraarchachai et al. 2010). Five studies used two to five reviewing physicians.

Table 2 Characteristics of the reviewers

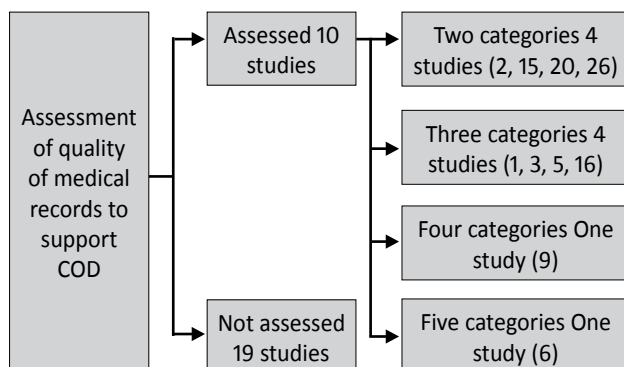
	No. of studies	Percentage	Study reference (see Appendix 1)
Reviewers in the study			
Physicians	19	65.6%	1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 16, 17, 22, 23, 24, 25, 26, 27*
Other “professionals”	1	3.4%	14
Not mentioned	9	31.0%	8, 13, 15, 18, 19, 20, 21, 28, 29
Skills and experience of the reviewers			
Specific training provided on correct death certification	15	51.8%	1, 2, 3, 4, 5, 6, 11, 14, 16, 18, 19, 20, 21, 22, 23
No mention of specific training	14	48.2%	7, 8, 9, 10, 12, 13, 15, 17, 24, 25, 26, 27, 28, 29
Number of reviewing physicians (19 studies)			
One physician	4	21.0%	1, 12, 16, 27
Two to five physician	5	26.3%	4, 6, 7, 9, 10
Six to ten physicians	1	5.3%	3
Eleven to twenty physicians	2	10.5%	5, 11
More than 21 physicians	1	5.3%	2
Number of reviewing physicians not given	6	31.6%	17, 22, 23, 24, 25, 26

* Used a physician and researcher

Assessment of the quality of records to support the cause-of-death diagnosis

The accuracy of the COD diagnosis in hospitals and medical record reviews often depends on the information available in the medical record. Ten studies specifically assessed the quality of the information available for reliably identifying a UCOD and classified this into a number of quality categories, ranging from two (adequate vs. inadequate) to five categories (excellent, good, average, weak and poor) (see Box 2). One study, of the remaining 19, excluded deaths for which the medical records were judged to be too incomplete for reliably identifying a COD, although there is no specific mention of the criteria used (Moussa et al. 1990). The rest of the studies do not provide any information about the quality of the medical records used in the review, which is poor practice.

Box 2 Assessment of the availability and quality of information in medical records to support the diagnosis



Use of diagnostic criteria for diagnosis

Correctly diagnosing a disease and its place in a clinical or pathological sequence of events leading to death can be a complex task. This is particularly likely to be the case when the certifying physician has not treated the patient. Diagnostic accuracy depends very much on physician knowledge, diagnostic ability, and experience. To improve the utility of findings from a medical record review, specific training should be given to the reviewing physicians in how to correctly diagnose the UCOD from medical records. Nonetheless, the possibility remains that physician biases or expectations about prevalent diseases in the community will influence their

conclusions when reviewing medical records of patients they have not attended. To avoid the possibility of physician-specific factors affecting the accuracy of the UCODs derived from medical records review, “standard diagnostic criteria” (SDC) should be determined in advance of the study. In this way, study physicians would only certify a death as being due to a particular cause if the evidence from the medical records met, either fully or within a pre-defined acceptable margin of uncertainty, the clinical definition for that cause. Such SDC have been developed for other international research efforts aimed at removing local physician biases and variations in COD certification (Murray et al. 2011).

Several of the studies had developed clear *ex-ante* diagnostic criteria for the most common COD of interest, that is, criteria for which evidence must be contained in the medical records for a given diagnosis to be attributed. Use of such strict and standardised diagnostic criteria also increases reproducibility of the method and enhances comparability of the findings. In our review, nine studies used SDC to arrive at a COD (Table 3). Further information and some examples of SDC are provided in Appendix 3 (Standard diagnostic criteria for medical record review).

We also investigated what approaches were used when no SDC were included in the study design and when there was uncertainty about the UCOD from medical record review. Fourteen studies included in the review did not provide information about how the final diagnosis was determined when the COD was not clear to the reviewing physician. In nine studies, the solution was to have the case reviewed and discussed by a panel of physicians engaged in the review, whereas in three studies, autopsies were carried out to determine the COD. One study referred the diagnosis to another physician, and two other studies referred the diagnosis to an external expert.

Table 3 Methods and criteria applied to arrive at final diagnosis of cause of death

	No. of studies	Percentage	Study reference (see Appendix 1)
Use of diagnostic criteria to arrive at COD			
No diagnostic criteria used or not mentioned	20	69.0%	1, 2, 4, 5, 6, 7, 8, 9, 13, 14, 15, 17, 18, 20, 21, 23, 24, 25, 26, 27
Diagnostic criteria used	9	31.0%	3, 10, 11, 12, 16, 19, 22, 28, 29
Method used when there is competing COD			
No information provided	14	48.3%	5, 7, 8, 12, 13, 14, 15, 17, 18, 20, 22, 23, 24, 25
Case by case within the review committee/ panel	9	31.0%	1, 2, 3, 4, 10, 26, 27, 28, 29
Referred to a second physician for diagnosis	1	3.4%	9
Autopsy report considered as gold standard	3	10.3%	16, 19, 21
Relevant expert opinion was obtained	2	7.0%	6, 11

Capacity of hospitals to diagnose cause of death

It is reasonable to assume that the availability of diagnostic facilities in hospitals would influence the diagnostic accuracy of diagnosis of patient CODs. For example, a hospital with ECG facilities is likely to be able to diagnose more accurately a patient who arrived with chest pains. The diagnosis of malaria in a patient would similarly be easier in hospitals that have lab facilities and can confirm a diagnosis by a blood film positive for malaria. Knowing which diagnostic facilities are available in the hospitals included in a study is thus highly relevant for medical record reviews. Only the Chinese study (Rao et al. 2007) specifically mentions that urban hospitals were selected in order to include hospitals with adequate diagnostic facilities, but these were not specified in the study protocol. All the other studies reviewed do not refer to or discuss the specific diagnostic capacity of the hospital(s) included in the study (Table 4).

Table 4 Capacity of study hospitals to diagnose causes of death

	No. of studies	Percentage	Study reference (see Appendix 1)
Mentioning of capacity of hospitals to diagnose			
Mentioned	1	3.4%	1
Not mentioned	28	96.6%	2–29
Types of hospitals included in the review			
No deliberate selection of hospitals (all hospitals within selected geographic area or all hospitals where the selected deaths had occurred)	25	86.2%	2, 3, 5, 6, 7, 8, 10, 11, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29
Secondary/tertiary hospitals	4	13.8%	1, 4, 9, 12
Quality of patient diagnosis and management in those hospitals			
Mentioned	3	10.3%	12, 28, 29
Not mentioned	26	89.7%	1–11, 13–27

Accuracy of coding and sequence of events leading to death

Death certification and coding are two separate but interrelated processes. Physicians complete the death certificate and coders use the information provided in the death certificate to select the UCOD and to assign the corresponding ICD code. The ability of the coder to correctly identify the UCOD from what the physician has written in the death certificate is clearly of great importance. Many studies have compared the original diagnosis with the diagnosis from the medical record review using their respective ICD codes. If the ICD codes are not correctly selected and assigned, the comparison would not reflect the true concordance between the two diagnoses. Only one study included in this review seemed to have also assessed the quality and accuracy of coding of the original death certificates (Fajardo et al. 2009). With the exception of the Thai study (Pattaraarchachai et al. 2010), the accuracy of the sequence of events leading to death has not been evaluated, although this is important information for coders when selecting the UCOD.

Misclassification of cause of death

Most of the studies included in this review assessed the concordance between the original COD diagnosis and the COD derived from an independent review

of medical records, including in some cases the original death certificate, and reported the pattern and extent of misclassification in matrices or in the form of percentages. A number of studies also used various metrics to quantify the extent of diagnostic misclassification. These metrics varied from simple concordance based on measures of sensitivity and specificity, to Kappa statistics and chance-corrected concordance. It is important to note the extent of misclassification reported in almost all the studies (summarised in Table 5). It is also worthwhile pointing out that the diagnostic misclassification reported in these studies was found to apply to some of the most common CODs, including IHD, cerebrovascular disease, diabetes mellitus and external CODs. In a number of studies, ill-defined CODs constituted a significant proportion of the study sample, and the impact of allocating these to more definitive causes has also been demonstrated in some studies (Khosravi et al. 2008).

Table 5 Summary of main findings related to misclassification patterns

Country (ref)	Language	Study sample	Main findings related to misclassification
China (1)	English	2917	IHD was misclassified to stroke, diabetes, pneumonia, and other heart diseases. Hepatitis deaths were misclassified as other liver diseases, pneumonia as other respiratory diseases, and there was poor distinction between hypertensive disease and genitourinary system disorders.
Thailand (2)	English	3316	Cases of pneumonia (470) deaths were primarily reassigned after review to cerebrovascular diseases (55), HIV/AIDS (44), and pneumonia (38). Ill-defined deaths (447) were reassigned after review to IHD, other heart diseases (36), COPD (39) and cerebrovascular (25).
Mexico (3)	English	1589	The UCOD concordance ranged from 38.5% for children to 66.5% for adults. For adult deaths, prostate cancer, suicide, HIV/AIDS, leukaemia/lymphomas and cervical cancer had the highest concordance.
Mexico (4)	English	300	At ICD chapter-block levels concordance was 69.2%. At ICD 2-digit level the agreement was 50.4%.
Iran (5)	English	1462	Ill-defined conditions (582 deaths) were reassigned after review to IHD (194), cerebrovascular (75) and to injuries (56).
Sri Lanka (6)	English	602	The concordance level at ICD 3-character level was 41.4%. Thirty per cent of deaths due to IHD had been misclassified to diabetes mellitus and other heart diseases; 25% of deaths due to diabetes mellitus had been misclassified to various diseases of the circulatory system; and deaths due to diseases of the liver had been misclassified into a wide range of causes.
France (7)	English	625	Differences were found mainly for cardiovascular diseases (20.6% in the study vs. 32.5% in the national mortality register) and ill-defined CODs.
Sweden (8)	English	600	The overall agreement between death certificate COD and the study was 77% at ICD-9 basic tabulation list level. Diagnosis of malignant tumours had the highest accuracy.
Tonga (9)	English	945	There were 32% major discrepancies and 6% minor discrepancies between the death certificate and medical record review.
USA (10)	English	491	Death certificates overestimated coronary heart disease deaths by 51%.
South Africa (11)	English	703	Agreement was only 55.3% at ICD 10 mortality tabulation list level. 21.6% of IHD deaths were incorrectly identified as diabetes mellitus, 17.6% as non-cardiovascular diseases, 13.7% as ill-defined natural causes and 11.8% as hypertension.
Kuwait (12)	English	470	Original death certificates underestimated cerebrovascular by 69.2%, diabetes mellitus by 60%, IHD by 33.5% and hypertension by 31.8%.
Venezuela (13)	Spanish	226	Authors classified deaths in seven groups: infectious diseases, cancer, endocrine diseases, cardiovascular diseases, perinatal deaths, external causes, and ill-defined other. They found a concordance of 53% between the death certificates and the medical records (n=266), and a concordance of 52.9% between the death certificates and the autopsy reports. No significant differences in concordance between the death certificates and medical records were found when comparing deaths certified by the physician who provided treatment vs. other personnel.
Spain (14)	Spanish	2226	Deaths were classified in 17 groups. The simple concordance between the Catalunya mortality records vs. the clinical records (forensic pathology) from the Institute of Legal Medicine of Catalunya, considered as gold standard, was 54.8% (95% CI 52.7, 56.8), with a Kappa of 46% (95% CI 44.1, 48.0). Validity of mortality records based only on statistical documents is low for deaths requiring a legal action, mainly because of the high proportion of ill-defined deaths and the underreporting of external causes (traffic injuries, poisoning and suicide).
Spain (15)	Spanish	585	Deaths were classified in 17 groups. The simple concordance between the COD as stated in the formats used by the Catalunya mortality registry vs. a gold standard conformed by medico-legal autopsies, toxicology reports, pathological anatomy reports and medical records was 72.3% and 65.9% respectively. The sensitivity (detection rate) was 65.9% for external causes and 79% for natural causes; the confirmation rate (positive predictive value) was 69% for external causes and 75.5% for natural causes.

Country (ref)	Language	Study sample	Main findings related to misclassification
Venezuela (16)	Spanish	136	The study compared the CODs stated in death certificates in which the phrase “myocardial infarction” appeared anywhere in the CODs, vs. the COD based on the review of medical records or other information from health facilities in which the deaths occurred. Authors found an overestimation of myocardial infarction rates of 32%.
Uruguay (17)	Spanish	135	Authors compared COD in death certificates vs. medical records as gold standard. Cases were classified into three categories: I. Complete and correct registration; partially correct/complete registration; and III. Incorrect registry. About death certificate completeness: 75% of cases referred to the Judicial Morgue were correctly referred. 12.86% of cases were classified as category I, 53.53% to category II, and 28.73% to category III.
Costa Rica (18)	Spanish	101	The study compared the COD coded directly from death certificates as filled in by physicians, vs. the official coding conducted at the National Institute of Statistics and Census of Costa Rica. The concordance between these sources was 66% for deaths that occurred at home, and 67% for deaths that occurred in hospitals.
Cuba (19)	Spanish	125	Authors found a concordance of 71% between death certificates and autopsy reports/medical records for overall deaths (n=125), going up to 90% for deaths due to cardiovascular causes (n=30).
Costa Rica (20)	Spanish	173	The study found a discordance of 44.8% between COD from clinical records vs. autopsy reports.
México (21)	Spanish	23	The study found a discordance of 48% between COD from the death certificate vs. from autopsy.
Cuba (22)	Spanish	264	The study found that 15.9% of cases classified as acute myocardial infarction (AMI) in the death certificate were not confirmed as such in the autopsy, and autopsy detected 23.5% of cases that had not been classified as AMI in the death certificate.
Brazil (23)	Portuguese	452	The authors compared the COD in death certificates vs. the COD obtained from interviews and medical records (called the ‘modified COD’). The simple concordance in the COD for those sources was 38% at 3-digit character level of the ICD, and 33% when considering 4 digits.
Brazil (24)	Portuguese	552	The authors compared the COD from medical records vs. a gold standard constructed through the review of medical records, the legal medicine institute, registries from the University of São Paulo, and interviews with relatives. The study found a good concordance for CODs at 3-digit character level of the ICD, with a Kappa of 76% (CI 95% 0.75–0.77).
Brazil (25)	Portuguese	950	The authors compared the COD as stated in the death certificate vs. gold standard constructed with information from medical records. Disagreement between the original DC and new DC occurred in 16.1% of cases. The sensitivity of the management information system in identifying problems with UCOD was 64.1%, and specificity was 75.5%.
Brazil (26)	Portuguese	1703	The authors compared the quality of the original death certificates of infants less than one year with information from hospital records. Only 52% of the UCOD on the death certificates was maintained as correct. Other items on the death certificate which were evaluated included indication of time interval, place of occurrence, age of mother and birth weight.
Brazil (27)	Portuguese	97	The authors studied the reliability of reported CODs from a sample of reported stomach cancers. New death certificates were prepared based on clinical and laboratory data showing a 91% concordance with the stomach cancer diagnosis. The conclusion of the study was that the reliability of the reported mortality data by stomach cancer was good in the municipality of Rio de Janeiro where the study was undertaken.
Brazil (28)	Portuguese	966	The purpose of the study was to assess the reliability of the reported deaths from cancer in Salvador. The coded UCOD on the death certificate was compared to hospital records and pathology reports. The death certificates were found to be correct in 65% of the reported cancer deaths. However, 35 histologically confirmed cancers were found in the sample, which indicated other causes. The authors therefore conclude that approximately 700 more cancer deaths might have been hidden among the total deaths for that year.
Brazil (29)	Portuguese	188	The study looked at the reliability of death certificates reporting uterine cancers in Belém. After review of medical records and histopathological reports, the concordance was 94%, suggesting high reliability. However, the study was also able to reduce the number of unspecified uterine tumours by 63%.

Part II: Guidelines for conducting medical record review studies

Although all of the studies included in this review were carried out for the same basic purpose—that is, to assess the quality of death certification in a hospital, municipality or country or for a specific disease or age group—there is considerable variation in study designs and approaches used. However, we can identify four basic steps that are common to most medical record review studies: i) selection of sample, ii) tracing of corresponding medical records, iii) independent review of medical records, and iv) comparison of original diagnosis of the UCOD (i.e. COD as reported by the hospitals to the vital registration system) and the “new” COD from the review of medical records in order to evaluate the quality of the original COD assignment (see Figure 1).

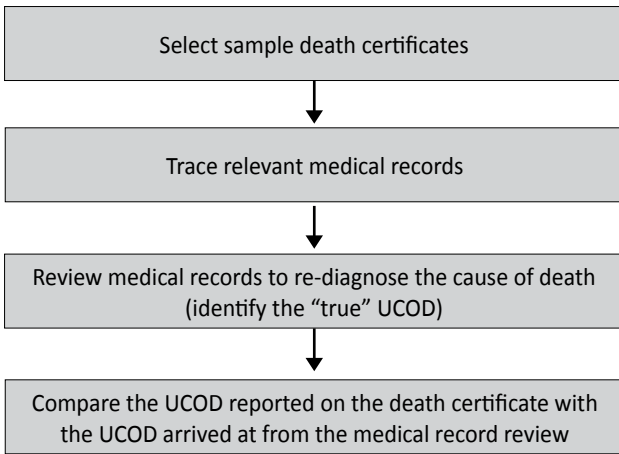


Figure 1 Typical steps used in medical record review studies

Based on our review and empirical experience in using this method we have elaborated on this basic structure and methodology and propose in the next section a more detailed framework that can be used by countries and researchers as guidance for future studies.

As our literature review of these studies has suggested, medical record reviews have been successfully used in different countries and contexts to evaluate the quality of hospital COD statistics. However, it is likely that countries wanting to conduct such evaluation studies will find little help in the literature, as no standard framework to do so

exists apart from the basic steps summarised in Figure 1. Given the importance of accurate COD statistics for health policy and planning, all countries would benefit from more detailed guidance on how to periodically conduct reliable medical record reviews to evaluate the quality of their reported COD statistics.

As stated earlier, the quality of COD reporting by hospitals depends on a number of factors, including the complexity and nature of disease in the community, diagnostic facilities available at the hospital, the form of the death certificate used, training and qualification of the certifier, and accuracy of mortality coding. Studies that aim to investigate the quality of COD statistics and use this evidence to recommend strategies and actions for improvement need to identify the contribution of each potential step where misclassification can occur. Building on the methodological findings from our literature review and our own empirical knowledge of the topic, we propose below a generic methodological framework that countries can use as a guide to set up medical record review studies (Box 3). The framework outlines all the important factors in the review that need to be considered and evaluated. Each of these is further clarified in the discussion that follows.

Box 3 Recommended framework for medical record reviews

Select hospital(s) to be reviewed

- Determine scope of investigation
- Get agreement for hospital cooperation
- Census of available diagnostic facilities in included hospitals

Select sample death certificates

- Determine sample size
- Determine the sampling method and identify the number of death certificates to be included in the study
- Draw the sample of death certificates from the vital registration database/hospital mortality register
- Retrieve corresponding medical records from the hospitals
- Validate the quality of ICD coding for the sample

Develop standard diagnostic criteria (SDC) for major CODs

- Set up a small expert group of physicians to develop SDC
- Decide which diseases to define criteria for
- Develop and pilot diagnostic criteria on sample

Select physicians to re-diagnose COD

- Provide training in COD certification

Trace the relevant medical records

- Decide on criteria to assess the quality of the records
- Decide on rules to determine which records can be used and which are too incomplete
- Reassess the sample size and losses due to poor or untraceable records
- Prepare a summary of medical records quality, availability and storage

Review medical records

- Design form for new death certificate
- Diagnose COD using pre-defined SDC
- Develop a 'new' study death certificate including identifying the UCOD

Code the new COD according to ICD-10

- Check that coding is correct

Compare the two CODs and analyse findings

- Determine the extent of misclassification
- Draw up a misclassification matrix for all ages, both sexes (and by age and sex if numbers allow)
- Reassign the ill-defined causes based on the misclassification matrix
- Compare the new COD distribution of study cases with the original

Write final report

- Describe the study design and methodology
- Provide sample design and explanation
- Discuss findings and implications
- Propose improvement steps for COD certification, coding and medical records

Select hospital(s) to be reviewed

The selection of hospitals will depend closely on the aim of the study. If the aim is to review the accuracy of the overall COD distribution for the country, based on deaths recorded and certified in hospitals, then a nationally representative selection of hospitals should be chosen. If resources are more limited, it may only be possible to select one or two hospitals of different types (e.g. secondary, tertiary) or from different regions of the country. In this case, the hospitals selected for evaluation should be those that contribute the largest volume of deaths to the national vital registration system, which are likely to be located in large urban areas.

As death certificates and medical records are confidential legal documents with personal information, obtaining permission from relevant authorities to conduct the study is usually among the first steps that need to be taken. Likely authorities to engage would include civil registration offices or national statistics offices, ministries of health and provincial health authorities, relevant hospital administrators and medical records rooms in charge.

While we do not advocate limiting medical record reviews to hospitals with better diagnostic facilities, it is important that studies take into consideration the limiting factors for patient diagnosis and management to ensure that the findings of the analyses are interpreted accurately and fairly. For example, if the hospital has an ECG machine and physicians skilled in identifying ECG changes consistent with a myocardial infarction, correct diagnosis of AMI in that hospital ought to be expected. A census of diagnostic facilities in participating hospitals is one of the key missing steps we identified during our literature review. When analysing the findings from a medical record review study, we strongly recommend that the level of certainty related to the availability of diagnostic information in the medical records is taken into account. Since all hospitals, irrespective of the availability of diagnostic equipment, contribute data to the health information system, it is useful to make a distinction between well- and poorly equipped hospitals and to carry out validation studies in both. When this is not possible, at least the type of hospitals should be clearly identified to better interpret the results from the study.

Select sample death certificates

The selection of the sample of death certificates for the review will depend largely on the study protocol and objectives. When analysing specific CODs, the sampling frame should not be limited only to the cause under investigation but should be broad enough to detect cases with the disease under study that were not classified as such (i.e. false negatives). A nationally representative sample selected from the official mortality register would be the ideal but may not be possible for budgetary reasons. In that case, a smaller random sample of all other causes can be drawn and investigated to detect whether there were any cases missed of the cause under investigation.

Even in a small local study involving one or two hospitals, it is important to get the original COD from the death certificates rather than from discharge papers, since these two diagnoses are often quite different. For public health policy and prevention, the UCOD as reported in the death certificate is the more important. Hospital discharge diagnoses tend to emphasise the main condition for which the patient was treated during the last hospital stay, which may not be identical to the UCOD.

To compare the original and the reference COD diagnosis, most of the medical record review studies have used the UCOD selected and coded according to the ICD. Agreement or disagreement between the original and reference diagnosis codes could, however, be influenced by inaccuracies in coding and in the selection of the UCOD based on the information given on the death certificate. Therefore, we suggest inclusion of an additional step in the review process that assesses the accuracy of the local mortality coding. This means that a sample of the selected death certificates should be re-coded by an expert coder using ICD mortality coding rules. This step is also useful for identifying the areas where interventions are most needed in order to improve the quality of the CODs.

Develop standard diagnostic criteria or guidelines for major causes of death

To help the review physicians diagnose the COD from the medical records, and to enhance comparability across the findings from different physicians' opinions about the true UCOD, we strongly recommended to

define SDC in advance for all common causes. This will help ensure the accuracy of the gold standard diagnosis, remove subjectivity and improve reproducibility. The SDC could be defined by convening a small group of expert physicians from the common specialities consistent with the likely COD pattern in the community. Thus, for example, if cancer, vascular diseases and diabetes were among the leading CODs, specialists familiar with the clinical criteria for these diseases should be consulted and asked to develop SDC for diagnosing deaths from these diseases. Some diagnostic standards for diseases (at least for the common COD) can be adopted from published studies (Murray et al. 2011; Murray et al. 2012). An example of such SDC is given in Appendix 3.

A useful quality framework to guide the physicians in assessing the reliability of the evidence in the medical records used to arrive at a diagnosis is given in Box 4. For example, a diagnosis of AMI can be accompanied by one of the four levels of diagnostics certainty shown. That is, cases meeting only the standards of Level 4 would be most uncertain and with the least information to support the diagnosis, while Level 1 refers to cases where the diagnosis was made based on the strongest possible clinical measurements and evidence to support a diagnosis of AMI.

Box 4 Levels of diagnostic certainty

Level 4	Unsupported clinical diagnosis only
Level 3	Clinical diagnosis based on characteristic and history
Level 2	Sudden death within six hours of characteristic chest pain and shock witnessed by a physician
Level 1	Availability of ECG changes consistent with AMI or enzyme changes

Source: Murray et al. (2011).

It is important to note a practical implication of the use of diagnostic standards. Depending on the quality of the medical records, a proportion of records may not meet the standards simply because they do not have enough information to reliably assign a COD. When some cases do not comply with the required criteria for any given COD, it may be necessary to include more cases than was originally planned in order to arrive at the desired sample size for the disease, or for the study overall. This may be more expensive, but the added cost is worth the

added certainty about the diagnosis being used as the gold standard for the study.

Select physicians to re-diagnose cause of death

It is advantageous to have the physician reviewers involved in the study from the beginning so that the purpose of the study is well understood. Even experienced physicians may benefit from some refresher training in ICD-compliant death certification practices and medical record reviews before the study to ensure the accuracy of the reference diagnosis. As stated earlier, many physicians do not get enough opportunity in their training to learn correct death certification practices. If no diagnostic criteria have been defined, we recommend introducing quality assurance techniques, such as using two physicians for diagnosis, or re-diagnosing a selected sample of medical records by an expert, or providing refresher training during the period of the medical record review.

Trace the relevant medical records

The traceability of the medical records depends on the medical record-keeping practices of the selected hospital. Researchers would have a better chance of retrieving the required medical records from hospitals that practice systematic storage of medical records. The studies in Sri Lanka, Tonga and South Africa had difficulties in retrieving the corresponding medical records for a proportion of selected death certificates. Inability to retrieve a significant proportion of the relevant medical records from the original sample would introduce a systematic sample bias into the study findings. Therefore, it is important to take all measures to retrieve the medical records for as much as possible of the total sample and to state the number of missing records by which the sample was reduced. A formal analysis of the COD distribution of the final sample and the original sample chosen for the study should be carried out to ascertain the extent of any compositional bias that may have arisen due to inability to locate medical records disproportionately for some CODs (e.g. HIV/AIDS).

It is essential that the whole process of selecting the final sample is described in detail and included in the study methodology so that readers are aware of possible

biases. In instances where a significant proportion of the selected records cannot be traced for the review (e.g. more than 10%), this should be stated in the final report, and the hospital(s) in question should be recommended to review their medical record-keeping practices and apply the guidelines for standard medical record keeping practices available in the *Handbook for doctors on cause-of-death certification* (Health Information Systems Knowledge Hub 2012b).

Review medical records

Correctly certifying CODs requires a sound knowledge about pathophysiology, diseases and their complications and associations. Physicians acquire this knowledge in their undergraduate training as well as in their internship. Only a physician can reliably and accurately identify the sequence of events leading to death and thus diagnose a COD. It is therefore critical that COD validation studies should only use physicians as reviewers. Reporting the qualifications and background of the reviewers used in the study will help the reader to judge the reliability of findings.

Even with extensive training, COD diagnosis by physicians is likely to result in some subjective variations because of different training, experiences and diagnostic ‘fashions’ (Maudsley & Williams 1994). In studies where no diagnostic criteria are provided as guidance, it might be necessary to institute measures to minimise such subjective bias, such as using two physicians to diagnose each death, or at least those that are dubious or likely to cause problems.

Code the new cause of death according to ICD-10

ICD-10 mortality coding rules were developed to be used with death certificates that are aligned with the international standard COD certificate (see Appendix 5). Therefore, it is important that validation studies use the standard death certificate format in the medical record review. For instance, the two studies undertaken in Iran and Sri Lanka both mention that they have used the international standard death certificate for medical record review, despite the country not using this particular form in clinical settings.

Compare the two causes of death and analyse findings

In the case where the specific goal of the study is to assess the quality of the COD distribution as reported by vital registration, we recommend establishing a misclassification matrix of diagnoses from the cases that are reported from hospitals to the vital registrations system, and the diagnoses of these cases independently assessed in a review of medical records. Some examples of misclassification matrices based on empirical research carried out in China, Thailand, Iran and Sri Lanka are given in Appendix 2. Once the matrices have been established, they will show the extent of misclassification and the most common certification errors. From this analysis, hospital/health authorities can decide how best to address these through improved training of their hospital physicians.

If the study is based on a nationally representative sample it may also be useful to derive correction factors that can be applied to the vital registration data to estimate the true UCOD pattern at the population level, as discussed earlier in Part 1.

Write final report

Once the medical record review is complete, the findings should be written up in a final report to be communicated and shared with relevant parties. A strong report is always important to convince the policymakers and administrators to implement the recommendations from the review. The final report should describe the study design and methodology, provide sample design and explanation, discuss findings and implications and propose improvement steps for COD certification, coding and medical records.

Additional practical guidance for carrying out medical record reviews is given in Appendix 6.

Conclusions

All the studies included in our review are based on the recognition that even medically certified CODs are not necessarily correct. These studies validated medical records to ascertain the quality of the reported COD. However, as shown in our literature review, there is no standard framework or guidelines for performing these studies, and we found substantial variation in approaches used for assessing the quality of reported COD. From the methodological descriptions in the studies, we were able to gain insight into some additional steps that some studies had applied to more effectively use medical record reviews for correcting implausible COD distributions. Building on these findings and our own empirical experience, we have proposed a standard framework that covers basic and additional key steps. These steps will guide future medical record reviews studies to more effectively validate the CODs reported in vital registration systems in countries.

The framework proposed is applicable for COD evaluation studies using medical records from nationally representative samples of all CODs, as well as to studies of one specific cause from one hospital or municipality. It outlines a clear process and explains the important steps to follow, from the design of the study, selection of the sample, the development of diagnostic criteria, the review of the medical records, the comparisons of the two CODs and the analysis and interpretation of the findings.

While the proposed new framework needs to be further tested in empirical studies, we consider it sufficiently robust to be applied in a variety of settings and contexts and recommend its application in countries with an interest in assessing the true quality of their COD statistics. Indeed, we believe that all countries can benefit from routinely querying the quality of their hospital COD data. With the evidence from a misclassification matrix (constructed from a medical record review study), medical authorities will truly know whether their recorded CODs are of sufficient quality for the important policy uses that are made of them. The matrix will inform them about which are the most common diseases that are misclassified, and this knowledge can be used to guide improvement plans and better target training practices to specific local needs. To help countries improve their COD statistics and certification practices, there are several useful, free tools and training materials available (see Appendix 4), which will be helpful.

Appendices

Appendix 1: Articles included in the study

Country (ref)	Language	Year of review	Article title	Journal	Reference
China (1)	English	2002	Validation of cause-of-death statistics in urban China	<i>International Journal of Epidemiology</i>	Rao, C, Yang, G, Hu, J, Ma, J & Lopez, AD 2007, 'Validation of cause-of-death statistics in urban China', <i>International Journal of Epidemiology</i> , vol. 36, pp. 642–651.
Thailand (2)	English	2005	Cause specific mortality patterns among hospital deaths in Thailand: validating routine death certification	<i>Population Health Metrics Journal</i>	Pattaraarachai, J, Rao, C, Polprasert, W, Porapakkham, Y, Pao-in, W, Singwerathum, N & Lopez, A 2010, 'Cause-specific mortality patterns among hospital deaths in Thailand: validating routine death certification', <i>Population Health Metrics</i> , vol. 8, iss. 1, pp. 12.
Mexico (3)	English	2009	Assessing quality of death certification: Concordance between gold standard diagnosis and underlying cause of death in selected Mexican hospitals	<i>Population Health Metrics Journal</i>	Hernandez, B, Ramirez-Villalobos, D, Romero, M, Gomez, S, Atkinson, C & Lozano, R 2011, 'Assessing quality of medical death certification: Concordance between gold standard diagnosis and underlying cause of death in selected Mexican hospitals', <i>Population Health Metrics</i> , vol. 9, iss. 1, pp. 38.
Mexico (4)	English	2005	Validity of underlying cause of death statistics in Hermosillo, Mexico	<i>Salud Pública de México</i>	de Carvalho, MH, Alvarez-Hernández, G, Denman, C & Harlow, SD 2011, 'Validity of underlying cause of death statistics in Hermosillo, Mexico', <i>Salud Pública de México</i> , vol. 53, pp. 312–319.
Iran (5)	English	2003–2004	Impact of misclassification on measures of cardiovascular disease mortality in the Islamic Republic of Iran: a cross-sectional study	<i>Bulletin of the World Health Organization</i>	Khosravi, A, Rao, C, Naghavi, M, Taylor, R, Jafari, N & Lopez, AD 2008, 'Impact of misclassification on measures of cardiovascular disease mortality in the Islamic Republic of Iran: a cross-sectional study', <i>Bulletin of the World Health Organization</i> , vol. 86, pp. 688–696.
Sri Lanka (6)	English	2013	Assessing the reliability of causes of death reported by the Vital registration System in Sri Lanka: Medical record Review in Colombo	<i>Health Information Management Journal</i>	Rampatige, R, Gamage, S, Peiris, S & Lopez, AD 2013, 'Assessing the reliability of causes of death reported by the vital registration system in Sri Lanka', medical records review in Colombo', <i>Health Information Management Journal</i> , May 29 [Epub ahead of print].
France (7)	English	1999–2004	Do we really know the cause of death of the very old? Comparison between official mortality statistics and cohort study classification	<i>European Journal of Epidemiology</i>	Alpérovitch, A, Bertrand, M, Jouglu, E, Vidal, JS, Ducimetière, P, Helmer, C, Ritchie, K, Pavillon, G & Tzourio, C 2009, 'Do we really know the cause of death of the very old? Comparison between official mortality statistics and cohort study classification', <i>European Journal of Epidemiology</i> , vol. 24, pp. 669–675.
Sweden (8)	English	1995	Unexplained differences between hospital and mortality data indicated mistakes in death certification: an investigation of 1,094 deaths in Sweden during 1995	<i>Journal of Clinical Epidemiology</i>	Johansson, LA, Björkenstam, C & Westerling, R 2009, 'Unexplained differences between hospital and mortality data indicated mistakes in death certification: an investigation of 1,094 deaths in Sweden during 1995', <i>Journal of Clinical Epidemiology</i> , vol. 62, pp. 1202–1209.

Country (ref)	Language	Year of review	Article title	Journal	Reference
Tonga (9)	English	2008	Causes of death in Tonga: quality of certification and implications for statistics	<i>Population Health Metrics Journal</i>	Carter, K, Hufanga, S, Rao, C, Akauola, S, Lopez, A, Rampatige, R & Taylor, R 2012, 'Causes of death in Tonga: quality of certification and implications for statistics', <i>Population Health Metrics</i> , vol. 10, iss. 1, pp. 4.
USA (10)	English	2003	Overreporting of deaths from Coronary Heart Disease in New York City Hospitals, 2003	<i>Preventing Chronic Disease</i>	Agarwal, R, Norton, JM, Konty, K, Zimmerman, R, Glover, M, Lekiachvili, A, McGruder, H, Malarcher, A, Casper, M, Mensah, GA & Thorpe, L 2010, 'Overreporting of deaths from coronary heart disease in New York City hospitals, 2003', <i>Preventing Chronic Disease</i> , vol. 7, iss. 3, A47.
South Africa (11)	English	2003–2004	Validation of study of cause of death statistics in Cape Town, South Africa, found poor agreement	<i>Journal of Clinical Epidemiology</i>	Burger, EH, Groenewald, P, Bradshaw, D, Ward, AM, Yudkin, PL & Volmink, J 2012, 'Validation study of cause of death statistics in Cape Town, South Africa, found poor agreement', <i>Journal of Clinical Epidemiology</i> , vol. 65, pp. 309–316.
Kuwait (12)	English	1990 (published year)	Reliability of death certificate diagnoses	<i>Journal of clinical epidemiology</i>	Moussa, M, Shafie, M, Khogali, M, el-Sayed, A, Sugathan, T, Cherian, G, Abdel-Khalik, A, Garada, M & Verma, D 1990, 'Reliability of death certificate diagnoses', <i>Journal of Clinical Epidemiology</i> , vol. 43, iss. 12, pp. 1285–1295.
Venezuela (13)	Spanish	1995	Quality of underlying cause of death certification, Lara State, 1995. Calidad de la certificación de la causa básica de la muerte. Estado Lara 1995	<i>Boletín Médico de Postgrado</i>	García Pérez, D & Muñoz, C 2001, 'Calidad de la certificación de la causa básica de la muerte. Estado Lara, 1995', <i>Boletín Médico de Postgrado</i> , vol. 8, iss. 2.
Spain (14)	Spanish	2004–2006	Validation of underlying cause of death in deaths requiring forensic intervention. Validación de la causa básica de defunción en las muertes que requieren intervención medicolegal	<i>Revista Española de Salud Pública</i>	Gotsens, M, Mari-Dell'Olmo, M, Rodríguez-Sanz, M, Martos, D, Espelt, A, Pérez, G, Pérez, K, Brugal, MT, Barbería Marcalain, E & Borrell, C 2011, 'Validación de la causa básica de defunción en las muertes que requieren intervención medicolegal', <i>Revista Española de Salud Pública</i> , vol. 85, pp. 163–174.
Spain (15)	Spanish	1996	Accuracy of mortality statistics for deaths due to external and natural causes with legal intervention in Cataluña, 1996. Exactitud de las estadísticas de mortalidad por causas externas y naturales con intervención médico-legal en Cataluña, 1996	<i>Gaceta Sanitaria</i>	De Arán Barés, M, Pérez, G, Rosell, J & Molina, P 2000, 'Exactitud de las estadísticas de mortalidad por causas externas y naturales con intervención médico-legal en Cataluña, 1996', <i>Gaceta Sanitaria</i> , vol. 14, iss. 5, pp. 356–362.

Country (ref)	Language	Year of review	Article title	Journal	Reference
Venezuela (16)	Spanish	1997	Validation of "myocardial infarction" as cause of death on death certificates in Barquisimeto, Lara State, Venezuela. Validación de infarto de miocardio como causa de muerte en certificados de defunción, Barquisimeto, Estado Lara, Venezuela	<i>Cadernos de Saúde Pública</i>	Granero, R, Ortiz, R, Gómez-Marín, O, Isaacura, C, Goyo, A & Rodríguez, J 1997, 'Validación de infarto de miocardio como causa de muerte en certificados de defunción, Barquisimeto, Estado Lara, Venezuela,' <i>Cadernos de Saúde Pública</i> , vol. 13, iss. 3, pp. 383-387.
Uruguay (17)	Spanish	2009	Quality of registry of death certificates in a reference public hospital in Montevideo, Uruguay, October–November 2009. Calidad del registro en el certificado de defunción en un hospital público de referencia. Montevideo, Uruguay, octubre–noviembre 2009	<i>Revista Médica del Uruguay</i>	Rodríguez Almada, H, Ciriacos, C, Piñeyría, M, Logaldo, R & González González, D, 2009, 'Calidad del registro en el certificado de defunción en un hospital público de referencia'. Montevideo, Uruguay, octubre–noviembre 2009', <i>Revista Médica del Uruguay</i> , vol. 26, pp. 216–223.
Costa Rica (18)	Spanish	1999	Causes of death in a diabetic population of Costa Rica and the quality of their death certificates. Causas de muerte en una cohorte de diabéticos tipo 2 de Costa Rica y la calidad de su certificado de defunción	<i>Acta Médica Costarricense</i>	Lacé-Murray, A 2012, 'Causas de muerte en una cohorte de diabéticos tipo 2 de Costa Rica y la calidad de su certificado de defunción', <i>Acta Médica Costarricense</i> , vol. 54, iss. 1, pp. 23–30.
Cuba (19)	Spanish	2005–2009	From the death certificate to the protocol of necropsy: basic causes of death. Del certificado de defunción al protocolo de necropsias: causas básicas de muerte	<i>Archivos Médicos de Camagüey</i>	Durruthy Wilson, O, Sifontes Estrada, M, Martínez Varona, C & Olazábal Hernández, A 2011, 'Del certificado de defunción al protocolo de necropsias: causas básicas de muerte', <i>Archivos Médicos de Camagüey</i> , vol. 15, iss. 3, pp. 542–552.
Costa Rica (20)	Spanish	2000	Clinical study of the discrepancy between death diagnosis and the findings of autopsy in the Hospital Calderón Guardia. Estudio de la discrepancia entre diagnóstico de defunción clínicos y los hallazgos de autopsia en el Hospital Calderón Guardia	<i>Acta Médica Costarricense</i>	Casco Jarquin, A & Mita Albán, LC 2003, 'Estudio de la discrepancia entre diagnóstico de defunción clínicos y los hallazgos de autopsia en el Hospital Calderón Guardia', <i>Acta Médica Costarricense</i> , vol. 45, iss. 1, pp. 15–19.

Country (ref)	Language	Year of review	Article title	Journal	Reference
México (21)	Spanish	1999	Concordance between death certificate and anatomopathological diagnosis by necropsy in the Hospital Central Militar. Concordancia entre el diagnóstico de defunción y el diagnóstico anatomopatológico por necropsias en el Hospital Central Militar	<i>Revista de Sanidad Militar</i>	González Medina, A & Martínez Natera, O 2001, 'Concordancia entre el diagnóstico de defunción y el diagnóstico anatomopatológico por necropsias en el Hospital Central Militar', <i>Revista de Sanidad Militar</i> , vol. 55, iss. 3, pp. 95–101.
Cuba (22)	Spanish	2004–2005	Death certifications vs. pathological studies in acute myocardial infarction. Certificados de defunción vs. estudios necrópsicos en el infarto miocárdico agudo	<i>Revista Ciencias Médicas</i>	Piñón Pérez, J, Hernández Amaro, Y, Lores Echevarria, C, Lemus Sarracino, A & Alvarez Miranda, C 2006, 'Certificados de defunción versus estudios necrópsicos en el infarto miocárdico agudo', <i>Revista Ciencias Médicas</i> , vol. 10, iss. 3, pp. 61–70.
Brazil (23)	Portuguese	1986–7	Reliability of reported underlying causes of neonatal death: implications for the study of preventable mortality. Confiabilidade da declaração da causa básica de óbitos neonatais: implicações para o estudo da mortalidade prevenível	<i>Revista Saúde Pública</i>	Carvalho, ML & Silver, LD 1995, 'Confiabilidade da declaração da causa básica de óbitos neonatais: implicações para o estudo da mortalidade prevenível', <i>Revista Saúde Pública</i> , vol. 29, iss. 5, pp. 342–8.
Brazil (24)	Portuguese	1997	Validity of information on occupation and cause of death in Botucatu, Sao Paulo. Validade das informações ocupação e causa básica em declarações de óbito de Botucatu, São Paulo	<i>Cadernos de Saúde Pública</i>	Cordeiro, R, Penaloza, ERO, Cardoso, CF, Cortez, DB, Kakinami, E, José J, Gomez de Souza, JJ, Souza, MTM, Fernandez, RA, Guercia, RF & Adoni, T 1999, 'Validade das informações ocupação e causa básica em declarações de óbito de Botucatu, São Paulo', <i>Cadernos de Saúde Pública</i> , vol. 15, iss. 4, pp. 719–728.
Brazil (25)	Portuguese	2004	Accuracy of the Mortality Information System team in the specification of underlying cause of death in a State capital in southern Brazil. Acurácia da equipe do Sistema de Informações sobre Mortalidade na seleção da causa básica do óbito em capital no Sul do Brasil	<i>Cadernos de Saúde Pública</i>	Fajardo, S, Aerts, D & Bassanesi, S 2009, 'Acurácia da equipe do Sistema de Informações sobre Mortalidade na seleção da causa básica do óbito em capital no Sul do Brasil', <i>Cadernos de Saúde Pública</i> , vol. 25, iss. 10, pp. 2218–2228.

Country (ref)	Language	Year of review	Article title	Journal	Reference
Brazil (26)	Portuguese	1990	The quality of the filling in of death certificates of children below one year of age in the metropolitan region of Rio de Janeiro. Qualidade do preenchimento de atestados de óbitos de menores de um ano na região metropolitana do Rio de Janeiro	<i>Revista Saúde Pública</i>	Niobey, FML, Cascao, AM, Duchiate, MP & Sabroza, PC 1990, 'Qualidade do preenchimento de atestados de óbitos de menores de um ano na região metropolitana do Rio de Janeiro', <i>Revista Saude Publica</i> , vol. 24, iss. 4, pp. 311–18.
Brazil (27)	Portuguese	1997	Reliability and accuracy of reported causes of death from cancer. II Accuracy of stomach cancer reported in the municipality of Rio de Janeiro. Confiabilidade e validade dos atestados de óbito por neoplasias. II Validação do câncer de estômago como causa básica dos atestados de óbito no Município do Rio de Janeiro	<i>Cadernos de Saúde Pública, Rio de Janeiro</i>	Monteiro, G, Koifman, R & Koifman, S 1997, 'Confiabilidade e validade dos atestados de óbito por neoplasias. II Validação do câncer de estômago como causa básica dos atestados de óbito no Município do Rio de Janeiro', <i>Cadernos de Saúde Pública</i> , Rio de Janeiro, vol. 13 (Supl. 1), pp. 53–65.
Brazil (28)	Portuguese	1990	Analysis of the declaration of the basic cause of death by cancer in Salvador, Brazil. Análise de fidedignidade da declaração da causa básica de morte por câncer em Salvador, Brasil	<i>Revista Saúde Pública, São Paulo</i>	Schnitman, A 1990, 'Análise de fidedignidade da declaração da causa básica de morte por câncer em Salvador, Brasil', <i>Revista Saúde Pública</i> , São Paulo, vol. 24, pp. 490–96.
Brazil (29)	Portuguese	2004	Reliability and validity of uterine cancer death certificates in the municipality of Belém, Para, Brazil. Confiabilidade e validade das declarações de óbitos por câncer de útero no município de Belém, Pará, Brasil	<i>Cadernos de Saúde Pública, Rio de Janeiro</i>	Nunes, J, Koifman, JR, Mattos, IE & Monteiro, GT 2004, 'Confiabilidade e validade das declarações de óbitos por câncer de útero no município de Belém, Pará, Brasil', <i>Cadernos de Saúde Pública</i> , Rio de Janeiro, vol. 20, iss. 5, pp. 1262–1268.

Appendix 2: Examples of misclassification matrices reported in medical record reviews: China, Iran, Thailand and Sri Lanka

Table A2.1 Misclassification pattern observed in China

Registration diagnoses	Medical record diagnoses													Total registration deaths	
	Cerebrovascular diseases	IHD	Rheumatic heart disease	Hypertensive diseases	COPD	Pneumonia	Other respiratory diseases	Diabetes mellitus	Genitourinary diseases	Viral hepatitis	Gastric and duodenal ulcer	Diseases of the liver	Other digestive diseases		All other diseases
Cerebrovascular diseases	422	12	4	6	4			10	4		1		3	11	477
IHD	13	195		4	6		2	2	1				2	6	231
Rheumatic heart disease	2	3	24												29
Hypertensive diseases	5	3	1	11			1	3	1					1	26
Other heart diseases ^a	4	8	2	3	9		2						1	7	36
COPD	7	9	1	3	178	3	5	2	4				4	12	228
Pneumonia	10	15		3	15	11	7	6					2	7	76
Other respiratory diseases ^b	8	6		1	5	6	18	4			1	1	2	8	60
Nervous system diseases	8	3		1	2		4	1						34	53
Diabetes Mellitus	17	13		3	5		1	65	1				6	9	120
Genitourinary diseases	6	5		23	5		2	10	45		1	2	2	17	118
Viral hepatitis										72		8		9	89
Gastric and duodenal ulcer	1										11	2	1	1	16
Diseases of the liver										38	1	56		3	98
Other digestive diseases ^c	1	1		1			2	1	1		2	5	42	7	63
All other diseases	13	8	1	2	13		3	0	3	4	4	2	7	1137	1197
Total Medical Records deaths	517	281	33	61	242	20	47	104	60	114	21	76	72	1269	2917

Source: Rao et al. (2007)

a: I26–I51

b: J00–06, J30–J39, J60–J98

c: K00–K22, K28–K66, K80–K92

Table A2.2 Misclassification pattern observed in Thailand

Causes of death *	Medical records diagnoses																All other causes	Total
	20	31	34	46	52	66†	67	68	69	74	76	80	81	84	96			
Vital registration diagnoses	20	31	34	46	52	66†	67	68	69	74	76	80	81	84	96			
Septicaemia (12)	44	2	3	3	53	6	8	3	55	38	16	27	19	47	2	144	470	
Ill-defined conditions (94)	16	6	7	5	27	16	75	36	25	14	39	10	14	13	9	135	447	
Cerebrovascular diseases (69)			1		7	1	4	5	203					1	9	31	262	
Ischaemic heart diseases (67)	1		2		26	5	138	9	3	2	3		3	6		16	214	
Pneumonia (74)	40		3		9	1	4	2	25	44	21	7	1	10	3	37	207	
All other external causes (103)					1	1	2	1	25	1					93	61	185	
Genitourinary diseases (84)	1	1		1	37	24	2	3	3	1	1	5	2	58		17	156	
Lung cancer (34)		1	85	6					1		4					5	102	
Transport accidents (96)							1								91		92	
Liver diseases (80)	2	2			1		2		2			63	2	1		11	86	
HIV/AIDS (20)	79											1				3	83	
Other cancers (46)	1	14	3	24						2				1		34	79	
COPD (76)	1		2		2		3	3	2	3	54			2		5	77	
Other digestive diseases (81)	3	1	2			2	1		2		1	16	17	1	1	27	74	
Other respiratory diseases (77)	5		2	1	4	1	5		8	3	12	3		3	1	25	73	
Other heart diseases (68)	1		1		1	4	15	14	4	1	4	1	1	5	1	18	71	
Liver cancer (31)		58		2			1					3				4	68	
Other infectious diseases (25)	18			1	3			1	5	1	1	1	1	3		17	52	
Tuberculosis (5)	20				1						2					17	40	
Other nervous system disorders (61)	10				2			1	4			1				10	28	
Diabetes (52)				1	16		2		1	1				2	1	2	26	
All other causes	14			8	9	8	5	3	18	1	1	9	4	6	2	294	424	
Total	256	85	111	52	199	69	267	82	386	112	159	147	64	159	213	955	3316	

* Figures in column headings indicate ICD code for causes of death as per ICD Mortality Tabulation List 1 (see matched figures in parentheses in row headings)

† 66 = Hypertensive diseases

Source: Pattaraarchachai et al. (2010).

Note: The total of the row 'All other causes' should read 382, not 424, the total of the column 'All other causes' should read 913, not 955, and, consequently, the total number of deaths should read 3274, not 3316. This error was in the original study, as cited. In this paper, we have chosen to use the total number of 3316. Table A2.3 Misclassification pattern observed in Sri Lanka

Vital registration diagnosis	Certain infectious and parasitic diseases	Cancers of the GI tract	Liver cancer	Trachea, bronchus and lung cancer	All other neoplasms	Blood and immune disorders	Diabetes mellitus	Other diseases of the nervous system	Hypertensive diseases	Ischaemic heart diseases	Cerebrovascular diseases	Other heart diseases	Pneumonia	Chronic lower respiratory diseases	Other diseases of the respiratory system	Diseases of the liver	Diseases of the skin	Genitourinary diseases	Perinatal conditions	Congenital malformations	Symptoms and ill-defined conditions	External causes	All other codes	Total
Certain infectious /parasitic diseases	9		1	1	1	1	1					2		1		1					1	2	2	23
Cancers of the GI tract		4			1																		1	6
Liver cancer			4													2						1	1	7
Trachea, bronchus and lung cancer	1			2			1				1													5
All other neoplasms				1	22	1				2	2	2		4										32
Blood and immune disorders	1					2	1			2		1												7
Diabetes mellitus	3				3		34	1	4	22	9	1	3	2		3	1					1	7	94
Other diseases of the nervous system	2							3		2			1		1	2								11
Hypertensive diseases	4						2		12	9	10		1	3		1		1					1	44
Ischaemic heart diseases	2						9		2	54	5	3	1	5		4				1		1	2	89
Cerebrovascular diseases						1	1	1	2	1	17	1		1	1	1								28
Other heart diseases	1	1	1		2		3		2	17	4	21	1	4	1	3	1	1	1	2	1		3	70
Pneumonia					1	1	1	2		1	1	1	9	2							2		3	23
Chronic lower respiratory diseases	1			1			1			7	1	1	1	13						1			1	28
Other diseases of the respiratory system				1			1	1	1	1	1	1	1		3	2	2	2				1	1	15
Diseases of the liver	4		2				2	1	2	2	2	3		1		39	1	1					2	60
Diseases of the skin		1								1						1							1	4
Diseases of the genitourinary system											1													1
Perinatal conditions																			4					4
Congenital malformations	1																			3				4
Symptoms and ill-defined conditions																1								1
External causes of mortality	3			1	2		3		2	3		1		1		2		1				1	3	24
All other causes		1			1		2	2	1	3	2	1	1	1		2		1					4	22
Total	32	7	8	7	34	6	62	11	27	127	54	35	19	38	6	64	3	7	5	8	4	6	32	602

Source: Rampatige et al. (2013).

Table A2.4 Misclassification pattern observed in Iran (age 15–69)

Medical record diagnosis	ICD-10 code	Death registration diagnosis						Total
		Other cardiac diseases	Other and unspecified disorders of the circulatory system	Heart failure	Hypertensive disease	Other respiratory diseases	Senility and unknown ^b	
Other cardiac diseases	I27–I29, I44–I49, I51	1	0	3	1	6	2	13
Other and unspecified disorders of the circulatory system	I90–I99	0	0	0	1	0	0	1
Heart failure	I50	4	1	5	1	5	1	17
Hypertensive disease	I10–I13	4	5	5	1	3	3	21
Ischaemic heart disease	I20–I25	23	27	60	14	63	7	194
Cerebrovascular disease	I60–I69	2	46	12	5	9	1	75
Other specified cardiovascular diseases	^a	1	2	4	2	15	0	24
Influenza and pneumonia	J12–J18	0	0	1	3	0	0	4
Chronic lower respiratory diseases	J40–J44	1	4	4	8	3	1	21
Other respiratory diseases	J64–J84, J87–J99	1	0	0	10	0	0	11
Diabetes	E10–E14	2	13	4	7	8	0	34
Neoplasms	C00–D48	0	3	6	10	5	4	28
Digestive diseases	K00–K93	1	0	2	1	2	3	9
Genitourinary diseases	N17–N98	1	5	2	6	5	4	23
Infectious diseases	A00–B99	2	3	1	4	3	0	13
Injuries	V01–Y98	4	5	6	12	5	24	56
Other causes	–	4	4	10	8	9	3	38
Total	–	51	118	125	94	141	53	582

^a Codes for this category includes I26, I30–43, I70–79

^b Because of the relatively small number of deaths assigned to the two component causes, they have been aggregated for analytical purposes

Source: Khosravi et al. (2008).

Table A2.5 Misclassification pattern observed in Iran (age 70)

Medical record diagnosis	ICD-10 code	Death registration diagnosis						Total
		Other cardiac diseases	Other and unspecified disorders of the circulatory system	Heart failure	Hypertensive disease	Other respiratory diseases	Senility and unknown ^b	
Other cardiac diseases	I27–I29, I44–I49, I51	1	5	3	4	8	3	24
Other and unspecified disorders of the circulatory system	I90–I99	1	1	1	0	1	0	4
Heart failure	I50	14	0	7	1	15	3	40
Hypertensive disease	I10–I13	5	16	1	4	8	3	37
Ischaemic heart disease	I20–I25	24	43	65	15	56	16	219
Cerebrovascular disease	I60–I69	3	60	15	11	23	9	121
Other specified cardiovascular diseases	^a	2	5	5	0	5	2	19
Influenza and pneumonia	J12–J18	0	2	0	4	2	4	12
Chronic lower respiratory diseases	J40–J44	1	7	6	17	17	3	51
Other respiratory diseases	J64–J84, J87–J99	2	0	1	7	6	0	16
Diabetes	E10–E14	0	12	1	3	19	4	39
Neoplasms	C00–D48	0	1	0	5	6	0	12
Digestive diseases	K00–K93	4	2	9	5	10	7	37
Genitourinary diseases	N17–N98	2	4	4	6	8	1	25
Infectious diseases	A00–B99	2	5	2	1	3	5	18
Injuries	V01–Y98	4	4	3	7	13	4	35
Other causes		0	6	6	3	9	5	29
–								
Total		65	173	129	93	209	69	738

^a Codes for this category includes I26, I30–43, I70–79

^b Because of the relatively small number of deaths assigned to the two component causes, they have been aggregated for analytical purposes

Source: Khosravi et al. (2008).

Appendix 3: Standard diagnostic criteria for medical record review

The table gives indicative standards for medical record review of hospital diagnoses in low-income and middle-income countries. They are a revision of clinical standards developed for the Population Health Metrics Consortium (PHMRC) gold standard verbal autopsy validation study (Murray et al. 2011), which have now been applied to a hierarchical cause list of 291 diseases and injuries used for the Global Burden of Disease 2010 study (Murray et al. 2011; Murray et al. 2012).

The standards are designed to objectively classify the strength of clinical and pathological evidence available in medical records to permit completion of the sequence of events on the death certificate and allow the selection of the UCOD. The standards have four levels of certainty, shown below in decreasing order:

- **Level 1** describes the diagnosis of a particular condition at the highest level of certainty possible for a particular condition (pathological or radiological evidence). For example, typical ECG and cardiac enzyme elevation are Level 1 diagnosis for AMI, and CT evidence of cerebral haemorrhage is Level 1 diagnosis for haemorrhagic stroke.
- **Level 2** describes diagnosis at a high level of certainty. Although diagnostic investigation support is not available, the high level of certainty is defined in terms of characteristic history and examination findings by a physician. For example, diagnosis of stroke can be made on history and examination findings by a physician. However, distinguishing between haemorrhagic and ischaemic haemorrhage is not possible at this level.
- **Level 3** describes diagnosis that gives a reasonable justification but not at a high level of certainty. For example, diagnosis of death from AMI is possible on characteristics of pain described in the history (constricting retrosternal pain radiating to left arm or neck associated with sweating in an elderly person).
- **Level 4** (not shown here) describes diagnosis based on inadequate evidence. For example, diagnosis of stroke on history of weakness of a limb or diagnosis of AMI based on history of chest pain alone (not characteristic pain).

The PHMRC study only included cases that satisfied the first two levels, and defined these cases as 'gold standards' to validate verbal autopsies.

The standards aim to place appropriate emphasis on clinical history, measurement and examination and also to indicate what investigations are required for hospitals to have the capacity to make accurate diagnoses. Some examples of the criteria for various levels for selected diseases are given in Table A3.1 below.

Table A3.1 Indicative clinical standards for review of hospital diagnosis

	Level 1	Level 2	Level 3	Comments
A1.1 Pulmonary tuberculosis	1. Clinical history consistent with active pulmonary tuberculosis during terminal illness AND 2) Sputum smear or culture positive	Clinical history consistent with active pulmonary tuberculosis during terminal illness AND rapid assay	Clinical history consistent with active pulmonary tuberculosis during terminal illness AND typical radiographic findings	Ratio of bacteriologically confirmed to unconfirmed cases is an indicator of quality
A.2.3. Acute lower respiratory infections (ALRI/pneumonia): Adults	Identification or isolation of pathogens	Three of: 1. Productive cough 2. Rapid respiratory rate: >24 breaths/min. 3. Pleuritic chest pain 4. Abnormal findings on auscultation 5. Lung infiltrate on chest x-ray	Clinical description not meeting Level 2	Standards refer to community-acquired pneumonia. Level 1 requires aetiological diagnosis based on laboratory investigations. Clinical and radiological findings are unreliable indicators of aetiology
A.2.3. Acute lower respiratory infections (ALRI/pneumonia): Children	Identification or isolation of pathogens	Three of: 1. Cough 2. Rapid respiratory rate: <2 months: >60 breaths/min. 2-12 months: >50 breaths/min. 1-5 years: >40 breaths/min. ≥5 years: >20 breaths/min. 3. Chest indrawing 4. Abnormal findings on auscultation 5. Lung infiltrate on chest x-ray	Clinical description not meeting Level 2	
B.1.5. Trachea, bronchus and lung cancers	Histology	Presence or absence of history of smoking or radiation therapy, cough, wheeze, haemoptysis, chest pain, hoarseness; signs of pleural effusion AND mass on x-ray	History and radiological diagnosis suggestive of lung cancer but does not meet Level 2 criteria	ICD codes would include C33-C34
B.2.2.3 Ischaemic heart disease: acute coronary syndrome, ST elevated myocardial infarction	Rise and/or fall of cardiac biomarker AND imaging shows new loss of viable myocardium	Symptoms of ischaemia and either the development of pathologic Q waves or new significant ST-segment-T wave (ST-T) changes or new left bundle branch block (LBBB)	Substernal pain or discomfort radiating to jaw or arm; exclusion of other causes of chest pain	ICD codes would include I21-I22
B.3.1. Chronic obstructive pulmonary disease (COPD)	Spirometry showing air-flow limitation pre- and post-bronchodilator administration	Detailed history of smoking; exertional dyspnoea, chronic cough, and sputum production; exacerbations and remissions. Clinical evidence of hyperinflation, and wheezing and basal crackles on auscultation.	Suggestive history and examination not meeting Level 2 criteria	COPD is characterised by airflow limitation that is usually progressive. Exacerbations and co-morbidities contribute to the overall severity.

Appendix 4: Material available for training physicians in death certification and coders in ICD coding

World Health Organization ICD online training tool

The WHO has developed this interactive and self-training online tool to improve understanding and enhance the use of the ICD-10. The tool can be found at

<http://apps.who.int/classifications/apps/icd/icd10training/>.

Handbook for doctors on cause-of-death certification

Developed by the University of Queensland HIS Hub, this handbook is written for physicians and medical students in developing countries (Health Information Systems Knowledge Hub 2012b). It can be read and used as provided, or it can be used as the basis for training in interactive workshops. The handbook is part of a package of resources, which includes a workbook of case studies and references for self-learning and a trainer's manual for running workshops. These resources have been specifically developed for adaptation to individual country contexts. The handbook can be found at **<http://www.uq.edu.au/hishub/docs/Handbook/HISHUB-Handbook-for-doctors.pdf>**.

Physicians' handbook on medical certification of death

This handbook provides guidance for physicians and medical students in the United States on how to complete death certificates. Although it covers the basic knowledge required for certification, it is mainly based on the death certification system used in the United States. Although its applicability to developing countries may be limited, the examples it contains may be useful for understanding the main principles of death certification and developing confidence in its importance. The handbook can be found at **http://www.cdc.gov/nchs/data/misc/hb_cod.pdf**.

Source: Health Information Systems Knowledge Hub (2012a).

Training tool on ICD implementation in a country

Developed by the Health Information Systems Knowledge Hub of the University of Queensland, this mini-tool gives guidance to countries introducing ICD. The tool is available for download at **<http://www.uq.edu.au/hishub/tools-and-guidelines>**.

Appendix 5: International Standard Death Certificate

Good quality morbidity and mortality statistics depend on how well a physician diagnoses the diseases and conditions patients were treated for and that sometimes led to a person’s death. However, these data are also influenced by how well the treatment given is documented in medical records and that the discharge records and death declaration forms are correctly filled in and coded. As part of introducing ICD, it is also important to introduce the use of the WHO International Form of Medical Certificate of Cause of Death (Figure A5.1) which is specifically designed to facilitate the correct reporting of the causes and conditions that led to death.

INTERNATIONAL FORM OF MEDICAL CERTIFICATE OF CAUSE OF DEATH

Cause of death		Approximate interval between onset and death
I Disease or condition directly leading to death* <i>Antecedent causes</i> Morbid conditions, if any, giving rise to the above cause, stating the underlying condition last	(a) _____ due to (or as a consequence of)	_____
	(b) _____ due to (or as a consequence of)	_____
	(c) _____ due to (or as a consequence of)	_____
	(d) _____	_____
II Other significant conditions contributing to the death, but not related to the disease or condition causing it	_____	_____
	_____	_____

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

Figure A5.1 International Form of Medical Certificate of Cause of Death

Appendix 6: Further practical guidance for country application of medical record reviews

How often should these studies be conducted?

The decision about how often to conduct medical record reviews would depend on the need to improve and resources available to conduct the studies. It is generally recommended that studies should be conducted every 3–5 years until a satisfactory quality level is achieved. It is important that the findings of the studies are well communicated to the physicians and local medical associations and that the recommendations of the study be implemented, monitored and widely circulated among hospitals.

Selection of hospitals for the study

Medical record reviews can and should be carried out in all hospitals where deaths occur and are certified, particularly in the main hospitals that contribute most deaths. However, it is important to acknowledge that some level of diagnostic facilities is required to realise gold standard diagnoses in the study hospitals. Further information is given in the Appendix 3 (Standard diagnostic criteria for medical record review). Even within the same hospital, these diagnostic facilities can vary from disease to disease.

Selection of sample and sample size

The size and the selection of the sample of cases (medical records) for the study should be based on the study objectives, feasibility, local contexts and the resources available for the study. A nationally representative sample of hospitals, and CODs within hospitals, should be chosen if resources permit. When resources are limited, the study can be limited to a review of a small sample of medical records in selected hospitals or even in a single hospital, and serve as an audit of medical record practices at institutional levels. Small-scale studies at individual facility level—while not representative—are helpful in informing hospital authorities about the quality of the COD statistics being produced at their facility.

Study instrument

The level of detailed information that needs to be extracted from the medical records should be decided

upon according to the study objectives, medical records contents and the resources available for the study. An example of a study instrument has been included in Appendix 7. This should be adapted to suit local conditions and needs.

Death certificate to be used

Use of the standard international COD certificate is essential for correctly identifying the

UCOD. All cases for which a medical record review is carried out should lead to a new 'study specific' COD certificate based on international best practice. A copy of the international standard death certificate and accompanying details are given in Appendix 5.

Training of study reviewers

Using a properly trained group of study physicians is critical for the success of the study. It is very

important that study physicians and coders are well trained to ensure that the gold standard diagnosis based on their medical record reviews is indeed 'gold standard'. Training of the study physicians has to be planned carefully to ensure that they can derive the best diagnosis possible using the evidence available in the medical record. This is especially important in those studies where the principal investigator is not medically trained. Study physicians should be provided with good reference materials, which are now freely available on the internet (see Appendix 4).

Data extraction from the medical records

It is recommended that standard data extraction forms are used by reviewers to record essential information from the medical records in a standardised format. It is also recommended to use physicians to extract the critical information and data from the medical records after training them in medical certification of COD. However, in situations where it is not possible to use physicians to extract data, due to unavailability or expense, carefully trained nurses or other research assistants with some basic clinical knowledge can be used to extract the information. The gold standard COD certificate, however, must be constructed by a physician using the information extracted from the medical records review. Constant monitoring and support of staff involved

in the clinical data extraction and completion of the COD certificate is very important.

Blinding the reviewers to original COD

The study physicians should not be influenced by knowledge of the original COD assigned, nor should they see the original death certificate. If the original COD is attached to the medical record of the deceased person, it should be detached before the review to avoid bias. The study physicians MUST independently derive their own COD certificate based on the training they receive specifically for the study.

Selection of underlying cause of death and coding

Coding of study gold standard death certificates should be done by experts trained in ICD coding rules and procedures, and should NOT be carried out by the study physicians, whose role is to prepare the death certificate as completely as possible. Details about ICD mortality coding rules can be found in Chapter 4 of the ICD-10 volume 2 at http://www.who.int/classifications/icd/ICD-10_2nd_ed_volume2.pdf (World Health Organization 2010). Information related to introducing ICD-10 to a hospital or country is available at the Health Information Systems Knowledge Hub website <http://www.uq.edu.au/hishub/publication-tools> (Introducing the International Statistical Classification of Diseases and Related Health Problems (ICD) in countries: guidelines for the implementation of COD certification, morbidity and mortality coding).

Statistical analysis

To ascertain the reliability of the UCOD for study cases, based on the medical record reviews, it is recommended to use the ICD-10 Mortality Tabulation List 1 consisting of 103 cause categories for analysis. This gives adequate precision for public health purposes and allows comparison of findings with similar studies. The results should be analysed using simple statistics and presented in easy to understand formats. The commonly used methods for presentation of findings from medical record review studies are misclassification matrices (see Appendix 2, agreement between original and 'gold standard' or comparator causes of death, sensitivity, specificity and positive predictive values). Details on the calculation of several of these indicators are provided below.

Table A6.1 Two-by-two table demonstrating metrics used in the analysis

True		Medical record diagnosis		
		False	Total	
Vital Registration diagnosis	True	a	b	a+b
	False	c	d	c+d
		a+c	b+d	a+b+c+d

Sensitivity

$$= \frac{\text{No. of COD confirmed by medical record (MR) review (a)}}{\text{No. of COD confirmed by MR review (a) + reassigned by MR review from other causes (c)}} \times 100$$

Positive predictive value

$$= \frac{\text{No. of COD confirmed by medical record (MR) review (a)}}{\text{No. of COD confirmed by MR review (a) + reassigned by MR review to other causes}} \times 100$$

Cause specific mortality fraction

$$= \frac{\text{Number of deaths from one specific cause}}{\text{Total number of deaths}}$$

Change in cause-specific mortality fraction (CSMF)

$$= \frac{\text{CSMFMR} - \text{CSMFVR}}{\text{CSMFVR}} \times 100$$

MR = medical record; VR = vital registration

Study ID [][][][][] Death Registration ID [][][][][] - [][][][][][][][][][] - [][][][][][][][][][] - [][][][][][][][][][]

Medical Record/Hospital No. [][][][][][] - [][][][][][][][][][]

MEDICAL DATA AND AUDIT FORM

SECTION 1: BASIC INFORMATION

1.1 Name of Deceased _____
Family Name First Name Middle Name

1.2 Department/Ward 1 Medical 2 Surgical 3 Pediatric 4 OB/Gyne
 5 NICU 6 Non-hospital 9 No info

1.3 Father's Name _____ 9 No Info
If < 12 years old Family Name First Name

1.4 Mother's Name _____ 9 No Info
If < 12 years old Family Name First Name

1.5 Name of Spouse (or partner) _____ 9 No Info
If relevant Family Name First Name

1.6 Name of Informant _____ 9 No Info
If not written on Q1.3-Q1.5 Family Name First Name

1.7 Relationship of Informant to the Deceased 9 No Info _____
Verbatim Code

1.8 Sex of Deceased 1 Male 2 Female 9 No Info

1.9 Date of Admission [][][] [][][] [][][] 8 Not Applicable 9 No info
mm dd yy

1.10 Date of Birth [][][] [][][] [][][] 9 No Info
mm dd yy

1.11 Date of Death [][][] [][][] [][][]
mm dd yy

1.12 Age at Death _____ years (if ≥ 1 yr) _____ months (if <12 months) _____ days (if <28 days)

1.13 Location where form filled in 1 Hospital _____
 2 Health Center _____
 3 Other _____

1.14 Place of Death 1 Home _____
 2 Hospital _____
 3 Health Facility _____
 4 On the road _____
 5 Others _____
 9 No Information _____
Hospital Code

1.15 Place of Death _____

1.16 Residence of the Deceased (as detailed as possible) _____
Hospital Code

1.17 Name of MO who signed death certificate _____
Family Name First Name

1.18 Date MDAF filled in [][][] [][][] [][][]
mm dd yy

1.19 Name of Study Nurse who collected information _____

1.20 Name of Study Physician who assigned final study status _____

1.21 If patient died within 24 hours of admission, how soon after admission did the patient die? _____ hours
 8 Not Applicable

Study ID

Death Registration ID

Medical Record/Hospital No.

SECTION 2: DEATH CERTIFICATES

2.1 Causes of death from death certificate	Interval between onset & death	ICD10 codes						
1a Immediate Cause					-			
1b Antecedent Cause					-			
1c Antecedent Cause					-			
1 d Underlying cause					-			
II Other significant conditions contributing					-			
					-			
					-			
					-			
					-			

2.2 Causes of death from medical audit or study physician	Interval between onset & death	ICD10 codes						
1a Immediate Cause					-			
1b Antecedent Cause					-			
1c Antecedent Cause					-			
1 d Underlying cause					-			
II Other significant conditions contributing					-			
					-			
					-			
					-			
					-			

SECTION 3: MEDICAL AUDIT OR STUDY PHYSICIAN REVIEW

3.1 Was it necessary to change the underlying cause of death (UCOD)? 1 Yes 2 No 3 Not relevant
 If YES, go to Q3.2; If NO, go to Q3.4.

Quality of clinical records
 3.2 Did changes in diagnosis on the DC lead to a change in UCOD? 1 Yes 2 No 3 Not relevant
 If YES, go to Q3.4; If NO, go to Q3.3.

Comments _____

Study ID Death Registration ID - - -

Medical Record/Hospital No. -

Accuracy of the death certificate

3.3 Did changes to the sequence of causes lead to a change in UCOD? 1 Yes 2 No 3 Not relevant
If YES, go to Q3.5; If NO, go to Q3.4.

Coding of the death certificate

3.4 If UCOD unchanged, was it necessary to change the coding of UCOD? 1 Yes 2 No 3 Not relevant

Quality of diagnosis

3.5 Ranking of medical audit or study physician death certificate:

1 GS1 2 GS2A 3 GS2B 4 GS3 5 GS4 6 Other

Final comments _____

SECTION 4: STUDY STATUS

	ICD10 Code	ICD/GC13 Diagnosis	GC13 Code
4.1 Primary diagnosis*			
4.2 Other diagnoses of interest	1		
	2		
	3		
	4		

* If this is a residual category, fill out the ICD10 category in full. Otherwise enter the GC13 category.

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The Knowledge Hubs for Health Initiative

The Health Information Systems Knowledge Hub is one of four hubs established by AusAID in 2008 as part of the Australian Government's commitment to meeting the Millennium Development Goals and improving health in the Asia and Pacific regions. All four hubs share the common goal of expanding the expertise and knowledge base to help inform and guide health policy.

The Knowledge Hubs are funded by AusAID's Strategic Partnership for Health Initiative.

Health Information Systems Knowledge Hub

The University of Queensland

Aims to facilitate the development and integration of health information systems into the broader health system strengthening agenda, and increase local capacity to ensure that cost-effective, timely, reliable and relevant information is available. The Health Information Systems Knowledge Hub also aims to better inform health information systems policies across Asia and the Pacific.
www.uq.edu.au/hishub

Human Resources for Health Knowledge Hub

The University of New South Wales

Aims to contribute to the quality and effectiveness of Australia's engagement in the health sector in the Asia–Pacific region by developing innovative policy options for strengthening human resources for health systems. The hub supports regional, national and international partners to develop effective evidence-informed national policy-making in the field of human resources for health.
www.hrhub.unsw.edu.au

Health Policy and Health Finance Knowledge Hub

*The Nossal Institute for Global Health
(University of Melbourne)*

Aims to support regional, national and international partners to develop effective evidence-informed national policy-making, particularly in the field of health finance and health systems. Key thematic areas for this hub include comparative analysis of health finance interventions and health system outcomes; the role of non-state providers of health care; and health policy development in the Pacific.
www.ni.unimelb.edu.au

Compass: Women's and Children's Health Knowledge Hub

Compass is a partnership between the Centre for International Child Health, The University of Melbourne, Menzies School of Health Research and Burnet Institute's Centre for International Health.

Aims to enhance the quality and effectiveness of women's and children's health interventions and focuses on supporting the Millennium Development Goals 4 and 5—improved maternal and child health, and universal access to reproductive health. Key thematic areas for this hub include regional strategies for child survival; strengthening health systems for maternal and newborn health; adolescent reproductive health; and nutrition.
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The Knowledge Hubs for Health are a strategic partnership initiative funded by the Australian Agency for International Development

