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MINISTRY OF HEALTH - ETHIOPIA

CONFIDENTIAL ENQUIRY INTO MATERNAL, PERINATAL MORTALITY AND MORBIDITY

(CEMPMM)

National Guideline

Jun 2024

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LIST OF ACRONYM AND ABBREVIATIONS

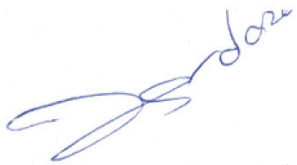
AKI	Acute Kidney Injury
APH	Antepartum Hemorrhage
ARM	Annual Review Meeting
CE	Confidential Enquiry
CEMD	Confidentiality Enquiry into Maternal Death
CENNM	Confidential Enquiry into Neonatal near miss
CEO	Chief Executive Officer
CEPD	Confidential Enquiry into Perinatal Death
NCPAP	Nasal Continuous Positive Airway Pressure
CPR	Cardiopulmonary Resuscitation
DHIS2	District Health Information Software 2.
IVC	Intra Vascular Coagulation
EAA	Ethiopian Anesthesia Association
EDHS	Ethiopian Demographic and Health Survey
EMwA	Ethiopian Midwifery Association
EPHI	Ethiopian Public Health Institution
ESOG	Ethiopian Society of Obstetrics and Gynecology
FMOH	Federal Ministry of Health
GTD	Gestational Trophoblastic Diseases
HELLPC	Hemolysis, Elevated Liver enzymes, and Low Platelet Count
ISCD	International Statistical Classification of Diseases
ISCD-MM	International Statistical Classification of Diseases in to Maternal Mortality
ID code	Identification Code

LMIC	Low and Middle Income Countries
MPDSR	Maternal and Perinatal Death Surveillance and Response
MMR	Maternal Mortality Rate
MoH	Ministry of Health
MNMCR	The Maternal Near-Miss Case Review
NYHA	New York Heart Association
EPAESO	Ethiopian Professional Association of Emergency Surgical officer
PHEM	Public Health Emergency Management
QoC	Quality of Care
SDG	Sustainable Development Goals
TWGs	Technical Working Groups
UNFPA	United Nations Population Fund
WHO	World Health Organization
UNICEF	United Nations Children's Fund

FOREWORD The need to accelerate the reduction of maternal and neonatal mortality in Ethiopia is one of the important priorities of the health sector during HSTP II. The Maternal and Perinatal Death Surveillance and Response (MPDSR) system provides information on causes of death, associated factors, and sociodemographic characteristics which guide maternal and perinatal health intervention strategies.

To realize this goal of accelerating the reduction of maternal and perinatal mortality in Ethiopia, the Ministry of Health has taken several measures to strengthen data-driven program monitoring and decision-making practices and capacity. To reach the target set for the reduction of maternal and neonatal mortality, the Maternal Child and Adolescent Health Services Lead Executive Office has developed the National Confidential Enquiry system into maternal and perinatal mortality and morbidity (CE-MPMM) technical guide in collaboration with the Ethiopian Public Health Institute.

The purpose of CE system is conducting an in-depth review of maternal and perinatal deaths as well as near-misses and the care provided by a team of independent reviewers to address the Ministry`s information demands for timely monitoring and improvement actions. Furthermore, the system is also intending to strengthen the usefulness, leadership support, and the engagement of senior clinicians in the national mortality and morbidity audits, including the Maternal and Perinatal Death Surveillance and Response (MPDSR) system. Withh this, the ministry would be committed to implementing the National Confidential enquiry system into maternal and perinatal mortality and morbidity (CE-MPMM).



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1: INTRODUCTION

1.1 Background

Globally, about 295,000 maternal deaths occurred in 2017, and 94% of all maternal deaths occurred in developing countries. Sub-Saharan Africa alone accounted for roughly two-thirds (196,000) of maternal deaths. Ethiopia still has the highest rate of maternal deaths with an estimated 10,000 maternal deaths in the year 2020. The overall maternal mortality ratio (MMR) in Ethiopia is 267 maternal deaths per 100,000 live births (1). According to the United Nations (UN) report, there were 2.5 million neonatal deaths (18 deaths per 1,000 live births), with 41% of deaths occurred in Sub-Saharan Africa in 2018 mostly due to preventable pregnancy related complications (2). Worldwide, there were also about 2.6 million stillbirths estimated to be 18.4 per 1000 births in 2016 (3). Ethiopia is also among the countries with the highest perinatal mortality rate in the world. Moreover, the 2016 Ethiopian Demographic and Health Survey (EDHS) estimated that the perinatal mortality was 33 deaths per 1000 total births (4). The majority of maternal and perinatal deaths can be prevented through the provision of well-established, effective, and good quality care during preconception, pregnancy, childbirth, and postnatal period (1, 5).

Most maternal deaths can be averted with known and effective interventions, but countries require information about which women are dying, why, and what has been done to prevent such deaths (Sexual and Reproductive Health Matters RHM, 2017 Annual Report). According to the Ethiopian MPDSR 2012 and 2013 annual reports, the major causes of maternal mortality in Ethiopia, like in most parts of the low and middle-income countries (LMIC) are hemorrhage, complications from hypertensive diseases in pregnancy, sepsis, obstructed labor, abortion complications, and other direct obstetrics and indirect causes.

To improve maternal health in the context of the Sustainable Development Goals (SDGs), further action is needed to reduce national MMR in order to bring the global MMR down to less than 70 per 100,000 live births and perinatal deaths (stillbirth and neonatal deaths) to less than 12 per 1000 live births by 2030 (6). Having targets for mortality reduction and better coverage of services is important, but it also requires improving systems for accurate measurement, analyses of factors or circumstances leading to maternal or perinatal death which help to identify health system gaps and take corrective actions linked to quality of care improvement to prevent such deaths in the future.

Major initiatives implemented in Ethiopia to reduce maternal and perinatal mortality and morbidity during the MDG era focus on increasing access to skilled attendants at birth and institutional delivery as well as strengthening health care systems. As a result, more women are now delivering in health facilities in Ethiopia. About 50% of deliveries were attended by a skilled provider and 47.5% of births took place in a health facility in 2019 (7). Despite the increase in coverage of facility delivery and skilled birth delivery, the reduction in maternal mortality remains inadequate, and does not provide information about the quality of care the women received during pregnancy, labour and delivery.

As per the UN estimate, more than 10,000 maternal deaths and 187,798 perinatal deaths per year (stillbirth 90,323 and neonatal death 97,475) occur in Ethiopia. Ending preventable maternal and perinatal deaths is continuing to be a significant part of the national public health agenda (1, 2). Therefore, death reviews along with consistent surveillance provide opportunities to take action at multiple levels to improve access and quality of health care to prevent future deaths and ultimately attain the SGD targets by 2030 (6).

In cognizant of this and following, the World Health Organization (WHO) published a Maternal Death Surveillance and Response (MDSR) Technical Guidance in 2013 as a key strategy which emphasizes the need for systematic and continuous surveillance of maternal deaths by linking the health information system as well as response actions linked with quality improvement processes from local to national levels, including the implementation and monitoring of recommendations (8). Ethiopia has been implementing MDSR system since 2013, and later on, the country revised the guideline and added perinatal death surveillance, review, and response (PDSR) in 2017, which was named as national technical guidance for MPDSR (9). Though the introduction and operationalization of MPDSR have made notable progress in documenting maternal and perinatal deaths and providing valuable information for actions, galvanizing this initiative which is driven by a desire to improve care and involve senior experts to further augment death review and generate more in-depth evidence to guide the necessary actions required. Confidential enquiry (CE) is one of the most widely used approaches for in depth reviews of maternal and perinatal mortality and morbidity or near-misses. A confidential enquiry (CE) is defined as a systematic, multi-disciplinary, and anonymous investigation of all or a representative sample of maternal deaths occurring at an area, regional (state), or national level. It identifies the numbers, causes, and avoidable or remediable factors associated with them. CE requires the existence of either a functioning statistical infrastructure (vital records, statistical analysis of births and deaths, human resources, recording clerks, etc.) or nominated professionals in each facility to regularly report maternal deaths to the enquiry.

1.2 Rationale for confidential enquiry

Every maternal death is a tragedy to the families left behind, to the staff involved, and to the wider communities. Failure to learn lessons from such deaths for future care, as well as failure to continuously improve maternity services, would be an even greater tragedy.

Since the national-level MPDSR has been implemented, progress has been made in identifying, and reviewing deaths in facilities and communities, and responding over time. However, there is still more to be done regarding the depth and quality of the review process, which is also more fragmented, and the response component as well appears poorly developed, implemented, and monitored.

The challenges faced in the implementation of the MPDSR system, combined with the health workers' capacity gaps in death review and uncertainty as to their validity, propose the need for rigorous evaluation of deaths and appropriate responses. Moreover, weak national coordination and leadership support for the review system, coupled with low engagement of relevant professional associations in the programs pose challenges

The confidential enquiry process goes beyond that of a death review or audit. The details of each death or incident are reviewed in-depth by a team of appointed experts to ascertain whether any deaths or adverse events were avoidable, establish whether clinical standards were met, and also ensure that the right clinical decisions were made in the circumstances. Recommendations for action are then made and implemented. It seeks to improve health and health care by collecting evidence on aspects of care, deficiencies, or weaknesses in the health care system and disseminating recommendations based on these findings.

We believe that establishing a confidential enquiry system in Ethiopia as part of a comprehensive set of activities that considers the existing MPDSR system may provide a coherent picture of avoidable factors, needs, and information gaps in the provision of quality maternity services. This may yield the best results in achieving a progressive reduction of maternal mortality in Ethiopia.

1.3 Purpose of the Guideline

The purpose of this guideline is to provide guidance on how to conduct CE into MPDs and near miss by confidential enquiry review committee at regional and national levesl: Specifically, it will give guidance to:

1. Clarify the definitions, principles, processes, and concepts used in CE.
2. Guides the methods and approach for topic selection, data collection, case review and report writing. Plan data collection and determine the time frame for reporting and completion.
3. Guide how to regularly assess maternal and perinatal mortalities and morbidity, collect and analyze the findings and prepare recommendations for action.
4. Disseminate the findings, and recommendations.
5. Provide a framework for CE monitoring and evaluation.
6. Clarify roles and responsibilities for maternal and perinatal health across the health system

1.4. Scope of the CE guideline

- The CE guideline covers an in-depth analysis of maternal deaths, perinatal deaths, maternal near-misses and neonatal morbidity.
- The report is forwarded to policy makers,' facilities, and stakeholder partners for a better response plan.
- The information generated from the CE review will only be utilized for the improvement of maternal and perinatal health outcomes.

1,5. Concept of confidential Enquiry

- The Maternal and Perinatal Death Surveillance and Response (MPDSR) program is a massive-scale quality improvement program in maternal and child care. On a regular basis, often annually, country level reports are produced, and this information is shared with service providers and policymakers (stakeholders).
- Confidential enquiry is one type of death and near-miss review that uses both quantitative and qualitative methods of assessment for selected deaths in respective facilities.
- It is a systematic, multi-disciplinary, anonymous investigation of all or a representative sample of maternal and perinatal deaths, including near-misses occurring at an area, regional (state), or national level. It identifies the numbers, causes, and avoidable or remediable factors associated with them.
- Its main aim is to enable an in-depth analysis of cases of maternal and perinatal deaths and mothers who have survived severe acute complications (near-misses).
    - *To assess the quality of healthcare,*
    - *To stimulate improvement in safety and effectiveness*
    - *To highlight the key areas of intervention for the health sector and community*
    - *To provide guidance to improve clinical outcomes.*
- One of the prerequisites for the implementation of confidential enquiry is the presence of existing functional statistical infrastructure (vital records, statistical analysis of births and deaths, human resources, recording clerks, etc.) or nominated professionals in each facility to regularly report deaths and near-misses to the enquiry. In Ethiopia, the possible data sources for CE were DHIS_2 and the PHEM system.

1.6. Comparison of the death review approach

- There are different review approaches used for reviewing a wide range of aspects of health care, including structures, outcomes, and processes.
- We discuss the application of these approaches for two distinct health outcomes (maternal and perinatal deaths and women who survive life-threatening complications) and for a specific procedure (clinical care).
- This section provides a summary definition of each methodology and presents considerations relevant to identifying the cases to be reviewed.
- It describes some of the key differences between the approaches and the essential prerequisites that need to be in place before a specific approach can be considered.
- There are five approaches to generating information on maternal outcomes or maternal health care. Those are

- *Community based-maternal death review (Verbal Autopsy)*
- *Facility based-maternal death review*
- *Confidential enquiry into maternal death*
- *Survey of savior morbidity (Near Misses)*
- *Clinical Audit*

1.7. Community-based maternal death review (verbal autopsy)

Operational definition:- A method of finding out the medical causes of death and ascertaining personal, family, or community factors that may have contributed to the deaths of women who died outside of a medical facility. The verbal autopsy identifies deaths that occur in the community and consists of interviewing people who are knowledgeable about the events leading to the death, such as family members, neighbors, and traditional birth attendants.

Prerequisites:- The review requires cooperation from the family of the woman who died, and sensitivity is needed in discussing the circumstances of the death.

Advantages

- In settings where most women die at home, verbal autopsy provides a means to determine the medical causes of death.
- It allows medical and nonmedical factors to be explored in an analysis of events leading up to a maternal death and thus provides a more comprehensive picture of the determinants of maternal mortality.
- The verbal autopsy provides a unique opportunity to include families and the community's opinion on the access to and quality of health services in efforts to improve maternal health services.

Disadvantages

- Medical causes obtained from verbal autopsies are not perfect, and different assessors may reach different conclusions regarding the medical causes of death.
- The assignment of avoidable factors largely remains a matter of subjective judgement and depends on many elements.
- Causes of death obtained from lay informers are not always in accordance with those obtained from death certificates.
- Underreporting is a particular concern for early pregnancy deaths and for deaths from indirect causes, while indirect causes of maternal deaths may also be overreported.

1.8. Facility-based maternal death review

Operational definition:- A qualitative, in-depth investigation of the causes of and circumstances surrounding maternal deaths occurring at health facilities. Deaths are initially identified at the facility level, but, where possible, such reviews are also concerned with identifying the combination of factors at the facility and in the community that contributed to the death and which ones were avoidable.

Prerequisites:- The review requires cooperation from those who provided care to the woman who died and their willingness to report accurately on the management of the case.

Advantages

- The idea of reviewing maternal deaths that occur in facilities is not new and may already be a routine practice. Thus, approval and support for the review process at a particular facility may be easy to obtain.
- The review process enables a more complete picture to be obtained of the circumstances surrounding a death in terms of avoidable factors at the facility, where possible, supplemented with information from the community.
- Since they tend to be carried out by facility staff already in posts, local facility-based maternal deaths reviews are usually less expensive to conduct than other investigative methods.
- The review process provides good learning experiences for all grades of staff.
- The review does not require written and agreed standards of care to be available from the outset but can stimulate further enquiries and lead to specific actions, which may include the setting of standards.

Disadvantages

- Facility-based maternal death reviews are not as systematic as a clinical audit and can generate a large volume of information that can be difficult to understand and synthesize.
- The review requires committed and skilled individuals at the facility to drive the process and to follow through on any recommendations.
- Maternal death reviews provide no information on deaths that occur in the community.
- Hospital managers and administrators must be supportive, allowing staff to follow up on the community aspects of these cases by providing either transport or funds for public transport.
- There may be difficulty in tracing the dead woman's family in the community, sometimes because the death resulted in them moving.

1.9. Confidential enquiries into maternal deaths

A systematic multidisciplinary and anonymous investigation of all or a representative sample of maternal deaths occurring at an area, regional (state), or national level that identifies the numbers, causes, and avoidable or remediable factors associated with them. Through the lessons learned from each woman's death, and through aggregating the data, they provide evidence of where the main problems in overcoming maternal mortality lie and an analysis of what can be done in practical terms. These highlight the key areas requiring recommendations for health sector and community action and provide guidelines for improving clinical outcomes.

Prerequisites:- The existence of either a functioning statistical infrastructure (vital records, statistical analysis of births and deaths, human resources, recording clerks, etc.) or nominated professionals in each facility to regularly report maternal deaths to the enquiry.

Advantages

- The confidential enquiry can make recommendations of a more general policy nature than would be the case for enquiries carried out only within specific facilities.
- It provides a more complete picture of maternal mortality than is generally available from vital records, invariably revealing more maternal deaths than those identified by the vital registration system alone.
- Because the enquiry is usually published and available to a wide public, it can be used for advocacy to press for improvements in the quality of care.
- The aim of an enquiry is to learn lessons for the future, and the results can be widely disseminated for public use by several groups.
- The commitment of the government is indicated by the involvement of the regional or national health departments. This should lead to close cooperation between policymakers and those delivering the services.
- The absolute number of maternal deaths is often not very large, even where the maternal mortality ratio is relatively high. This limited number of events enables an in-depth investigation.

Disadvantages

- The confidential enquiry provides information on maternal deaths (numerator data) only. It does not provide information about the characteristics of all women giving birth.
- Where maternal mortality is high and populations are large, there may be many maternal deaths, making the analysis of cases complex and time-consuming. This can be addressed by taking a representative sample of deaths for an in-depth review.
- The review can lack richness and value if the enquiry concentrates only on medical aspects and does not address the underlying demographic and socioeconomic factors that contribute to maternal mortality, such as poverty, malnutrition, or geographical location.
- A confidential enquiry requires commitment from all participants and may be resource intensive.

1.10. Surveys of severe morbidity

Overall definition for the review of cases of severe morbidity:- "any pregnant or recently delivered woman (within six weeks after termination of pregnancy or delivery), whose immediate survival is threatened, and who survives by chance or because of the hospital care she receives." A more specific operational definition will be required for case identification from medical records.

Prerequisites:- a good-quality medical record system; a management culture where life-threatening events can be discussed freely without fear of blame; a commitment from management and clinical staff to act upon findings.

Advantages

- Cases of severe morbidity occur in larger numbers than deaths, allowing quantification of avoidable factors.
- The study of women who have survived life-threatening complications may be less threatening to health providers than the study of deaths.
- It is possible to interview the woman herself in addition to a proxy, such as a member of the family.
- Reviewing cases of severe morbidity can provide useful complementary insights into the quality of care.
- The likelihood of preventable life-threatening events recurring and resulting in death could be greatly reduced if addressed adequately through audit recommendations.

Disadvantages

- Cases of severe morbidity can usually only be identified in health facilities. Identifying cases of severe maternal morbidity requires sophisticated tools and clear definitions.
- Defining life-threatening severe obstetric morbidity is not straightforward and requires a concerted effort by all the providers involved in the review process.
- Case ascertainment may require reviewing many registers and case notes in each hospital.
- In settings with a high volume of life-threatening events, selection criteria will be required for in-depth case reviews (for example, focusing on weekend events or a complication).
- Women will still be alive, and their consent should be sought before interviewing them. Asking for consent may raise their concerns about the quality of care they received.

Clinical audit

Clinical audit is "a quality improvement process that seeks to improve patient care and outcomes through the systematic review of care against explicit criteria and the implementation of change. Aspects of the processes and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level, and further monitoring is used to confirm improvements in health care delivery."

Prerequisites:- It must be possible to identify relevant cases from facility registers and retrieve the case notes. Health care personnel must feel able to openly discuss case management and be willing to envisage the application of revised protocols for care.

Advantages

- The participatory element of clinical audit provides an effective mechanism for bringing about improvements in care.
- It is an excellent educational tool and, when properly carried out, is nonpunitive.
- It provides direct feedback to facility staff on practice and performance, and the participatory process enables them to help identify realistic means for improvement.
- It can be initiated locally and results in the production of locally relevant and immediately actionable information.
- It can be less expensive than other forms of audit, as nonmedical personnel can do the necessary data extraction.
- It provides a structured framework for information and involves less subjective assessment of case management than in facility-based death reviews or confidential enquiries, for example.
- The audit process can help to highlight deficiencies in both recording inpatient records and record storage.

Disadvantages

- A clinical audit is limited to the clinical care in the facility in which it is carried out and cannot deal with community issues.
- A clinical audit can only address certain causes of death at any one time and will not provide a complete overview of all maternal deaths.
- The concepts of evidence-based practice and audit may be unfamiliar or appear threatening to some health professionals. Workshops may be needed to familiarize and reassure them of the concepts of evidence-based practice.
- An audit requires that an appropriate set of criteria be available or that local criteria be developed.
- Nonmedical audit assistants (usually records staff) must be available to find patient records and undertake the extraction of information.
- There must be a willingness to close the audit loop with at least one further round of reviewing practice.

2: CONFIDENTIAL ENQUIRY IN ETHIOPIA

2.1 General framework of National Confidential Enquiry System

This confidential enquiry into maternal and perinatal mortality and morbidity is designed based on the lessons learned from international experiences. Its main aim is to enable an in-depth analysis of cases of maternal and perinatal deaths: mothers and newborns who are survivors of severe acute complications (near miss). In addition, it enables us to assess the quality of healthcare and brings about improvements in safety and effectiveness by systematically enabling clinicians, managers, and policymakers to learn from adverse events and other relevant data. As depicted in figure 1, the process of the system consists of nine steps.

Confidentiality Review Process

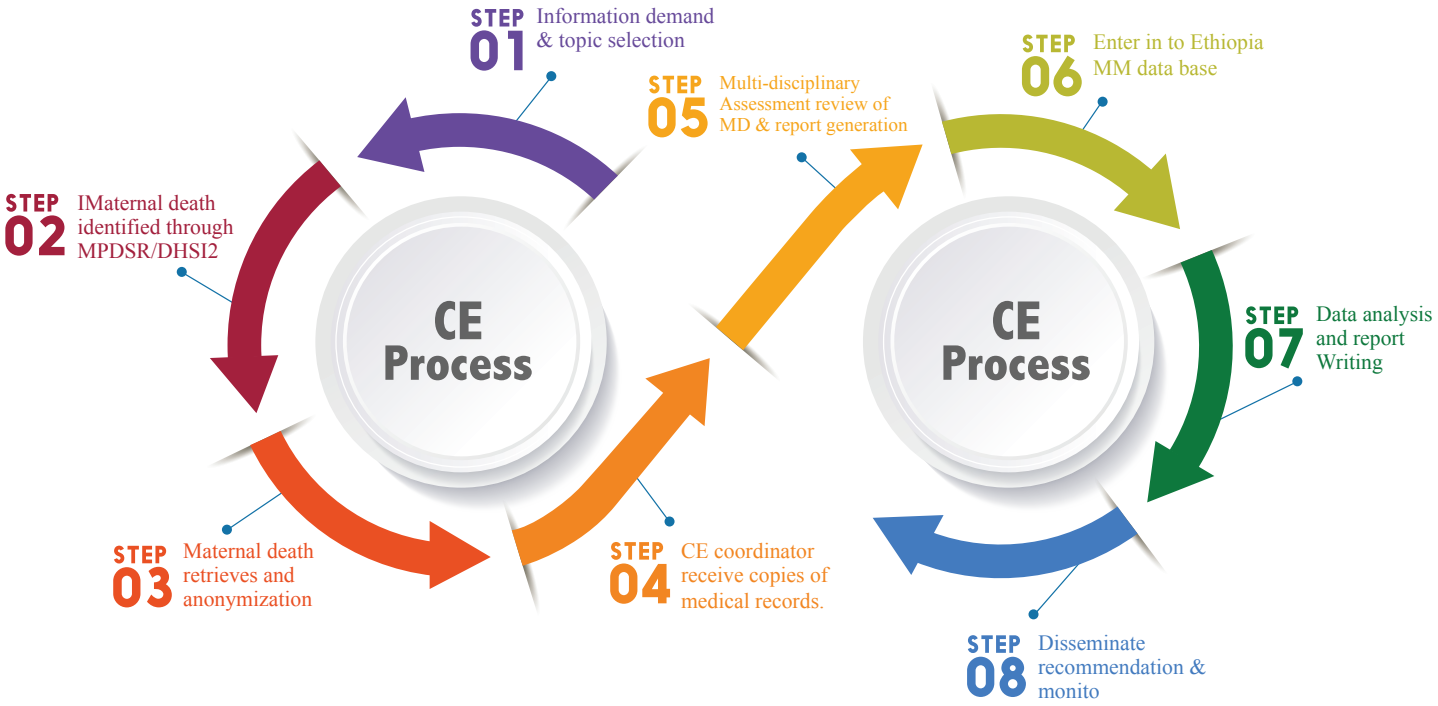
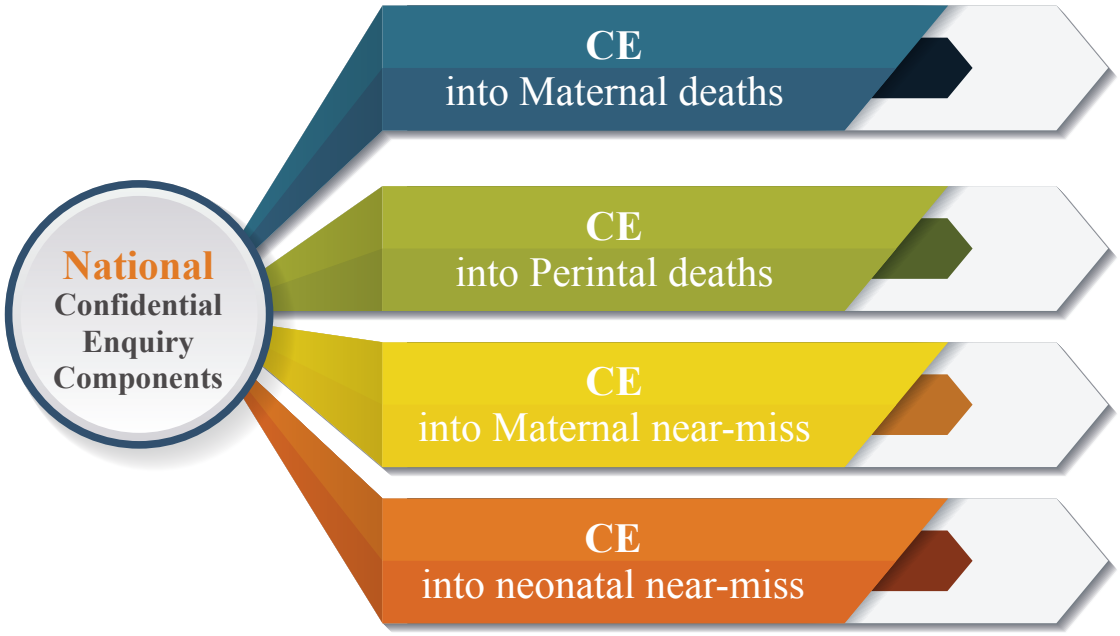


Fig1 . Ethiopian CEMM process

This guideline provides step-by-step guidance on planning and conducting confidential enquiry. The description of the tasks for each step in the audit cycles is categorized and presented by section based on four components of the national confidential enquiry system (Figure 2).

Figure 2: National Confidential Enquiry Framework



2.2. Confidential Enquiry into Maternal death

Introduction

It is important to understand the definition of maternal death before identifying and reporting maternal deaths. A maternal death, as defined by the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD), is "the death of a woman while pregnant or within 42 days of the end of the pregnancy, irrespective of the duration and the site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes (8). Steps of confidential enquiry into maternal deaths

Topic and case selection process

The national confidential enquiry system has adapted the topic and case-based approach that allow us to address information gaps in an efficient way. Therefore, the process of determining the topic and cases to be enrolled and included in the review needs to be standardized through the following procedures at the national and regional level.

2.2.1 Topic selection

The topic selection process is coordinated by the Ministry of Health (RMNCAH-N Lead Executive Office) in collaboration with EPHI/PHEM and their respective corresponding TWGs.

The national CE coordinator at the Ministry of Health is responsible for conducting the following activities:

- Facilitate topic selection using the topic selection format.
- Communicate with members of the national SMH TWG, national and regional reviewers, and professional societies and associations (ESOG, EMwA, PAESOE, EPS, EAA, etc.).
- Organizes meetings to discuss issues related to selected topics.

Box 1: Criteria for topic selection

The presence of one or more of the following conditions warrants selecting topics for an annual in-depth review, considering the feasibility of

- The magnitude of the causes of maternal death
- A new pattern of causes of deaths and risk groups (age, geographic area) were identified in the MPDSR data analysis findings.
    - Conditions that need further data for designing an effective targeted response, such as community and government concerns.

2.2.2 Case selection

The number of cases to be reviewed under the selected topic depends on the number of cases reported through MPDSR that entered the national database and the available resources.

Box 2: As a general rule, the sample size of cases to be reviewed is determined by the assumption of one reviewer per five cases, with a minimum of twenty reviewers.

- ✓ If the total cases are less than 100, review them all.
- ✓ If the cases are greater than 100, take at least 100 cases randomly for review.

• Steps of case selection

- ➢ Prepare a list of the cases under the topic from the national MPDSR database.
- ➢ Categorize cases by region or facility type.
- ➢ Proportional allocation of cases to regions and facility types
- ➢ Allocate the number of cases to be selected for each category (the proportion of the total cases reported by the type of facility multiplied by the total number of cases determined to be reviewed).
- ➢ Select cases randomly from each category using simple random sampling.
- ➢ Prepare a list of the selected cases with their addresses.

Note: Unselected government, NGOs, and private health facilities will be considered in special situations; for example, in cases that were referred from health centers or other hospitals, which require further information to understand what happened at the referring health facilities and during referral.

Table 1: Topic and case selection for confidential enquiry into maternal death

Activities	Source of data	Responsible person	Time	Methods and tools
Topic selection	National MPDSR data base/annual report, DHIS2	National coordinator / SMH TWG	February	TWG Meeting-Tools- selection format
Cases selection	National MPDSR data base/annual report/ DHIS2/ facility registry	National/regional	March	Multi stage Sampling

Table 2: Allocation of cases (MD) selected for regions by level of health facility

Region	Type of facility					Proportion
	Primary hospital	General hospital	Referral/teaching hospital	Health center	Private facility	
1						
2						
3						
4						
5						

2.2.3 Data collection process

The data collection process encompasses chart retrieval, anonymizing, and checking the quality of the data. The national coordinator coordinates the process of case note retrieval through regional and zonal focal persons and coordinators. The national coordinator communicates the selected topics and proportional sample size to the respective regional coordinator. The regional coordinator in turn communicates with the zonal coordinator for the retrieval of the case notes from the health facilities of the selected cases based on the list of the selected cases by facilities.

2.2.4 Case retrieval and anonymization

The process for case retrieval and anonymization is as follows:

1. First-stage anonymization of the medical records is made by the health facility MCH head in the presence of the zonal coordinator.

   The responsibilities of the facility MCH head during the data collection and anonymization process are:

   - With the exception of the logo and name of the health facility, it anonymizes the copies of deceased files or charts at the health facility level by erasing fluid in the presence of the health facility CEO or medical directors, PHEM focal person, Matron, and zonal coordinator. Additionally, it anonymizes the names of the referring facilities (if any).
   - Check for the completeness and anonymity of the case notes.
   - The anonymizing team (CEO or medical directors, PHEM focal person, Matron, and zonal coordinator) ensures the anonymization is complete by signing a minute.

   The responsibilities of the zonal coordinator include the following:

   - Visit the health facilities during the case retrieval process for any woman who has died in these facilities. The facility CEO or medical director at all health facilities shall be included in and consent to every maternal death case note retrieval process.
   - Carefully track the retrieval process by recording the number of cases retrieved against the list requested.
   - Make two copies of all records, including referral notes (if any), for each selected case.
   - Check for legibility, scan, and send the copy to the regional coordinator through postal mail.
   - Check for the completeness and anonymity of the case notes.
   - Ensures the anonymization is complete by signing the minute, collecting it, and sending it to the regional coordinator.

The regional coordinator (MCH director) will:

- Provide guidance and coordination support to initiate the CE process at regional and lower health structure levels;
- Assign a responsible technical person to follow the details of the process of collecting the cases from the respective zones;
- Ensure selected cases are as per the request from the national coordinator;
- Ensures the collected files of selected cases are delivered to the national coordinator,
- Follow the implementation of recommendations from the national team.

2. Second stage: anonymize the addresses, logos, and names of hospitals.

The national coordinator will:

- Checks for completeness, anonymity, and legibility for rescanning and resending or dropping copies of the case note (soft or hard copy).
- Allocates a unique ID code for each maternal or perinatal death (which includes the date of data received and the code for regions, zones, woredas, and health facilities). The code shall be given a numerical value.
- Allocates and distributes cases for reviewers.
- Sends the copied or scanned deceased files to reviewers with a disclaimer form (annexed).
- Make sure a single case is sent to two reviewers.
- Ensures cases are not assigned to reviewers working in the same facility.
- Properly keep files (list of cases allocated, signed disclaimer form).

Anonymization of copied or scanned deceased files

This procedure involves the removal of identifiers from the clinical notes, such as the deceased woman's name and contact details, the contact details of next of kin, names, addresses, and logos of hospitals, and the names and signatures of staff who have attended the deceased woman. The national CE will anonymize deceased files manually by reading through the entire set of notes and using correction fluid to cover the identifying information.

NB: addresses, logos, and names of hospitals will be anonymized by the national coordinator.

Table 3: Schedule of the data collection process

S.N	Tasks	Responsible person	Timeframe	Methods and tools
1	Chart retrieval	National or Regional coordinator/zonal focal person	April	Photocopy or scan copy to be sent via EMS or DHL Tool- format which states the number of pages per case sent to the national level
2	Anonymization	Zonal coordinator / hospital CEO/CED/MD	April	Erasing fluid to cover the identifying information
3	Checking the completeness/ and quality of the data and the second anonymization	National coordinator	May	Visual ,checklist
4	Allocation of cases to reviewers	National coordinator	May	Copied deceased files will not be sent to reviewers who come from the same facility. ((disclaimer form annexed)

2.2.5 Case Review process

The review is done annually by the members of the national confidential enquiry review committee. Under the national review committee, there are teams that are responsible for reviewing maternal deaths, perinatal deaths, maternal near misses, and neonatal morbidities.

The national coordinator:

- Initiates the review process by allocating one case to two or more reviewers. A maximum of 10 charts should be assessed by one reviewer annually.
- Reviewers conduct detailed assessments of maternal death, attribute the cause of deaths based on WHO ICD-MM, complete a maternal death assessment form (annexed) for each death, and report the completed assessment forms back to the national coordinator within 3-4 weeks.
- Compare the findings of each case by two reviewers and make note where there is a significant discrepancy between reviewers. In the occurrence of such situations, the case will be sent to a third reviewer before being presented to the review panel for a final decision.
- Organize a write-up workshop where a multidisciplinary panel meets to finalize the review in groups.
    - **The agenda includes**: Presentations are given by each reviewer, followed by a plenary discussion and approval by the panel. Difficult cases, such as those with significant discrepancies between reviewers regarding causes and care received, are presented. If there is still a discrepancy with the third reviewer, the case will be referred to a panel of experts for a final

decision. This process aims to identify key findings of the review (gaps and positive practices), determine issues requiring action, and provide recommendations for action (policy, strategy, program, interventions, etc.).

- Address issues that need further study.
- Compile, clean, and enter the data into software, or make it ready for analysis.
- Conduct analysis based on the analysis plan (with indicators).
- Generate the result of the analysis for report writing.

The death review form has seven sections:

1. Sociodemographic Data,
2. Initial Clinical Diagnosis
3. Primary Cause Of Death
4. Contributory Conditions
5. Associated Factors,
6. Clinical Management
7. Summary

Table 4: Schedule for case review process

Activities	Responsible person	Time	Tool
1. Assigning causes of death	Individual national reviewers	June	WHO application of ICD-MM
2. Determining contributing or associated factors	Individual national reviewers	June	Delay model/road to death
3. Assessing quality of care	Individual national reviewers	June	National guides, Protocols /WHO quality standards
4. Data analysis and report writing	National review committee	August and October	
5. Dissemination workshop	Steering and National review committees	December and January	

2.2.6. Determining causes of death

The World Health Organization application of the International Statistical Classification of Diseases and Related Health Problems, tenth revision (ICD-10/11) to deaths during pregnancy, childbirth, and the puerperium: ICD maternal mortality (ICD-MM), is the standard tool to guide the collection, coding, tabulation, and reporting of maternal and perinatal mortality. In assigning causes of death, the reviewers follow the steps below:

a. Underlying cause of a maternal death

The underlying cause of a maternal death is the disease or condition that initiated the morbid chain of events leading to death. The single identified cause of death should be as specific as possible. The underlying cause of death is grouped based on the ICD 10-MM classification.

b. Contributory factors

Contributory factors are medical conditions that may have contributed to or may be associated with a maternal death; they are not reported as the sole condition on the death certificate or selected as the underlying cause of death. Contributing causes may predispose women to death as either a pre-existing condition or a risk factor. These are health conditions that are unlikely to cause death but may have contributed to it. Conditions may pre-exist or develop during the sequence of events leading to death.

c. Associated factors

The reviewers will make an overall assessment of the care provided to women and see if the quality of care received by different managers could have made a difference in the outcome.

They categorize their judgment regarding the quality of care as

- No QoC issues identified.
- Suboptimal care but with no impact on outcome.
- Suboptimal care with a possible impact on outcome.
- Suboptimal care with significant impact on outcomes.

A list of non-medical factors associated with maternal deaths was developed using the 3-delay model. The list developed was categorized into 4 groups (health worker, administrative, patient/family, and community factors) (Table 2). Associated factors under phase one delay (decision to seek care) and phase 2 delay (notifying and reaching medical facility) were categorized under the patient/family and community groups, while associated factors under phase 3 delay (quality of care) were categorized under the health worker and administrative groups. This list was used to identify associated factors during the review process.

Factors related to the phase one delay and phase two delay were based on information available in the case

notes only. The quality of this information depends on the type of information collected and documented from the deceased woman, her family members, and caregivers prior to arriving at the healthcare facility. Multiple sources of information regarding the maternal death were reviewed to determine the quality of care provided and the factors associated with receiving adequate and appropriate treatment, as determined by the reviewers (phase 3delay).

i. Maternal death assessment form

Case number:_____

I. BACKGROUND INFORMATION	
a) Age at death (in years)	
b) Parity	
c) Gestational Age (in weeks)	
d) Place of delivery (home, on the way, index hospital, referring hospital, referring health center)	
e) Date of delivery (dd/mm/yy)	
f) Mode of delivery(vaginal, assisted vaginal, Caesarean section)	
g) Birth outcome (live birth, still birth)	
II. FACILITY EPISODE	
a) Date and time of admission (dd/mm/yy and time according to local)	
b) Day of admission (working day, weekends, and holidays)	
c) Hour of admission (working hours, night)	
d) Reason for admission	
e) If the patient was referred, type of refereeing facility *(health center, primary hospital, general hospital, referral hospital, private clinic, private hospital)*	
f) Date and time of death (dd/mm/yy and time in local)	
g) Timing of death in relation to pregnancy (antepartum, intrapartum, postpartum)	

III. CAUSE OF DEATH (Determine the cause of death according to the ICD-MM classification and coding guidelines.)	
underlying cause	
Contributory medical conditions	

IV. ADVERSE/FAVOURABLE FACTORS/EVENTS: (Please write under avoidable factor gaps related to the patient, healthcare providers, and health system that could have prevented the deaths, and if there are good aspects, mention them as strengths under favorable factor.)		
	Avoidable factors	*Favorable factors*
1. PATIENT RELATED		
h) Personal circumstances		
i) Family Circumstances		
j) Any others		
2. ADMINISTRATIVE / HEALTH SYSTEM FACTORS		
2.1. Administrative factor		
a) Transport facility		
b) Availability and functionality of equipment for obstetric care		
c) Availability of qualified staff		
d) Availability of lab facilities		
e) Availability of supplies (drugs, fluids, and others)		
f) Availability of blood transfusion		
2.2. Health care provider-related factors		
a) Qualification of the most senior attending health professional		
b) Competence of the provider		
3. Clinical management of the woman (*evaluate by comparing to the national clinical guideline/protocol*)		
a) Initial assessment		
b) diagnosis		
c) Treatment		
d) follow up /monitoring		
e) Resuscitation/emergency care		
f) Consultation		

g) Any other aspects of care , please specify and evaluate.	
V. AVAILABILITY OF INFORMATION (State what sort of information was missing from the case notes, or if you think the records available are illegible, missing, good, complete, incomplete, etc.)	
DATA ITEM	**COMMENT**
History taking	
Clinical examination	
Lab, radiology, etc. investigations	
Diagnosis	
Post mortem reports	
Antenatal card	
Anesthesia records	
Nursing notes	
Observation chart	
Drug charts	
Fluid input/output	
Any other item, please specify and comment.	
Summary of quality of care	
Antenatal care	
Intrapartum care	
Intra-operative care (if applicable	
Post-Op care	
Postpartum care	
Any other?	

VI. RECOMMENDATIONS AT CLINICAL, PROGRAMMATIC, AND POLICY LEVELS (Please describe what could have been done to save the women and what should be done to prevent similar deaths in the future.)	
Date:	
Name of assessor:	

2.3. Confidential Enquiry into Perinatal Death

2.3.1. Topic and case selection process

The topic selection for perinatal review basically follows the same procedure as that for CEMM. The national MCH Lead Executive Office will decide the topic for review every year. For example, the topic could be aspects of care for the top leading causes of neonatal deaths and stillbirths (table 5).

Table 5: Topic and case selection for confidential enquiry into perinatal death

Activities	Source of Data	Responsible person	Time	Methods and tool
Topic selection	National MPDSR data base/annual report/DHIS2	National coordinator / NCH/SMH TWG	July-august	TWG meeting Tools-selection format
Case selection	National MPDSR data base/annual report/DHIS2	National coordinator		Random Sampling

Table 6: Allocation of cases selected for regions by level of health facility (perinatal death)

s.n	Still birth	Early neonatal death	Late neonatal death
1			
2			
3			
4			
5			
6			
7			

Case selection

The number of cases to be reviewed under the selected topic depends on the number of cases reported through MPDSR and entered into the national database and the available resources.

Box 3: General rules for the sample size of cases to be reviewed

As a general rule for the sample size of cases to be reviewed, assume one reviewer per five cases and a minimum of twenty reviewers. If there are fewer than 200 cases, go through them all. If there are more than 200 cases, select at least 200 at random for evaluation.

Steps of case selection

- **Steps of case selection**
    - Determine the sample of cases to be selected;
    - Based on the selected topic, use the national MPDSR data base to categorize cases by region and facility.Proportionally allocate cases to regions and facilities;
    - Select cases using simple random sampling;
    - Prepare a list of the selected cases with their addresses.

Note: Unselected government, NGOs, and private health facilities will be considered in special situations, for example, in cases that were referred from health centers or other hospitals. This requires understanding what happened at health centers and after referral on the way to hospitals.

Table 7: Sample format for allocation of cases selected for regions by level of health facility

S.N	Type of Health Facility	Selected Causes of Neonatal Deaths	Causes of Stillbirths
1	Primary hospital		
2	General Hospital		
3	Referral/teaching hospitals		

2.3.2. Data collection process

The data collection process encompasses retrieving charts, anonymizing the data, and checking its quality. The quality refers to the medical records of the deceased woman or perinate such as a vital sign sheet, medication sheet, laboratory result, operation and post-operation note, discharge or death summary, and referral sheet. The file of the deceased woman is carefully reviewed to confirm that all necessary information is included in the above-mentioned standard formats. The national coordinator oversees the retrieval of case notes through regional and zonal focal people coordinators. The national coordinator informs the regional coordinator about selected topics and the proportional sample size for the respective regional coordinator. The regional coordinator then contacts the zonal coordinator to retrieve case notes from the chosen health institutions based on a predetermined list.

2.3.3. Case retrieval and anonymization

Two steps of anonymization:

1. First stage anonymization of the medical records is made by the health facility MCH head in presence of zonal coordinator.

Responsibilities of the facility MCH head during data collection anonymization process:

- With exception of the logo and name of the health facility; anonymizes the copies of deceased files/ charts at health facility level by erasing fluid in presence of the health facilities CEO or medical directors, PHEM focal person, Matron and zonal coordinator. Additionally, anonymizes the name of the referring facilities (if any).
- Check for completeness and anonymity of the case notes.
- The anonymizing team (CEO or medical directors, PHEM focal person, Matron and zonal coordinator) ensures the anonymization is complete through signing a minute.
- The process of case retrieval and anonymization involves two steps. The first step of the anonymization of medical records is conducted by the MCH head of the health facility in the presence of the zonal coordinator. The responsibilities of the facility's MCH head during the data collection and anonymization process include anonymizing copies of deceased women's files by erasing identifiable information, excluding the facility's logo and name, in the presence of the health facility CEO, medical directors, PHEM focal person, Matron, and zonal coordinator. The anonymizing team (CEO or medical directors, PHEM focal person, Matron, and zonal coordinator) ensures the anonymization is complete by signing a minute.

The responsibilities of the zonal coordinator include the following:

- Visit the health facilities during the case retrieval process for any woman who has died in these facilities. The facility CEO or medical director at all health facilities shall be included in and consent to every maternal death case note retrieval process.
- Carefully track the retrieval process by recording the number of cases retrieved against the list requested.
- Make two copies of all records, including referral notes (if any), for each selected case.
- Check for legibility, scan, and send the copy to the regional coordinator through email, fax, or postal mail.
- Check for the completeness and anonymity of the case notes.
- Ensures the anonymization is complete by signing the minute; collects and sends the minute to the regional coordinator.

2. **Second stage: anonymize the addresses, logos, and names of hospitals.**

The national coordinator will:

- Checks for completeness, anonymity, and legibility for rescanning, resending, or dropping copies of the case note (soft or hard copy).
- Allocates a unique ID code for each maternal or perinatal death (which includes the date of data received, the code for regions, zones, woreda, and health facilities). The code shall be given a numerical value.
- Allocates and distributes cases for reviewers.
- Sends the copied or scanned deceased files to reviewers with a disclaimer form (annexed).
- Make sure a single case is sent to two reviewers.
- Ensures cases are not assigned to reviewers working in the same facility.
- Properly keep files (list of cases allocated, signed disclaimer form).

Anonymization of copied or scanned deceased files

This procedure involves the removal of identifiers from the clinical notes, such as the deceased's name and contact details; the contact details of the next of kin; the names, addresses, and logos of hospitals; and the names and signatures of staff who have attended the deceased woman. The National CE coordinator will anonymize the deceased files manually by reading the entire set of notes and using correction fluid to cover the identifying information.

NB: addresses, logos, and names of hospitals will be anonymized by the national coordinator.

Table 8: Schedule of the Data Collection Process

S.N	Tasks	Responsible person	Timeframe	Methods and tools
1	Chart retrieval	National/Regional coordinator/zonal/ woreda focal person	April and May	Photocopy/scan copy to be sent via EMS/ DHL Tool- format which states the number of pages per cases send to national level
2	Anonymization	zonal coordinator / hospital CEO/CED/ MD	April and May	Erasing fluid to cover the identifying information

3	Checking the completeness and quality of the data and the second anonymization	National coordinator	April and May	Visual ,checklist
4	Allocation of cases for reviewers	National coordinator	April and May	Copied deceased files will not be sent to reviewers who come from the same facility. (disclaimer form annexed)

2.3.4. Case review process

The review is done annually by the members of the national confidential enquiry review committee. Under the national review committee, there are teams that are responsible for reviewing perinatal deaths and neonatal near-misses.

The national coordinator: Initiates the review process by allocating one case to two or more reviewers. A maximum of five cases should be assessed by one reviewer annually.

- Reviewers conduct detailed assessments of perinatal deaths, attribute the cause of death based on WHO ICD-PM, complete a perinatal death assessment form (annexed) for each death, and report the completed assessment forms back to the national coordinator within 3-4 weeks.
- Compare the findings of each case by two reviewers, and make note that where there is significant disagreement between reviewers, the case will be sent to a third reviewer before being presented to the review panel for a final decision.
- Organize a write-up workshop where a multidisciplinary panel meets to finalize the review in groups.
    - The agenda includes presentations by each reviewer and discussion in plenary and approval by the panel; presentations of difficult cases (e.g., where there is a significant difference between reviewers over the causes and care received); and the panel serves as a tiebreaker, identifying key findings of the review (gaps and positive practices); determining issues needing action; and identifying the recommendations for action (policy, strategy, program, interventions, etc.).
    - Address issues that need further study.
    - Compile, clean, and enter the data into software, or make it ready for analysis.
    - Conduct analysis based on the analysis plan (with indicators).
    - Generate the result of the analysis for report writing.

The death review form has seven sections:

1. Sociodemographic Data,
2. Initial Clinical Diagnosis
3. Primary Cause of Death
4. Contributory Conditions
5. Associated Factors,
6. Clinical Management
7. Summary

Table 9: Schedule for case review process

Activities	Responsible person	Time	Tool
Assigning causes of death	Individual national reviewers	June	WHO application of ICD-PM
Determining contributing/ associated factors	Individual national reviewers	June	Delay model/road to death
Assessing quality of care	Individual national reviewers	June	National guides, Protocols, WHO quality standards
Data analysis and report writing	National review committee	August and October	
Dissemination workshop	Steering and National review committees	December and January	

2.3.5. Determining causes of death

The World Health Organization application of the International Statistical Classification of Diseases and Related Health Problems, tenth revision (ICD-10/11) to deaths during the perinatal period-ICD perinatal mortality (ICD-PM)- is the standard tool to guide the collection, coding, tabulation, and reporting of maternal and perinatal mortality. In assigning causes of deaths, the reviewers follow these steps**:**

A. Underlying cause of perinatal death

The underlying cause of perinatal death is the disease or condition that initiated the morbid chain of events leading to death. The single identified cause of death should be as specific as possible. The underlying cause of death is grouped based on the ICD 10-PM classification.

B. Contributory factors

Contributory factors are medical conditions that may have contributed to or may be associated with perinatal death; they are not reported as the sole condition on the death certificate or selected as the underlying cause of death. Contributing causes may predispose perinatals to death as either a pre-existing maternal condition or a risk factor. (seeAnnex---). These are health conditions that are unlikely to cause death but may have contributed to it. Conditions may pre-exist or develop during the sequence of events leading to death.

C. Associated factors

The reviewers will make an overall assessment of the quality of care provided to the women during the prenatal period and the newborn in the postnatal period and see if the quality of care received by different management could have made a difference to the outcome.

They categorize their judgment regarding the quality of care as

- No QoC issues were identified.
- Suboptimal care with no impact on outcomes.
- Suboptimal care with a possible impact on outcomes.
- Suboptimal care with a significant impact on outcomes.

The non-medical factors associated with perinatal deaths were developed using the 3-delay model. The tool developed was categorized into 4 groups: health worker, administrative, patient or family, and community factors. Associated factors under delay one (decision to seek care) and delay two (notifying and reaching medical facilities) were categorized under patient, family, and community groups, while associated factors under phase 3 delay (quality of care) were categorized under the health worker and administrative groups. This list was used to identify associated factors during the review process.

Factors related to delay one and delay two were based on information available in the case notes only. The quality of this information depends on the type of information collected and documented from the deceased perinatal, family members, and caregivers prior to arriving at the healthcare facility. Multiple sources of information regarding the perinatal death were reviewed to determine the quality of care provided and the factors associated with receiving adequate and appropriate treatment (delay three).

Perinatal death assessment form

Case number:_____

I. CAUSE OF DEATH:		
Primary (underlying) cause of death	Specify:	
Contributory (or antecedent) cause/s	Specify:	
II. ADVERSE/FAVORABLE FACTORS/EVENTS:		
A. Patient related factors		
	Adverse factors	***Favorable factors***
Personal circumstances (age of the mother, gravidity parity, gestational age, etc.)		
Family (health seeking behavior of the mother-planned pregnancy, ANC attendance, place of birth/ delivery, mode of delivery, etc.)		
B. Health system factors		
	Favorable factors (strength)	***Adverse factors (gaps identified)***
Access to health care facility Give an explanation for factors related to access to care		
Availability of health care facilities Give an explanation for factors related to the availability of facilities for critical care specific to the reviewed case (ICU, ventilator, etc.)		
Availability of personnel Give an explanation for factors related to the availability of personnel		

Appropriately trained staff Give an explanation for factors related to training		
C. Maternal care		
Antenatal care		
Intrapartum care		
Intra-operative care (if applicable)		
Postpartum care (if applicable)		
D. Clinical management of the mother/Newborn		
Initial assessment		
Problem identification or diagnosis		
Management plan		
Continued monitoring		
III. AVAILABILITY OF INFORMATION		
State what sort of information was missing from the case notes, or if you think the records available are illegible, missing, good, complete, incomplete, timely, etc.		
	Comment	
History taking		
Clinical examination		
Lab, radiology, investigations , etc		
Diagnosis		
Vital sign sheet		
Order sheet		
Any others (please state)		
IV. Recommendation(clinical, programmatic, policy)		
Provide a summary of your opinion on your case and comment on any other positive or negative issues related to the case.		

Date:	
Name of assessor:	

2.4. Confidential Enquiry into Maternal Near Miss

According to the International Federation of Gynecology and Obstetrics (FIGO), when a woman nearly dies but survives a complication during pregnancy, childbirth, or the postpartum period, it is defined as a maternal near-miss. The maternal near-miss case review (NMCR) has been promoted by the WHO as an approach to improving quality of care (QoC) at the facility level. **Operational definition and/or setting criteria for near-miss cases (TRSC of eight public hospitals)**

- Hemorrhagic conditions such as PPH necessitate urgent lifesaving interventions like blood transfusions, plasma expanders, and/or laparotomies.
- Hemorrhagic conditions such as APH with deranged vital signs and active bleeding necessitate lifesaving intervention (severe abruption, major-degree placenta previa).
- Hemorrhagic conditions such as abortion, ectopic pregnancy, or GTD resulting in severe anemia and/or hypovolemic shock requiring urgent intervention (blood transfusion, laparotomy).
- Preeclampsia with severe features and end organ damage (AKI/HELLP syndrome, pulmonary edema DIC/ICHetc.).
- Eclampsia
- Obstructed labor with its complications (imminent uterine rupture, uterine rapture), which require intervention (blood transfusion, plasma expanders, laparatomies, destructive delivery, etc.)
- Septic shock due to septic abortion or severe puerperal sepsis with pelvic or generalized peritonitis, etc., which requires intervention (colloids, blood transfusion, parenteral therapeutic antibiotics, inotropic agents, laparotomies, etc.).
- Severe anesthesia complications (failed intubations, high or total spinal block, aspiration pneumonia, respiratory failure, subdural hematoma, etc.)
- Thromboembolism CNS pulmonary
- Amniotic fluid embolism, per partum cardiomyopathy
- Other indirect causes of maternal near-misses include severe malaria, NYHA class 3 and 4, hepatic failure, renal failure, metabolic coma, etc. Post-cardiac arrest who survived after intervention (CPR cardioversion, etc.).

Table 10: Topic selection and case selection process of maternal near miss

Activities	Source of Data	Responsible person	Time	Methods and tool
1. Topic selection: near-miss topics will be determined based on the topic selected for CEMD and/ or other topics that the committee considers to be reviewed.	National MPDSR data base/annual report,DHIS2.	National coordinator	February	Same with CEMD
2. Case selection	Facility register	Zonal/ woreda coordinator	January	Case selection form
Data collection processes				
3. Chart retrieval	Facility record office / Archive	zonal/woreda coordinator and facility MCH/ PHEM officer.	March	
4. Anonymization		zonal coordinator and Facility CEO/CMO/ matron/ MCH head.	April	
5. checking the completeness and quality of the data		National / regional coordinator	April	
Case review process				
6. Allocation of cases to reviewers		National coordinator	May	
7. Assigning or establishing causes of near miss		National/ regional Assesers/reviewer	May	
8. Underlying / Associated causes		National/ regional Assesers/reviewer	June	
9. Assessing the quality of care		National/ regional Assesers/reviewer	June	
10. Data analysis and report writing		National review committee	September to November	
11. Dissemination		National coordinator and National review committee	December and January	

2.5. Confidential Enquiry into Neonatal Near Miss

Confidential enquiry into neonatal near miss (NNM) could contribute to the assessment and improvement of obstetric practice, perinatal and neonatal care. For every newborn who dies, many others develop severe complications.

Analogous to the definition of maternal near miss, neonatal near miss would correspond to a morbid event that almost resulted in the death of a neonate during the neonatal period, including criteria such as diseases, interventions, and organ dysfunctions. A fundamental aspect of the near-miss concept is the similarity between deaths and near-miss cases. The ideal near-miss case would mirror a death, the only difference being that the infant is alive at the point of assessment of the vital status.

A Neonatal Near Miss (NNM) is a neonate who had a severe morbidity (organ dysfunction or failure) but who survived this condition within the first 28 days of life. Hence, a NNM is considered when the newborn meets at least one of the following proposed criteria but survives those complications.

Even though there is currently no gold-standard definition or any internationally agreed upon identification criteria for neonatal near-miss cases, for the identification of neonatal near-misses, two groups of criteria are being used based on the results of previous studies on the topic. The first was formed by the following pragmatic criteria:

- Apgar score of 7 at 5 minutes
- Gestational age of 33 complete weeks and below

  As a proxy for organ dysfunction, the second group was characterized by the following management criteria:
- Parenteral antibiotic therapy (up to 7 days and
- before 28 days of life)
- Nasal continuous positive airway pressure (CPAP)
- Any intubation during the first 28 days of life
- Phototherapy within 24 hours of life
- Cardiopulmonary resuscitation
- Use of vasoactive drugs
- Use of anticonvulsants
- Use of surfactant
- Use of blood products
- Use of steroids for the treatment of refractory hypoglycemia
- Any surgical procedure

- Use of antenatal steroid
- Use of parenteral nutrition
- Identification of major congenital malformations (cardiac, hydrocephaly)

Table 11: Topic selection and case selection process of neonatal near miss

Activities	Source of information	Responsible person	Time	Methods and tool
1. Topic selection: near-miss topics will be determined based on the topic selected for CEPD and or other topics that the committee considers to be reviewed	National MPDSR data base/annual report, DHIS2.	National coordinator /SMH/NBCS TWG	November	Same with CEPD
2. Case selection	Facility register	Zonal/ woreda coordinator	December	Case selection form
Data collection processes				
3. Chart retrieval	Facility record office / Archive	zonal/woreda coordinator and facility MCH/PHEM officer.	January and February	
4. Anonymization		zonal coordinator and Facility CEO/ CED/MDmatron/ MCH & NICU heads.	January and February	
5. checking the completeness and quality of the data		National / regional coordinator	January and February	
Case review process				
6. Allocation of cases for assessors and reviewers		National coordinator	January and February	
7. Establish causes of near miss		National/ regional reviewer	March	
8. Underlying / Associated causes		National/ regional reviewer	March	
9. Assessing the quality of care		National/ regional reviewer	March	
10. Data analysis and report writing		National review committee	May to July	
11. Dissemination		National coordinator and National review committee	September and October	

2.6. Data analysis and report writing

The data analysis will be done during the review workshop using both qualitative and quantitative approaches. Software will be designed or adapted to support the data analysis process. Once the assessment form is completed, the national coordinator compiles the final results of the review and enters the data into the database. The analysis result will be produced based on the predetermined indicators in the analysis plan.

Based on the report template in the analysis plan, the report will be written by an assigned small team for each section (chapters). Epidemiologists, public health experts, and statisticians will be part of the report writing team. In the workshop, the first draft will be produced. Then this draft will be shared with relevant individuals for review, comments, and finalization. The final draft report will be presented to the steering committee for approval.

Dissemination

Dissemination will be made using a variety of communication channels to enable a wide range of people to access it.

- Dissemination workshop
- Produce an annual report.
- Publication in national journals (professional society journals),.Policy brief for policymakers
- FMOH Annual Review Meeting (ARM) special bulletin
- Facility-based team meetings
- Community meeting
- Professional conferences and training programs
- Ministry of Health and professional society websites

3. CE MONITORING AND EVALUATION

What is the purpose of monitoring the CE system? Once the CE system has been established, it is essential to maintain and supervise the system by monitoring.

- To document the implementation of CE, including solutions recommended by the CE committee.
- To deliver improvements to the quality of care provided.

How is it done?

Monitoring should be conducted in two areas:

- Assessment of how well the CE system is functioning and whether the recommendations are being enacted; and
- Assessment of the maternal and perinatal health indicators to monitor changes.

Monitoring the CE system

- **A monitoring system should assess the following elements:**
  - whether the recommendations for action have been implemented
  - whether the recommendations are being implemented on a proposed timeline
  - whether the recommendations are achieving the desired results
  - where any problems may lie if the desired results are not being achieved.

Analyzing indicators and examining trends can provide a quick snapshot of whether the CE system is improving quality of care and outcomes and can suggest areas that need further improvement or where more efforts are needed. Users of the CE system may be more motivated to provide the needed data and enact recommendations if they periodically receive feedback linked to the data, such as long-term trends showing a reduction in the rate of intrapartum stillbirths over a five-year period.

This monitoring is done by continuously collecting and reporting information on output and outcome indicators such as:

- The number and percentage of maternal and perinatal deaths that were notified and reviewed (outcome indicator)
- The number and percentage of recommendations that were implemented (outcome indicator)
- Information on how many steering committee meetings were completed (output indicator)
- completeness of CE reporting (output indicator)
- whether recommendations were properly formatted and feasible to implement (output indicators)

(See annex: Framework for M and E)

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ANNEXES

Annex 1: Glossary

Maternal death is defined as the death of a woman while pregnant or within 42 days of the termination of pregnancy irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes. (ICD-10).

Direct obstetric deaths are maternal deaths resulting from complications of pregnancy, labor, post-partum, or from interventions, omissions, or incorrect treatment.

Indirect obstetric deaths are maternal deaths resulting from previously existing diseases or newly developed medical conditions that were aggravated by the physiologic change of pregnancy.

Late maternal death is defined as a maternal death that occurs from 42 to 365 days after the termination of a pregnancy. (ICD-10)

Pregnancy related death is defined as all deaths of women during or within 42 days of termination of pregnancy, regardless of cause. (ICD-10)

Maternal near-miss is defined as a woman who nearly died but survived a complication that occurred during pregnancy, childbirth, or within 42 days of termination of pregnancy. In practical terms, women are considered near-miss cases when they survive life-threatening conditions (i.e., organ dysfunction).

Severe maternal outcomes: are maternal near misses and maternal deaths.

Maternal death surveillance and response (MDSR) has been defined as "a component of the health information system that permits identification, notification, quantification, and the determination of causes and avoidability of maternal deaths for a defined time period and geographic location, with the goal of orienting the measures necessary for its prevention.".

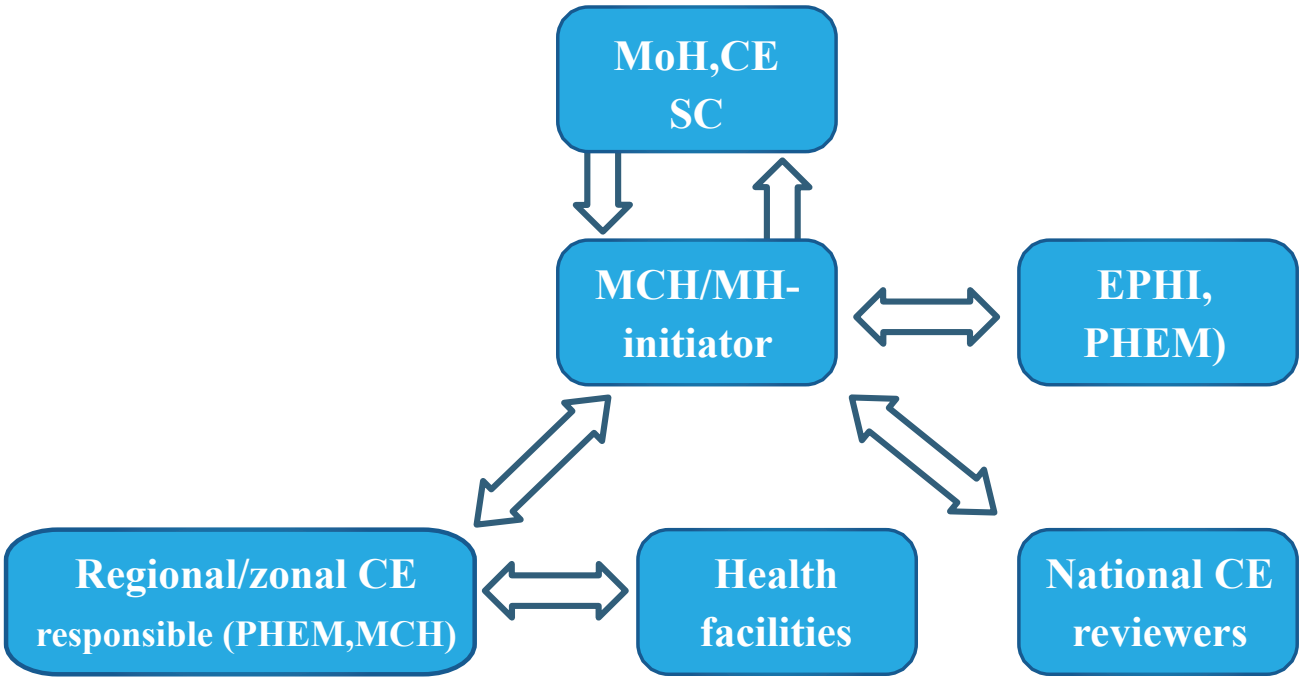
Maternal Death Audit (MDA) is used to describe maternal death case reviews, confidential enquiries, and maternal death surveillance.

Clinical audit has a more specific meaning and has recently been described as "a quality improvement process that seeks to improve patient care and outcomes through the systematic review of care against explicit criteria and the implementation of change."

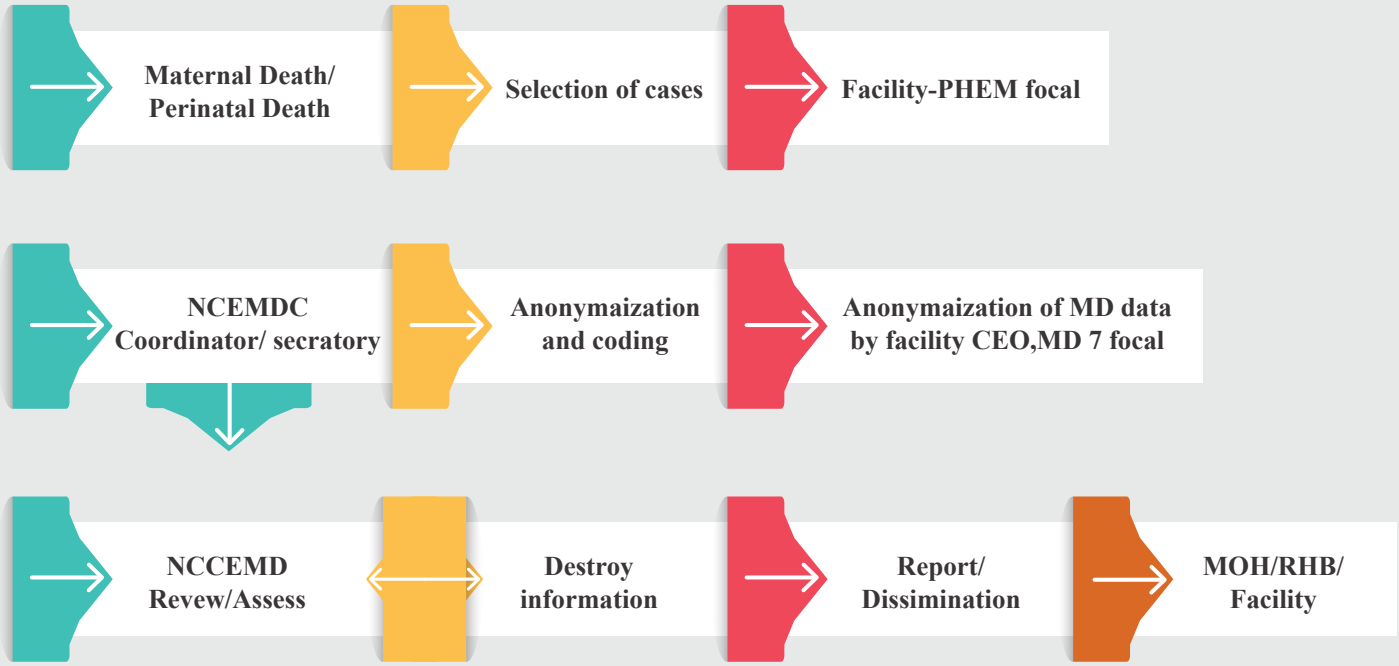
Verbal autopsy (community-based maternal death review) is a method of identifying the determinants of death and ascertaining the personal, family, or community factors that may have contributed to the deaths of women who died outside of a medical facility. It identifies deaths that occur in the community and consists of interviewing people who are knowledgeable about the events leading to the death, such as family members, neighbors, and traditional birth attendants.

Maternal Death Review (facility-based maternal deaths review) is a qualitative, in-depth investigation of the causes of and circumstances surrounding maternal deaths occurring at health facilities. Deaths are initially identified at the facility level, but such reviews are also concerned with identifying the combination of factors at the facility and in the community that contribute to maternal death.

Annex 2: Structure of national CE-MPMM program



Annex 3: Steps for Confidential Enquiry



Annex 4: Factors associated with maternal death included:

❖ health work force related factors

- No treatment
- Unsafe medical treatment
- No Information
- Wrong treatment
- Partograph incorrectly used / not used
- Wrong diagnosis
- Delay in deciding to refer
- Inadequate antenatal care
- Inadequate resuscitation
- Lack of obstetric lifesaving skills
- No avoidable factors
- Initial assessment incomplete
- Prolonged abnormal observation without action
- Inadequate monitoring
- Inadequate clinical skills

❖ Administrative Factors

- Absence of trained staff on duty 44 12.5
- Infrastructural problems 44 12.5
- Lack of equipment for obstetric surgery 41 11.6
- Lack of availability of blood transfusion 39 11.0
- Lack of qualified staff 32 9.1
- Transport problems between health facilities 13 3.7
- Communication problem between health facilities 12 3.4

- Lack of laboratory facilities
- Lack of antibiotics 9 2.5
- Lack of uterotonic drugs 4 1.1
- Lack of antihypertensive/anticonvulsants 4 1.1
- Lack of equipment for MVA 1 0.3
- Lack of equipment for AVD 1 0.3
- No avoidable factors identified

❖ Patient/Family Factors

- Delay in reporting to health facility 142 42.4
- Delay in decision-making 110 32.8
- No antenatal care 40 11.9
- Unsafe traditional/cultural practices 25 7.5
- Unsafe self-medication treatment 19 5.7
- Use of traditional medical practice 13 3.9
- Lack of transport from home to facility 2 0.6
- No avoidable factors

❖ Community factors

- Failure to recognize danger signs 21 12.2
- Delay in deciding to refer 19 11.0
- Failure to accept limitations 4 2.3
- Use of traditional medicine 3 1.7
- No avoidable factors

❖ Contributory conditions identified included:

- Abnormalities of labor, such as obstructed and prolonged labour
- complications from a caesarean section

Gaps noted in the care at different levels of health care

Distribution of women by level care along the path to death

- Community
- Dispensary
- Health Centre
- Sub-County Hospital
- County Hospital
- Secondary Referral Hospital
- National Teaching and Referral Hospitals
- Private/faith-based 82

Gaps identified by level of care

❖ Examples of Gaps identified at Primary hospital

- Incorrect management after making correct diagnosis 54 54
- No/infrequent monitoring 45 45
- Prolonged abnormal observation noted but no action taken 34 34
- Problem with recognition/diagnosis 20 20
- Initial assessment 18 18
- Incorrect diagnosis and management 15 15
- Delay in referring the patient 8 8
- Managed at inappropriate level 5 5
- Lack of information 4 4
- No avoidable factors

❖ Examples of Gaps identified at referral hospitals

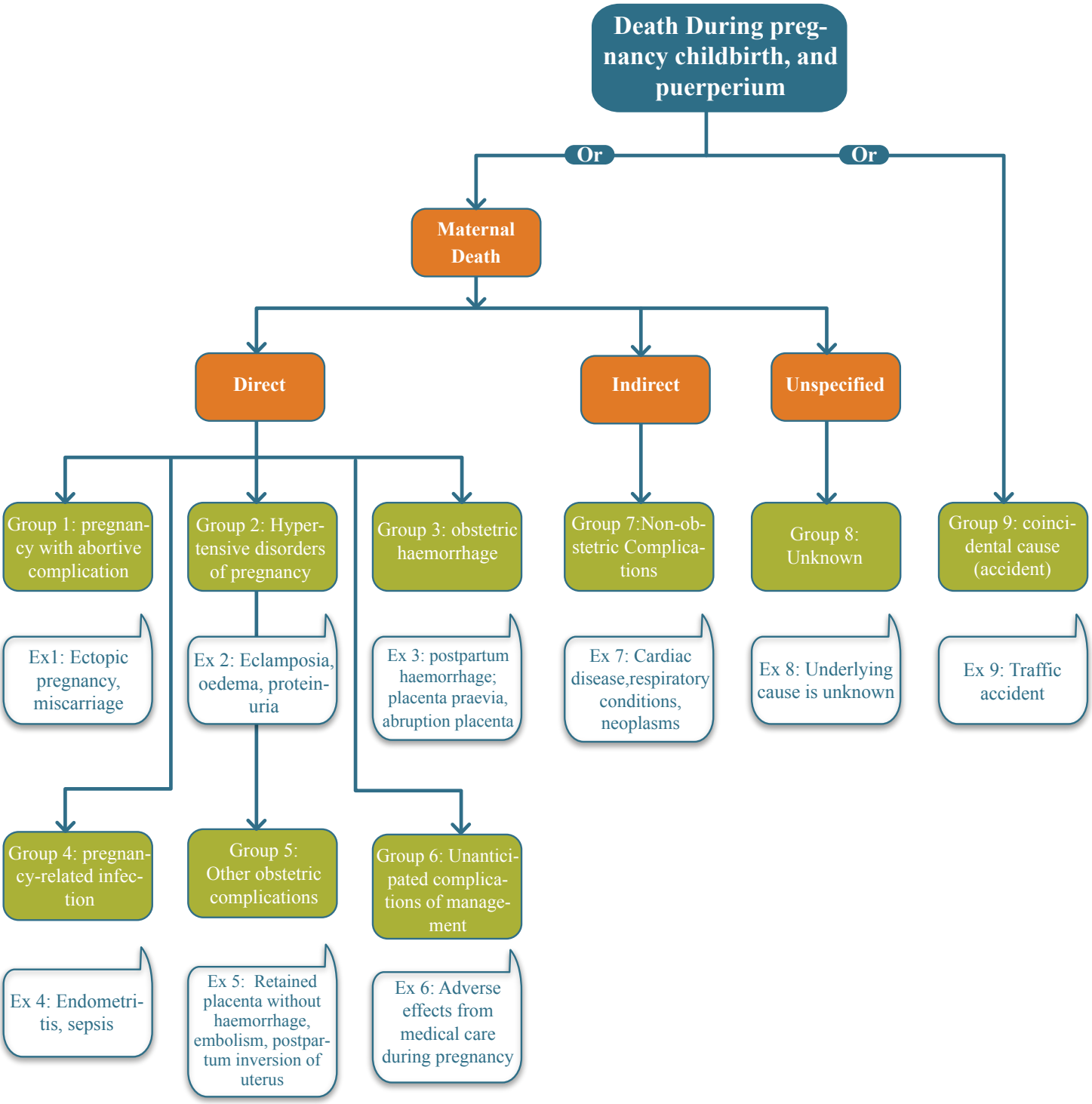
- Incorrect management after making correct diagnosis 31 32.6
- Prolonged abnormal observation noted but no action taken 28 29.5
- No/infrequent monitoring 21 22.1
- Lack of information 15 15.8
- Problem with recognition/diagnosis 13 13.7
- Incorrect diagnosis and management 8 8.4
- Initial assessment 7 7.4
- Managed at inappropriate level 1 1.1
- No avoidable factors 29 30.5

❖ Examples of Gaps identified at health center level

- Delay in referring the patient 19 39.6
- Lack of information 14 29.2
- Managed at inappropriate level 12 25.0
- Initial assessment incomplete 8 16.7
- Incorrect management after making correct diagnosis 7 14.6
- Prolonged abnormal observation noted but no action taken 7 14.3
- Problem with recognition/diagnosis 6 12.5
- Incorrect diagnosis and management 6 12.5
- No/infrequent monitoring 6 12.5
- No avoidable factors 8 16.7
- Delay in starting treatment 24 25.0
- Initial assessment incomplete 22 22.9
- Inadequate clinical skills 20 20.8
- Inadequate monitoring 19 19.8
- Prolonged abnormal observation without action 19 19.8

- Inadequate resuscitation 15 15.6
- Inadequate antenatal care 15 15.6
- Incorrect diagnosis and management 11 11.5
- Delay in deciding to refer 9 9.4
- Unsafe medical treatment 7 7.3
- Partograph incorrectly/not used 7 7.3
- Incorrect management after making correct diagnosis 5 5.2
- No treatment 3 3.1
- Lack of obstetric lifesaving skills 3 3.1
- No information 11 11.5
- No avoidable factors 18 18.8

Annex 5: Flow charts of assigning causes of death processes



Annex 6: Death Assessment forms

1. Death Assessment Form for Maternal Death Chart Abstraction

Instruction:

- Please keep the copies of the patient chart you received safe.
- Use the code number on the anonymized copy of the patient chart you received for the case number on this form.
- Use one assessment form to document the findings of one case.
- Please assess based on the instructions given in the bracket with an italic letter for each section.
- If the space is not enough, you can expand the same raw and write your findings and comments.
- Submit the completed assessment form to the national CE coordinator (MoH) with copies of the patient chart you reviewed before the due date.
- If you have any queries, please call the coordinator.

Health Facility ID:_____

Case Unique ID:_____

VARIABLES	RESPONSE
1 . HEALTH FACILITY BACKGROUND INFORMATION	
a) Type of the facility	
b) Level of the facility	
c) Address of the facility	
d) Ownership of the facility	
2. DECEASED BACKGROUND INFORMATION	
a) Age at death	
b) Educational Status	
c) Employment status	
d) Address (Region, Zone/city, District)	
e) Usual Residence (Rural vs urban)	
3. OBSTETRIC INFORMATION	
a) Parity	
b) Gestational Age (in weeks)	

c) Place of delivery (Home, on the way, index Hospital, Referring hospital, Referring health center)	
d) Date of delivery (dd/mm/yy)	
e) Mode of delivery (vaginal, assisted vaginal , Caesarean Section)	
f) Birth outcome (live birth, still birth)	
4, FACILITY EPISODE	
a) Date of admission (dd/mm/yy)	
b) Time of admission according to local time	
c) Day of admission (working day, weekends, and holidays)	
d) Hour of admission (working hours, night)	
e) Reason for admission	
f) Was the patient referred? (yes/no/unknown)	
g) If the patient was referred , type of refereeing facility (health center, primary hospital, General hospital, referral hospital, private clinic, private hospital)	
h) Date of death (dd/mm/yy)	
i) Time of death (according to local time)	
j) Timing of death in relation to pregnancy (antepartum, intrapartum, postpartum)	
5. CAUSE OF THE DEATH (Determine cause of death according to ICD-MM classification and coding guideline)	
a) underlying cause	
b) Contributory medical conditions	

6. ASSOCIATED/AVOIDABLE FACTORS : (Please write under avoidable factor gaps related to the patient, healthcare providers and health system that could have prevented the deaths . If there are good aspects of the care , please mention them as strengths under favorable factor)		
	Avoidable factors (missed opportunities)	Favorable factors
6.1. Patient related Factors		
• Personal circumstances		
• Community/family circumstances		

• Any others		
6.2 Administrative related factors		
• Availability of transport facility		
• Availability of equipment for obstetric care		
• Availability of qualified staff		
• Availability of lab facility		
• Availability of supplies (drugs, fluids, blood, and others)		
6.3. Healthcare Provider related factors		
• Presence of the healthcare providers		
• Qualification of the most senior attending healthcare provider		
• Provision of preventive/routine maternity/neonatal care during (appropriate, correct, timely)		
• Antenatal period (screening for risks and managing according to the guidelines)		
• Intrapartum period		
• Postpartum period		
• Provision of obstetric emergency care during Intrapartum period		
• Initial assessment		
• diagnosis		
• Treatment/plan		
• Resuscitation/emergency care		
• Consultation		
• follow up /monitoring		
• Any other aspects of care , please specify and evaluate.		
• Provision of obstetric emergency care during the intrapartum period		
• Initial assessment		
• diagnosis		
• Treatment/plan		
• Resuscitation/emergency care		

• Consultation		
• follow up /monitoring		
• Any other aspects of care , please specify and evaluate.		
7. DOCUMENTATION OF (State what sort of information was missing from the case notes, or if you think the records available are illegible, missing, good, complete, incomplete, etc.)		
a) Relevant history of the patient (complete, incomplete, partially complete)		
b) Clinical examination		
c) Investigations report (Lab, radiology, etc.)		
d) Diagnosis		
e) Management/treatment plan		
f) Post-op /procedure note		
g) Anesthesia note		
h) Nursing note		
i) Vital sign including fluid input/output		
j) Any other item , please specify and comment.		
8. LEVEL OF QUALITY OF THE CLINICAL CARE PROVIDED TO THE DECASED WOMAN (evaluate by comparing to the national clinical guideline/protocol) (Correct/appropriate, timely, standard, substandard, Poor)		
a) Initial assessment		
b) diagnosis		
c) Treatment		
d) follow up /monitoring		
e) Resuscitation/emergency care		
f) Consultation		
g) Any other aspects of care , please specify and evaluate.		
9. RECOMMENDATIONS FOR IMPROVEMENT (at Clinical , Programmatic and Policy Levels)(Please describe what could have been done to save the women and what should be done to prevent similar deaths in the future)		

Date completed	
Name of assessor:	

2, Death Assessment Form for Neonatal Death Chart Abstraction

Instruction:

- Please keep the copies of the patient chart you received safe.
- Use the code number on the anonymized copy of the patient chart you received for the case number on this form.
- Use one assessment form for documenting the findings of one case.
- Please assess based on the instructions given in the bracket with an italic letter for each section.
- If the space is not enough, you can expand the same raw and write your findings and comments.
- Submit the completed assessment form to the national CE coordinator (MoH) with copies of the patient chart you reviewed before the due date.
- If you have any queries, please call the coordinator.

Health Facility ID: _____

Case Unique ID: _____

I. CAUSE OF DEATH:		
Primary (underlying) cause of death	Specify:	
Contributory (or antecedent) cause/s	Specify:	
II. ADVERSE/FAVORABLE FACTORS/EVENTS:		
A. Patient related factors		
	Adverse factors	Favorable factors
Personal circumstances (age of the neonate, feeding practice, etc)		
Family (health seeking behavior of the mother-planned pregnancy, ANC attendance, place of births/ delivery, timely seeking of care for sick baby etc.)		
B. Health system factors		
	Adverse factors	Favorable factors
Access to health care facility *Give explanation for factors related to access to care*		
Availability of health care facilities *Give explanation for factors related to availability of facilities for critical care specific to reviewed case (ICU, CPAP, ventilator etc.)*		
Availability of personnel *Give explanation for factors related to availability of personnel*		
Appropriately trained staff *Give explanation for factors related to training*		
C. Maternal care		
Antenatal care		
Intrapartum care		
Intra-operative care (if applicable)		
Postpartum care (if applicable)		
D. Clinical management of the baby		
Initial assessment		
Problem identification or diagnosis		

Management plan		
Continued monitoring		

III. AVAILABILITY OF INFORMATION	
State what sort of information was missing from the case notes, or if you think the records available are illegible, missing, good, complete, incomplete, timely etc.	
	Comment
History taking	
Clinical examination	
Lab, radiology, etc investigations	
Diagnosis	
Vital sign sheet	
Order sheet	
Any others (please state)	

IV. Recommendation(clinical, programmatic, policy)
Provide a summary of your opinion on your case and comment on any other positive or negative issues related to the case.

Date:	
Name of assessor:	

Annex 7: List of underlying causes

1, Sub-groups of MDs due to obstetric hemorrhage in pregnancy, childbirth, and the puerperium, detailed description

	Subgroup	Description
1	Placenta Previa	Placenta Previa with hemorrhage
2	Premature separation of placenta [abruptio placentae]	Other premature separation of placenta
		Premature separation of placenta, unspecified
3	Antepartum hemorrhage, not elsewhere classified	Antepartum hemorrhage, unspecified
		Other antepartum hemorrhage
4	Labour and delivery complicated by intrapartum hemorrhage, not elsewhere classified	Intrapartum hemorrhage with coagulation Defect
		Intrapartum hemorrhage, unspecified
		Other intrapartum hemorrhage
5	Other obstetric trauma	Obstetric laceration of cervix
		Rupture of uterus before onset of labour
		Rupture of uterus during labour
6	Postpartum Hemorrhage	Delayed and secondary postpartum haemorrhage
		Other immediate postpartum hemorrhage
		Postpartum coagulation defects
		Third-stage hemorrhage

2, Sub-groups of MDs due to hypertensive disorders in pregnancy, childbirth, and the puerperium detailed description

Sub group	Description	
Eclampsia	Eclampsia in labour	
	Eclampsia in pregnancy	
	Eclampsia in the puerperium	
	Eclampsia, unspecified as toTime	
Pre-eclampsia	HELLP syndrome	
	Severe pre-eclampsia	
Pre-eclampsia superimposed on chronic hypertension		

Annex 8: List of Contributory conditions

Complications following abortion and ectopic and molar pregnancy

- Genital tract and pelvic infection following abortion and ectopic and molar
- pregnancy 6 1.2
- Delayed or excessive haemorrhage following abortion and ectopic and
- molar pregnancy 11 2.3
- Shock following abortion and ectopic and molar pregnancy 17 3.5
- Renal failure following abortion and ectopic and molar pregnancy 8 1.6
- Metabolic disorders following abortion and ectopic and molar pregnancy 1 0.2
- Damage to pelvic organs and tissues following abortion and ectopic and
- molar pregnancy 6 1.2
- Other venous complications following abortion and ectopic and molar
- pregnancy 1 0.2
- Other complications following abortion and ectopic and molar pregnancy 2 0.4
- Complication following abortion and ectopic and molar pregnancy, unspecified

Excessive vomiting in pregnancy 5 1

- Other vomiting complicating pregnancy 2 0.4
- Vomiting of pregnancy, unspecified 3 0.6

Venous complications in pregnancy 1 0.2

- Varicose veins of lower extremity in pregnancy 1 0.2

Maternal care for other conditions predominantly related to pregnancy 13 2.7

- Other specified pregnancy-related conditions 7 1.4
- Pregnancy-related condition, unspecified 6 1.2

Abnormal findings on antenatal screening of mother 21 4.3

- Abnormal haematological finding on antenatal screening of mother 10 2.1
- Abnormal biochemical finding on antenatal screening of mother 1 0.2
- Abnormal ultrasonic finding on antenatal screening of mother 1 0.2
- Abnormal radiological finding on antenatal screening of mother 2 0.4
- Abnormal chromosomal and genetic finding on antenatal screening of mother 1 0.2
- Other abnormal findings on antenatal screening of mother 5 1
- Abnormal finding on antenatal screening of mother, unspecified 1 0.2

Complications of anaesthesia during pregnancy 2 0.4

- Spinal and epidural anaesthesia-induced headache during pregnancy 2 0.4

Multiple gestation 10 2.1

- Twin pregnancy 8 1.6
- Triplet pregnancy 2 0.4

Maternal care for known or suspected malpresentation of fetus 9 1.9

- Maternal care for breech presentation 1 0.2
- Maternal care for transverse and oblique lie 4 0.8
- Maternal care for multiple gestation with malpresentation of one fetus or more 2 0.4
- Maternal care for compound presentation 2 0.4

Maternal care for known or suspected abnormality of pelvic organs 5 1

- Maternal care due to uterine scar from previous surgery 1 0.2
- Maternal care for other abnormalities of cervix 1 0.2
- Maternal care for other abnormalities of gravid uterus 1 0.2
- Maternal care for other abnormalities of pelvic organs 1 0.2
- Maternal care for abnormality of pelvic organ, unspecified 1 0.2

Maternal care for known or suspected foetal abnormality and damage 4 0.8

- Maternal care for (suspected) central nervous system malformation in fetus 3 0.6
- Maternal care for (suspected) damage to fetus from viral disease in mother 1 0.2

Maternal care for other known or suspected foetal problems 18 3.7

- Maternal care for intrauterine death 17 3.5
- Maternal care for other specified foetal problems 1 0.2

Other disorders of amniotic fluid and membranes 3 0.6

- Oligohydramnios 1 0.2
- Disorder of amniotic fluid and membranes, unspecified 2 0.4

Premature rupture of membranes 8 1.6

- Premature rupture of membranes, onset of labour within 24 hours 1 0.2
- Premature rupture of membranes, onset of labour after 24 hours 4 0.8
- Premature rupture of membranes, unspecified 3 0.6

Placental disorders 12 2.5

- Other placental disorders 5 1
- Placental disorder, unspecified 7 1.4

False labour 1 0.2

- False labour before 37 completed weeks of gestation 1 0.2

Preterm labour and delivery 16 3.3

- Preterm labour without delivery 2 0.4
- Preterm spontaneous labour with preterm delivery 12 2.5
- Preterm delivery without spontaneous labour 2 0.4
- Failed induction of labour 5 1
- Failed medical induction of labour 5 1

Abnormalities of forces of labour 4 0.8

- Primary inadequate contractions 2 0.4
- Precipitate labour 2 0.4

Long labour 31 6.4

- Prolonged first stage (of labour) 21 4.3
- Prolonged second stage (of labour) 9 1.9
- Delayed delivery of second twin, triplet, etc. 1 0.2

Obstructed labour due to malposition and malpresentation of fetus 10 2.1

- Obstructed labour due to breech presentation 1 0.2
- Obstructed labour due to face presentation 2 0.4
- Obstructed labour due to shoulder presentation 2 0.4
- Obstructed labour due to compound presentation 2 0.4
- Obstructed labour due to other malposition and malpresentation 2 0.4
- Obstructed labour due to malposition and malpresentation, unspecified 1 0.2

Obstructed labour due to maternal pelvic abnormality 5 1

- Obstructed labour due to generally contracted pelvis 2 0.4
- Obstructed labour due to other maternal pelvic abnormalities 1 0.2
- Obstructed labour due to maternal pelvic abnormality, unspecified 2 0.4

Other obstructed labour 33 6.8

- Obstructed labour due to shoulder dystocia 2 0.4
- Obstructed labour due to unusually large fetus 1 0.2
- Obstructed labour due to other abnormalities of fetus 1 0.2
- Failed trial of labour, unspecified 2 0.4
- Other specified obstructed labour 4 0.8
- Obstructed labour, unspecified 23 4.7

Labour and delivery complicated by foetal stress distress 29 6

- Labour and delivery complicated by foetal heart rate anomaly 10 2.1
- Labour and delivery complicated by meconium in amniotic fluid 9 1.9
- Labour and delivery complicated by foetal heart rate anomaly with meconium in amniotic fluid 4 0.8
- Labour and delivery complicated by biochemical evidence of foetal stress 1 0.2
- Labour and delivery complicated by other evidence of foetal stress 2 0.4
- Labour and delivery complicated by foetal stress, unspecified 3 0.6

Labour and delivery complicated by umbilical cord complications 4 0.8

- Labour and delivery complicated by prolapse of cord 2 0.4
- Labour and delivery complicated by cord around neck, with compression 2 0.4

Perineal laceration during delivery 11 2.3

- First degree perineal laceration during delivery 1 0.2
- Second degree perineal laceration during delivery 1 0.2
- Third degree perineal laceration during delivery 3 0.6
- Fourth degree perineal laceration during delivery 1 0.2
- Perineal laceration during delivery, unspecified 5 1
- Other complications of labour and delivery, not elsewhere classified 77 15.8
- Maternal distress during labour and delivery 4 0.8

- Shock during or following labour and delivery 66 13.6
- Pyrexia during labour, not elsewhere classified 3 0.6
- Delayed delivery after spontaneous or unspecified rupture of membranes 2 0.4
- Vaginal delivery following previous caesarean section 2 0.4

Single spontaneous delivery 18 3.7

- Spontaneous vertex delivery 15 3.1
- Spontaneous breech delivery 2 0.4
- Single spontaneous delivery, unspecified 1 0.2

Single delivery by forceps and vacuum extractor 2 0.4

- Vacuum extractor delivery 2 0.4

Single delivery by caesarean section 47 9.7

- Delivery by elective caesarean section 3 0.6
- Delivery by emergency caesarean section 38 7.8
- Delivery by caesarean hysterectomy 1 0.2
- Other single delivery by caesarean section 3 0.6
- Delivery by caesarean section, unspecified 2 0.4

Other assisted single delivery 7 1.4

- Breech extraction 2 0.4
- Other manipulation-assisted delivery 1 0.2
- Delivery of viable fetus in abdominal pregnancy 1 0.2
- Other specified assisted single delivery 2 0.4
- Assisted single delivery, unspecified 1 0.2

Multiple delivery 3 0.6

- Multiple delivery, all spontaneous 1 0.2
- Multiple delivery, all by caesarean section 1 0.2
- Other multiple delivery 1 0.2

Complications specific to multiple gestation 4 0.8

- Continuing pregnancy after intrauterine death of one fetus or more 1 0.2
- Other complications specific to multiple gestation 3 0.6

Complications of anaesthesia during the puerperium 3 0.6

- Spinal and epidural anaesthesia-induced headache during the puerperium 3 0.6

Annex 9: Monitoring Framework

Indicator	Purpose	Numerator	Denominator	Source of information	Frequency of data collection, target
Input/Process					
national Coordination mechanism established and human resources		Staffs assigned for coordinating CE at MOH			
National CEMPD committee					
National CE committee established and multidisciplinary (OB/GYN, pediatrician, ….others)					
Proportion of planned national CE committee meetings conducted to review the cases	Measures the practice to perform reviews	Number of planned national CE committee meetings conducted	Number of planned national CE committee meetings	Minutes of CE committee meetings, scheduled of planned meetings	At least quarterly, 100%
Process					
Number of Topic selected for review					
Proportion of maternal & perinatal deaths identified for review based on the topic	Measures the performance of the CE system	Number of maternal & perinatal deaths identified for review that were reported from pilot sites to the EPHI/MoH through MPDSR / PHEM system	Number of maternal & perinatal deaths reported from Pilot sites through MPDSR / PHEM system	PHEM Data base,	Annually, 100%

Proportion of maternal near misses identified for review based on the topic	Measures the performance of the CE system	Number of maternal near misses identified for review that were reported from pilot sites to the EPHI/MoH through MPDSR / PHEM system	Number of maternal near misses reported from Pilot sites through MPDSR / PHEM system		Annually, 100%
Proportion of maternal perinatal deaths case Summary produced and checked for completeness					
Proportion of maternal perinatal deaths reviewed by CE committee	Measures the performance of the CE system	Number of maternal & perinatal deaths reviewed by CE committee	Number of maternal & perinatal deaths identified for review	PHEM Data base,	Annually, 100%
Recommendations & Implementation					
Proportion of SMART recommendations formulated based on findings from death reviews a and provided or fed back to the MOH/EPHI/ Facility	Measures the response and implementation of recommendations	Number of recommendations formulated and provided at National/site level	Number of recommendations formulated and provided at National/site level		
Proportion of recommendations implemented at the national level/site level at desired timeframe	Measures the response and implementation of recommendations	Number of recommendations implemented at the national level/ site level	Number of recommendations reported at the national level / site level	Supervision & Observation of Implementation plans and records	At least quarterly, #% Semi-annually, #%

Evidence of integration of recommendations within annual health plans, strategies and packages	Measures integration of recommendations at the national level and coordination of health systems and policies	Recommendations included in annual health plans and health-system packages	n/a	Annual health plans, strategies and packages	Annually, yes
Proportion of recommendations implemented achieved the desired results					
Proportion of maternal near misses reviewed by CE committee	Measures the performance of the CE system	Number of maternal near misses reviewed by CE committee	Number of maternal near misses identified for review	PHEM Data base,	Annually, 100%
Annual report developed					
Completion of national annual confidential enquiries into maternal and perinatal deaths report	Measures production and dissemination of confidential enquiries data and implementation of recommendations	Annual report developed and published including performance of the CEMPD programme, description of implementation of recommendations, and follow up on recommendations		Annual report	Annually, yes
Review meeting					
Policy brie prepared and disseminated					
IMPACT					
Institutional maternal mortality ratio					
Institutional perinatal mortality rate specific to the pilot site					

Maternal mortality ratio					
Perinatal mortality rate					
Maternal deaths by cause (ICD-MM)					
Perinatal deaths by cause (ICD-PM)					

Annex 10: Standard Operating procedures for Medical Record / Chart retrieving process

I. Purpose of the SOPs

- The Ministry of Health Maternal and Child Health Directorate has launched the national Confidential Enquiry into Maternal and Perinatal Mortality and Morbidity (CE-MPMM) in November 2022.
- According to the national implementation guideline, CE Review Protocol chart retrieval is one of the steps in the CE review process. It can be done in two ways: passively and actively. Passive chart retrieval refers to getting the medical records of the selected cases for an in-depth review and sending them to the national or regional level CE coordinators, while active chart retrieval is when retrievers are assigned to facilitate the process of retrieval by supporting in person the facility and zonal CE focal persons as well as facility management. However, the national review protocol doesn`t provide detailed steps to be followed by retrievers during the retrieval. Hence, having a detailed guide is deemed necessary to ensure a standardized implementation of the process at all sites.
- This SOP is intended to be used by those engaged in the chart retrieval process for CE, including the facility and ZHD CE focal person/coordinator and facility CE focal person.

II. Steps for chart retrieval process

A. Active chart retrieval approach

1, Step 1: Select health facilities for chart retrieval based on the following criteria:

1.1. Health facilities are selected for active chart retrieval purposefully in cases of the following

- If the team felt that there would be a delay based on the facility reporting trend,
- If there is a need for secondary retrieval of documents for the review (e.g., evidence from a referring facility, which can be a health center or hospital),

1.2. Communicating with the national MPDSR team at EPHI

1.3. The MOH and MCHD provide the required sample of cases from each facility to EPHI and receive a code.

1.4. Data collectors receive the case code from MOH and MCHD.

1.5. Prepare a line listing of selected cases from the database, consisting of the following information (Annex 1).

1.6. Assigning IDs for the selected cases and facilities using a line-listing format

2. Step 2: Preparation for travelling to the site

2.1. Get orientation on the process of retrieval at the facility level.

2.2. Collect a support letter before leaving the site.

2.3. Arrange logistics (transportation means per diem) and formats (minute template, chart registration form, line listing form).

2.4. Before traveling to the site, contact the CE focal persons of the selected facilities and their respective

2.5. Prepare fluid for anonymization: we should prepare "do you think the institution can have this?".

2.6. Contact the zonal health department to inform and agree on the schedule prepared for the facility visit for retrieval- not clear

2.7. Travel to the site and get to the facility in time on the agreed-upon day.

3, retrieving chart at the facility

3.1. Arrange and conduct a briefing meeting with the facility management team

- Conduct a briefing meeting in the presence of at least the Medical Director/CEO and Matron, the CE focal person of the facility and the respective zonal health department, and any other person whom the facility management wants to participate in.
- Start with acknowledgment for their time, introduce yourself, and hand over the support letter (the original one).
- Explain the general overview of the purpose and process of the national CE MPMM program ;
- Present also the topic selected for the current national CE review and its purpose (reasons); the selected facilities for the review at the national level: and timelines.
- Present the general MPDSR reporting status of the facility (number and type of cases that have been reported from the facility by year) and the cases selected for the current review and why they were selected. hand over a copy of the line-listing of the reported cases (MDRF/ PDRF) from the facility.
- Take note of key points of the discussion: any questions or concerns raised and agreement reached; this will be summarized in the checklist (Annex 1) and minutes (Annex 3: Minute template).
- Once you have reached an agreement or created rapport, then request the assignment of someone from the facility to facilitate the process of retrieval from the record section (if the CE facility focal person is present, that is sufficient); let the head write his or her decision and order on the copy of the support letter.
- End the briefing session by reminding the head that there will be a debriefing session and letting

him/her decide the date and time for debriefing. Explain that it is during this session that anonymization will be done, a non-disclosure form will be signed, and minutes about the whole process will be approved and signed by all those who participated in the process of retrieval.

- Get information about the identification of the selected cases (name, address, date admitted, date of death) from copies of the case notification and/or MDRF that were filled out at the facility by the MPDSR focal person, and then prepare a list of the selected cases.

- Together with the focal person/assigned person and the zonal focal person, go to the facility record/card room (let them communicate with the responsible person in the room) and submit a copy of the support letter on which the head approved the request and the list of cases whose charts are required to be retrieved.

- Give time for the process (e.g., a half day) and agree when you come back to collect the charts.

- Back to the card room at the time of the appointment and collect the charts.

3.2. Do a quick review of the charts

- Before taking the charts, rapidly look into the charts to assess their completeness and availability in various forms (lab result, operation note, etc.). It would be good to discuss when to drop the chart.

- Let the facility focal person keep the retrieved charts.

- Document on the chart registration form whether all charts of the selected cases were retrieved or not and the status of their completeness, as well as those newly added cases due to either their absence or poor quality (fill out the form in two copies). (Annex 2)

3.3. Retrieve charts from recent to oldest cases in terms of their occurrence

- Based on the line listing, retrieve charts starting from the most recent case and go backward in time until you reach the sample size allocated for the specific facility.

- If the chart of the first case couldn`t be obtained or its completeness is below 30%, then proceed to the next recent case, and so on.

3.4. Finalize your work by having a debriefing meeting with the facility management

- Start the session by thanking them for their time and support. Report what has been performed since the first day of the meeting (the number of charts that could be retrieved; if you have made any changes, e.g., replacing the case because of incompleteness or the missing chart of the initially selected cases).

- Submit a copy of the chart registration form to the head, and retain one copy to be submitted to the national CE coordinator.

- Anonymize the retrieved charts using correction fluid according to the guidelines.

- Scan or copy two copies of all the content of the chart and ensure its illegibility and anonymity are complete.

- Get signed non-disclosure agreement forms from all who participated in the process.

- Complete the minute template in two copies with carbon and get it signed by all; give the original to the facility head to be filled, and retain the other copy to be submitted to the national or regional CE coordinator.

4, Submission of retrieved charts

- Prepare a short report of the field work.

- Organize the copies of the retrieved chart by the ID provided on the line listing form.

- Submit copies of the charts (soft copies if they are scanned), the chart registration form, and copies of the minutes to the national CE coordinator within twoworking days after the end of the field-work.

B. Passive chart retrieval approach

Step 1. Select a health facility for passive chart retrieval if the following situations are fulfilled:

- Health facilities whose management and focal person had taken program orientation at the national level.

- Health facilities with proactive and enthusiastic management members.

- Health facilities that have a good working relationship with the Ministry, or RHBs.

- Health facilities that are accessible for telephone communication and data collection

Please follow similar steps under active chart retrieval as described in the previous section.

Step 2: preparation and retrieval will follow similar steps described for active retrieval (see the previous section).

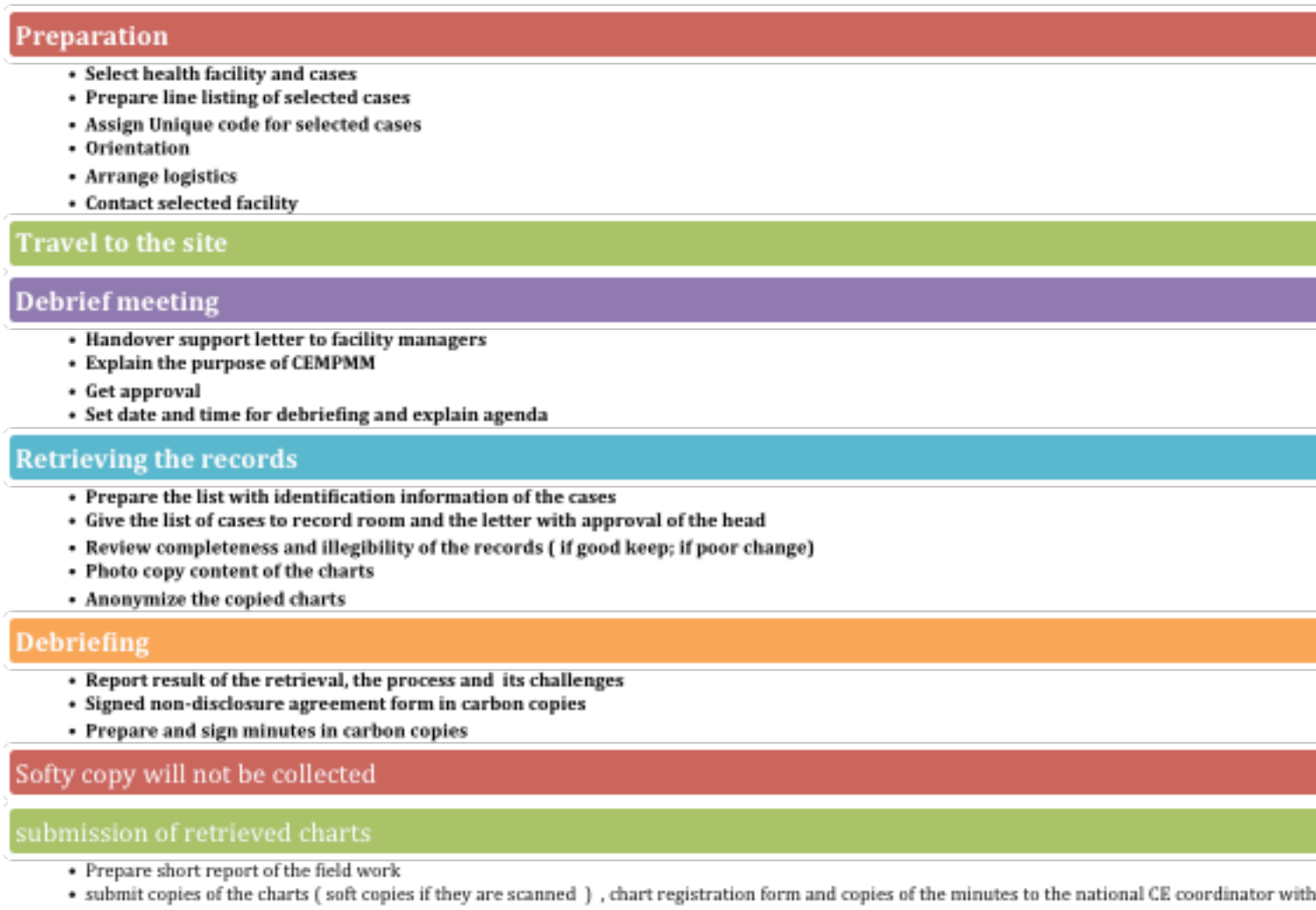


Figure : Summary work flow for chart retrieval process

Annex 11. Standard Operating Procedures for Case Review and Data Analysis

I. Types for case review

There are three steps of case review adopted for CE-MPDMR system:

Individual case review

Under this stage, each reviewer will review the medical chart allocated to him/her based on the protocol and complete DAF, review questions, checklist, and review summary form.

Paired case review

This is achieved by allocating a minimum of two reviewers for each case to be reviewed.

Joint case review

This is performed by organizing a joint review panel meeting and a three- to five-day workshop. In this meeting, all reviewers are expected to present their findings on the cases assigned. The panel of joint reviewers will discuss the assessment results, provide comments, and reach consensus. Furthermore, in situations where agreement can't be reached, the panel will decide whether the case should be reviewed by a third reviewer as a tiebreaker. II. steps for case review and data analysis

The focus of the assessment is twofold: first, to identify those aspects of care where improvements are required; and second, to identify good practices and provide examples of excellent working across the care continuum.

Step 1: Reflect on the care using review questions

To support the assessment of the quality of specific aspects of care for each element of the care to be reviewed, a checklist consisting of questions for review is designed based on national standards and/or guidelines. The reviewers reflect on and make 'judgements' about the care provided using this checklist. For detailed standards and corresponding possible questions for reviewing each component of preventive and clinical care for both routine and emergency obstetric and neonatal care

Step 2: Identify issues with care and contributory factors

Each aspect of care along the continuum of maternity service issues is identified. Issues with care are identified by identifying instances where appropriate care has not been provided and comparing them with the standards of care according to the national guidelines and clinical protocol. For example, if a woman was eligible for blood transfusion and this was not offered or a risk factor for PPH was not identified and responded to, then an 'issue' with care will be generated. At the end of each review, the issues generated within that review are presented as a list.

Step 3. Grading of care

Grading was done at two levels: for the provision of care at each component of maternity care and for overall care provision. This is because the basis of the allocation of the grade of quality of care may be based on one aspect alone, so an improvement in care might be identified for a case that had excellent care throughout the continuum of care except for one element. Alternatively, a case may have had poor care during ANC, delivery, and the immediate postpartum period, affecting the outcome. In contrast, a case may have had several aspects of care quality that did not affect the outcome but may have required improvement not specifically for the management of similar causes but for others as well.

NB: The evaluation of the optimality of the care across the continuum of maternity care is done in relation to the national guidelines:

a) Grading for each aspect of care to be reviewed:

Issues with each aspect of the care provided to the mother were evaluated with respect to the quality of care provision as follows:

The current standards and guidelines for good practice are used as references when evaluating the care provision from the case notes allocated.

It is not possible to grade the presence or absence of good clinical practice markers in isolation. The markers of good clinical care set out below need to be graded within the clinical context of each individual case. What might not have influenced the outcome in one case might well do so in another. How each is graded will depend on the assessor's clinical interpretation of how the various aspects of care were delivered in relation to the circumstances of the particular case being reviewed.

Grade	Description	Factors to consider and examples
0	none - good quality care identified (comply with national guideline, implement more than expected actions)	If the care was provided according to the national guidelines and within the scope of care permitted for the provider or the facility
1	minor - minor issues with the quality of care identified;	If the care was provided according to the guidelines within its scope but the death was unavoidable because of reasons that were beyond the scope of the provider or facility ; for example *- delayed arrival of the patient in critical conditions (death on arrival);* *- if the needed care is not available at the facility either because of the scope of care or lack of facilities/equipment that require huge investment (e.g., not being able to do laparotomy because of lack of OR equipment) ;* *- if the contribution of the care that was failed to be provided is so minimal in changing the outcome (saving the particular woman`s life/halting the progress of the morbid condition).* *- due to policy related issues*
2	significant - significant issues with the quality of care identified;	In cases where different management or care may have changed the outcome .This is mainly due to issues related to the organization of care and/or health system related issues such as *-lack of readiness of the facility in terms of supplies (blood, fluids, medications), and human resources;* *-delay in referring due to lack of transportation/ambulance;* *-not able to assess the care because of either poorly documented/recorded information or totally absent relevant information in the medical charts ;* *-lack of guidelines/job aids etc.* *-Poor management support/working environment (e.g lack of electricity/light in OR*

3	major - major issues with the quality of care identified.	In cases where a different management could have changed the outcome (save the woman): this is usually if the problem with the provision of the care is due to issues related to the provider/team that is responsible for the care delivery; for example: *-not providing care according to the national guidelines, clinical protocols, or best practices (with a clear deviation) ;* *-absence of providers from the workplace or duty time* *-managing cases beyond their scope;* *-clear delay of the providers in assessing , attending or acting (not consulting timely; failing to inform /alert all responsible body about the condition or situations of the patient, etc.)*

b) Summary grading of the quality of care reviewed for each case:

A summary grade is provided about the quality of care provision for each case, identifying whether factors could have affected the outcome for the mother. A four level-grading of care (adapted from standard criteria adapted by all enquiries from MBRRACE-UK/PMRT) was used to summarize the assessment of the overall quality of care for each case as follows:

Overall grade of quality of care

1: Good care; no improvements identified overall grade.

2: Improvements in care* were identified that would have made no difference to the outcome.

3: Improvements in care* identified that may have made a difference to the outcome.

Step 4: Determine the relevance of the care issue to the outcome

The review team is then selected for each issue the factor(s) contributing to the failure to provide appropriate care, using the adopted framework from the National Patient Safety Agency Contributory Factors Framework [4]. Following the assignment of contributory factors, the review team is then asked to consider the contribution of each issue, in turn, to the outcome using the following scale: An issue can be:

Relevance of the grade of care to the outcome:

0: Not relevant

1: Possibly relevant

2: Probably relevant

3: Almost certainly relevant

An example of an issue that was not relevant to the outcome but for which action is needed is when a mother met the criteria for screening for diabetes mellitus but was not offered screening. While the baby died from a cause unrelated to diabetes, system-level action is nevertheless required to ensure that, in the future, all eligible women are offered gestational diabetes screening.

Step 5: Identify recommendations for improvement

For each issue that requires action(s), the review team identifies actions that focus on the system rather than individual members of staff to improve care in the future. All the actions for all the issues are then combined into an action plan. A key responsible individual for each recommended action and a timeline are added.

Annex 12. Procedure for Chart Allocation Process

1. Steps for allocating the retrieved charts to the national reviewer

i. Prepare an overall line list and provide a serial number, according to the order of the death occurrences, for the retrieved charts (e.g., 1, 2, 3, etc.).

ii. Assign a code for each retrieved chart based on the national MPDSR coding procedure;

- first 3 letters of the name of the region
- first 3 letters of the name of the zone or sub-city first 3 letters of the name of the woreda
- first 3 letters of the name of the hospital or health center
- serial number of the chart or the month and year of death occurrence

iii. Check the availability of the national reviewers (by phone or email).

iv. Allocate the charts to available reviewers using the chart allocation registration form.

Chart allocation registration form

SN	Reviewer name	Code of Chart allocated (3 to 5 charts /re-viewers)
Pair 1	Reviewer a: (e.g. Dr. Brihanu	A=
	Reviewer b ((e.g. Dr Tizita)	B C D E
Pair 2	Reviewer c	F
	Reviewer d	G H I J
Pair 3	Reviewer	

v. 5. Photocopy each into two or scan the copies.

vi. 6. Deliver the hardcopies to the reviewers manually or send emails through password-protected folders.

2, Steps for reviewing process

Check the national guidelines / and review protocol

3. Schedule for review process

Activities	Responsible	Timeline
Secondary anonymizations	MH Team	
Allocation of charts		
Prepare total line list	National coordinator and MH coordinator	
Assign code	>>	
Copy /scan	>>	
Allocate charts to available Reviewers		
Send the allocated charts to reviewers		
Individual review using the procedure in the national guideline	Individual national reviewer	
Submit the summary of the finding and recommendations to National coordinator	>>	
Pair and joint review	Pair and Joint review	

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