Enhancing Quality Management in Mortality Surveillance: A Comprehensive Audit and Evaluation

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Abstract

Mortality surveillance plays a pivotal role in identifying disease trends and evaluating risk factors, enabling early detection and targeted preventive interventions. The data derived from observed causes of death, collected through death certificates, could empower policymakers to effectively allocate resources, prioritise health programmes and assess the impact of interventions. Furthermore, this mortality information contributes to improving official vital statistics. In Portugal, the Death Certificates Information System (SICO), managed by the Directorate-General of Health (DGS), fosters coordination among entities involved in death certification and reporting. SICO promotes data accuracy, accessibility, and citizen privacy, aligning with the World Health Organization's (WHO) strategies for the enhancement of vital statistics and health policy implementation.

An in-depth internal audit of 408 death certificates from SICO was conducted, focusing on compliance with essential criteria for a quality vital statistics system. Adopting a quality management systems approach, the audit aimed to assess the quality of the death certification process and integrated risk management practices to identify potential errors or inconsistencies. Criteria included adherence to established WHO and United Nation standards, encompassing the completeness of the National Health Service user number, Part I and Part II sections, accurate recording of the basic cause of death, logical sequencing of the causes of death, singular cause per line, specification of cancer type and location, detailing relevant microorganisms in infectious causes, specifying heart failure etiology, recording the duration between disease onset and demise, maintaining consistent time intervals between different sections, and avoidance of abbreviations.

Conformity proportions were computed to gauge observance of the aforementioned criteria. The audit results revealed both best practices and areas requiring improvement within the death certificate completion process. Identified challenges encompassed inadequate completion of Part II, causes of death not organized in a sequence, unspecified cancer types and microorganisms, lack of information detailing heart failure etiology, and incomplete disease onset information. Additionally, when autopsies were waived by the public prosecutor's office, an opportunity was found to improve access to supplementary information when causes of death were unknown.

This comprehensive audit highlights the importance of stringent quality management systems for death certificates, crucial for accurate cause-of-death statistics. These findings underscore the need for refining existing protocols, prioritising continuous quality improvement initiatives, and implementing robust risk management strategies to enhance accuracy, reliability, and completeness in death certificate documentation. Such an approach ensures better data integrity, facilitating more informed decision-making processes.

Keywords: quality management, health information management, audit, death certificates, information systems

1. Introduction

1.1 Quality in Health

Portugal's National Strategy for Health Quality 2015-2020 prioritises improving clinical and organisational quality, highlighting the reinforcement of mechanisms for continuous quality improvement implementation. Within this framework, audits – processes of a systematic, independent and documented nature, aimed at objectively gathering and assessing evidence, in order to determine to what extent the audit criteria are satisfied (NP EN ISO 9001:2015), – play a crucial role. Aligned with the PDCA cycle (Plan, Do, Check, Act), audits contribute to iterative and continuous improvement in the processes of an organisation.

Internal auditing, as defined by the Institute of Internal Auditors, serves as an independent activity designed to enhance operations and add value to organisations by evaluating risk management, control and governance processes systematically (NP EN ISO 9001:2015). By scrutinising existing practices, audits ascertain effectiveness and compliance against predefined objectives and standards, identifying gaps or areas for improvement. Incorporating audit findings into the PDCA cycle's planning and action stages empowers organisations to enact evidence-based enhancements, fostering a consistent cycle of continuous improvement.

1.2 Mortality Surveillance

Public health surveillance involves continuous, systematic and structured collection, consolidation and evaluation of relevant data, swiftly disseminating the respective results to stakeholders responsible for implementing measures or actions (Chiolero, 2020). Mortality surveillance holds particular significance, as it allows the monitoring, analysis and comprehension of mortality patterns and causes of death observed within populations. Through the systematic analysis of mortality data, trends and risk factors associated with certain diseases and injuries can be identified, contributing to their early detection and the implementation of targeted preventive interventions. Mortality surveillance serves as an essential source of data for policymakers, aiding in effective resource allocation, health program prioritisation and impact assessments of health interventions (World Health Organization, 2010).

Several targets and respective indicators of the United Nations' third Sustainable Development Goal refer to mortality reduction, underscoring its global importance. The World Health Organization (WHO)'s Strategic Implementation Plan for Vital Statistics and Civil Registration 2021-2025 can contribute to obtaining and improving these indicators, following the four established strategic objectives: strengthening cause of death reporting; training for mortality and causes of death data analysis and application in health policies; production and dissemination of vital statistics including causes of death; as well as strengthening coordination between the health sector and its partners.

In Portugal, according to the Law no. 15/2012, of April 3, the Death Certificate Information System (SICO) was established to streamline the death certification process, promoting rational use of resources and improving information quality, accuracy, and speed of access, while ensuring citizens' privacy. Legally, treatment of this information system falls under the Directorate-General of Health (DGS), which coordinates public health surveillance, as well as ensuring the production and dissemination of related health statistics. In this context, situations that could potentially endanger public health are identified and the causes of death are coded according to the International Statistical Classification of Diseases and Related Health Problems. These activities are primarily conducted within the DGS's Mortality Surveillance and Coding Functional Area, an integral part of the Division of Epidemiology and Statistics of the Directorate of Information and Analysis.

Evaluating a mortality surveillance system involves assessing quality indicators of the data collected and the information produced by the system, against reference standards, encompassing precision, completeness, consistency, timeliness, relevance, accessibility and comprehensibility (ISO 8000-1:2022). To this end, SICO and the mortality surveillance system have been subject to several internal audits, focused on the following areas: a) quality of the management system and compliance with national legal requirements, b) quality of coding underlying cause of death due to COVID-19, and c) quality of information provided to the National Program for Cerebro-Cardiovascular Diseases. These audits highlighted opportunities for system improvement, including the need for clear objectives, process documentation, minimum system requirements, and criteria for death certificate validation.

In order to deepen our knowledge of the mortality surveillance system's quality, an internal audit was conducted, specifically targeting the quality dimension of information within SICO. This audit aimed to enhance the overall quality of the mortality surveillance system by assessing the degree of compliance with international standards regarding quality of the information obtained, proposing preventive and corrective measures for any identified discrepancies, and identifying opportunities to improve the mortality surveillance system and its performance. Focused on the processes of mortality monitoring and surveillance, as well as death certification and SICO, this audit examined the quality of information registered on death certificates.

2. Methods

Audit activities were organised into seven phases (audit preparation, opening meeting, collection of audit evidence, analysis of evidence and preparation of the preliminary audit report, closing meeting, writing of the final report and preparation of the quality manual), and adhered to a predetermined schedule spanning from July 1st to November 30th, 2023.

During the audit preparation phase, in order to better understand the auditee's operations and prepare the activities, a thorough review of relevant documented information was carried out, including previous audit reports. At the same time, a literature review on international standards for the quality of information on death certificates informed the selection of audit criteria and the formulation of the respective working documents.

The audit criteria were prepared in accordance with the requirements described in the identified reference documentation (Table 1).

Table 1: Reference documentation for the audit

• Law no. 15/2012, of April 3;
• DGS Guideline No. 020/2013 – Electronic death certificate – Use of the Death Certificate Information System (SICO);
• Directorate-General for Health (2021). Mortality coding manual (version 2.2021);
• Directorate-General for Health (2023). Coding Plan 2023;
• World Health Organization (2023). WHO Recommendations for conducting an external inspection of a body and filling in the Medical Certificate of Cause of Death;
• World Health Organization (2010). Improving the quality and use of birth, death and cause-of-death information: guidance for a standards-based review of country practices;
• World Health Organization (2010). Rapid assessment of national civil registration and vital statistics systems;
• World Health Organization (2013). Strengthening civil registration and vital statistics for births, deaths and causes of death: resource kit;
• United Nations (2014). Principles and Recommendations for a Vital Statistics System – Revision 3;
• United Nations (2021). Handbook on Civil Registration and Vital Statistics Systems. Management, Operation and Maintenance – Revision 1.

A total of 24 criteria were obtained, as shown in Table 2, organised in three audit areas.

After the opening meeting, where the audit plan was presented and agreed upon by all involved parties, evidence collection commenced between August and November, overseen by the coordinating auditor with support from technical experts. The sampling strategy aimed for a sample size of 408 death certificates, covering the twelve-month period preceding evidence collection (August 1, 2022 to July 31, 2023). The number of death certificates needed per region was calculated, in order to maintain the same distribution of deaths in the sample. Then, the death certificates were distributed across the different months, allocating more certificates to the months with the highest mortality. Finally, a random order of the hours of the day was created. Thus, for each day of the respective month, the first death certificate issued at the time obtained by randomization was selected. The process was repeated until all death certificates were selected, depending on the pre-established number, per month and per region.

Table 2: Audit criteria by audit area

Audit area	Audit criteria
1. Quality of medical certification	1. The SNS user number of the deceased person, if it exists, was filled in on the death certificate by the certifying doctor. 2. The chain of events leading directly to death was completed in Part I. 3. Other major illnesses, conditions, or injuries that contributed to the death but did not result in the underlying cause of death were completed in Part II. 4. The underlying cause of death was filled in on the death certificate. 5. The death certificate contained an etiological sequence that ends with the terminal condition. 6. Only one cause of death per line was filled in. 7. In cancer deaths, cancer type was mentioned on the death certificate. 8. In cancer deaths, cancer site was mentioned on the death certificate. 9. In deaths due to infectious etiology, the microorganism was mentioned in the certificate of death. 10. In deaths due to heart failure, the specific etiology was mentioned. 11. The duration between the onset of illness and death was filled in on the death certificate. 12. The time intervals indicated in Part I of the death certificate increased or remained stable from top to bottom. 13. No abbreviations were used on the death certificate.
2. Compatibility and consistency of data integration processes	1. SICO received information from the national registry about the death certificate number, its date and the registry office where it was drawn up. 2. In situations of violent death or an unknown cause, when the death occurred in public or private health institutions, the Clinical and/or Circumstantial Information Bulletin (BIC) was filled out. 3. In situations of violent death or an unknown cause, when the death occurred in public or private health institutions, the death certificate was not issued until the Public Prosecutor's Office decided on whether to carry out a medico-legal autopsy or its dismissal. 4. Information on the cause of death resulting from clinical and medico-legal autopsies was registered in SICO associated with the respective death certificate.
3. Mortality surveillance	1. Death certificates for mortality ages 0 to 30 were coded in real time. 2. Maternal mortality death certificates were coded in real time. 3. Fetal mortality death certificates were coded in real time. 4. Maternal mortality death certificates were object of multiple codification. 5. Death certificates for fetal and neonatal mortality were object of multiple codification. 6. Death certificates for mortality up to 5 years of age were object of multiple codification. 7. Death certificates registering a notifiable disease were object of multiple codification.

Evidence analysis and preparation of the preliminary audit report constituted the next phase, involving multiple meetings of the auditing team, in order to evaluate findings, determine compliance (discussing and resolving any divergent opinions), and propose corrective actions. Non-conformities were identified, potential causes examined, and corrective measures discussed. The compliance proportions were calculated, both globally and by audit area and also for each of the audit criteria whose evidence was obtained through death certificate sampling. The process culminated in the completion of the checklist and the drafting of a preliminary report.

The closing meeting provided an opportunity to present audit findings, conclusions, and improvement recommendations. Subsequently, the final audit report was delivered and a quality manual was created, marking the conclusion of the audit process. Throughout, utmost consideration was given to maintaining confidentiality and security while ensuring the integrity of the audited activities.

3. Results

Having assessed the audit evidence and analised the audit findings, overall compliance was found in 19 out of 24 audit criteria, while 5 criteria exhibited non-compliance. This assessment revealed a compliance rate of 79.17% and a non-compliance rate of 20.83%. To provide further insight, compliance proportions were calculated for each audit area, as outlined in Table 3.

Table 1: Summary of audit findings

Audit Area	Proportion of compliance
1. Quality of medical certification	69.23%
2. Compatibility and consistency of data integration processes	75%
3. Mortality surveillance	100%

In accordance with NP EN ISO 19011:2019, non-conformities pertaining to the same topic were grouped, in order to facilitate the monitoring of preventive and corrective actions and the recommended improvement opportunities.

Table 3 highlights that full compliance was achieved only in the "3. Mortality surveillance" area. Area "2. Compatibility and consistency of data integration processes" demonstrated a 75% compliance rate, indicating a concerted effort towards information sharing among stakeholders.

It was recommended to implement the corrective measures and recommendations summarised in Table 4.

Table 4: Summary of recommendations by audit area

Audit Area	Recommendations
1. Quality of medical certification	Provide targeted training for certifying doctors.
	Implement auxiliary alerts in the certification system.
	Establish procedures for handling unknown causes of death.
2. Compatibility and consistency of data integration processes	Implement electronic alerts for missing autopsy reports.
	Implement electronic alerts for mandatory notifications.
3. Mortality surveillance	Include regional analysis in mortality monitoring.
	Use intuitive quality indicator analysis tools, such as ANACoD3.

These proposed enhancements aim to enhance clarification of processes, procedures and activities within the mortality team.

4. Conclusions

Upon reflecting on the audit's broader implications, it became evident that its primary utility lies in the development of the checklist, which amalgamates various reference documents. Although the absence of a singular reference standard initially posed challenges, the availability of this checklist will enable regular audits and facilitate the monitoring of improvement implementation from now on.

Regarding the proposed corrective measures, the adoption of the ANACoD3 tool is considered a priority, given its ease of implementation and its capacity to address multiple audit criteria effectively. Challenges may arise in implementing corrective measures reliant on external entities' actions or those imposing a substantial workload on team members or necessitating increased human resources availability.

Furthermore, it may be pertinent to evaluate other aspects of the mortality surveillance process. For instance, conducting a new audit focusing on the content of death certificates, with the aim of identifying systematic errors, or selecting certifying doctors with the high volumes of death certificate issuance and evaluating their compliance with audit criteria. These actions would contribute to a comprehensive understanding of the mortality surveillance process and aid in further refining its efficacy.

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