Beyond the Numbers

Reviewing maternal deaths and complications to make pregnancy safer

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Acknowledgements

The impetus for this document arose during a series of inter-regional meetings on monitoring maternal mortality organised by WHO Headquarters and Regional Offices during 1998 and 1999. At these meetings, participants stressed that measuring the levels of maternal mortality was not enough and called for methods and approaches that would help elucidate the underlying causes of maternal deaths and identify what could be done to avert them. *Beyond the numbers* is a response to such calls.

Many talented and committed individuals have contributed to *Beyond the numbers.* Authors of specific approaches, named in each relevant chapter, are Cynthia Berg, Colin Bullough, Jean-François Etard, Veronique Filippi, Wendy Graham, Gwyneth Lewis, Carine Ronsmans and Gijs Walraven.

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Foreword

Pregnancy is a normal, healthy state which most women aspire to at some point in their lives. Yet this normal, life-affirming process carries with it serious risks of death and disability. The statement that worldwide, over half a million young women die every year as a result of complications arising from pregnancy and childbirth has been repeated so often that it no longer shocks. Yet most of these deaths could be avoided if preventive measures were taken and adequate care available. For every woman who dies, many more suffer from serious conditions that can affect them for the rest of their lives.

The international health and development community has repeatedly called for action to address this problem and governments have formally committed themselves to doing so, notably at the *International Conference on Population and Development* (Cairo 1994) and the *Fourth World Conference on Women* (Beijing 1995) as well as their respective five-year follow up conferences, and more recently in the *Millennium Declaration* in 2000. Improvement of maternal health is enshrined in the Millennium Development Goals as one of the essential prerequisites for development and for poverty reduction.

Maternal mortality offers a litmus test of the status of women, their access to health care, and the adequacy of the health care system in responding to their needs. However, it is difficult to measure, particularly where civil registration of deaths and of causes of deaths is weak. Different approaches have been developed for measuring maternal mortality in such circumstances but they are of limited use for regular, short-term monitoring.

Furthermore, the information that countries need to address maternal mortality goes beyond just measuring the level of the problem. Policy-makers ask "Why do maternal deaths occur and what can be done to prevent them?" Programme managers ask "Where are things going wrong and what can be done to rectify them?" Answering these questions is as important as knowing the precise level of maternal mortality. *Beyond the numbers* proposes ways of finding the answers to such questions and offers diagnostic tools that shed light on what needs to be done to prevent maternal deaths. We hope that all those working in the area of maternal health will find this document useful.

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Preface

"Whose faces are behind the numbers?
What were their stories? What were their dreams?
They left behind children and families.
They also left behind clues as to why their lives ended early".[1]

Key messages of this guide

Avoiding maternal deaths is possible, even in resource-poor countries, but it requires the right kind of information on which to base programmes.

Knowing the level of maternal mortality is not enough; we need to understand the underlying factors that led to the deaths.

Each maternal death or case of life-threatening complication has a story to tell and can provide indications on practical ways of addressing the problem.

A commitment to act upon the findings of these reviews is a key prerequisite for success.

What is this guide about?

Every year some eight million women suffer pregnancy-related complications and over half a million die. In developing countries, one woman in 16 may die of pregnancy-related complications compared to one in 2800 in developed countries.

Most of these deaths can be averted even where resources are limited but, in order to do so, the right kind of information is needed upon which to base actions. Knowing the statistics on levels of maternal mortality is not enough—we need information that helps us identify what can be done to prevent such unnecessary deaths.

Beyond the numbers presents ways of generating this kind of information. The approaches described go beyond just counting deaths to developing an understanding of why they happened and how they can be averted. For example, are women dying because:

- they are unaware of the need for care, or unaware of the warning signs of problems in pregnancy?

or

1 Berg C et al. (Eds). *Strategies to reduce pregnancy-related deaths: from identification and review to action*. Atlanta, GA, Centers for Disease Control and Prevention, 2001.

- the services do not exist, or are inaccessible for other reasons, such as distance, cost or sociocultural barriers?

or

- the care they receive is inadequate or actually harmful?

Experience in the use of these approaches from around the world has shown that successful implementation can take place at all levels, from an individual health care facility up to the national level.

A fundamental principle of these approaches is the importance of a confidential, usually anonymous, non-threatening environment in which to describe and analyse the factors leading to adverse maternal outcomes. Ensuring confidentiality leads to an openness in reporting which provides a more complete picture of the precise sequence of events.

Participants, including health care and community workers and family members, should be assured that the sole purpose is to learn from past tragedies and save lives in the future—not to apportion blame. These reviews seek only to identify failures in the health care system. They must never be used to provide the basis for litigation, management sanctions or blame.

These approaches can be used to review a range of aspects of health care, including structures, outcomes, or processes. In *Beyond the numbers*, we describe reviews of two specific health outcomes (maternal deaths and life-threatening complications or near misses) and one kind of process (clinical care). Reviews can be conducted at the community, health care facility, district or national level. Not all locations are best suited to reviewing all three types of issue. For example, reviewing clinical practice is only feasible at the facility level. It is unlikely to be possible to review severe complications at the community level because of the complexity of applying a standard and unambiguous definition of "near miss". However, maternal deaths can be reviewed at any level.

Who is this guide for?

Beyond the numbers is directed at health professionals, health care planners and managers working in the area of maternal and newborn health who are striving to improve the quality of care provided. They should be in a position and willing to take remedial action based on the findings of these reviews and should use the information collected to help improve maternal health outcomes. This can be done through empowering health professionals to critically evaluate current practices and change them, if necessary. Because action is the ultimate goal of these reviews it is important that those with the ability to implement the recommended changes actively participate in the process.

What is the structure of this guide?

This guide presents five approaches to generating information on maternal outcomes or on maternal health care.

Chapters 1 and 2 present introductory materials and brief descriptions of each approach, along with a summary of advantages and disadvantages.

Chapter 3 describes underlying principles for implementation and key practical issues which are generally applicable to all of these approaches.

Chapters 4, 5 and 6 focus on learning from maternal deaths in different settings, through community-based case reviews (verbal autopsy), facility-based case reviews and confidential enquiries.

Chapter 7 examines the possibility of reviewing severe maternal morbidity and "near misses" rather than maternal deaths.

Chapter 8 describes clinical audit, which focuses on examining the content and quality of care for specific clinical conditions measured against explicit criteria or standards rather than analysing outcomes in terms of maternal death.

Before deciding which approach may be most appropriate for a particular setting and the available resources, users of this guide are encouraged to read the entire volume, paying special attention to addressing the issues raised in Chapters 2 and 3.

A separate CD-ROM consists of sample data collection and analysis forms to serve as a basis for local adaptation.

Summary of approaches described in this guide

Name	Operational definition	Prerequisites
Community-based maternal death reviews (verbal autopsies)	A method of finding out the medical causes of death and ascertaining the personal, family or community factors that may have contributed to the deaths in women who died outside of a medical facility.	Requires co-operation from the family of the woman who died and sensitivity is needed in discussing the circumstances of the death.
Facility-based maternal deaths review	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 contributed to the death, and which ones were avoidable.	Requires co-operation from those who provided care to the woman who died, and their willingness to report accurately on the management of the case.
Confidential enquiries into maternal deaths	A systematic multi-disciplinary 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.	Requires 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.
Surveys of severe morbidity (near misses)	The identification and assessment of cases in which pregnant women survive obstetric complications. There is no universally applicable definition for such cases and it is important that the definition used in any survey be appropriate to local circumstances to enable local improvements in maternal care.	Requires a good-quality medical record system, a management culture where life-threatening events can be discussed freely without fear of blame, and a commitment from management and clinical staff to act upon findings.
Clinical audit	Clinical audit is a quality-improvement process that seeks to improve patient care and outcomes through systematic review of aspects of the structure, processes, and outcomes of care against explicit criteria and the subsequent implementation of change. Where indicated, changes are implemented at an individual, team or service level and further monitoring is used to confirm improvement in health care delivery.	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.

1 Introduction

Key messages

- ✓ Avoiding maternal deaths is possible, even in resource-poor countries, but it requires the right kind of information on which to base programmes.
- ✓ Knowing the level of maternal mortality is not enough; we need to understand the underlying factors that led to the deaths.
- ✓ Each maternal death or case of life-threatening complication has a story to tell and can provide indications on practical ways of addressing the problem.
- ✓ A commitment to act upon the findings of these reviews is a key prerequisite for success.

1.1 Background

The stark figures of the global burden of pregnancy-related deaths are now so well known that they can be repeated by rote, like mantras, without really stopping to think about what can be done, in even a very small way, to tackle what appears to be such an overwhelming problem. A problem which may appear particularly difficult in the face of the challenging goals and targets which countries have set themselves for the reduction of maternal mortality.[1]

Simply put, the numbers are these: each year, approximately eight million women suffer pregnancy-related complications and over half a million die.[2] In developing countries, one woman in 16 may die of pregnancy-related complications compared to one in 2800 in developed countries. Each death or long-term complication represents an individual tragedy for the woman, her partner, her children and her family. More tragically, most deaths are avoidable. The main causes are known, and more than 80% of maternal deaths could be prevented or avoided through actions that are proven to be effective and affordable, even in the poorer countries of the world. For example, surveys conducted in Egypt[3] and elsewhere have shown that the quality of care provided to the women is a key determinant in maternal outcome and that simple changes in practice can save many lives.

The numbers are stark enough, but they tell only part of the story. In particular, they tell us nothing about the *faces behind the numbers*, the individual stories of suffering and distress and the real underlying reasons why particular women died. Most of all, they tell us nothing about why women continue to die in a world where the knowledge and resources to

prevent such deaths are available or obtainable. While it is important to keep monitoring overall levels of maternal mortality at global, regional and national levels, for both identification and advocacy purposes, simple statistics about the level of maternal mortality do not help us identify what can be done to prevent or avoid such deaths.

Today, with better understanding of the difficulties involved in measuring levels of maternal mortality, there is increasing interest in directing a larger share of limited resources into efforts to understand why the problem persists and what can be done to avert maternal deaths and cases of severe morbidity. Answering these questions is vital for programme planners and service providers. Different strategies and tools have been developed to help find out why mothers die. This document describes the main existing approaches and provides practical guidance on how to generate information that looks *beyond the numbers* to the underlying avoidable causes of maternal death.

1.2 The purpose of this document

The purpose of this document is to help generate information that can be used by health professionals, health care planners and managers to save women's lives by improving the quality of care provided. The approaches described for collecting this information go beyond counting the numbers of cases of death to understanding why they happened and how they can be prevented or avoided. The approaches can be adapted for use in any country and in any setting by anyone with a commitment to safe motherhood. Acting on the results of these studies offers an opportunity for all involved in planning and providing services for pregnant and recently delivered women to make a real and lasting difference to their lives and those of their families and communities.

Ultimately, the findings of the approaches described in this guide will be used by those in a position to act upon them to make changes to improve the provision of health care. However, the approaches themselves can be implemented by safe motherhood advocates or, indeed, by any individual or institution committed to reducing maternal mortality and morbidity. Experience has shown that although the initial implementation is often on a small scale by a few committed individuals, the approaches can subsequently be implemented on a broader scale, even at the national level.

Maternal mortality and safe motherhood committees, as well as all other stakeholders in maternal health such as international agencies, nongovernmental organizations, community groups and health advocates, will also be able to use the information generated from applying these approaches. The results of these studies can have a powerful advocacy role and can also be used by politicians and those in other positions of influence to raise awareness and mobilize resources.

The approaches for investigating maternal deaths described here have been developed mainly for countries where levels of maternal mortality are high.

However, the investigation of maternal deaths is also important in settings where maternal mortality is low. Evidence has shown that, even in such settings, many maternal deaths are the result of substandard care and could be prevented.

1.3 Why mothers die: a new approach

This guide focuses on finding out exactly why mothers die. For example:

Is it because they are unaware of the need for care, or unaware of the warning signs of problems in pregnancy?
or
Is it because the services do not exist, or are inaccessible for other reasons, such as distance, cost or sociocultural barriers?
or
Are women dying because the care they receive is inadequate or actually harmful?

Answering such questions and taking positive action on the results is often more important than knowing the precise level of magnitude of maternal mortality. The approaches described in this guide will enable health professionals and authorities to act on the answers to these and other important questions about why women die during pregnancy and childbirth.

1.4 The importance of "telling the story"

Most of the approaches described in this guide are observational studies which take account of the medical and other factors that led to a woman's death. They provide data on individual cases, which, when aggregated together, can show trends or common factors for which remedial action may be possible. They *tell the story* of how individual women died.

Participating in reviews such as those described here, whether by describing their contribution to the care of a particular woman, extracting information from the case notes or by assessing the case anonymously, is, in and of itself, a health care intervention. Experience has shown that the use of these approaches can have a major impact on those involved. Often, those participating in the review are motivated to change their practice or service delivery, even before the formal publication of the results. These health care workers, who have seen for themselves the benefits from such relatively simple reviews, including the adoption of simple changes in local practice, become advocates for change. They then motivate and enthuse others to undertake similar work and to help spread evidence-based best practice guidance.

Those participating in such reviews also never forget that each woman's death is an individual personal and family tragedy. Nor do they forget she had a unique story to tell. Tracing her path through the community and health care system, and describing the actions that might have prevented her

death has a meaningful personal effect. In the United Kingdom, as long ago as 1954, it was recognized that participating in such a study (in this case a confidential enquiry into maternal deaths) had a "powerful secondary effect" in that "each participant in these enquiries, however experienced he or she may be, and whether his or her work is undertaken in a teaching hospital, a local hospital, in the community or the patient's home must have benefited from their educative effect."[4]

Participating in these studies also builds on the natural altruism of individuals or teams of health care professionals who are prepared to freely give their time and effort in order to learn lessons to help save women's lives. These personal experiences lead to self-reflective learning, which is as valuable a tool for harnessing change as anonymous statistical reporting, perhaps more so.

But perhaps one of the most powerful reasons for such reviews, reported by clinicians and midwives in different countries, is the personal and long-lasting impact the death of a woman known to them has had on their own clinical practice and that of their institution. Most will say that having to seriously evaluate the care given to a particular woman, whose face they can still see and whose grieving family they can still remember, changed their clinical practice and subsequently saved many lives.

A fundamental principle of all the approaches described here is the importance of a confidential, usually anonymous, non-threatening environment in which to describe and analyse the factors leading to individual women's deaths. Ensuring confidentiality leads to an openness in reporting which provides a more complete picture of the precise sequence of events. Participants, including health care and community workers and family members, should be assured that the sole purpose of the study is to save lives and not to apportion blame. A prerequisite, therefore, is that strict confidentiality and anonymity must be maintained. These reviews seek only to identify failures in the health care system, not to provide the basis for litigation, management sanctions or blame.

1.5 Learning lessons is a prerequisite for action

Learning lessons and acting on the results is the whole purpose of using these approaches. There is no point in committing valuable resources to collecting information that just gathers dust on shelves. The information collected must be used to help improve maternal health outcomes and empower health professionals to examine their current practices or those of the facility in which they work. Because action is the ultimate goal of these reviews, it is important that those with the ability to implement the recommended changes actively participate in the process. It therefore needs to be agreed at the outset that the information obtained will be used as the basis for action.

The results of these reviews will determine what, if any, avoidable or remediable clinical, health system or community-based factors were present in the care provided to the women. The lessons derived will enable health care practitioners and health planners to learn from the errors of the past. They will provide evidence of where the problems are and highlight the areas requiring recommendations for health sector and community action as well as clinical guidelines. The results can form a baseline against which the success of changing practice can be monitored. Therefore, there should be an objective method built into the system to monitor how the recommendations are being implemented. This has two benefits; it provides a stimulus for health sector action and it reminds the study team to be sure that their recommendations are based on firm evidence.

All of the approaches described here will result in recommendations for change. It is important that the recommendations should, particularly in poorer countries, be simple, affordable, effective, and widely disseminated. They should also be evidence-based. Most of the clinical recommendations likely to emerge will be very similar to the evidence-based guidelines for the Integrated Management of Pregnancy and Childbirth (IMPAC)[a] and these could be adapted to local circumstances and introduced swiftly without the need to start developing guidelines from scratch.

References

1 Joint WHO/UNFPA/UNICEF/World Bank statement on reduction of maternal mortality. Geneva, World Health Organization, 1999.

2 WHO/UNICEF/UNFPA, *Maternal mortality in 2000: estimates developed by WHO, UNICEF and UNFPA*. Geneva, World Health Organization, 2004.

3 Kassas M et al., The national maternal mortality study of Egypt 1992-1993, *International Journal of Gynecology and Obstetrics* 1995; 50 (Sup. 2):S101-S108.

4 Walker AL et al., Report on confidential enquiries into maternal deaths in England and Wales, 1952-1954. London, HMSO, 1957 (Reports on public health and medical subjects No. 97).

[a] IMPAC is a comprehensive set of norms, standards and tools that can be adapted and applied at the national and district levels to support country efforts to reduce maternal and perinatal morbidity and mortality. Available from the Department of Reproductive Health and Research, World Health Organization, Geneva. Consult web site http://www.who.int/reproductive-health for further information.

2 The approaches

Key messages

- ✓ The approaches described in this document can be used to study maternal deaths, cases of severe morbidity and clinical practice.
- ✓ The objective of all these approaches is to reduce maternal and neonatal mortality and morbidity by improving the quality of care provided.
- ✓ These approaches can be used at community, health care facility or at regional or national level.
- ✓ Different approaches are appropriate for different circumstances or levels of implementation and to review different outcomes.

2.1 Introduction

The approaches described in this document can be used for reviewing a wide range of aspects of health care, including structures, outcomes, or processes. In this document, we describe the use of the approaches for two specific health outcomes (maternal deaths and women who survive life-threatening complications) and for one kind of process (clinical care). However, it is important to be aware that audits and case reviews can also be used for reviewing other outcomes (such as perinatal outcomes or assisted deliveries), other processes (such as patient satisfaction), or structures (such as availability of facilities or equipment). The general principles will be the same, whatever the topic reviewed.

This chapter provides a summary definition of each methodology and presents considerations relevant to identifying the cases that will be reviewed. It describes some of the key differences between the different approaches and essential prerequisites that need to be in place before a specific approach can be considered. Finally, it provides a summary of each approach along with its major advantages and disadvantages. Using this information should help when choosing the most appropriate technique to adopt for a particular situation. Chapter 3 describes the practical issues that then need to be considered when planning and implementing the methodology.

2.2 Deciding which approach to use

Deciding which of the approaches described in this document to use is influenced by two considerations, namely, which level is appropriate for the review, and what kind of cases will be studied. In terms of level, there are

essentially five options—the review can be conducted at the community, health care facility, district, regional or national level. In choosing which cases to study, a decision needs to be taken whether these will be outcomes or processes. Not all locations are suited to reviewing all types of cases. For example, reviewing clinical practice is, for resource-poor countries, feasible at the facility level but would not be possible at the community level. On the other hand, both outcome and process are amenable to review at the facility level. It is unlikely to be possible to review severe complications at the community level because of the complexity of applying a standard and unambiguous definition of near-miss. Box 2.1 summarizes the different possibilities.

Box 2.1—Different approaches at different levels and for different topics

Outcome / Level	Maternal deaths	Severe complications	Clinical practice
Community	Verbal autopsy (Community-based death reviews)	No	No
Facility	Facility-based deaths review	Case review of near-misses	Local clinical audit
National/ regional/ district	Confidential enquiry into maternal deaths	Confidential enquiry into near-misses	National clinical audit

It is commonly assumed that the best outcome to review is maternal death. While it is true that this is the most dramatic adverse outcome, it is not necessarily always the most statistically appropriate. An important consideration relates to the number of events that will need to be studied, which is a function of the prevailing level of maternal mortality and the number of births in that setting, be it in a facility or a community. Table 2.1 shows the numbers of maternal deaths that can be anticipated at different levels of maternal mortality and births.

Table 2.1 Expected number of maternal deaths per year

Annual births in the facility or community	Expected annual maternal deaths for a given maternal mortality ratio (MMR—maternal deaths per 100 000 live births) and annual births			
	MMR 200	MMR 400	MMR 600	MMR 800
260	0.5	1.0	1.6	2.1
520	1.0	2.1	3.1	4.2
1300	2.6	5.2	7.8	10.4
2600	5.2	10.4	15.6	20.8
5200	10.4	20.8	31.2	41.6

Before deciding whether or not to use maternal deaths as the outcome for review, it is important to consider how many maternal deaths are likely to occur in a given setting. Too large a number will result in an unmanageable and cumbersome process and require an expenditure of time and resources that may be too large, although it is also possible to focus the review on the leading causes of death only. On the other hand, too small a number of maternal deaths will limit the applicability of the results. While there is certainly something to be learned from every death studied, it is more helpful to be able to review a series of deaths that will permit a more analytical study of causes, determinants and avoidable factors. In an individual facility, it is reasonable to review between at least 10 and 20 deaths in a given period. At the district level, it should be possible to review larger numbers of deaths drawn from a representative selection of facilities. At the national level, the numbers of deaths reviewed can be even greater.

However, where levels of maternal mortality and numbers of births are high, and there are correspondingly very large numbers of maternal deaths available for review, it is often advisable to draw upon a representative sample for in-depth review rather than attempt to study them all. Case selection can be by district or by facility, though care must be taken to ensure that the sample selected is indeed representative of the population as a whole. In settings where there are very few maternal deaths, it may be necessary to accumulate reports over a period of years in order to draw some general conclusions. In these circumstances, it is often more helpful to use alternative outcomes for study, such as near-misses or infant outcomes.

2.3 Advantages and disadvantages of different approaches

This guide presents five approaches to generating information on maternal outcomes or on maternal health care. They are presented in ascending order with regard to the level at which the review is undertaken, starting with the community and facility and going on to the regional or national level. Three approaches focus on studying maternal deaths, namely, verbal autopsy (community-based case reviews), facility-based deaths review and confidential enquiries (Chapters 4, 5 and 6). Chapter 7 examines the possibility of reviewing cases where women survived serious obstetric complications (severe morbidity) rather than maternal deaths. In fact, cases of severe morbidity can be taken as the outcome of interest in a facility-based case review, a confidential enquiry or as the subject of clinical audit. Chapter 8 describes the clinical audit process, which focuses on examining the content and quality of care provided for women with specific clinical conditions assessed against explicit criteria or standards rather than analysing outcomes in terms of maternal death. Tables 2.2 through 2.5 provide the operational definitions for each of the approaches presented in Chapters 4 through 8, as well as the advantages and disadvantages associated with each. Chapter 3 describes underlying principles for implementation and key practical issues which are generally applicable to all of these approaches.

2.4 Principles for adaptation

A step-by-step description of how to undertake or adapt the specific techniques is contained in the individual chapters relating to each approach. The step-by-step processes will not be directly applicable in all countries and facilities, and readers must therefore adapt the methodology according to their own resources and requirements. Variations on modifying the approach to suit specific circumstances are discussed in each chapter and the overarching principles are identified in Chapter 3. The CD-ROM available with *Beyond the numbers* contains specific questionnaires and other tools that have already been developed and used in a number of settings for many of these approaches and which can be freely adapted and used by those wishing to undertake such studies.

Table 2.2 Definition, advantages and disadvantages of community-based maternal death reviews (verbal autopsies) as presented in Chapter 4

Community-based maternal death review (verbal autopsy)

Operational definition: A method of finding out the medical causes of death and ascertaining the personal, family or community factors that may have contributed to the deaths in 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, neighbours and traditional birth attendants.

It may also be used to identify contributing factors for deaths occurring within a health care facility.

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	Disadvantages
In settings where the majority of women die at home, verbal autopsy provides a means to arrive at 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 the family's and the community's opinion on the access to and the quality of health services, in efforts to improve maternal health services.	Medical causes obtained from verbal autopsies are not perfect, and different assessors may arrive at different medical causes. The assignment of avoidable factors largely remains a matter of subjective judgement and depends on a large number of elements. Causes of death obtained from lay informers are not always in accord 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.

Table 2.3 Definition, advantages and disadvantages of facility-based maternal deaths review as presented in Chapter 5

Facility-based maternal deaths 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	Disadvantages
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.	Facility-based maternal deaths 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 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.	The review requires committed and skilled individuals at the facility to drive the process and to follow through on any recommendations.
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.	Maternal deaths reviews provide no information on deaths that occur in the community.
The review process provides good learning experiences for all grades of staff.	Hospital managers and administrators must be supportive, in particular allowing staff to follow up the community aspects of these cases by providing either transport or funds for public transport.
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.	There may be difficulty in tracing the dead woman's family in the community, sometimes because the death resulted in them moving.

Table 2.4 Definition, advantages and disadvantages of confidential enquiries into maternal deaths as presented in Chapter 6

Confidential enquiries into maternal deaths

Operational definition: a systematic multidisciplinary anonymous investigation of all or a representative sample of maternal deaths occurring at an area, regional (state) or national level which identifies the numbers, causes and avoidable or remediable factors associated with them. Through the lessons learnt 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	Disadvantages
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.	The confidential enquiry provides information on maternal deaths (numerator data) only. It does not provide information about the characteristics of all women giving birth.
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.	Where maternal mortality is high and populations are large, there may be a large number of maternal deaths, making the analysis of cases complex and time-consuming. This can be addressed by taking a representative sample of deaths for in-depth review.
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 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.
The aim of an enquiry is to learn lessons for the future, and the results can be widely disseminated for public use by a number of groups.	A confidential enquiry requires commitment from all participants and may be resource-intensive.
The commitment of the government is indicated by the involvement of the regional or national health departments. This should lead to close cooperation between the policy-makers 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 in-depth investigation.	

Table 2.5 Definition, advantages and disadvantages of surveys of severe morbidity as presented in Chapter 7

Surveys of severe morbidity

Operational definition: The West Africa Near-Miss Audit Network uses the following 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), in whom 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	Disadvantages
Cases of severe morbidity occur in larger numbers than deaths, allowing quantification of avoidable factors.	Cases of severe morbidity can usually only be identified in health facilities.
The study of women who have survived life-threatening complications may be less threatening to health providers than the study of deaths.	Identifying cases of severe maternal morbidity requires sophisticated tools and clear definitions.
It is possible to interview the woman herself in addition to a proxy, such as a member of the family.	Defining life-threatening severe obstetric morbidity is not straightforward and requires a concerted effort by all the providers involved in the review process.
Reviewing cases of severe morbidity can provide useful complementary insights into quality of care.	Case ascertainment may require reviewing a large number of registers and case notes in each hospital.
The likelihood of preventable life-threatening events recurring and resulting in a death could be greatly reduced if addressed adequately through audit recommendations.	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 particular type of 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.

Table 2.6 Definition, advantages and disadvantages of criterion-based clinical audit as presented in Chapter 8

Clinical audit

Operational definition: Clinical audit is "*a quality improvement process that seeks to improve patient care and outcomes by 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 willing to envisage the application of revised protocols for care.

Advantages	Disadvantages
The participatory element of clinical audit provides an effective mechanism for bringing about improvements in care.	Clinical audit is limited to the clinical care in the facility in which it is carried out and cannot deal with community issues.
It is an excellent educational tool and, when properly carried out, is nonpunitive.	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.
It provides direct feedback to facility staff on practice and performance, and the participatory process enables them to help identify realistic means for improvement.	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.
It can be initiated locally and results in the production of locally relevant and immediately actionable information.	Audit requires that an appropriate set of criteria be available or that local criteria be developed.
It can be less expensive than other forms of audit, as nonmedical personnel are capable of doing the necessary data extraction.	Nonmedical audit assistants (usually records staff) must be available to find patient records and undertake the extraction of information.
It provides a structured framework for gathering information and involves less subjective assessment of case management than in facility-based deaths reviews or confidential enquiries, for example.	There must be a willingness to close the audit loop with at least one further round of reviewing practice.
The audit process can help to highlight deficiencies, in both recording in-patient records and record storage.	

3 Practical issues in implementing the approaches

Gwyneth Lewis, Cynthia Berg

Key messages

- ✓ All the approaches proposed in this guide are founded on common principles, but also have their own specific objectives and requirements.
- ✓ The purpose of these approaches is to stimulate action to reduce maternal deaths and morbidity. Without anticipating the need for improvements, there is little point in committing scarce and valuable resources to undertake any of these studies.
- ✓ The actions proposed may involve community interventions as well as clinical or health service issues.
- ✓ It is essential that those persons with the ability to promote and effect the necessary changes be involved in the process of study from the start.
- ✓ The quality of the case notes available for study is an important determinant of the information required upon which to base the final recommendations.

3.1 Introduction

All of the approaches described in this guide have a number of key issues and principles in common. The background information contained in this chapter will be of practical relevance in undertaking any of the approaches, and readers are encouraged to refer to this chapter at the planning stage. More specific information appropriate for each particular methodology is given in the relevant chapter. The overarching issues and principles include:

- General information requirements
- The surveillance cycle
- Deciding which approach to adopt
- Definitions of maternal death
- Identifying maternal deaths
- Planning and implementing the approach
- Analysing results
- Translating findings into action
- Disseminating findings and recommendations
- Evaluation
- Ensuring confidentiality and the legal and ethical framework

3.2 General information requirements

A number of different types of information and actions are needed to reduce maternal mortality. The information required includes data related to the magnitude of the problem and who is affected by it *(levels/numbers)*, information explaining the factors that directly cause or contribute to the problem and which can lead to the identification of potential solutions *(determinants* and *interventions)*, and information on the basis of which efforts to reduce the problem can be planned, carried out and assessed (*progress*). All these types of information can draw attention to the problem of maternal mortality (*advocacy*). No single data collection tool can provide information to meet all of these needs. This guide suggests which data might be the most helpful in improving quality of care in a particular circumstance.

In considering which methodology to adopt, it is important to identify what types of information on maternal deaths and severe morbidity are already available. Health care planners, managers and professionals have access to multiple sources and types of information that should help to identify strengths and weaknesses in the maternal health care system and which they can use in their planning and management activities. Population-based data such as demographic and health surveys, censuses, and vital registration systems can provide information on the population as a whole, including data on the level of maternal mortality, maternal health coverage, and community knowledge, attitudes and practices. Routine health information activities and systems, facility-based situation analyses, and maternal health needs assessments provide health service-related information such as that on health infrastructure, health resources, and health care practices in facilities.

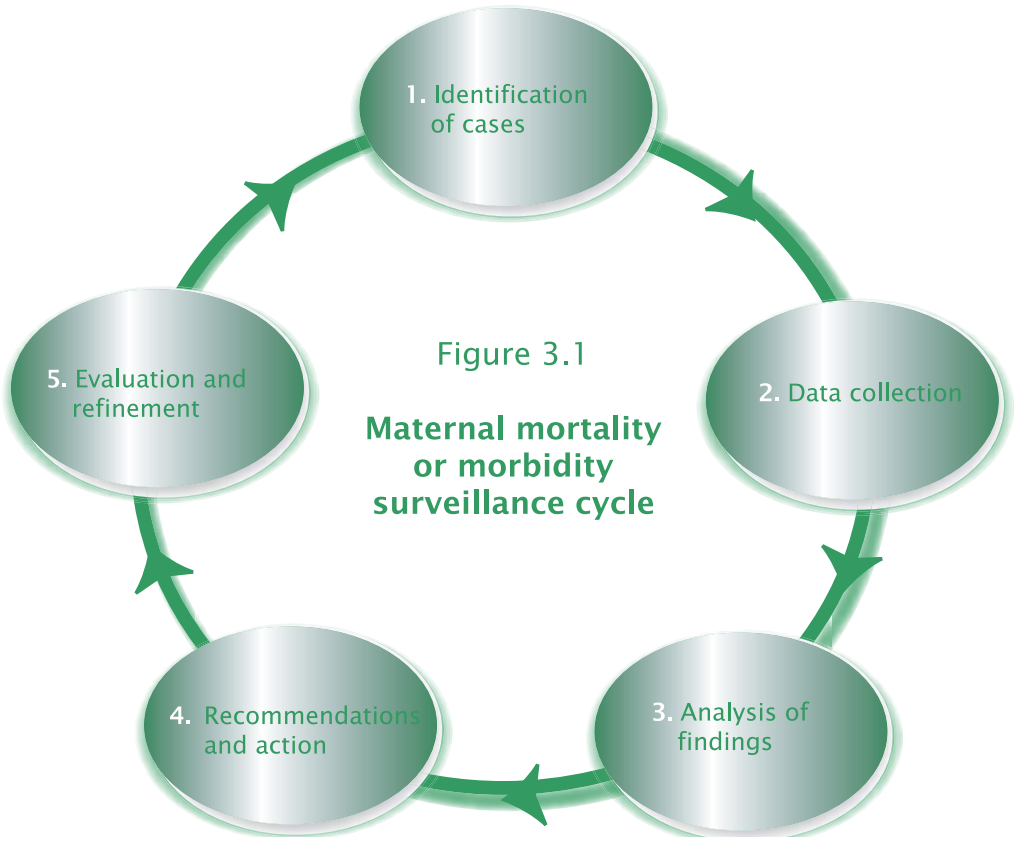

Figure 3.1

Maternal mortality or morbidity surveillance cycle

3.3 The surveillance cycle

Any approach designed to investigate maternal mortality or morbidity or clinical practices in order to improve maternal health uses, as its guiding principle, the *surveillance cycle*. This is the ongoing process of identifying cases, collecting and analysing information, using it to formulate recommendations for action, and evaluating the outcome (Figure 3.1). The ultimate purpose of the surveillance process is action—not simply to count cases and calculate rates. All these steps—identification, data collection and analysis, action and evaluation—are crucial and needed in a continuing fashion in order to justify the effort and make a difference.

3.4 Deciding which approach to adopt

The approaches described in this guide can be used in a variety of situations, from communities or local facilities to the district, regional or country level. When planning the investigation, a number of questions must be considered:

- What is the objective of the study?
- How will cases be identified?
- Where and by whom will cases be examined?
- How many cases are expected and what is the workload likely to be?
- What resources are available?
- Who can act on the results?
- What or who is the driver for change?
- Who are the key stakeholders?

All these factors need to be taken into account when planning which approach to adopt. The number of cases investigated will depend on the number of cases identified and the resources available. The number should be large enough to provide information on a variety of factors associated with death or severe morbidity and to allow conclusions to be drawn. Other factors which might determine the methodology to be selected include:

- The availability of local, regional or national commitment from politicians, policy-makers, health care managers and health care workers.
- Existing data about the causes of maternal mortality, morbidity and clinical practice in specific countries, health facilities or communities. Do any areas seem to have higher than average rates of mortality and morbidity?
- Existing data about trends in mortality rates from specific causes, if available. Are certain causes of death increasing or failing to be reduced despite local or national strategies to address this?
- The availability of resources and expertise in undertaking such surveys.

Community-based surveys

Where large numbers of women die outside of health care facilities in the community, identifying the main causes of death and preventable factors can be particularly difficult. These deaths are no less important to investigate, however, since they can provide a unique insight into the medical and nonmedical factors and barriers to care that led to the woman's death. These barriers may include lack of awareness of the need for care, cultural norms and beliefs, the use of dangerous or inappropriate traditional practices, lack of facilities or transportation, or affordability. The approach usually used in these circumstances is that of *verbal autopsy* (a community-based case review). Acting on the results of community-based surveys can save lives not only through introducing or refocusing health education messages and improving community awareness and knowledge, but also by adopting changes in clinical practice and reconfiguring local services to make them more acceptable, accessible and available.

Community-based case reviews are usually based on cases identified by community health care workers or traditional birth attendants and undertaken through interviews with the woman's family. Interviews can be structured (the interviewer has written questions which she/he reads), open-ended (the interviewer listens to the respondent without a prearranged plan), or semi-structured (the interviewer has a list of areas or questions that need to be covered and guides the respondent to these topics). Structured interviews are best suited for collecting numerical data in areas where much is already known and the potential responses can be listed. Less structured interviews are most helpful when trying to discover reasons for behaviour or to look at complex sequences of events.

Facility-based surveys

Often health care workers wish to or have already undertaken surveys in their own facilities in order to improve local care practices. This does not necessarily require commitment from regional or national health care planners or professional organizations. Facility-based case reviews of maternal death are the simplest of these studies and are already practised in many facilities as part of ongoing good practice. To investigate certain clinical practices, health care workers may initiate *a clinical audit*, where the care provided to the woman is measured against existing best practice guidelines or standards. Either of these approaches can be further expanded to include cases of *severe morbidity*. As the sophistication and complexity of the approaches increases, so does the need for things like written practice guidelines, definitions of severe morbidity, additional resources and personnel with experience in the use of these approaches.

Facility-based approaches can consider both the clinical and non-clinical aspects of the woman's care. They result mainly in beneficial changes to local clinical practice, but may also improve the general organization and provision of care in the facility. However, the results may only be relevant to local conditions.

Regional/nationwide approaches

The methodology with the potential to make the greatest impact on the largest number of women's lives is that of a confidential enquiry into maternal deaths. These enquiries consider all or a representative sample of maternal deaths in a particular city, area, region or country, and draw up both clinical and service recommendations suitable for widespread implementation. These enquiries need to be supported by stakeholders working at a level where they can influence policy and guideline development. Their ownership by various health care groups leads to the development or revision, dissemination and implementation of professional clinical guidelines. They also provide data for use by health care planners and politicians to change or develop policies and raise investment levels in health care, where practicable.

Confidential enquiries depend on the participation of health care professionals and require sustained commitment on the part of policy-makers and/or professional organizations with the ability to influence change. Properly conducted and followed through, such enquiries offer the greatest opportunity of all the approaches discussed here to make the most beneficial impact on women's lives.

There are a number of ways in which confidential enquiries can be organized. In some circumstances, the detailed investigation of deaths may be limited to certain causes of death or certain sectors of the health care system, such as public health facilities in countries where access to records in private institutions is unobtainable. In large countries, or countries where maternal mortality rates are very high, it may be more appropriate to organize the enquiries at the level of a region or province. A further option is to limit the detailed enquiry to the two or three leading preventable causes of death and disability, while still recording basic details on all maternal deaths. Confidential enquiries may also be applied to cases of severe morbidity.

3.5 Definitions of maternal death

While the approaches described in this guide may involve reviewing cases of maternal morbidity or clinical practice, most of them are used to investigate maternal deaths. As methods to define severe maternal morbidity are at this time not well established, the following sections are limited to the definition and identification of maternal deaths. A discussion of severe morbidity can be found in Chapter 7.

Before it is possible to identify maternal deaths, it is important to understand the definitions. A maternal death, as defined by the ninth and tenth revisions 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*."

The above definition requires that there was both a temporal and a causal link between pregnancy and the death. When the woman died, she could have been pregnant at the time, that is, she died before delivery, or she could have had a pregnancy that ended in a live or stillbirth, a spontaneous or induced abortion or an ectopic pregnancy within the previous 6 weeks. The pregnancy could have been of any gestational duration.

In addition, the death was caused by the fact that the woman was or had been pregnant. Either a complication of pregnancy or a condition aggravated by pregnancy or something that happened during the course of caring for the pregnancy caused the death. In other words, if the woman had not been pregnant, she would not have died.

Maternal deaths can be subdivided into further groups as shown in Table 3.1. *Direct maternal deaths* are those resulting from conditions or complications, or their management, which are unique to pregnancy and occur during the antenatal, intrapartum or postpartum period. *Indirect maternal deaths* are those resulting from previously existing disease or disease developing during pregnancy which was not due to direct obstetric causes, but which was aggravated by physiologic effects of pregnancy. Examples of indirect deaths include epilepsy, diabetes, cardiac disease and hormone-dependent malignancies. The United Kingdom Confidential Enquiry into Maternal Deaths (UKCEMD) also classifies most deaths from suicide as indirect deaths, as they were usually due to puerperal mental illness, although this is not recognized in the ICD coding of such deaths. In the USA, deaths from suicide during or in the year after the end of pregnancy are coded as being caused by pregnancy only if the relationship between pregnancy and the death is explicitly stated on the death certificate, such as in cases of death due to postpartum depression.

In some countries HIV infection may be one of the leading causes of death among pregnant or recently delivered women. The relationship between HIV and pregnancy is a complex one, but in general these deaths, particularly in developing countries, should be regarded as *indirect.* Although including deaths from HIV may increase the workload of some of these approaches, it is important to include them wherever possible, as they will represent challenges to be addressed by health programme managers and providers.

Deaths that would have occurred even if the woman had not been pregnant, namely those from accidental or incidental causes, are not considered maternal deaths. ICD classifies them as *fortuitous maternal deaths.* Here we will refer to them as *incidental deaths*.

ICD-10 introduced two new terms related to maternal deaths. One of them is *pregnancy-related death*, defined as the death of a woman while pregnant or within 42 days of termination of pregnancy, *irrespective* of the cause of the death. Like maternal deaths, pregnancy-related deaths can be associated with any pregnancy outcome, and can occur at any gestational age. The difference is that pregnancy-related deaths include deaths from *all causes*, including accidental and incidental causes.

In countries with low levels of medical certification of cause of death and/or where many deaths occur outside medical facilities, it is frequently difficult to determine if a death was causally related to the pregnancy or not. Since the proportion of deaths during pregnancy or within 42 days of the end of pregnancy due to pregnancy complications is extremely high, especially in developing countries, use of the *pregnancy-related death* definition allows maternal deaths to be identified and counted even if a cause cannot be determined.

The other new term introduced in ICD-10 is *late maternal death*, defined as the death of a woman from direct or indirect obstetric causes more than 42 days but less than one year after the termination of pregnancy. Identifying late maternal deaths makes it possible to count deaths in which a woman had problems that began during pregnancy, even if she survived for more than 42 days after its termination.

Table 3.1 Definitions of maternal deaths

Maternal deaths[a]	Deaths of women while pregnant or within 42 days of the end of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes.
Direct[a]	Deaths resulting from obstetric complications of the pregnant state (pregnancy, labour and puerperium), from interventions, omissions, incorrect treatment, or from a chain of events resulting from any of the above.
Indirect[a]	Deaths resulting from previous existing disease, or disease that developed during pregnancy and which was not due to direct obstetric causes, but which was aggravated by the physiologic effects of pregnancy.
Late[b]	Deaths occurring between 43 days and one year after abortion, miscarriage or delivery. They can be due to *direct* or *indirect* causes.
Pregnancy-related deaths[b]	Deaths occurring in women while pregnant or within 42 days of termination of pregnancy, irrespective of the cause of the death.
Fortuitous[c] or Incidental	Deaths from unrelated causes which happen to occur in pregnancy or the puerperium.

[a] ICD-9
[b] ICD-10
[c] ICD-9 classifies these deaths as "fortuitous".

Approaches that rely on qualitative information collected only at the community level seek to identify pregnancy-related deaths. This is because such approaches are only able to reliably determine the temporal relationship between pregnancy and the death, and are unable to determine the definite cause of death itself. Since determining specific causes of death, especially indirect versus accidental/incidental causes, is very difficult to do accurately using nonmedical community sources, it is preferable to include all deaths during pregnancy through 42 days postpartum.

Most deaths caused by pregnancy complications occur close to the time of delivery or relatively soon after the termination of pregnancy. In developed countries, late maternal deaths are responsible for between 5% and 20% of all maternal deaths. However, in less developed countries, where sophisticated treatments and the technology to prolong life are not readily available, the proportion of late maternal deaths is small.

3.6 Identifying maternal deaths

Identifying maternal deaths is the first step in the surveillance process. Women die at home, on the road and in health facilities. They die before, during and after delivery, as well as in early pregnancy from complications of abortion and ectopic pregnancy. To gain a representative picture of the causes of maternal deaths in an area or population, there needs to be as complete a picture of the women who died as possible. The determinants of deaths in women who never reach a health care facility may differ from those of women who die in medical facilities. Deaths among women who die in the obstetric ward will tend to have different underlying causes from deaths occurring in the gynaecology ward or in the emergency room.

The way that the deaths to be investigated are identified will be influenced by several factors: who will be doing the investigation (health care facility versus district, regional or national government), the place where the deliveries and deaths occur (home versus facility), and whether vital registration and medical certification of cause of death in the country are complete or, on the contrary, poor or non-existent.

For each approach, a combination of methods should be used to identify as many of the deaths as possible. Ideally, it would be helpful to identify the problems and patterns for a geographical area, for a particular population, or for a health service catchment area.

Maternal deaths are extremely difficult to identify in the absence of vital registration systems with complete coverage of events coupled with reliable cause of death data through medical certification of deaths. Even where good vital registration and medical certification exist, active follow-up and analysis of the deaths of women of reproductive age are needed in order to identify maternal deaths comprehensively. Few developing countries currently have such capabilities and, in general, the settings where maternal mortality is highest are precisely those where the ability to measure it is most limited. Different techniques can be used in these situations. Table 3.2 provides a summary of the various sources of information on maternal deaths.

Vital records

When available, death certificates are the first line in the effort to identify maternal deaths. Although death certificates will not identify all maternal deaths, even with universal vital registration and good certification of cause of death, they should be the starting point if they are available.

Table 3.2 Methods to identify and review maternal deaths

Base/starting point	Frequency of data collection	
	Continuous/routine	Occasional/special
Civil authorities	**Identification** Vital registration (passive—no active case-finding)	**Identification** Active case-finding—special studies using linkage of vital records RAMOS[a] Censuses
	Review Confidential enquiries into maternal deaths	**Review** Confidential enquiries into maternal deaths
Community	**Identification** Demographic/population surveillance systems (long-term)	**Identification** Household surveys using direct estimation Sisterhood surveys RAMOS
	Review Verbal autopsies	**Review** Verbal autopsies
Health facility	**Identification** Health care worker reporting Hospital record review	**Identification** Health care worker reporting Hospital record review
	Review Facility-based case reviews Clinical audits against agreed criteria or standards	**Review** Facility-based case reviews Clinical audits against agreed criteria or standards

Maternal deaths are those with an underlying cause of death coded in ICD-9 between 630 and 676.9, or, in general, in ICD-10 between O00 and O99.

Use of all the cause of death information on the certificate—immediate as well as underlying causes of death—will increase the number of maternal deaths identified. Sometimes reviewing the certificates for handwritten notes will reveal additional maternal deaths, even when the cause of death does not indicate this.

In some countries, identification is helped through specific questions or check boxes on death certificates asking whether the woman was pregnant at the time of death or had been pregnant within a specified period of time prior to death. If the death occurred during or shortly after pregnancy, chances are the death was causally related to the pregnancy. Box 3.1 describes the increase in case ascertainment following such an exercise in Brazil.

[a] Reproductive Age Mortality Study. The reproductive age group usually includes those women aged 15 to 45 years. However, the ages included in this population subgroup may vary from country to country.

Box 3.1—Vital events registration and maternal mortality investigation in Brazil[1]

Brazil has a well-established Civil Registration System for vital events, and approximately 900 000 deaths are registered each year, representing about 90% of the total deaths in the country. The international version of a death certificate has been used since 1950, and physicians are required by law to fill in the death certificate, including the cause of death.

It is known that causes of death related to pregnancy, childbirth and the puerperium are the poorest recorded on death certificates in Brazil. To improve the quality of these data, the Ministry of Health introduced an item into the certificate for physicians to indicate if a deceased woman 10 to 49 years old was pregnant at the time of death or in the 12-month period prior to death.

There is a national committee on maternal mortality linked to the maternal and child health section of the Ministry of Health. At lower levels, there are state and local committees that investigate maternal deaths.

The starting point for investigating a maternal death in municipalities in Brazil is the death certificate. Some local committees investigate all deaths of women aged 10 to 49 years, and others investigate all declared maternal deaths and cases that, according to pre-established criteria, are presumed to be maternal. The criteria as applied to death certificates containing a single declared cause of death include septicaemia, pulmonary embolism, haemorrhage, haemorrhagic shock, convulsive crisis, peritonitis, or other diagnoses that suggest a maternal cause. Other cases presumed to be maternal deaths are those where the certificate presents more than one cause, and the underlying cause includes, for example, respiratory failure due to septicaemia, shock due to haemorrhage, septicaemia due to peritonitis, cardiac arrest due to pulmonary embolism, etc.

The utilization of this methodology has made it possible to correct maternal death data in areas where a maternal mortality committee is working. For example, in the southern state of Paraná, all municipalities have such a committee, and in 1998 and 1999, the following results were obtained:

	1998	1999
Number of live births	185 113	186 111
Number of maternal causes identified from death certificates	80	76
Number of maternal deaths not declared on death certificates but identified by the committee according to the described methodology	70	71
Number of late maternal deaths	4	16
Maternal mortality ratio per 100 000 live births by causes listed on death certificates	43.21	40.83
Maternal mortality ratio per 100 000 live births after more complete investigation	81.03	78.98

In countries with computerized vital registration systems for both births and deaths, linkage strategies are increasingly being used. In these cases, the computer can be used to link deaths of women of reproductive age to birth certificates, to look for women who died during or after childbirth. This strategy can identify many maternal deaths, even when the ICD code for the cause of death does not indicate pregnancy. However, it cannot identify deaths where there is no birth certificate, such as those of women who died before delivery whose still-born child was not recorded in a birth register, or those who died after an abortion or from an ectopic pregnancy.

Patient records

Patient records from hospitals or other health care facilities may be another good source for identifying maternal deaths, especially for hospital-based investigations such as criterion-based clinical audits and facility-based case reviews. How one identifies maternal deaths from patient records depends on the size and record-keeping procedures of the facility.

Hospitals that perform deliveries will have a delivery room log book or register in addition to maintaining patient notes. These log books or registers frequently include information on maternal deaths and will supplement but not replace the information contained in the patient record. The importance of accessing patients' files is underlined by the fact that deaths from abortion complications or ectopic pregnancies will usually not be listed in delivery logs and must be identified by other means. Admission and discharge as well as operating room and gynaecology ward registers are other good sources. Some hospitals keep mortality logs or registers as well, with the names of all individuals who died in the facility.

Patient records of all women of reproductive age who died should be reviewed for evidence of pregnancy. This may be especially important in referral hospitals, since, when the cause of death is coded for maternal deaths occurring at referral centres, the relation of the pregnancy to the death is frequently lost. In a small hospital, all discharges can be scanned for maternal deaths. Hospitals with computerized records or discharge summaries will indicate the status of patients at discharge, including a code for *deceased*.

Many countries have several parallel health care systems that may include ones run by the Ministry of Health, the Social Security System and the private sector. Frequently, reviewing maternal deaths is limited to those that occur under the Ministry of Health. Ideally, one would like to be able to include all maternal deaths that occur within an area. Although this may require negotiation, it provides a more complete picture of the health of women in that area.

Community identification

In some countries or areas, many births and deaths occur at home. Identifying the maternal deaths among deaths occurring at home can be particularly difficult. However, it is important to investigate them since

they can provide insight into factors and barriers that lead to maternal death by delaying or preventing utilization of health care. In these cases, it is particularly important to use multiple sources to identify the maternal deaths occurring in the community.

Health centres and/or district health offices can be focal points for coordinating the identification of cases of maternal death. Health promoters and village or community health workers can be trained to report these events as part of their jobs, as can midwives who provide prenatal care and attend deliveries. Traditional birth attendants (TBAs) should also be encouraged to identify and report maternal deaths. *Key informants*—a village leader or designated person—may be given the responsibility of watching for maternal deaths and conveying the information to the local health care system that one has occurred. In some areas, investigators have surveyed cemeteries and funeral homes to identify deaths of women of reproductive age or have had schoolteachers query their students about their knowledge of any such deaths.

Involving the community in identifying maternal deaths is not only very important for ensuring accurate data but also, and perhaps even more importantly, it raises community awareness of the issues and facilitates advocacy.

Maternal deaths may also be identified during household surveys, including censuses. The deaths of women of reproductive age that are identified during the survey can then be followed up and investigated.

Disease surveillance systems

Some countries have formal, government-run disease surveillance systems to which certain specified diseases or conditions must be reported on a routine, timely basis (obligatory notification). Some of these countries include maternal deaths on their list of conditions to be reported. That is, they require that all maternal deaths, regardless of whether they occur in health facilities or at home, be reported to the surveillance system. These formal surveillance systems are usually the responsibility of the epidemiology or disease surveillance unit of the Ministry of Health, and not of the maternal and child health unit. The chain of reporting usually goes from the local level to the regional/state level to the national level, although hospitals sometimes report directly to the national level.

3.7 Planning and implementing the approach

Having decided which approach to use, standardized questionnaires for data collection need to be developed. Frequently, data surveillance systems collect too much data without a clear plan for their use. If a use for the data cannot be identified, then the data should not be collected. When developing the form, it is important to bear in mind the purpose of the survey and to remember that they may be completed by a range of health care or

community workers or community members. The language and content of the instrument will need to reflect this, as well as being sensitive to different cultural needs.

Key principles for data collection

- Decide what data should be collected and what you want to learn before developing core data sets.
- Keep it simple. Bigger is not always better.
- Regard data sets as "work in progress" that can be amended or added to as experience is developed or particular issues of concern are identified.
- If possible, data collection should continue to monitor trends, audit outcomes and be prepared to expand as expertise and data systems develop.
- The forms should be developed and pilot tested in terms of specific content, language and format.

It is important at the outset to decide what pieces of information need to be collected for what specific purposes. This in turn depends on having a clear understanding of what the plan is for analysing the data, which is discussed further in section 3.8.

Selecting and training data collectors, interviewers and assessors

Everyone involved in the study process needs to be motivated to collect or assess the kind of information required for the investigation. They need to be literate, numerate, fluent in the local language, and familiar with local terms.

Data collectors

Local data collectors, particularly for facility-based approaches and confidential enquiries, are responsible for ensuring the report forms are completed appropriately. They may also act as local coordinators and interviewers for the survey. If the number of cases expected is very large, they may be specially appointed to the project, but usually they are already working in the facility or community and take this work on as an additional paid or unpaid responsibility. They may be midwives or obstetricians, research workers or other staff in the local community health department.

While the training of data collectors should be for the most part practical, these staff should know the purpose of the investigation and the importance of obtaining the information without bias. Some basic didactic knowledge will be needed. However, most of the training should be focused on the skills that will actually be used to collect data. Training should include practice exercises, learning by doing and, particularly for those who will be interviewing family and community members, role-playing. The less structured the data collection instrument, the more skilled and trained the data collector will need to be.

Interviewers

Interviewers are data collectors who will obtain information by talking—usually to relatives, community members and health care workers. They should be taught different ways to obtain information, how to probe for information in a sensitive manner and without biasing the responses of the person being interviewed, and how to help respondents recall dates. They should learn how not to upset the respondents, and what to do when the interviewee has questions or wants information. They should learn that the information they hear is confidential and that privacy must be ensured.

In general, interviewers should be of the same sex and of the same or similar social class as those interviewed, as they will need to establish rapport with the people they are interviewing. It is crucial that interviewers be able to be neutral, and not impose their personal opinions or beliefs on the interviewees. The more unstructured the interview, the more highly skilled and trained the interviewers will need to be. Because frequent changes in personnel can make it more difficult to collect consistent data, it is desirable that the interviewers be available for the long term.

Structured interview questions should be short, clear and in the local language using local terms. They should be phrased in a neutral way, not suggesting a correct answer. Otherwise, the answer may be biased to what the respondent thinks the interviewer wants, not necessarily what is true. More sensitive questions should be asked later in the interview. This allows the interviewer to establish rapport with the respondent before asking about such topics.

Supervision

Supervision of data collection, whether from case notes and report forms or from interviews, is extremely important to the final quality of the information. The scope of the work will determine the number and structure of the supervisors needed. Supervision is needed for training data collectors, for checking their work and correcting their errors, and for reinforcing the standards and protocols of the project. At the beginning of data collection, more frequent checks and/or visits by supervisors should be made. A schedule of supervisory responsibilities and a protocol or checklist of tasks will make this function more effective. The reports and findings of supervisory visits should be kept with the other data collected.

Expert assessors

All the approaches described in this guide require the cases to be evaluated or assessed to identify remedial actions that might be taken in the future. Examples of areas that might be assessed include medical factors that were avoidable in light of local best practice and barriers encountered by the woman in accessing the health care system.

Some of the approaches will benefit from or need expert assessment. Such assessors are usually health care professionals with expertise in the area of health being reviewed. For example, the United Kingdom's confidential enquiry regional assessment committees consist of a public health physician with knowledge of local service provision, an obstetrician, a midwife, a pathologist and an anaesthetist. All are highly competent and well respected

by their peers, usually being nominated by their professional organizations. None assess their own cases; these are passed on to others with no previous knowledge of or involvement in the case.

It is important that quality control issues be considered in order to ensure standardized and consistent review and reporting. These can be agreed upon through meetings between the assessors, by two assessors reviewing each case or by random reviews by independent assessors.

3.8 Analysing results

Whatever approach is used, the analysis of the information collected will be helped by the availability and quality of patient notes. Each case should be individually assessed for the factors that led to the woman's death, especially those that could have been prevented or avoided. The deaths should then also be considered as a group—aggregating the data to look for patterns or similar factors.

Both quantitative and qualitative analysis provide insights into the causes of maternal deaths. A combination of both can provide more insights into maternal deaths than either can provide alone. Quantitative analysis shows which groups of women may be at higher risk of maternal death, such as women from specific ethnic groups or places of residence, or who have other characteristics in common. Qualitative analysis then provides more detailed information on the precise causes of death for individual women. For example, were there differences in lifestyle, health beliefs, or access to and availability of antenatal, intrapartum or postnatal care? What were the characteristics and level of training of the health care workers who cared for the woman? What lessons can be drawn from this information? There are useful references to these techniques in *Why mothers die*,[2] *Strategies to reduce pregnancy-related deaths*[3] and *Guidelines for maternal mortality epidemiological surveillance*[4] which are summarized below:

Quantitative analysis

The purpose of quantitative analysis is to identify and compare any patterns or trends among the women on the basis of a variety of characteristics.

Person. Age, race/ethnicity, socioeconomic status, education.

Place. Where she lived (urban, rural, postal code); if and where she received antenatal care; where she delivered; where she died.

Time. Date and time of day of her death, day of the week, season.

Parity and gravidity. Number of previous pregnancies and births.

Pregnancy outcome. Undelivered, spontaneous or induced abortion, ectopic or molar pregnancy, live birth, stillbirth, multiple pregnancy.

Gestation. At delivery or at time of her death, if undelivered.

Antenatal care. Week or month of pregnancy when first attending; where, how often and by whom this was provided; distance of facility or clinic from place of residence.

Type and place of delivery and delivery attendant.

Time of death in relation to gestation or delivery.

Postnatal care

Stated cause of death.

Enquiry-determined cause of death.

Qualitative analysis

The purpose of qualitative analysis is to look at the factors which may have led to a specific woman's death in more detail.

For example, if a woman died of haemorrhage, was it because she had not sought care, that care was unavailable or too expensive for her, the distance to a health facility was too great, that no senior staff were available, the care she received was inadequate or that no blood transfusion facilities were available? In other words, describe the course of her individual pregnancy within the community or health care system. Part of this assessment includes seeking a history of her feelings about pregnancy and the need for health care. A description of the treatment she received is also needed, not only from her case notes, but ideally from a written report obtained in confidence from the health care workers who cared for her. The assessment also includes describing the availability of any resources she may have required, including trained attendants, antenatal or postnatal care, facilities for operative delivery, and so on. In this way, the true cause of a woman's death can be established, which is often at variance with the information on the death certificate, if available.

One useful way to develop a systematic approach to analysing the problems that might lead women to die is to consider the barriers women face when in need of health care. A framework has been developed to help direct efforts for assessing the situation, particularly in developing countries, to find out exactly why mothers die.[5]

- Is it because they were unaware of the need for care, or unaware of the warning signs of problems in pregnancy?
- Were the services non-existent, or inaccessible for other reasons, such as distance, cost or sociocultural barriers?
- Are women dying because the care they receive is inadequate or wrong?

Traditionally, maternal death reviews have concentrated on issues at the third level. However, looking at more than just clinical factors reinforces

the fact that the purpose of the survey is not to solely focus on the clinical aspects of care, but to find ways to reduce such deaths by actions at all levels of the health care system including interventions at the community level.

3.9 Translating findings into action

Taking action is the reason for all the previous work. What action is taken may depend on the approach used, who was responsible for the investigation, stakeholder involvement and the findings of the analysis. Actions may include interventions in the health services or the community, in public education, in communication and transportation systems, or the development of clinical guidelines or standards. It is important that the people with the ability to implement the needed actions be involved in the process throughout, so there are "no surprises" when the report is published and the need to take remedial action, or defend inaction, has already been considered.

Information from facility-based approaches, clinical audits and surveys of severe morbidity may lead to local changes in clinical practice or modifications to service provision. Community-based approaches such as verbal autopsies may also lead to the development of health promotion and education programmes as well as possible changes in community service provision. Information from the findings of a confidential enquiry can cover all these issues on a far wider basis and are used at institutional, local and national levels by politicians, health service planners, professionals, public health personnel, educators and women's advocacy groups. They may also lead to the development of national or regional clinical guidelines.

What sort of recommendations should be made?

The action taken to decrease maternal mortality will be determined by the findings of the review process and analysis. Recommendations for action must be evidence-based, arising from analysis of the data collected, otherwise they can be open to challenge. Enquiry personnel must be able to justify the basis of the findings and recommendations. Recommendations for changes in service delivery must be backed up by facts and figures. Clinical guidelines or standards must be based on the best available evidence. The Integrated Management of Pregnancy and Childbirth (IMPAC) set of guidelines, published by WHO, may be easily adapted for this purpose, particularly in resource-poor countries.[6]

During the process of evaluation, the emerging findings often become apparent early and if firm trends are identified, then preparation for guidelines and recommendations can start prior to the publication of the report. It is more useful to publish a report which also contains firm guidelines and recommendations than to suggest these be developed in future. Furthermore, the sooner after the end of the reporting period the final report is produced, the more immediate impact it will have on local practice.

Recommendations to improve maternal health and decrease maternal mortality fall into three types:

Primary prevention strategies

These strategies aim to prevent the condition from occurring through education and services. Examples include improving sex education and providing family planning services, improving pre-conception care and improving diagnosis and treatment of sexually transmitted infection to prevent ectopic pregnancy and intrapartum and postpartum infections.

Secondary prevention strategies

These strategies detect and treat conditions early in order to minimize the effects. Examples include increasing community awareness and patient knowledge about normal pregnancy and the signs and symptoms of possible problems, increasing emphasis on patient satisfaction with care in order to improve patients' adherence to the recommendations of their health care workers and improving antenatal, labour and delivery techniques and postpartum follow-up.

Tertiary prevention strategies

These strategies provide direction on how to treat conditions in an optimal fashion in order to reduce mortality and morbidity rates. Examples include improving obstetric and medical treatment of complications and improving practices, facilities, referral services and organization of services.

Individual country level enquiries will be able to determine, from their own results, which mixture of strategies will suit their own circumstances best. Changes in behaviour and clinical practice are often difficult to achieve without widespread promotion and visible support from leading and well-respected advocates, professionals and professional organizations. The choice of people to involve in developing the recommendations is therefore crucial to ensure that recommendations for change will be implemented.

3.10 Disseminating findings and recommendations

A plan to disseminate the results of any investigation should be determined in advance, although flexibility should be built in, particularly in the face of unexpected results. The format and dissemination of the report depends on the circumstances in which it will be produced and the resources available. It is important to note that at the outset it will be impossible to identify the likely final recommendations.

A key principle of any report, published or otherwise (for example, the results of a local verbal autopsy), is that the team involved in

undertaking the work be fully involved in developing and implementing the recommendations and acting as advocates for change. For community surveys it is equally important to involve, from the beginning, key community members in order to present the findings back to their communities and engage them in helping to develop local solutions for local problems and to promote beneficial educational activities.

Published reports should focus on ways to improve the system and not single out particular errors that have been committed. Before publication, the contents will need to be carefully reviewed to avoid breaches in confidentiality and misuse of information.

The information will need to be disseminated in a manner that enables most people to access it. Short summaries of key findings and recommendations are cheaper and easier to disseminate widely than large documents arising from detailed surveys such as confidential enquiries. Similarly, reports published solely in professional journals tend to be overlooked by other people concerned with improving the quality of women's lives. In general, the shorter the document the more widely read it is likely to be.

It is crucial to get the information to the right audience, namely those who can act on it. The potential recipients should be identified in the planning stage, and the recommendations written in such a way that they are easily understood by a wide audience.

Who to inform of the results

The types of groups or individuals to consider when disseminating the information and results will depend on the scope and scale of the methodology used. But it is important to get the key messages to those who can implement the findings and make a real difference towards saving women's lives. They may include:

- Ministries of health
- Local, regional and/or national health care planners, policy-makers and politicians
- Health care professionals from all disciplines involved at local to national level including obstetricians, midwives, anaesthetists and pathologists
- Leaders in other health care systems, such as Social Security and the private sector
- Health promotion and education experts
- Public health or community health departments
- Academic institutions
- Local health care managers or supervisors
- Local government
- National or local advocacy groups
- The media
- Representatives of specific faith or cultural institutions or other opinion formers who can facilitate beneficial changes in local customs
- All those who participated in the survey

Methods that can be used

Large, expensive, very detailed reports are of no use if they cannot be widely disseminated. It may be that producing a comprehensive report for health care planners and policy-makers could be supplemented by the use of shorter "executive summaries" for health care workers. These summaries could be a simple newsletter or short booklet, preferably with an introduction written by the Ministry of Health or leaders of the health care professional organizations.

The following are all methods that have been used for dissemination of results:

Community/Facility level

- Team meetings
- Community meetings
- Printed reports
- Training programmes
- Posters

Subnational or national level

- Scientific articles
- Statistical publications
- Web-sites
- Newsletters and bulletins
- Fact sheets
- Press releases
- Training programmes
- Professional conferences
- Posters
- Media

3.11 Evaluation

Closing the surveillance loop and evaluating the impact of the recommendations that were made is the vital last step in any review of maternal deaths and morbidity. The main purpose of evaluation is to consider if the process improved the health, well-being and safety of pregnant women. It is important to recognize that achieving significant reductions in overall mortality or morbidity rates may take time, although local changes in practice can show quite rapid effects.

The process can be evaluated by looking for improvements in the community, in the health care system, or in society in general. Depending on what factors were found to be responsible for maternal deaths and severe morbidity and what actions were taken, different aspects of the overall process might be evaluated. The evaluation then leads back into the

surveillance process, which continues to identify and investigate cases in order to refine the actions needed to make pregnancy safer for women.

Evaluation should also examine the total costs of the surveillance process and make an assessment of cost-effectiveness. This is of particular importance in terms of the sustainability of the process. Ideally, surveillance should be a regular or even an ongoing process, but this is unlikely if the process is too costly in terms of human and/or financial resources.

In general, the purpose of evaluation is twofold: to ensure the approach used is both efficient in the way it works and effective in instituting beneficial practices.

Efficiency

Evaluation of efficiency includes checking the internal coherence of the approach itself to ensure it is working smoothly and producing the required outcomes. For example: Are there any barriers to its smooth operation? How can these be overcome? Could it be made more efficient? If so, how might this be achieved?

Effectiveness

Evaluation of effectiveness determines if the recommendations for action have been put into place, and identifies where any shortcomings or problems may lie. Exactly how this effectiveness evaluation should be carried out will depend on the particular circumstances in each facility or community and health care system. Using the maternal mortality ratio as the only form of evaluation is not appropriate: it is difficult and time-consuming to determine it accurately, and large numbers of deliveries are needed to see any effect on the ratio. It is far more important to determine *how* the specific findings and recommendations arising from these studies have been acted upon and with what results. For example, what reduction in the number of women dying from a particular condition was seen following the introduction of a specific guideline for the management of this condition?

3.12 Ensuring confidentiality and the legal and ethical framework

Throughout the world, legal and ethical considerations are important when investigating maternal deaths. The laws and customs of a particular country or culture can have a significant impact on the process of investigation, helping or hindering access to information, the involvement of families and health care professionals, the conduct of the investigation, and the ways the findings are used.

The ethics of maternal death investigation are perhaps more universal, while the legal aspects vary from one country to another. In addition, a supportive health policy framework that encourages the ongoing investigation of all maternal deaths can facilitate the process immensely.

Legal considerations

Laws can affect access to information, protection of the people involved in the investigation and of the findings of the investigation, and the ways in which the information is used. Most countries have laws covering many or all of these issues. In some countries, the laws may even vary from state to state.

The presence or absence of legal protection may make individuals reluctant to participate in the review or provide information to the death investigators. In some countries with a high level of malpractice cases, fear of lawsuits has led to the abandonment of maternal death investigations. Those undertaking one of these approaches may need to find out what the laws are in their area, and lobby for changes if they are needed.

Access to information

As part of some of these approaches, investigators may need to review prenatal or hospital records, speak with the woman's family or friends, and/or interview health care workers. Legal access is needed for the review of various types of records, which may include those of clinics, individual physicians and hospitals. Permission to speak with family members and health care workers who were involved with the case may be needed as well.

Local data collectors will usually be the only people in the enquiry process who know the names of the women and the health care workers. Although these details should not be asked on report forms, it is the responsibility of the local data collectors or coordinator to remove any possible identifying information from the report form before it is sent to the assessors for completion. They must maintain confidentiality and ensure that the record is securely kept when not in use.

Protection of participants and results

Laws may be needed to protect those investigating maternal deaths from civil and professional liability based on actions taken as part of the investigation (*immunity*). Laws are also needed to protect the information gathered during the investigation from disclosure and use in subsequent lawsuits (*confidentiality*). It is important to get legal advice when planning an investigation, so that the investigative process can occur with protection of those involved as well as of the deceased patient's privacy.

Use of the results

The goal of these approaches is to identify reasons why maternal deaths and near-miss morbidity occur so that strategies to prevent them can be developed. It is not to discipline providers or review their qualifications. It

is not even necessary to know the identities of the patients or practitioners. This type of investigation should have more legal protection and less legal liability than those done for disciplinary purposes. However, in some cases where negligence or malpractice is found, the appropriate authorities may need to be notified.

Ethical considerations

There are a number of ethical issues that need to be considered when investigating maternal deaths and severe morbidity. *Autonomy* means that women and families need to be fully informed about the purpose of the investigation and that their participation is voluntary. They should know that they can end an interview at any time.

Privacy is an ethical consideration that is important for both families and health care workers. On the one hand, the deceased and her family have the right to privacy, but on the other it is almost impossible to investigate a maternal death and maintain complete privacy. Relatives and health care workers need to be assured that, as much as possible, their privacy will be maintained, and that the identities of the women whose deaths are being investigated, their families, and the health care professionals involved in their care will be kept confidential, known only to those doing the actual investigation. Data collection forms, case summaries, review meetings, and any reports or dissemination of results should not contain personal identification. This is particularly necessary when the death has occurred as a result of an illegal abortion.

In some cases, such as confidential enquiries, complete *anonymity* is the rule. However, in others, such as facility- and community-based case reviews, it is usual to identify both the deceased and the health workers involved in the care. When caregivers are identified in any approach, their willingness to cooperate in subsequent investigations will be greater if confidentiality is maintained within the group carrying out the review.

These approaches should be a tool to discover why women are dying and to make changes to reduce these events. They should not be used to blame individuals or institutions, nor to punish persons or groups. Investigations that are carried out in a manner seeking to attribute blame for an adverse event inhibit the willingness of people to cooperate with the process.

On the other hand, health workers need to be accountable for their actions. Accountability can be encouraged by carrying out any approach in a way that seeks to improve care by educating both the caregivers and the community. However, it will occasionally be necessary for appropriate persons (e.g. supervisors, licensing boards, general medical councils) to discipline health workers who are persistently negligent, in spite of efforts to encourage and educate.

3.13 Sources of further information

A CD-ROM available with this guide provides sample questionnaires that have been used for similar studies elsewhere which may be adapted to local circumstances.

The investigative methods described in this guide use qualitative and, in some cases, quantitative information or data. Further information on the principles of surveillance and audit can be obtained from a number of sources including:

National Institute for Clinical Excellence and the Commission for Health Improvement. *Principles for best practice in clinical audit*. London, Radcliffe Medical Press, 2002 (http://www.nice.org.uk).

Campbell O et al. *Social science methods for research on reproductive health*. Geneva, World Health Organization, 1999 (WHO/RHR/HRP/SOC/99.1).

Reports and papers in French that may be of interest include:

Comité national d'experts sur la mortalité maternelle, Rapport au Ministre. Paris, 2001 (http://www.sante.gouv.fr/htm/pointsur/maternite).

Bouvier-Colle MH. Enquêtes confidentielles avec comités d'experts, audits et soins obstétricaux. In: Blondel B, Goffinet F and Bréart G, eds. *Évaluation des soins en obstétrique : pour une pratique fondée sur les preuves.* Paris, Masson, 2001:209-232.

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2 Lewis G, ed. *Why mothers die 1997–1999. Fifth report of the confidential enquiries into maternal deaths in the United Kingdom*. London, Royal College of Obstetricians and Gynaecologists, 2001 (http://www.cemd.org.uk).

3 Berg C et al., eds. *Strategies to reduce pregnancy-related deaths: from identification and review to action*. Atlanta, Centers for Disease Control and Prevention, 2001 (http://www.cdc.gov/reproductivehealth/02_pub_elec.htm)

4 Berg C, Danel I, Mora G, eds. *Guidelines for maternal mortality epidemiologic surveillance*. Washington, DC, Pan American Health Organization, 1996 (English and Spanish).

5 Graham WJ, Filippi VA, Ronsmans C. Demonstrating programme impact on maternal mortality. *Health Policy and Planning*. 1996; 11:16–20.

6 World Health Organization, *Managing complications in pregnancy and childbirth. A guide for midwives and doctors*. Geneva, World Health Organization, 2000.

4 Verbal autopsies: learning from reviewing deaths in the community

Carine Ronsmans, Jean-François Etard, Gijs Walraven

Key messages

- ✓ Communities are a valuable source of information on why women die.
- ✓ This approach can be promoted when there are high numbers of maternal deaths occurring outside health facilities. In some settings, the verbal autopsy may be able to complement a facility-based maternal death case review.
- ✓ Data on causes of maternal death obtained from verbal autopsies lack precision and should only be used to obtain a general impression of the pattern of causes of death in a community.
- ✓ Verbal autopsies usually include an ascertainment of the factors that may have contributed to maternal mortality and findings may identify general areas for improvement outside of the health care system, such as reconfiguration of local transport services.

Community-based maternal death reviews relying on verbal autopsies have been used for more than two decades and their definition has evolved over time. Initially, a verbal autopsy was strictly seen as a method to find out the magnitude and the medical causes of maternal death, based on an interview with family members or neighbours.[1] Over time, however, the need to obtain information on the non-medical factors that may contribute to maternal deaths has been acknowledged. Verbal autopsies are now used more widely to provide information on medical as well as nonmedical causes of maternal death. This broad focus sharply contrasts with that seen in the context of child mortality, where verbal autopsies are usually done with the sole purpose of arriving at a medical cause of death.[2]

4.1 What is a verbal autopsy for maternal deaths?

A verbal autopsy for maternal deaths is *a method of finding out the medical causes of death and ascertaining the personal, family or community factors that may have contributed to the death in women who died outside of a medical facility*. The verbal autopsy consists of interviewing people who are knowledgeable about the events leading to the death such as family members, neighbours and traditional birth attendants. The main purposes of a verbal autopsy are to:

- Identify deaths that have occurred in pregnant or recently delivered women.
- Provide broad categories of causes of maternal death.
- Understand the factors that may have contributed to the deaths.

- Describe the background characteristics of women who died from maternal causes, such as age, parity, education and other social variables.
- Offer a tool to be used by national, provincial or district health offices to foster action to remove obstacles to high-quality obstetric care for all pregnant women.

The philosophy behind the verbal autopsy approach is based on the maternal mortality and morbidity cycle described in Chapter 3, and the cycle as relevant to this method of review is shown in Figure 4.1.

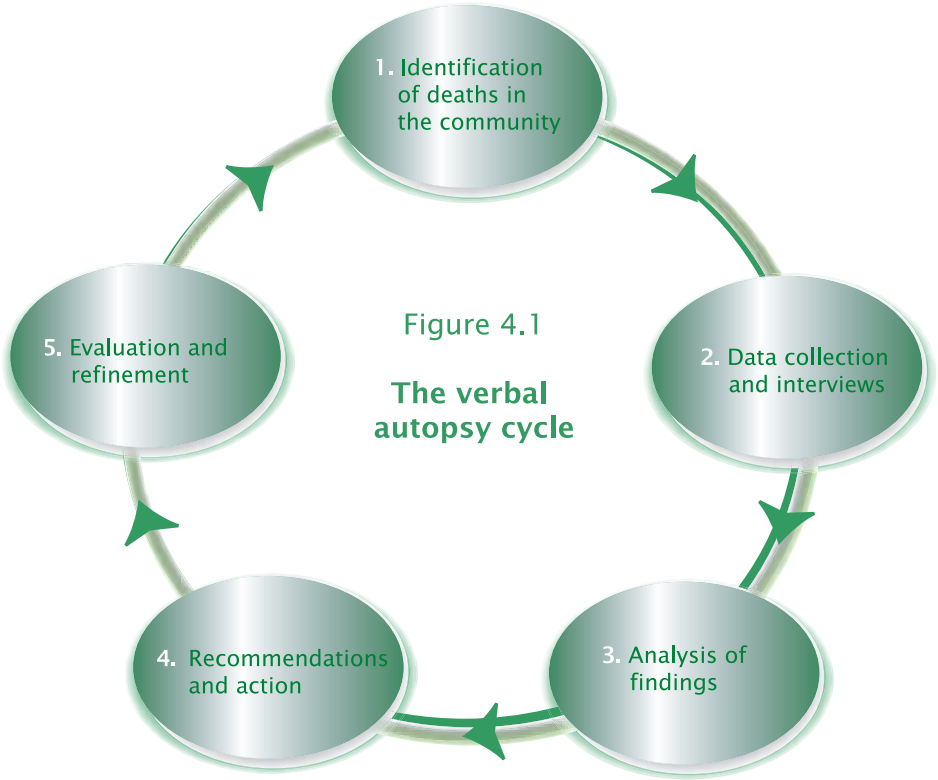

Figure 4.1

The verbal autopsy cycle

Although verbal autopsies have sometimes been used to determine the magnitude of maternal mortality in a defined population, this chapter focuses on verbal autopsies as a tool to ascertain the causes of, and the factors contributing to, maternal mortality and *not* on measuring the size of the problem.

Most verbal autopsies are done periodically, for example, every three months, every six months or once a year, on all maternal deaths that were notified for that period. They are usually organized at district level and are generally applied to deaths occurring in the community. However, in settings where the quality of medical records is poor, it may be useful to conduct a verbal autopsy on all deaths that have occurred in a given community, whether or not the woman died in a health facility. In other words, in some settings, the verbal autopsy may be able to complement a *facility-based maternal deaths case review*.

To ensure that all maternal deaths are identified in a defined population, it is important to conduct verbal autopsies on all reported deaths of women of reproductive age, rather than on only those deaths that have been coded

as a maternal death on the death certificate. Many pregnancy-related deaths still go unnoticed or unreported, and substantial errors in the estimates of maternal mortality persist, even in developed countries with complete vital registration systems.[3] Underreporting is a particular concern for early pregnancy deaths, namely those due to ectopic pregnancy or abortion complications, and for deaths from indirect causes such as hepatitis, cardiovascular diseases, and so on. Failure to include all maternal deaths can result in misleading results, and the likely under-notification of some causes should always be considered when reporting causes of maternal death.

Representativeness is of less concern if the purpose of the verbal autopsy is to understand the factors contributing to maternal mortality, as even the story of one woman might be informative. However, care has to be taken not to overstate or generalize the findings from observations on a small number of deaths. The case study excerpt from Mexico described in Box 4.1 illustrates how useful insights on the constraints to using obstetric care might be gained from individual cases.[4]

Box 4.1—A verbal autopsy case study from Mexico[4]

In the fourth month she started to have severe headaches. We did not visit the doctor because we thought it was normal. She also had these headaches in previous pregnancies.

She got heavier and heavier, and she had great pain in her left arm. But she did not seek any help because doctors charge too much and we had no money.

4.2 The purpose of verbal autopsies

National, provincial and local authorities or communities may wish to know the causes of maternal deaths occurring in women in their communities. Although, as discussed in Chapter 1, the maternal mortality ratio is not seen as a very useful indicator for monitoring Safe Motherhood Programmes because it gives no indication of the real reasons why women are dying, obtaining a rough estimate of the causes of maternal death is useful for advocacy and planning purposes.

The results of verbal autopsies can be used to establish the relative public health importance of common avoidable or remediable factors relating to maternal deaths in order to identify priorities and appropriate interventions or changes. These factors may include lack of awareness of the need for care, harmful cultural practices or beliefs, lack of facilities or transportation, or financial barriers. Acting on the results of community-based surveys can save lives not only through introducing or refocusing health education messages and improving community awareness and knowledge, but also by adopting changes in clinical practice and reconfiguring local services to make them more acceptable, accessible and available.

Given the relatively imprecise nature of establishing the causes of maternal deaths based on verbal autopsies, however, caution is required when they are used for measuring changes in causes of maternal mortality over time or differences among geographical areas. Not only are a large number of maternal deaths required to make valid comparisons by cause, but also the lack of reliability of the verbal autopsy method constrains its use for precise quantitative comparisons.

A description of all the events surrounding each maternal death is seen as an essential component of verbal autopsies because it serves as a basis for the development of more comprehensive strategies for prevention. The nonmedical circumstances in which the woman dies help identify the many barriers to women's access to and use of comprehensive obstetric services.

In Mexico, for example, the verbal autopsy identified the relatives' inability to recognize the symptoms as abnormal or severe, the lack of money, and no adequate means of transport as the main barriers to reaching a health facility.[4] Similar contributing factors were observed in the Gambia, although substandard obstetrical referral care was seen as the main contributor to maternal mortality.[5] These findings not only sensitize policy-makers to the complex nature of maternal mortality, they may also lead to specific recommendations. In Mexico, the above findings led to the recommendation that, to reduce delays, antenatal care should not only teach women to recognize complications that require care, but also sensitize them to the possible need for emergency transfer and means of transport during labour and delivery.

Finally, verbal autopsies provide useful information on some of the demographic and social characteristics of the women who died.

4.3 The advantages and disadvantages of verbal autopsies

The advantages of the verbal autopsy include:

- In settings where the majority of women die at home, verbal autopsies are the only means for arriving at medical causes of death.
- The verbal autopsy allows medical and nonmedical factors to be explored in an analysis of events leading up to a maternal death. Documenting the personal, family and community barriers to women's access to and use of obstetric services, even where adequate services exist, provides a more comprehensive picture of the determinants of maternal mortality and enables appropriate remedial actions to be taken.
- The verbal autopsy provides a unique opportunity to include the family and community's opinion on the access to and the quality of health services, in efforts to improve maternal health services.
- The verbal autopsy provides information for community leaders and other advocates for maternal health to argue for changes or improvements in cultural, community, educational or health care practices or resources.

The disadvantages of the verbal autopsy include:

- *Lack of reliability of the medical cause of death*

In general, the quality of data obtained from verbal autopsies will depend on careful preparation, piloting and testing of the questionnaire, adequate training and supervision of field workers, and careful data management. Even so, medical causes obtained from verbal autopsies are not perfect, and different assessors may arrive at different medical causes. In Bangladesh, one physician attributed 41% of all maternal deaths to direct obstetric causes, while another group of physicians found this proportion to be 51%.[6] It is for this reason that data on causes of maternal death obtained from verbal autopsies should only be used to obtain a general impression of the pattern of causes of death in a community.

- *Subjectivity of the factors contributing to death*

The assignment of avoidable factors largely remains a matter of subjective judgement and depends on a large number of elements, including the ways in which the interviews were conducted and reported, the type and training of the interviewers and reviewers, and the familiarity of the reviewers with the local context. The extent to which different observers might identify different avoidable factors is not known, but one study in the Gambia suggests that the disagreement may be substantial.[5] In this study, three physicians were asked to read the verbal autopsy interviews and to assign contributing factors without any knowledge of the other reviewers' comments, guided by a checklist of potential factors. As many as half of the 18 maternal deaths were attributed to lack of access to appropriate obstetrical referral care, and there was little disagreement between the reviewers. The proportion of deaths that were attributed to not recognizing the severity of the problem by the family, on the other hand, substantially differed among the reviewers, ranging from 11% to 33%. Two reviewers thought that there were no obvious contributing factors in 28% of the deaths, while one reviewer saw a contributing factor in every death.

While it is extremely important to know how the family perceived the care that was received, a layperson's opinion on and perception of the technical quality of care may not reflect the medical profession's view of that quality. Verbal autopsies should not be used to examine the contribution of technical aspects of care delivery (e.g. weaknesses in diagnostic and management procedures) to maternal mortality, unless detailed case notes are available that can be reviewed by medically trained people and compared against an established standard (see Chapter 8 on *Clinical audit*).

However, the subjectivity in the interpretation of contributing factors should not discourage efforts to identify them. The verbal autopsy aims to identify general areas for improvement rather than quantifiable indicators, and a discussion around issues of access to and quality of services among all those involved in decision-making is more important than arriving at a precise list of contributing factors.

- *Unproven validity of the verbal autopsy method*

Causes of death obtained from lay informers are not always in accord with those obtained from death certificates. To date there is only one study on validating the causes of death from verbal autopsies.[7] Unfortunately, because the study was hospital-based, it was not possible to draw conclusions about the validity of verbal autopsies for women who died in the community.

- *Potential under- or overreporting of maternal deaths and specific causes*

Underreporting is a particular concern for early pregnancy deaths and for deaths from indirect causes. In Bangladesh, the routine demographic surveillance system missed 30% of abortion-related deaths and 58% of indirect obstetric deaths.[1] To detect abortion deaths, interviewers need to have special skills to establish a rapport with and gain the confidence of relatives who may be reluctant to talk about issues as sensitive as induced abortion. Indirect obstetric deaths are often reported as non-maternal because the non-obstetric cause tends to dominate the picture. For verbal autopsies with a questionnaire that pays special attention to pregnancy, however, underestimation of indirect causes should be less of a problem.

Indirect causes of maternal deaths, however, may also be overreported. The definitions of the different types of maternal deaths are given in Table 3.1 and section 3.5 in Chapter 3. Conceptually, an indirect maternal death is one that is due to a medical condition such as cardiac disease, epilepsy or diabetes aggravated by the effects of pregnancy. In practice, there may be some confusion as to which causes constitute an indirect obstetric death, although the definitions given in Chapter 3 should make this clearer. Those responsible for classifying maternal deaths often decide on a case-by-case basis whether or not they categorize certain causes as indirectly attributable or incidental to the pregnancy. When verbal autopsies are used, all deaths in pregnant or recently pregnant women[a] are commonly included in the maternal mortality statistic (whether or not they are attributable to the pregnancy), except for deaths due to injury. This might falsely inflate the maternal mortality statistic, particularly in settings where indirect causes are emerging as major causes of death during pregnancy, such as in areas with a high prevalence of HIV.[8, 9]

4.4 Step-by-step process for carrying out verbal autopsies for maternal deaths

Each of the steps for carrying out verbal autopsies for maternal deaths is described in detail below. In summary, the nine steps of the process are:

1. Set up the verbal autopsy process.
2. Identify cases of maternal death.
3. Determine the sources of information.
4. Develop the verbal autopsy questionnaire.

[a] *Recently pregnant* is defined as up to 42 days from pregnancy termination or delivery.

5. Select and train interviewers.
6. Select respondents.
7. Develop a mechanism to classify the medical causes.
8. Develop a mechanism to classify contributing factors.
9. Use the findings for action.

Step 1: Set up the verbal autopsy process

There are a number of prerequisites that must be met before a verbal autopsy can be started. Someone with experience and authority is needed to take overall responsibility for its coordination. Because verbal autopsies take place in the community, the cooperation of community members will need to be sought and a brief description of what is intended will need to be supplied. Since information may also be sought from health facilities, the relevant authorities at these facilities will need to be informed. Transport will need to be provided for field workers, and their safety will have to be ensured. Agreements will have to be reached about the costs for transport and personnel.

Step 2: Identify cases of maternal death

Verbal autopsies are initiated at the community level. A number of methods can be used to identify deaths among women of reproductive age in the community, including vital statistics and ongoing surveillance systems. Routine vital registration systems in developing countries often underreport deaths, particularly maternal deaths, and special demographic surveillance systems have been set up in some countries.[5, 9, 10, 11, 12] The latter are expensive, however, and the pattern of mortality observed in these research sites might not always be representative of that observed in broader geographical areas. Sometimes, large surveys (including sisterhood surveys) or census data may also be a good source of information on deaths in adult women, but adding verbal autopsy questions to a census or survey might substantially increase the cost.

In settings where no data exist on deaths in the community, information may be obtained from key informants such as community health workers, community leaders, traditional birth attendants, and so on, or through networking.

The length of the recall period has varied across studies. In Guinea-Bissau, where verbal autopsies were conducted up to eight years after death, the length of the recall period did not affect the quality of the medical information reported.[13] In general, however, it is advisable not to extend the recall period beyond five years.[1]

Step 3: Determine the sources of information

The verbal autopsy will mainly consist of an interview with people who are knowledgeable about the circumstances leading to the death. For deceased women who had been in contact with health services prior to death (whether because they attended antenatal care, because they were admitted to a hospital but were later discharged, or because they died in a health facility), additional information from medical or home-based women's records may be sought. This requires adequate recording of names and addresses in health facility registers, however, which may often not be the case. In the Gambia, for example, only two of the 14 records of women who had been in contact with a health facility prior to death were recovered, and these provided little additional information.[5] In general, therefore, verbal autopsies will mostly rely on information provided by the family.

Step 4: Develop the verbal autopsy questionnaire

Verbal autopsy interviews usually consist of a combination of structured, semi-structured and in-depth interviews. A question-answer format is often used to reconstruct the medical circumstances leading to death, while a more open respondent-led or semi-structured approach is used to arrive at the contributing factors.

Verbal autopsy questionnaires can have a number of different formats: open, checklist of symptoms, checklist with filter questions,[13] or a combination of these.[5, 7, 14, 15] Examples of verbal autopsy questionnaires used in the Gambia and Bangladesh are provided in a CD-ROM available with this guide. In general, the questionnaire starts with background information on the woman (e.g. age, number of births, social factors, etc.). This is followed by a blank page on which the interviewer reports the illnesses and circumstances leading to the death as they are spontaneously recalled by the relatives. This is usually followed by a more structured list of questions about the illness that preceded the death.

Step 5: Select and train interviewers

In general, nonmedically qualified but experienced interviewers are preferred over medically qualified staff as the latter may be too directive in their mode of questioning. Other factors influencing the choice of interviewers include mobility (in some settings women are not mobile), acceptability and availability.[1]

The interviewer needs extensive training, not only in some basic notions of the medical conditions and their associated symptoms that may lead to a maternal death, but also in the techniques of in-depth interview.[16] For an in-depth interview, the interviewer will have to be prepared with a number of topics to be investigated. These could be based, for example, on the "three delays" model proposed by Thaddeus and Maine.[17]

The interviewer should encourage the respondents to report their own experience of the events preceding the death. With particularly sensitive topics, such as abortion, it may be advisable to conduct repeated interviews with the same respondent to allow greater trust and rapport to evolve.

Nonmedically qualified interviewers require close supervision by medically qualified staff to ensure that all the relevant information on signs and symptoms prior to death have been noted. Repeat interviews might be necessary if it is believed that further details on specific illnesses will help identify the cause of death more accurately.

Step 6: Select respondents

The respondent is a person who knows about the illnesses that led to the death. The respondent may be the husband, sister, mother, father, mother-in-law, neighbour or traditional birth attendant.

To identify the signs and symptoms prior to death, it is useful to interview those people who were present at the time of death. To arrive at the nonmedical factors associated with death, it may also be useful to interview people who were not necessarily present at the time of death, but who knew the woman well enough to report on her general health status and care-seeking behaviour.

In many settings, it may not be appropriate to restrict the interview to a single respondent. In addition, interviewing a number of respondents might provide useful insights into the nature of relationships that may have affected decisions to seek care. Multiple respondents often discuss the facts among themselves, and this may help to obtain a more complete picture of the circumstances preceding the death. Some respondents might withhold information when interviewed in a group, however, and it might be necessary to return later and interview them alone.

Step 7: Develop a mechanism to classify the medical causes

Verbal autopsies cannot easily distinguish indirect obstetric deaths from those that are incidental to the pregnancy, except for deaths due to injuries. For that reason, verbal autopsies address pregnancy-related deaths rather than maternal mortality, and all deaths occurring during pregnancy or within 42 days of delivery, regardless of cause, are reported on. All deaths other than those due to direct obstetric causes or to injuries are generally classified as indirect deaths. Table 3.1 in Chapter 3 explains these definitions more fully.

Direct obstetric deaths are further classified into broad categories, such as early pregnancy death, haemorrhage, sepsis, eclampsia, obstructed labour/ruptured uterus, sudden death and unknown. Where possible, a second level of more specific categorizations can be used: for example, placenta praevia, abruptio placentae, and so on.

The procedures used to arrive at a medical diagnosis have varied across studies. In general, it is believed that a diagnosis should not be made at the time of interview, but that a panel of physicians should review the questionnaires at a later stage. For example, three physicians can be asked to give independent opinions on the maternal nature and cause of death.

The physicians first determine whether the death was pregnancy-related and then assign a likely cause. A death is considered pregnancy-related if at least two of the three physicians agree. Among all pregnancy-related deaths thus agreed, the diagnosis is considered final if at least two of the three physicians agree on the primary cause of death. In assigning a cause of death, physicians can be aided by flowcharts for causes of maternal death. These have been published by WHO[1] and by researchers in Guinea-Bissau.[13]

Currently there is insufficient experience with predefined diagnostic criteria to allow the assignment of medical causes of death in settings where physician review is not possible.

Step 8: Develop a mechanism to classify contributing factors

Although there is a strong drive to include contributing factors in the investigation of maternal deaths, it is not entirely clear how such factors should be arrived at nor how they should be classified. Hence, as shown in a number of papers, there currently exists no standard approach to the classification of contributing factors for maternal deaths.[4, 5, 18, 19, 20]

The approach in this chapter is to use *avoidable* factors because it is important to carefully consider for each individual death at what level(s) an intervention could potentially have changed the outcome. Avoidable factors should be sought within and outside the health care system, with the understanding that more than one factor might be present.

The framework for determinants of maternal mortality proposed by McCarthy and Maine[21] provides a useful guide for the analysis of avoidable factors. Although some authors have used the three delays model proposed by Thaddeus and Maine[17] to classify the factors contributing to maternal deaths, its use is not recommended for classification purposes. The three delays model examines maternal deaths for factors contributing to three different delays: (1) delays in the decision to seek care; (2) delays in arrival at a health facility; and (3) delays in the provision of adequate care. While this model is extremely useful to conceptualize the road to death and as a topic guide for an in-depth interview, it is not immediately helpful in formulating specific recommendations. Hence, the three delays framework should be seen as a guide for discussion, rather than as a tool for classifying deaths.

There is as yet no standardized approach to the study of avoidable factors. If substandard care is defined as a departure from the norms for medical care in a particular context, then criteria need to be available against which to assess the care. While a number of implicit criteria might exist (e.g. a

traditional birth attendant should refer a woman with obstructed labour), explicit norms are rarely available. In addition, the establishment of norms or criteria for factors that operate within the community might not be feasible, and the judgements made are likely to be subjective.

Avoidable factors are generally arrived at by a group of people together. In developing countries, those ascertaining the avoidable factors have almost invariably consisted of medical professionals or researchers.[4, 5, 19, 20, 22] It has been suggested, however, that a multidisciplinary team should review the data.[20]

So far, decision-makers or administrators have rarely been included among the assessors in verbal autopsies. For verbal autopsies to influence policy, however, detached research exercises should move on towards becoming more inclusive activities, and decision-makers, health professionals and community members should all take part in reviewing the circumstances leading to the deaths. The active participation in undertaking reviews to determine avoidable factors by all those concerned with saving mothers' lives is almost certainly a more powerful trigger for change than the mere presentation of statistics. Such an initiative is under way in Indonesia, where district-level verbal autopsies are being held in three provinces.[23] While no formal evaluation exists yet, the perceived success of the maternal and perinatal audit has led the Indonesian Government to commit itself to a countrywide expansion of these activities.

Step 9: Use the findings for action

Many surveys have documented the medical and nonmedical causes of maternal mortality by classifying deaths as avoidable and unavoidable, but few have offered a systematic means of monitoring progress towards changing these factors. The verbal autopsy system is not solely a means of identifying the causes of maternal deaths, but must, as with all the approaches suggested in this manual, act as a tool for change to improve women's understanding, access to and experience of high-quality health care.

Findings from verbal autopsies identify general areas for improvement, such as the need for health education programmes, to consider local transport needs, to strengthen referral systems or to upgrade health facilities, except when very specific needs are highlighted. Whether or not these commitments will be translated into specific strategies will largely depend on the commitment of decision-makers to institute change and health providers to accept responsibility for their actions. National, regional and district level commitment, as well as that of health care providers, is necessary to ensure that implementation of the actions suggested by the findings of the verbal autopsy will be feasible and sustainable.

4.5 Variants of the verbal autopsy

There are many potential variants to the verbal autopsy format. As with the other methods presented in these guidelines, verbal autopsies are adaptable and changes might be needed to make the verbal autopsy fit a particular country's circumstances.

The format of the questionnaires, for example, has differed substantially between settings, and hence the questionnaires provided on the CD-ROM (available on request) should be seen as a guide rather than a final model. Questionnaires will need adapting to the local context as well as extensive field-testing before being used.

Some studies have used medically trained interviewers, while others have used highly experienced but nonmedically trained interviewers as recommended in this guide. Medical professionals might be better qualified to probe about the specific illnesses leading to death, but might also be too directive in their mode of questioning.

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5 Facility-based maternal deaths review: learning from deaths occurring in health facilities

Colin Bullough, Wendy Graham

Key messages

- ✓ A maternal death is always a tragedy. Gathering reliable information from health professionals and relatives about the circumstances takes skill and sensitivity.
- ✓ It is always good practice to review the management of any complication that led to a maternal death.
- ✓ Case notes and people's memories of events contain valuable information that can help to improve the quality of care, and should be used appropriately.
- ✓ In many situations, only a small proportion of all maternal deaths occur in health facilities.

5.1 What is a facility-based maternal deaths review?

A *facility-based maternal deaths review* is a *"qualitative, in-depth investigation of the causes of, and circumstances surrounding, maternal deaths which occur in health care facilities."* It is particularly concerned with tracing the path of the women who died, through the health care system and within the facility, to identify any avoidable or remediable factors which could be changed to improve maternal care in the future. The information should, preferably, be supplemented by data from the community, but this may not always be possible.

In many situations, only a small proportion of maternal deaths occur in health facilities. The review processes described in this chapter can therefore only give a partial picture of the causes of maternal mortality for a particular population. The differences commonly found between the pattern of causes of maternal deaths at home and the pattern in health facilities show that it is important to be aware of this. In Nepal, for example, the most common cause of maternal deaths in hospitals is eclampsia, whereas the most common cause overall in the population is haemorrhage.[1] This difference is readily explained by the fact that women often die from massive bleeding before reaching a health facility.

Conducting a facility-based maternal deaths review is primarily an educational process for health professionals providing care to pregnant or recently delivered women, as well as for those in training. It is also a powerful means of maintaining accountability.

No facility-based maternal deaths review is complete unless it is linked with an attempt to respond to the findings with appropriate action. This is irrespective of whether the review consists of one or more isolated cases,

or of a large series where the findings have been aggregated. In the case of large reviews, this aspect should be taken into account during the planning phase.

A *facility-based maternal deaths review* is based on the surveillance cycle described in Chapter 3, and shown in Figure 5.1.

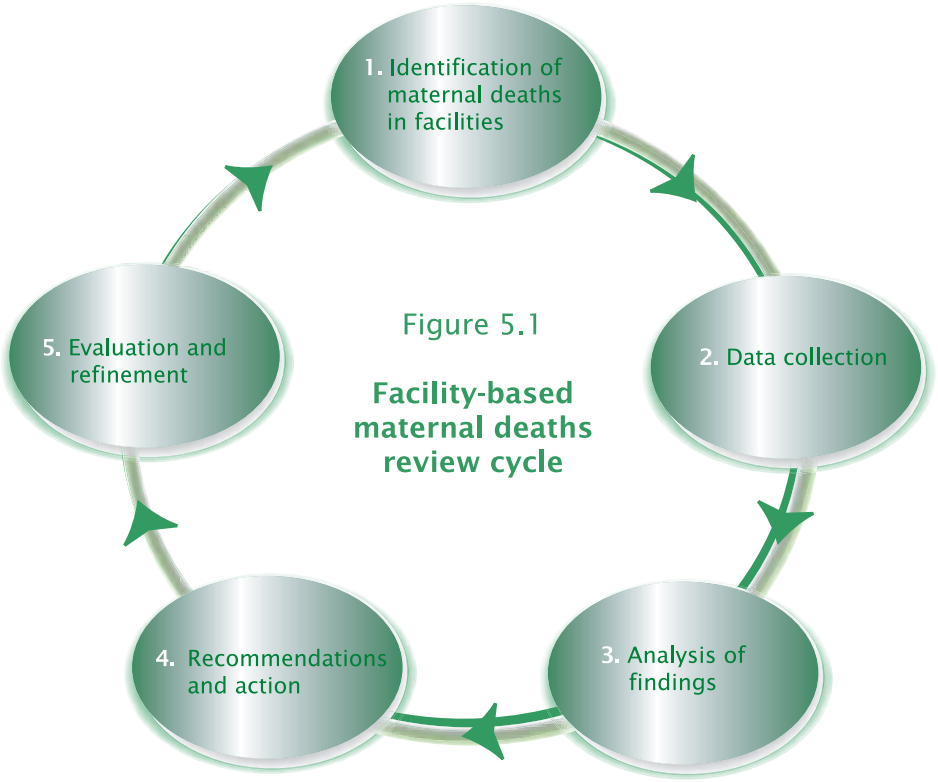

Figure 5.1

Facility-based maternal deaths review cycle

The levels at which a review may take place

Reviewing each case of maternal death in a facility

In many health systems it is already good clinical practice to review each case of a maternal death occurring in a facility at a multidisciplinary team meeting to consider what lessons may be derived from the management of the case and how local procedures might be improved for the benefit of future patients. Involving all those who managed the case, including obstetricians, nurses, midwives, pathologists and anaesthetists, ensures issues related to multidisciplinary local protocol development and ownership, cross-team working and areas of responsibility can also be clarified.

Reviewing all deaths occurring over time in one facility

Although reviewing each case separately is important and may yield some useful individual lessons, from time to time it is helpful to look for local factors and avoidable causes which may be common to several deaths. This may point to the need for more major service reconfigurations or adaptation of local protocols. It is therefore helpful to aggregate these and review them on a regular basis.

Including reviews of severe morbidity

In facilities where maternal deaths are relatively few in number, but where there is still a need to review cases to help identify areas for health care improvement, the cases to be reviewed may need to be selected on a different basis. One possibility is to include cases of *severe morbidity* as described in Chapter 7, but following the approach as described in this chapter.

Reviewing all or a subset of maternal deaths across a number of local facilities

A facility-based maternal deaths review may be conducted at a single health facility, or periodically across several facilities as part of a district or even regional assessment.[2] In this situation, the investigation may include every death in each facility for a fixed period of time, such as the last 12 months, or, if the number is too large to investigate in-depth, it may be carried out on a subset of these deaths. For example, it would be possible to review all deaths associated with Caesarean section carried out over a defined period. The study could, if desired, focus on particular aspects of the case such as the indications for the procedure, the time taken between the decision to operate and the start of the operation, or the postoperative care provided.

Expanding the review to include community factors

It is well known that social and environmental circumstances play a role in the causation of maternal deaths. Therefore, ideally, an attempt should be made to investigate the community factors involved in each case as well as these factors related to the care provided in the facility. Using this approach, the investigation starts by identifying maternal deaths occurring in the facility and then traces each one back into the community to ascertain the sequence of events. In this way, an attempt is made to reconstruct the story of the woman's pregnancy and labour, and uncover other relevant medical, social and service factors on her road to death.[3]

A facility-based maternal deaths review will not give a complete picture of events unless information about the events in the community is available. But obtaining this information by sending a data collector to the home after the death requires a much more sophisticated and expensive approach and sensitivity and, in many situations, is difficult to achieve.

An inability to do this should not, however, be taken as a reason for inaction. The important underlying factor for all the approaches suggested in this guide is to make the best use of what methods are available within given resources in order to improve maternal health. A review involving only the analysis of case notes is still far better than not undertaking such a review because there is a difficulty with community data collection.

One suggestion is to collect community data only in selected cases where it seems particularly important to do so. Another is to ensure that information

on community factors is routinely collected when women are admitted to the facility. This may provide the only opportunity to do this. Of course, where possible, such information may be supplemented after a death if relatives or other informants are available.

5.2 The history of maternal death reviews

The idea of conducting facility-based maternal deaths review is not new. It has been carried out in a variety of different forms in the past. With time, a progression has occurred—from simple to more complicated approaches—as shown in the following examples.

- A study of all deaths in a teaching hospital in Uganda from 1952 to 1959,[4] and a similar study of all deaths in a teaching hospital in southern India from 1960 to 1972,[5] classified causes of maternal deaths and allowed some conclusions to be reached about social and health service factors.

- A more representative study was conducted in Malawi in 1977[6] that included deaths occurring over one year in all 15 hospitals and 92 midwife-run maternity units in a region. This study also identified avoidable factors related to medical services as well as to the patient and home environment, leading to a recommendation to introduce traditional birth attendant (TBA) training.

- A retrospective study of all maternal deaths from 1988 to 1992 in all 24 health institutions with maternity facilities in three regions of Mali[2] was again more representative, and included interviews with staff to identify the problems they encountered in carrying out their work.

- In a retrospective study based on maternal deaths in 10 of the 17 hospitals in North Yemen during 1989–1991,[7] matching controls (women experiencing the same complications but surviving) were found for 177 of the 224 maternal deaths identified, thus allowing more valid conclusions to be reached. This study involved visits to the homes of the women who died as well as to the homes of their controls, and confirmed that rural residence, a lower standard of living and illiteracy were risk factors for maternal death.

- A final example demonstrates what can be achieved when action is taken based on case review findings.[8] Because the lack of resources made it impossible to investigate problems at the community level, a retrospective review was conducted of maternal deaths in a regional hospital in Tanzania over a three-year period. Based on the avoidable factors identified in the review, a further analysis was performed of hospital procedures, staffing and equipment, and a focused programme of interventions was instituted and continued for four years. The hospital maternal mortality ratio fell from 933 when the retrospective study began, to 186 per 100 000 live births. However, these results must

be interpreted with some caution. The confidence intervals were very wide and overlapping, so the decline was not statistically significant, and it is also possible that some other factors were responsible for the improved figures.

5.3 The advantages and disadvantages of a facility-based maternal deaths review

The advantages of conducting a facility-based maternal deaths review include:

Improved professional practice

- A facility-based maternal deaths review helps to identify where the clinical care that a particular patient received was below standard, so that steps can be taken to ensure that this is not repeated. This in turn may result in the development of new procedures or guidelines for case management, and may ultimately lead to conducting a clinical audit.

- Where substandard care is found to be the result of the negligence of a doctor, midwife or other staff member, appropriate remedial action should be taken. Action following a review with such findings would be likely to include making new arrangements for further practical training and supervision of the health worker concerned. Another appropriate action might be to review the arrangements for briefing trainees about the level of care they are allowed to undertake without asking for advice or requesting the support of a more senior member of staff.

Improved training

- Those responsible for either pre-service or in-service training may respond to the findings of a facility-based maternal deaths review by making changes in the curriculum, or introducing more appropriate teaching methods and supervisory/feedback mechanisms.

Improved resources

- The head of obstetrics or midwifery may use the findings to persuade managers or policy-makers about the resource needs (staffing, equipment and drugs) of the maternity service.

- Health managers at district, regional or national level could be provided with a summary of the review findings to help them identify service needs and prioritize resources.

Advocacy

- The findings of facility-based maternal deaths review*s* are never made known to the public. This is because the information cannot be guaranteed as anonymous. Nevertheless, there is a responsibility to provide generalized feedback to the community, nongovernmental organizations (NGOs), and public health authorities regarding any community-related factors. This could be done in face-to-face meetings, by written documents, or by writing articles for local newspapers. Feedback of this type might, for example, result in attempts to form local self-help groups to provide either cash or transport for those in urgent need of obstetric care.

Resources

- Since it tends to be carried out by facility staff already in post, a facility-based maternal deaths review is usually less expensive to conduct than other investigative methods. However, expanding the review process to cover a number of facilities or including a process of interviewing relatives and others in the community may require additional staff.

The disadvantages of conducting facility-based maternal deaths review include:

Lack of whole population data

- Apart from exceptional settings where *all* maternal deaths are registered at health facilities (even when the death occurred outside the facility), the case review approach cannot be regarded as population-based. A *facility-based deaths review* will not provide a complete picture about maternal deaths in a given population, particularly in countries or areas where most women die in the community.

Data regarding community factors leading up to the woman's death in the facility may be difficult to obtain

- A facility-based maternal deaths review will not give a complete picture of events unless information is collected about community factors related to the deaths of the women who died in the facilities. The simplest approach is to ensure that information on community factors and on events prior to admission are routinely gathered from the woman or her relatives at the time of admission. Obtaining this information by sending a data collector to the home after the death requires a much more sophisticated and expensive approach and sensitivity and, in many situations, is difficult to achieve.

The results are not as rigorous as clinical audit

- A facility-based maternal deaths review is not as systematic as *clinical audit* (see Chapter 8), and can generate a large volume of information that can be difficult to interpret and synthesize.

5.4 Step-by-step process for undertaking a maternal deaths review

This section provides a detailed step-by-step description of how a facility-based maternal deaths review can be conducted. In summary, the 10 steps of the process are:

1. Set up the facility-based maternal deaths review process.
2. Decide on the scope of the facility-based maternal deaths review.
3. Develop data collection forms and carry out a small pilot-study.
4. Select collaborators and train data collectors.
5. Identify cases of maternal death.
6. Identify sources of data.
7. Collect data at the health facility or facilities, and in the community if appropriate.
8. Synthesize the data, interpret the results, and draw conclusions.
9. Utilize the findings.
10. Decide whether to repeat the facility-based maternal deaths review at a later date or make it a continuous process.

Step 1: Set up the facility-based maternal deaths review process

There are certain essential prerequisites without which a facility-based maternal deaths review cannot be carried out:

- Someone with experience and authority is needed to take overall responsibility for coordination.

- The facility or facilities conducting the facility-based maternal deaths review must have a reasonable level of record-keeping in terms of registering deaths, retrieving case notes, and the quality of recording in the notes. For example, the addresses of patients need to be recorded to enable subsequent tracing of the family in the community, if this is to be part of the review.

- Health professionals initiating and/or conducting a facility-based maternal deaths review need the required authority and support, and this may have to be sought at different levels, for example:

Regional administration	Chief medical officer Senior administrator
Health facility	Medical superintendent or hospital chairman Head of the department of obstetrics Head of nursing/midwifery

Community	Regional medical officer Head of civil administration Local leaders and chiefs

- A protocol or description of what is intended may need to be supplied when requesting permission to conduct a facility-based maternal deaths review.

- Agreement will have to be reached about the costs and the use of personnel to conduct the review. Aggregating the results of a series of individual reviews and the collection of data on community factors, if thought feasible, require more resources than a simple review of individual cases limited to an analysis of facility-related factors.

- Lastly, a facility-based maternal deaths review team has to be formed. This team has the main responsibility for conducting the review, although the collaboration of a number of other people is essential. The team would normally consist of two to four individuals, with a balanced mix of professions and skills, but may be larger if the review is being conducted across a number of facilities, say at a district level. The team could, for example, consist of a nurse-midwife, an obstetrician, a public health doctor, and someone with community experience.

- Each of the team members may have different responsibilities for gathering data, depending on their skills. The most important criteria are that the members should have an interest in, and commitment to, investigating maternal deaths, and be able to devote sufficient time to the work to be done. If a community element is part of the review, they should have knowledge of the local language and an ability to develop rapport with community members. The inclusion of at least one senior person is important, to give the team some authority and to facilitate relationships with other agencies.

Step 2: Decide on the scope of the facility-based maternal deaths review

Where the review is planned to cover more than one facility or as a district or region-wide process, it is advantageous if comprehensive coverage of all facilities is attempted. However, where more deaths are known to occur than can be investigated, the first step is to select which facilities are to be included. It is usual to plan to seek information on at least 20 to 40 deaths, with four to six cases being the minimum, and to include deaths from a representative range of facilities. Help in making the selection based on these criteria can be obtained from Table 2.1 in Chapter 2, provided that at least a rough estimate of the local maternal mortality ratio is known.

A facility-based maternal deaths review is also suitable for use in single facilities, provided sufficient deaths are available for review. Where it is carried out in an obstetric referral facility, it would increase the representativeness of the review if any deaths that occur in peripheral

facilities within the catchment area of the referral facility were also included in the review.

Step 3: Develop data collection forms and carry out a small pilot-study

The development of data collection forms can be time-consuming, and some examples have therefore been provided on a CD-ROM available with this guide. The examples are taken from a draft of the WHO Safe Motherhood Needs Assessment Manual,[9] Part VI. The first four forms are for recording data from different sources—medical records, women-held records, staff interviews, and interviews of community members. The CD-ROM also includes a sample summary information sheet, a summary account of a maternal death, and a sample coding sheet for staff.

It can be seen that a lot of data can be collected, and it is emphasized that it is not expected that all the data will be entered into a computer and analysed. The information is collected in order to enable the review team to identify and classify avoidable factors, and recognize which are most common and which can be most easily avoided in future by selected interventions. Further information on the general principles of data collection and analysis is given in Chapter 3.

A pilot-study should be carried out of sufficient size to allow the review team to determine the feasibility of their plans and to test the data collection forms. It would normally be based on about four to six deaths. In conducting the pilot-study, the review team should follow Steps 4–8 below.

It is recommended that, in the pilot-study, members of the review team personally carry out all the required steps, including data collection. This will enable them to give better guidance to additional data collectors recruited for the main review.

Step 4: Select collaborators and train data collectors

If the case review is limited to one facility, then the review team alone may be sufficient to conduct the process. If, on the other hand, the review is being conducted across several facilities, a larger collaborating team may be needed.

Including a senior person from all the major facilities involved should enable the review team to gain cooperation within each facility. Otherwise, mid-level staff with about three to six years of professional experience may be the most suitable collaborators and data collectors because they have the appropriate knowledge and maturity, but are usually not heavily engaged in other administrative work. Involvement in the review should also provide a positive learning experience.

If a community element is to be included, it may be preferable to recruit some data collectors specifically for this function. This ensures that those

collecting data in the community do not know details about the management of cases in the facility, and thus cannot be drawn into potentially difficult discussions on this subject. Finally, having assembled sufficient data collectors, the review team will need to arrange a training course for them.

Agreement should be reached about whether or not data collectors can collect data in facilities other than their own. Provided it is apparent that they are carrying out their work with impartiality and with care to maintain confidentiality, this should be permissible. Indeed, when several facilities are included in the review, it is quite important that the same data collectors be used in all the facilities. Otherwise, different results may be obtained merely because of differences in the way the data were collected.

Step 5: Identify cases of maternal death

Maternal deaths to be reviewed are usually identified from health facility registers, such as ward admission and discharge registers, and delivery room, operating theatre and mortuary records. Other sources of information that may be available are informal records kept by health professionals. It is common for senior doctors and midwives to keep such records personally, or to delegate the job to another staff member. However, such *ad hoc* sources must always be complemented with or checked against routine registers.

Two factors complicate the search for cases of maternal death in a facility. First, a proportion of maternal deaths occurs outside obstetric or gynaecology wards, in particular those occurring in early pregnancy and those from indirect causes. Second, not all cases of maternal death are correctly classified and recorded as such. This means that the sources already mentioned will not be sufficient, and that all other available sources should therefore be accessed. The summary in Box 5.1 of the sources used to identify maternal deaths for a review in North Yemen demonstrates this point. Chapter 3 discusses other possible strategies to improve case ascertainment in more detail.

One way to overcome these problems is to compile a list of all deaths at the facility of women aged 15–49 years.[a] In compiling this list, all possible sources need to be accessed. This obviously includes the registers of not only the obstetric and gynaecology wards, but of all the adult wards. Once the list[b] is compiled, those deaths that are not the result of either direct obstetric causes or of conditions aggravated by pregnancy can be eliminated by inspection of the medical records.

[a] Or other locally relevant definition of the reproductive age, e.g. 12–54 years.

[b] For an example of one process followed, see the description of a surveillance system in Jamaica: McCaw-Binns A. Preventing maternal deaths in the Caribbean through surveillance. *Postgraduate Doctor Caribbean* 1996; 12(2): 72-80.

Box 5.1—Sources of maternal death identification in North Yemen[7]

The initial sources of identification for 224 maternal deaths in hospitals in North Yemen are provided below. Only 52.7% of these maternal deaths occurred on the obstetric and gynaecology wards.

Source of identification	Number	Percentage of total
Hospital general admission records	107	47.8%
Emergency room records	13	5.8%
Delivery ward admission records	60	26.8%
Death certificates	28	12.5%
Daily nursing reports	5	2.2%
Payment registry records	11	4.9%

If the review is to be conducted across several facilities in a region, then the vital registration system for deaths, if it includes the place of death, may provide an initial listing. Once again, it would be important to further investigate some deaths not certified as maternal, but occurring to women in the reproductive years, to gauge the scale of misclassification. The example from Brazil shown in Chapter 3 (Box 3.1) shows how doing this almost doubled the estimate of the maternal mortality ratio in one state.

When conducting a facility-based maternal deaths review for the first time, it may be decided to incorporate some deaths from a previous time period. No firm advice can be given about how far back to go, but if there are few deaths, it will be necessary to go back far enough to identify a minimum of four to six cases.

If there are more cases to review than there are resources available, then a selection must be made. One suggested approach in this case is to include at least one of the four major maternal complications (haemorrhage, pre-eclampsia/eclampsia, infection, obstructed labour), and make further selections incorporating a range of maternal characteristics, such as residence, referred case or not, primigravida or multigravida, etc.

Step 6: Identify sources of data

The circumstances surrounding each death are built up by collecting data from multiple sources, within both the health facility and the community. The aim is to gain as complete and accurate a picture as possible, knowing that different sources will yield different insights. The usual sources of information are summarized and grouped below.

Written:	Ward and operating theatre registers
	Facility antenatal notes
	Women's hand-held medical records
	Inpatient case notes
	Discharge letters

Interviews with:
- Doctors
- Midwives
- Other hospital staff
- Birth attendants in the community
- Relatives and neighbours
- Community leaders

In the health facility, patient records are usually the key source. However, they are nearly always lacking in some details and need to be supplemented with information from interviews with selected staff. The interviews need to be conducted in a nonjudgemental way and with the reassurance that information will be handled confidentially, especially if the interviewer is not a staff member of the facility concerned.

If the scope of the review is such that data other than those available from reviewing the notes or discussions with the health care professionals must also be collected, then arrangements need to be made for this. Obtaining detailed information about the sequence of events leading up to the woman's death will usually involve individual interviews with relevant people such as the husband or birth attendant, but can sometimes be done through focus groups or group interviews. Again, the interviewer should be nonjudgemental about what happened in both the community and the hospital.

Step 7: Collect data at the health facility or facilities, and in the community if appropriate

Facility data collection

In order to achieve greater accuracy of information, it is best to collect data as soon as possible after the death. The success in data collection may depend on how the issues of confidentiality and impartiality are handled.

The staff of all the facilities involved need to be certain that the review process does not involve apportioning blame for anything that happened. They need to know that all findings will be recorded and reported completely anonymously. Staff can be reassured about this at preliminary meetings, or through a brief written account of the working methods of the review. Specifically, staff may need to be assured that confidential codes will be assigned to each staff member for the purpose of data collection and that only the review team will have access to the codes.

The one exception is where instances of negligence are uncovered. These cannot be overlooked, and the usual procedures that are used in a facility for investigating such instances and acting upon the findings must be followed.

Even with the above reassurances, data collectors need to demonstrate tact, sensitivity and attention to detail if they are to be successful. The usual order in which they would carry out their work is as follows:

- Collect data from a review of the medical and nursing records. Nursing/midwifery records are not always filed with the medical records, and the help of a nurse/midwife may be needed to ensure that they are not missed.

- Interview all the staff involved in the patient's care—this is best done by members of the team who have a clinical, rather than a public health or community, background. Depending on the number of staff involved and the sensitivity shown, it may be decided to interview staff separately or in groups of approximately the same grade. In these interviews, the data collector should begin by encouraging the staff member(s) to give a free account of the events. Then he or she should ask directed questions to fill gaps in the account, or to expand on parts that are not understood or not consistent with other evidence.

For some deaths, it may be found that almost no information can be obtained. However, these deaths should not be omitted. Indeed, a special effort should be made to find out why there may be a lack of information, and to build a picture of relevant events from data collection in the community.

The accuracy of data collection should be ensured by applying some method of quality control. Mistakes can occur at several points in the process from, for instance, omitting some deaths or failing to interview key health personnel, to misreporting information from case notes. It is particularly important to detect such errors where small numbers of deaths are being reviewed. For example, the misrecording of admission-to-treatment intervals for just one death would have a disproportionately misleading effect where there were only a small total number of deaths.

One method of quality control is to provide good quality training for data collectors and to run refresher courses for them.[10] Other measures that can be taken include double-checking entries in data collection forms and repeating some of the data collection with different data collectors.

Plan community data collection if appropriate

It has already been stated that it would be ideal if data could be collected from community members during home visits sometime after the death. This may uncover valuable information about the circumstances that influenced the pregnancy or labour before help was sought. It also provides an opportunity to ask to see and review any patient-held records that are available.

It is realized, however, that home visits will not always be feasible. Distances or the logistical difficulties of finding the home may be too great. There may also be cultural barriers to paying visits during a period of mourning.

For areas where this step is feasible, this section addresses who should collect the data in the community, from whom they should collect the data, and how they should go about the task.

Who should collect the information?

It should be possible for this task to be carried out by an appropriately trained data collector without medical or midwifery experience. Alternatively, this could be done by a community health worker. Whoever undertakes the task will, however, require specific training.

From whom should information be collected?

This question may only be answerable after preliminary conversations with a number of people. The objective should be to identify and interview the two or three people with the most direct knowledge of the case, and to avoid collecting information that is second-hand. If the relevant people are either frightened or feel guilty, there may be difficulty in achieving this, but tact and perseverance may lead to success. In some circumstances, it may be decided that a group discussion is the most appropriate way of obtaining the desired information.

How should the information be collected?

Before engaging in anything more than preliminary discussions, the data collector should consider the need to pay a courtesy visit to a community leader and possibly obtain formal permission from them. When conducting the formal questioning, it is best to begin with an open question allowing informants to tell the story in their own words. This should be followed by directed questioning and, at the end, by completion of the structured questionnaire. Many of the questions will have been answered by that time. A sample checklist of questions is included on the CD-ROM.

The interviewer must always be sensitive to the fact that family members may have completely different perceptions of the events that took place, and may feel guilty or frightened. It is very important that the data collector keeps to the community factors, and does not comment on the case management in the facility or facilities. If community members ask about this, they should be referred to the appropriate person in the concerned facility.

Quality control of the data collection process is important. Steps that can be taken include supervisors or other review team members sitting in on interviews, or calling back on informants in the community to ensure that they were contacted.

Step 8: Synthesize the data, interpret the results, and draw conclusions

Review of individual maternal deaths should be carried out first. Second, the results of all cases should be synthesized to identify any common patterns. In both cases, avoidable factors related to events before admission, to the availability of health facilities, and to the care given by health professionals should be highlighted.

The normal procedure is to hold a meeting of all those concerned with the management of the case. Those invited to attend should include any health workers who cared for the patient before her admission to the hospital. Laboratory staff, pathologists and all those who may have relevant information should also be included.

The details of the case or cases should be presented in a factual, comprehensive and precise manner, without any initial judgements being made. Discussion should follow in an attempt to fully understand the chain of events. It is important that a nonrecriminatory atmosphere be maintained so that the discussion is honest and without fear of blame. This peer review should, however, be a nonanonymous and nonconfidential procedure. This improves accountability and the participants' willingness to cooperate in subsequent corrective measures.[11] Nevertheless, there has to be a code of confidentiality within the peer group participating in this step of the review.

The ultimate goal of these meetings is to identify factors that, if they had been avoided, might have prevented the death. Some maternal death investigators have substituted a search for evidence of substandard care instead of avoidable factors. This is because it is easier to recognize where care might have been better than to know if better care would have prevented a death. It is also thought that it makes it easier to take into account not only failures in clinical care, but also other factors that might have adversely affected care. These include shortages of resources for the provision of staff, administrative shortcomings, and failure to provide services such as blood transfusion.[12]

In the synthesis of the results of all cases, the important findings from the individual maternal deaths are combined in a search for common patterns. At this point, the aggregated data and results should be presented anonymously. This is particularly important if there is to be any publication of the findings.

One or two members of the team should first prepare the synthesis of the findings, which is then presented to a small group of staff. An attempt should be made to reach agreement about the significant findings. These could, for example, be that:

- A disproportionate number of deaths occurred to women from a particular locality.
- Insufficient use of blood transfusions was a common avoidable factor.
- Delays in seeking a second opinion occurred on a number of occasions.

These initial findings need further interpretation, however, since there could be several explanations for any of the above findings.

For example, some suggestions of why **insufficient use of blood transfusions** could be a common avoidable factor include:

- Were community members reluctant to donate blood?
- Was there an inadequate supply of *safe* blood?
- Were patients reluctant to receive blood, for reasons that include fear of HIV infection?
- Were laboratory assistants not available after hours?
- Were doctors unwilling to take donations or to group and cross-match blood?
- Were supplies inadequate, e.g. transfusion bags, blood-giving sets?
- Was there a repeated underestimation of blood loss or of the need for blood replacement?

The review team may thus have to undertake some more fact-finding before they can safely draw conclusions about the underlying cause(s) of avoidable factors.

Whatever measures the team takes, it is important to carry out further checks on the way the data have been synthesized and interpreted. Checks on the process of synthesizing the results could, for example, be done by comparing the patterns between facilities or districts to see if there are any major inconsistencies which point to mistakes in collating the material rather than real differences. Obtaining a second opinion or consensus opinion on the interpretation of findings is also likely to result in more valid conclusions being reached.

In most facility-based maternal deaths reviews, the investigators sift all the evidence and use their judgement to decide what happened. This can be a very difficult job, as the evidence from different sources is often both convincing and conflicting. If this is the case, it may be helpful to make use of an innovative approach for dealing with this problem called the Rashomon Technique.[13]

This technique consists of the nonjudgemental recording and subsequent analysis of the factual history given by a series of key witnesses of the events as shown in the examples in Box 5.2. No attempt is made to decide which of the accounts is the most accurate. Rather, the differences of perception and interpretation among the witnesses are used to develop insights into how matters appear to different people. From this, an attempt is made to draw conclusions about how interventions might change the behaviour of both community members and health workers in such a way as to improve maternal health.

Box 5.2—Findings from applications of the Rashomon Technique[14]

". . . for many family members the volume of blood produced after a birth was itself shocking, and . . . this shock was sufficient to cause fear or confusion, which could lead to either action or paralysis among the family members."

Sending family members on errands to find blood or medicine to 'save' the women often indicated the failure of health facilities to prepare for emergencies, and the tendency of health professionals to shift responsibility for treatment back on to the family.

"Interviews with health services staff found that the reasons for not providing emergency care during transportation are many and varied. They range from the simple, and probably valid, statement that the village midwife is needed to serve other patients . . . to the more complex issue of how the midwife would make arrangements . . . when she has no budget for such activities."

". . . a deeper level of difficulty [was] revealed in the hesitance of midwives, nurses and doctors to give any service to patients who will be immediately passed on to a higher level of referral. The term 'takut salah' (fear of making a mistake) often comes up, and it seems that such a fear is particularly acute when a patient is being sent to a specialist."

Step 9: Utilize the findings

The review team members must understand that it is their responsibility to ensure that all lessons learned are acted upon. Indeed, the provision of feedback to the appropriate people is a moral and ethical requirement. An action list should therefore be prepared at the conclusion of every review, whether it involved an individual death or a series of deaths. The list should note what needs to be done and who is going to do it, and who is going to contact others not present at the meeting. The list should be reviewed later to confirm that all actions have been taken. The range of people who may have action to take includes:

- The head of obstetrics and gynaecology or individual obstetricians
- The head of nursing/midwifery or individual nurses/midwives
- Senior anaesthetist or individual anaesthetists
- Community health staff
- Hospital pharmacist
- Laboratory chief
- Hospital manager or administrator
- Doctor or midwife at referral facility
- Community leaders

The actions required in the case of a particular death might include, for example:

- Pass on new information to close relatives of the deceased woman.
- Speak to the facility pharmacist about maintaining supplies of a particular drug.
- Make new arrangements for the collection of blood from the blood bank.
- Rewrite a section of a clinical guideline.
- Apply corrective measures and/or provide supplementary training for a staff member.
- Provide feedback to health educators, NGOs, and public authorities (e.g. water and transport) where findings are of relevance to their work.

Box 5.3—Case study 1: Facility-based maternal deaths review in Nepal[14]

A facility-based maternal deaths review was carried out in three districts of Nepal during 1996 and 1997. This was part of a study which included community-level verbal autopsies of maternal deaths, as well as case reviews of maternal deaths occurring at the hospitals and of cases of maternal morbidity in hospital inpatients.

The review was conducted in four hospitals of the three selected districts. Obstetric and gynaecology physicians and nurses in the maternity wards of the hospitals were trained in the process. The review was begun within 24 hours of the occurrence of a maternal death. The physician initiated the review and the doctor and/or the nurse completed a review form.

The review process was based entirely on the *no name—no blame* principle, with a primary aim to determine whether the maternal death was due to substandard care or to other factors. The selection of cause of death was made according to the guidelines in ICD-10 (WHO 1993). A questionnaire was used to review each maternal death, with information collected from the maternity and laboratory registers as well as from interviews with all staff members who were involved in providing care, including ward boys and hospital peons.

The review facilitated the collection of information about the dead women on social and economic factors such as religion, caste, occupation, marital status, education and age. Important maternal information such as cause of death, period of pregnancy, parity, gestational age at death, desire for the pregnancy, awareness of family planning, antenatal care, and place and type of delivery was also obtained.

The review highlighted the importance of skilled attendance at delivery and the timely recognition of danger signs in pregnancy, both at home and in the hospital. The review also identified avoidable factors, finding that most of these factors related to medical services (79%). Patient and family-related factors (13%) and transport and access to health facility factors (8%) were also noted. Among the medical service factors identified, institutional delay in treatment (23%), lack of blood (19%), and inappropriate institutional treatment (19%) were the main ones noted.

To avoid future deaths, it was determined that immediate attendance, evaluation and treatment needed to be carried out on the patient's arrival at the institutions. The review identified that coordination between the attending physician and the laboratory and blood bank staff should be reviewed and problems corrected. In order to address the problem of inappropriate treatment, it was felt that clinical protocols should be developed and followed by the staff.

The ultimate goal of all these activities is the prevention of similar cases of maternal death in the future. It can be expected that this will be partly achieved by the practical actions taken. An example of how a *facility-based maternal deaths review* in Nepal led to decisions to take practical actions is shown in Box 5.3. Box 5.4 shows the value of reviewing maternal deaths in West Java. But perhaps it should be stressed that the most long-lasting benefits are to be expected from what individual staff members learn as a result of the activities. Those conducting a facility-based maternal deaths review should therefore carry out the actions required in a manner that maximizes educational gains.

Step 10: Decide whether to repeat the facility-based maternal deaths review at a later date or make it a continuous process

It is important to complete the review process by reflecting on the experience. A decision should be made about whether or not a further or continuous process of review is justified, given the resources it takes and the benefits obtained in terms of actionable information. Useful lessons on the conduct of the review should be drawn and used to improve subsequent reviews.

Box 5.4—Case study 2: West Java[16]

The maternal deaths in this case study were identified through a perinatal surveillance system and were matched with data collected prospectively in both facilities and the community. It was therefore not a facility-based maternal deaths review as described in this chapter. Nevertheless it does highlight the way in which reviewing maternal deaths can identify common deficiencies in care and lead to decision-making to overcome the problem.

As part of a study of the risk approach in a rural area of West Java, Indonesia, all maternal deaths over a two-year period were identified and reviewed.

Half of the maternal deaths were due to haemorrhage, and two-thirds of the haemorrhage deaths were due to retained placenta. The case reviews from the latter group of deaths revealed very similar stories. After birth of the infant, the placenta would not deliver. The birth attendants, mostly trained TBAs, appropriately referred the women to a local health centre. At the health centre, the trained midwives, who had been taught theoretically how to manually remove a placenta, in practice were unable or unwilling to perform the procedure. Therefore, the women were sent to the district hospital, three hours down the road. Either the women died en route or arrived at the hospital in irreversible shock or with acute respiratory distress syndrome (ARDS or "shock lung"), and died.

Review of cases identified a discrepancy in the theoretical versus actual skills of health centre midwifery staff in dealing with retained placenta and the need for development of guidelines and retraining.

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6 Confidential enquiries into maternal deaths

Gwyneth Lewis

Key messages

- ✓ Confidential enquiries "tell the story" of how and why individual women died and trace their path through the health and community services.
- ✓ Confidential enquiries provide evidence of where the main problems in overcoming maternal mortality lie and an analysis of what can be done in practical terms, and highlight the key areas requiring recommendations for health sector and community action as well as guidelines for improving clinical outcomes.
- ✓ The ownership or involvement by those in a position to influence changes in the health care system means the findings can be used to develop national or regional maternal health care programmes.
- ✓ The ownership by the various health care groups involved can lead to the development of clinical guidelines or standards with subsequent dissemination, implementation and audit to improve quality of care.

In common with the other methodologies described in this handbook, the primary purpose of *confidential enquiries into maternal deaths* is to learn lessons in order to save lives and to reduce the burden of severe maternal and neonatal morbidity. Confidential enquiries are not exercises in counting numbers of deaths for statistical purposes, or for calculating maternal mortality ratios (MMR), although this may be an additional useful consequence if national coverage is complete. Instead, they provide evidence of where the main problems in overcoming maternal mortality lie and an analysis of what can be done in practical terms, and they highlight the key areas requiring recommendations for health sector and community action as well as guidelines for improving clinical outcomes. The information gained from such enquiries must be used as a prerequisite for action.

The major difference with this approach compared to the others discussed in this handbook is that, being owned at a level at which policies can be made or guidelines developed, the results and recommendations can have a far wider impact on maternal health than is the case for enquiries carried out only within local facilities or communities. Such wider enquiries provide data for health planners and ministers to change or develop policies and to raise investment levels in health care when practical. Their ownership by the various health care groups involved leads to professional clinical guideline development, dissemination, implementation and audit. The findings can be used to develop national or regional maternal health care programmes based on vision but grounded in reality.

A second difference is that although the data are initially collected in a confidential manner at the local level, it is then anonymized before collation and assessment by an independent multidisciplinary group of health professionals. This means the name of the woman who died, the health care workers who cared for her and the institution in which she died cannot be identified. This enables those who cared for the woman to have the confidence to provide an unbiased and frank account of the actual circumstances, and any deficiencies, surrounding her death without any fear of punitive action. Thus, a more realistic picture of the precise events and any avoidable or remediable factors in the care she received can be obtained.

Confidential enquiries are essentially observational studies, using qualitative and quantitative analysis, which take account of the medical, and sometimes, nonmedical factors that led to a woman's death. They provide data on individual cases, which when aggregated together can show trends or common factors for which remedial action may be possible.

Observational studies provide insights into the many factors that may have led to a woman's death. Although the medical causes as listed on death certificates may be the same, the underlying reasons why the woman died may be very different. For example, a woman may die of haemorrhage for several reasons: she may not have had any maternity care; she may have been unable to access care; she may not have appreciated the seriousness of her symptoms; she may have received inadequate care or she may not have had access to blood transfusion services.

As described later, confidential enquiries can also have a powerful effect in "telling the story" of how individual women died and provide commentaries if necessary.

6.1 Lessons from the first fifty years of the United Kingdom confidential enquiries into maternal deaths

The longest running example of a confidential enquiry into maternal deaths (CEMD) is that of the United Kingdom. During the 1920s, at a time when other health indicators such as infant mortality were improving, health care professionals and women's advocacy groups became concerned about the apparent lack of similar improvement in levels of maternal mortality. Consequently, in 1928, local health professionals started a system of case review audits.[1] Although not national in scope, these maternal death audits included a detailed review of adverse events. Over time, as commitment improved, these small-scale reviews or local facility audits evolved, by 1935, to wider area health authority-based systems of confidential enquiries, the recommendations of which played a major part in reducing the maternal mortality rate over the next two decades.

The early years of these enquiries were a time of dramatic progress, especially since women did not have universal access to free health care until the founding of the National Health Service in the late 1940s.

Since 1935, the overall maternal mortality rate in the United Kingdom of Great Britain and Northern Ireland has fallen from 400 to 11 per 100 000 maternities in 1999. With the exception of HIV and AIDS, the pattern of main causes of maternal deaths across the globe today, namely sepsis, haemorrhage, eclampsia and illegal abortion, are strikingly similar to those that were prevalent in the United Kingdom of Great Britain and Northern Ireland in 1935. The introduction of aseptic techniques reduced mortality from sepsis before the advent of antibiotics, and delivering higher risk women in hospital reduced deaths from haemorrhage as much as did the introduction of the blood transfusion service. So the adoption of the simple and, at the time, non-evidence-based, guidelines contained in the early reports played a significant part in the substantial decline in the maternal mortality rate in the United Kingdom of Great Britain and Northern Ireland.

The most dramatic decline in a local maternal mortality rate was achieved in Rochdale, an industrial town in the poorest area of England, which, in 1928, had a maternal mortality rate of over 900 per 100 000 pregnancies, more than double the national average of the time. Following local concern, the local public health department undertook a confidential enquiry, action on the results of which reduced the maternal mortality rate to 280 per 100 000 pregnancies, the lowest in the country, by 1934. This achievement was all the more remarkable as it took place during a time of severe economic depression, yet the report states: "it is important to note that the results were obtained by a change in spirit and method and without any alteration in the personnel or any substantial increase in public expenditure."[2] The survey ascertained that the leading causes of death were compounded by the women's ignorance of pregnancy and the far too frequent use of forceps and other techniques to deliver the women quickly. The local medical and midwifery professions worked together to introduce new standards of care and, as the published report states, "all available agencies such as the platform, the pulpit, the factory supervisor, and the press, were used to awaken the community to the need for antenatal care and the signs and symptoms of complications".[2]

In commenting on the impact of the findings of this and other earlier enquiries, Sir George Godber, a past Chief Medical Officer for England, stated, "All this procedure had been intended to do was to secure improvements by the local review of cases, but it was soon apparent that avoidable factors were too often present in antenatal and intranatal care for the opportunity for central remediable action to be ignored."[3] This led to the decision to undertake a national confidential enquiry for England and Wales in 1952, which was extended to cover the United Kingdom (UKCEMD) in 1985 and is a system which is still running, and improving maternal health care, 50 years later.

The first reports of the CEMD for England and Wales were very short documents, 24 to 40 pages long, and focused only on the three or four leading causes of death, rather than the all encompassing clinical and public health factors also considered today. This early approach is one that could easily be adapted for use by other countries today. The reports all demonstrate that the case needs to be made that information is a prerequisite for action.

What was also important in the early enquiries was that the recommendations made were simple, cheap, effective, and widely disseminated. Some were very similar to the evidence-based World Health Organization's guidelines for the Integrated Management of Pregnancy and Childbirth (IMPAC) in use today.[a] Both still remain as relevant to the United Kingdom of Great Britain and Northern Ireland as to many other countries.

Perhaps one of the most important features of the UKCEMD reports is that they have always included anonymous "vignettes", short case-summaries which "tell the story". The enquiry team never forgets that each woman's death is an individual personal and family tragedy. Neither do they forget the woman had a unique story to tell and tracing her path through the health care system and describing the action(s) that might have been taken to prevent her death, has a powerful effect on those who read the stories, many of whom report immediate changes in their practice as a result.

Participating in a confidential enquiry, either by providing data and writing-up the history of a woman whose face and family can still be remembered or even by assessing the case anonymously, can be regarded as a legitimate health care intervention. And, as a result, personal or local changes in practice based on this experience may occur long before the report and its recommendations are published. In the United Kingdom, as long ago as 1954, it was recognized that participating in a confidential enquiry had a "powerful secondary effect" in that "each participant in these enquiries, however experienced he or she may be and whether his or her work is undertaken in a teaching hospital, a local hospital, in the community or the patient's home, must have benefited from their educative effect."[4]

Personal experience is therefore as valuable a tool for harnessing change as anonymous statistical reporting, perhaps more so.

National enquiries, either continuous or undertaken at regular intervals, as well as subnational enquiries have subsequently been carried out in a number of countries, for example in Australia, some states in the USA and in certain European countries. More recently, confidential enquiries have been started in parts of Suriname, Malaysia, Israel, Indonesia and South Africa by using an adapted United Kingdom of Great Britain and Northern Ireland confidential enquiry methodology. Smaller time-limited enquiries have also been carried out in other countries such as Jamaica, the Netherlands and Egypt. A number of other countries have also expressed an interest in exploring the feasibility of undertaking such studies.

[a] IMPAC is a comprehensive set of norms, standards and tools that can be adapted and applied at the national and district levels in support of country efforts to reduce maternal and perinatal morbidity and mortality. Available from Department of Reproductive Health and Research, WHO, Geneva. Consult website http://www.who.int/reproductive-health for further information.

Vignette 1: A case of uterine rupture[5]

The following case study illustrates the avoidable factors, including inappropriate use of syntocinon, in the death of a woman with a ruptured uterus.

The woman was 32 years old when she died. She had given birth to three children, all of whom were alive at the time of the household interview, and her previous pregnancies and deliveries had been normal. The woman had been using an IUD for eight years, but removed it at her husband's request. During the pregnancy that led to her death, she had one antenatal care visit with an obstetrician in a private clinic. She had recurrent vomiting before her labour pains started. During labour she was seen at home by a midwife who gave her an injection of syntocinon. Eight hours later she was taken to the district hospital where a ruptured uterus was diagnosed. The hospital had no blood and within 15 minutes she was transferred to a governorate hospital for a hysterectomy. She died on the way.

Vignette 2: A case of postpartum haemorrhage[6]

A woman who had had a retained placenta with postpartum haemorrhage in her previous deliveries (on the first occasion being recorded as placenta accreta) had an induced delivery. Labour was induced over a weekend and, when the placenta was retained, there was midwifery delay in calling the registrar. When haemorrhage became profuse there was then a further delay before the registrar called the consultant and more delay in proceeding to hysterectomy under general anaesthesia. This was compounded by further delays in obtaining cross-matched blood from a hospital several miles away. Uncrossmatched O negative blood was appropriately given, but by then the situation was out of control and cardiac arrest occurred. Ergometrine had been given at delivery, but was not repeated.

It was inappropriate for this very high-risk woman to be booked for confinement in a hospital without an on-site blood bank. There was no overwhelming reason for induction, which increases the risk of 3rd stage complications, to be done at all and certainly not at a weekend.

Vignette 3: Lack of knowledge of symptoms and when to seek help[7]

A woman with one living child and in her fourth pregnancy was admitted to a local hospital with a history of severe headaches, epigastric pain and visual disturbances. The day before admission she lost consciousness. She died of eclampsia despite excellent subsequent care. She had not sought any antenatal care and she and her family were unaware of either the seriousness of her symptoms or of the need for care.

6.2 What is a confidential enquiry into maternal deaths?

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

Therefore, the main aim of a confidential enquiry is to save lives by determining any deficiencies in each woman's personal health care or in the health care system or community that may have contributed to her death, collating the sum of knowledge and evidence acquired from assessing the totality of cases and recommending appropriate changes as shown in Figure 6.1.

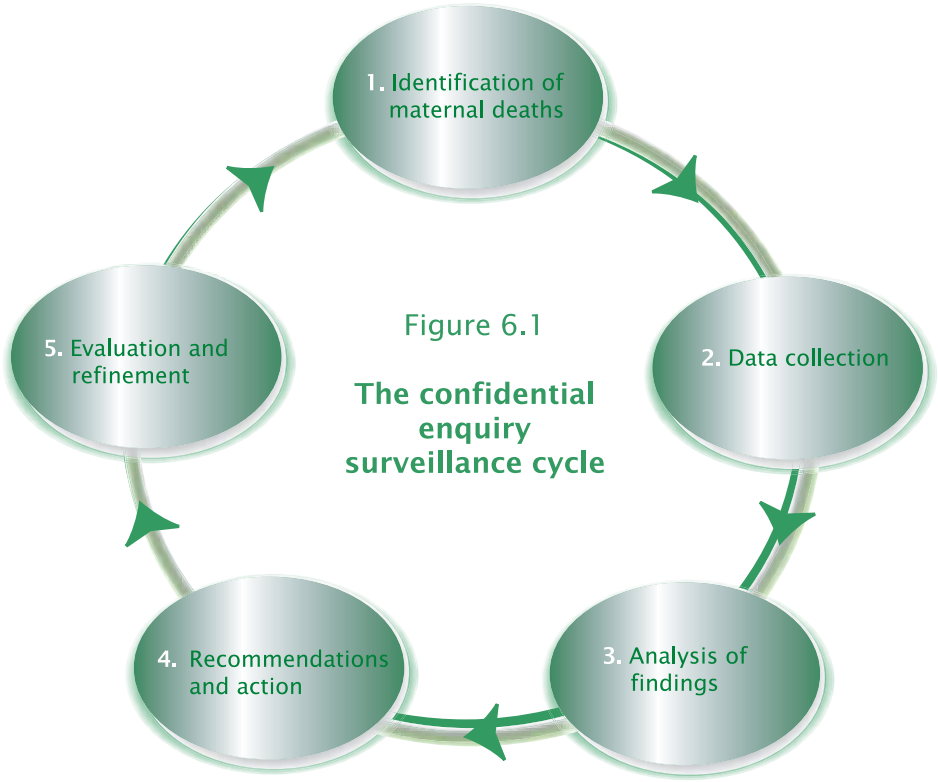

Figure 6.1

The confidential enquiry surveillance cycle

Characteristics of a confidential enquiry into maternal deaths

- It should be nationally or regionally owned and have the support of health care planners, professionals and the Ministry of Health. The data provided should be of sufficient robustness to enable:

- national or regional policy development for improvements in maternal health care programmes and to provide a sound basis for seeking an increase in programme funding, if and when available;

- the production of clinical guidelines and wider service development strategies which should impact directly at an individual level on saving women's lives; and

- feedback to be given to the community, women's groups or women in general to help them in their advocacy, and to understand key messages regarding their own health and pregnancy.

- It involves an anonymous multidisciplinary in-depth assessment of the causes and circumstances surrounding maternal deaths in selected groups of facilities, regions or countries. The focus can confine itself to specific clinical issues and barriers to care, or be all-encompassing by further examining the circumstances in the community or family that may have contributed to the woman's death. Each enquiry will have different objectives dependent on local priorities, factors and resources; there can be no set template for such studies.

- The process is confidential and all names of the women or any health care workers involved are removed before assessment. This provides a secure environment in which only anonymized cases are assessed, thus resulting in a greater openness and completeness in reporting with a more complete picture as to the precise sequence of events.

- It uses relatively inexpensive survey methods which do not have to depend on complete vital statistics nor on an accurate breakdown of causes of death as a precursor for action.

- It uses relatively simple reporting systems. In countries such as the United Kingdom, where maternal deaths are uncommon, a simple paper-based system is used and the use of a computer for storing anything other than completely anonymized data is precluded for reasons of data protection. On the other hand, the South African enquiry does use computer technology, as it is much larger in scale, considering over 1000 deaths a year. It has developed a simple anonymous programme which provides basic demographic data, causes of death and tables on avoidable factors. The data form is a single page and forms a checklist for assessors. This anonymous form is filled in by the assessors who either e-mail it or send it to the national office.

- Each case has a standardized confidential report form completed by all local health care workers who provided care to the woman who died. These may include the woman's primary care provider, the local doctor, obstetrician, anaesthetist, nurse or midwife who cared for her during her pregnancy, delivery or in the postpartum period, and any other physicians, surgeons and nursing staff who provided care for conditions associated with her death. Sections should also be completed by any

pathologist who may have been involved and autopsy details provided if available. In addition to medical details, if possible, information should be collected about the woman's socioeconomic, domestic and geographic circumstances and any cultural practices that might have had an effect on her death.

- These report forms are then anonymized by the local enquiry coordinator before being assessed by a regional multidisciplinary panel of assessors who were not involved in the woman's care. The assessors are usually based in another institution or another part of the country. Their evaluations are then collated and assessed by the central steering committee which prepares the final report and its recommendations.

- By covering all, or a representative sample, of maternal deaths, the numbers may not be so large as to appear overwhelming in their planning, undertaking and evaluation. And by acting on the findings and using existing guidelines such as the IMPAC handbooks alongside the studies to develop local as well as national protocols, the improvements in outcomes are visible and compelling to health care planners and professionals alike.

6.3 The advantages and disadvantages of a confidential enquiry into maternal deaths

The advantages of undertaking a confidential enquiry into maternal deaths include:

- Being able to make national or regional recommendations of a more general policy or clinical nature than would be the case for enquiries carried out only within local facilities.

- Providing evidence on which to argue for increased maternal health care resources.

- Strengthening the capacity to design and implement maternal health programmes in a variety of settings.

- Providing a more complete picture of maternal mortality than generally available from maternal health records.

- Enabling flexibility in considering outputs, which could range from considering all causes of maternal deaths to just focusing on the specific leading causes of maternal death.

- Providing a confidential, nonthreatening environment in which to analyse the factors leading to individual women's deaths. All records are anonymous and destroyed prior to publication and therefore do not provide a basis for litigation or apportioning blame.

- Motivating and enthusing staff who have been involved and who can see the real benefits from such a relatively simple study, which may lead

to the beneficial adoption of changes in local practice even before the actual report is published.

- Encouraging staff who have been involved to act as advocates for change within the local and national health care systems as well as helping others to institute similar methodologies.

The disadvantages of undertaking a confidential enquiry into maternal deaths include:

- Not providing a substitute for routine data collection on the causes of maternal death or the MMR.

- Providing numerator data only. Information about the characteristics of all women giving birth are not available through the enquiry, although basic numerator data is usually available. If possible the data about maternal deaths should be viewed in the context of the overall births registered, otherwise there is a risk of making conclusions that the data do not warrant.

- The process works better if there is a functioning statistical infrastructure (vital records and statistical analyses of births and deaths, human resources, recording clerks, etc.). However, the lack of such resources does not necessarily preclude the collection of what data is available. Telling and analysing even individual stories can act as a powerful motivator for change.

- In some cases, due to resource or manpower constraints or the sheer scale of the problem, the enquiries will only be able to focus on clinical issues and not address the underlying socioeconomic and demographic factors that contribute to maternal mortality, such as poverty, malnutrition or geographical location. However, even if it is not possible to undertake more than a limited clinical enquiry, provided the guidelines or recommendations are accepted and used, improvements in maternal health should follow.

- It is important to ensure mechanisms whereby the guidelines that are produced are actually implemented. Recommendations can be made and guidelines produced but they mean nothing unless they are translated into action.

- Because the confidential enquiries do not generally use interviews with relatives or others in the community, the results tend to focus on remediable clinical or health factors, although community issues can often be identified.

- A confidential enquiry will require more resources or personal commitment than some of the other methodologies discussed in these guidelines, but does not necessarily have to be hugely resource-intensive. Its methodology can be adapted to suit the resources available.

The majority of the work is usually undertaken by motivated local staff, although participation in the process can also be made explicit in job descriptions.

6.4 Key principles

The importance of national and local ownership

The importance of researchers collaborating or having the support of the government or state cannot be overemphasized. Although local *clinical audits* may have an important effect on reducing local maternal mortality rates and are to be encouraged, it is governments or states who can translate the activities and findings of confidential enquiries into national policies.

Many good programmes come to an end when funding ends. Governments and other key stakeholders need to be informed of progress and invited to meetings or sit on steering committees.

Also crucial to the success of such enquiries is the local support and participation of all relevant health care workers. It is usually these very people who act as the catalyst for such studies in the first place. Local ownership also improves feedback, and this point needs to be borne in mind when choosing assessors. Participants may need to be reassured that the process is confidential, that case assessments are anonymous and the sole purpose of the enquiry is to save lives and not to apportion blame. They need to feel that it provides a safe environment for discussing sensitive details about their professional practice without fear of provoking management sanctions or litigation.

Time scales

A confidential enquiry can take time to establish. Once up and running, the process of assessment is therefore generally continuous, though the reporting will be occasional, for example every year, every three years, etc., depending on the number of maternal deaths assessed in order to provide meaningful information. In Egypt, a successful confidential enquiry was undertaken for one time period only.[8] This approach was useful in determining what the main problems were and in which part of the country they were occurring. Most other confidential enquiries are continuous, not only because the value of continuity demonstrates the change (or lack of change) that the recommendations and guidelines have achieved and is an essential part of closing the audit loop, but also because it is once health professionals have seen the benefits of participation and the numbers of lives saved that they wish to continue to provide data to secure further improvements.

Identifying maternal deaths: the advantages of health care worker reporting

The trigger for the United Kingdom enquiry is through health care workers reporting maternal deaths to the enquiry team. This is supplemented through death certificate information, although up to 20% of indirect maternal deaths were coded incorrectly on the certificate for the last report *Why Mothers Die, 1997-1999* and would have been missed in the absence of direct reporting by health-care workers.[6] This method of case ascertainment usually leads to a slight rise in the number of maternal deaths reported in the first few years of an enquiry. This should be expected at the outset and should not act as a disincentive.

Countries where vital statistics are available should make use of these by passing death certificate information to the enquiry. However, hospital superintendents, clinicians or other health care workers should supplement this by also identifying maternal deaths and notifying the enquiry team. The advantage of this system is that the case can be assessed early when the circumstances of her death are still fresh in people's minds and the case notes probably available. Death certificate information may take many months or even years to be processed, by which time the memory of events has faded, the health care workers concerned may have moved elsewhere and the case notes may no longer be available.

Another mechanism is to make maternal deaths notifiable events similar to the example of TB in many countries. In the United Kingdom of Great Britain and Northern Ireland, health care workers have a duty to report a maternal death to the enquiry. In South Africa, failure to notify a maternal death is regarded as professional misconduct.

Countries where vital statistics are unavailable can still institute enquiries for the reasons outlined previously. Here a nominated person in each health facility should have the responsibility of identifying and notifying each death to the enquiry, and can also collect simple denominator statistics such as the number of women who deliver each year. Other solutions to case identification can also be found. For example, in Malaysia, the police notify the authorities about deaths of women 15 to 49 years of age occurring in private hospitals, and district health staff then conduct an assessment.

Using multiple methods to identify maternal deaths will help ensure that coverage is as complete as possible. Information about deaths in hospitals may be found by reviewing the delivery and operating theatre registers as well as case records. Deaths in the community are more difficult to identify, and if these are to be studied, then close cooperation with community staff is essential. If the vital registration system is complete, it is useful to obtain an overview of all deaths in women of reproductive age as well as information about known maternal deaths. This should identify those deaths not known to the maternity services.

The use of death certificates

Death certificate information is a valuable method of case finding, but has its limitations as previously discussed. The provision of a box on the death certificate, asking if the woman was pregnant or had delivered within a specified time period prior to death, can also help with ascertainment of maternal deaths. Many may be missed, however, either because the death did not occur in a maternity hospital or because it occurred outside the hospital some time before or after pregnancy. When death certificates of women of reproductive age are examined to identify maternal deaths, it is important to review all causes of death on the certificate, not only the underlying cause. For example, on examination of all causes it may be found that a death from pulmonary embolism resulted following caesarean section for massive placental abruption.

6.5 Translating findings into action

This is the whole purpose of the enquiry, for without action on the recommendations the process is worthless. It should therefore be agreed at the outset that the information obtained be used as a prerequisite for action. The results will determine what the main causes of death are and whether there are any avoidable or remediable factors in the care provided to the women. The enquiry enables practitioners and health planners to learn from the errors of the past. It provides evidence of where the problems are, and highlights the areas requiring recommendation for health sector and community action as well as clinical guidelines. The enquiry forms a baseline against which the success of changing practice can be monitored.[9] Therefore, in-built into the system, there should be an objective method to monitor how the recommendations are being implemented. This has two values; firstly, it provides a stimulus for health sector action and, secondly, reminds the enquiry authors to be sure of the evidence base for their recommendations.

Information from the findings of a confidential enquiry is used at institutional, local and national levels by health service planners, clinicians, educators and, increasingly, women's advocacy groups. At the national level, decisions in the planning of services are influenced by enquiry findings. For example, specific problem areas identified in the first interim report on confidential enquiries into maternal deaths in South Africa led to ten recommendations.[10] These ranged from specific management of pregnancy and labour issues to delivery of services for termination of pregnancy, and to the need for family planning services to counsel high-risk groups. Clinicians use the findings to inform their practice and to learn lessons for future management of certain complications. Educators use the findings for the training of junior midwives and doctors. Women's groups use the information so that they know what the problems are and can, for example, make more appropriate representations to the health authorities.

6.6 Step-by-step process for setting up a confidential enquiry

This section provides a checklist of the steps needed to be taken in planning a confidential enquiry. It should be read in conjunction with Chapter 3 where many of the explanations and practical issues common to all methodologies are covered in more depth.

In summary, the steps are:

1. Set up a national or regional maternal mortality committee, if one does not already exist.
2. Decide on national, regional or district data collection, which cases to include and which approach to adopt.
3. Plan data collection and determine the time frame for reporting and completion.
4. Set up regional teams of assessors and set up and train local coordinators.
5. Regularly assess deaths, collate and analyse the findings and prepare recommendations for action.
6. Disseminate the findings and recommendations.
7. Evaluation and refinement.

Step 1: Set up a national or regional maternal mortality committee, if one does not already exist

Committee members should have an interest in maternal health and should preferably be selected as representatives of the leaders of their professional organizations and the Ministry of Health rather than just individuals from particular disciplines. The aim of the enquiry is to stimulate action, and leadership structures of organizations have a greater ability than individuals to implement changes in policies and practices. In the United Kingdom, this committee has always been chaired by an official from the Ministry of Health, thus enabling the findings and recommendations to be taken to the heart of the policy-making process. The committee should not be too large as to be unworkable, but should include one or more persons from the following specialities as a minimum: obstetrics, midwifery/nursing, anaesthesiology, pathology, statistics, public health, and regional or local government.

The committee should examine all available national or regional data or other sources of information such as informal surveys to identify the number and causes of likely deaths that will require investigation. The final scope will be dependent on resource requirements and the capacity of the system. In deciding this, the committee may find it helpful to draw on the experience of other countries which have instituted similar enquiries.

The key roles of the committee are to:

- Identify and plan what type of enquiry to undertake, plan the mechanism for the enquiry and utilize what is best or most appropriate from existing enquiries where practical.
- Include key stakeholders from government, the health care system, professional organizations and community-based groups who can assume ownership and can act as advocates for change.
- Provide oversight and consultation to the local assessors.
- Oversee the pilot testing of the confidential enquiry system in selected areas.
- Provide support for extending the enquiry process to the whole region or country.
- Review the cases on an ongoing basis.
- Synthesize the data, interpret the results, make recommendations for action and prepare a report.
- Plan the dissemination of the report, obtain feedback and utilize the findings. The dissemination may include a national-level event, such as an official launch by the Minister of Health, with the involvement of the media, parliamentarians, and women's groups.

Step 2: Decide on national, regional or district data collection, which cases to include and which approach to adopt

National, regional or district?

There are a number of ways in which a confidential enquiry can be organized. In some circumstances, the detailed investigation of deaths may be limited to certain causes of death or certain sectors of the health care system, such as public health facilities in countries where access to records in private institutions is unobtainable. In large countries, or countries where maternal mortality rates are very high, however, it may be more appropriate to organize the enquiries at the district level or at the level of a region or province. In Brazil, for example, the confidential enquiry takes place at the municipal level where the data are collected, analysed and published, and then sent to the national level for consolidation. In Egypt, the national confidential enquiry (based on a representative sample of all health care districts) was supplemented by information derived using verbal autopsy. A further option is, while recording basic details on all maternal deaths, to limit the detailed enquiry to two or three leading causes of death, such has occurred in the earliest reports of the United Kingdom of Great Britain and Northern Ireland confidential enquiry.

Countries with incomplete vital registration systems need to consider whether the effort and resources required to identify all maternal deaths are feasible and sustainable. In these situations, smaller scale, less resource-intensive enquiries may prove as effective in producing findings for local action. In some cases, while the reporting of deaths is complete, it may not be possible to undertake a detailed investigation of all cases, such as those that occur in private facilities, for example.

The committee will need to decide, based on the number of expected deaths, resources available and the support of the professions, whether to start nationally or undertake pilot enquiries in certain regions or districts as a precursor to a national enquiry.

Which cases should be included? Direct deaths only or both direct and indirect deaths?

The committee will need to decide which maternal deaths it is feasible to investigate. The definitions of maternal deaths are shown in Table 3.1 in Chapter 3. An assessment of the likely number of deaths which are expected to occur and the resources available will enable an initial assessment of the likely numbers of cases it would be possible to investigate. Table 2.1 in Chapter 2 gives the likely number of expected deaths by known maternal mortality ratio.

In most countries the leading immediately avoidable causes of maternal death will be direct causes such as haemorrhage, eclampsia, obstructed labour and sepsis, and assessing these may also offer the potentially greatest short-term benefits in terms of lives saved in relation to available resources. It therefore may be more beneficial in countries with scarce resources and high death rates to limit the enquiry in the first instance to the leading remediable causes of maternal death and expand the enquiry to cover other causes once the methodology is well established and further resources are secured. Countries that have appropriate resources may choose to also include a detailed investigation of avoidable causes among indirect causes of death, such as those from cardiac disease, malaria, diabetes or anaemia.

In some countries, HIV infection may be one of the leading causes of death among pregnant or recently delivered women. The relationship between HIV and pregnancy is a complex one but, in general, these deaths, particularly in developing countries, should be regarded as indirect. Although including deaths from HIV may increase the workload of some of these approaches, it is important to include them wherever possible, as they will represent challenges to be addressed by health programme managers and providers.

Identify the approach to adopt

In some circumstances it may well prove too difficult at the start to institute an enquiry that covers specific details on all maternal deaths at the national or even regional level. In this case, the committee can adopt one of several approaches, depending on local circumstances and by focusing on the groups in which acting on the recommendations will have most potential impact. It is important to restate that a *confidential enquir*y is not dependent on excellent vital statistics and that enquiries based on incomplete data are equally valid in terms of the impact they may have at a local, regional or national level. There are two key issues to consider, namely (1) if all maternal deaths are to be investigated in detail or a subset of, say, the leading three or four direct causes of death, and (2) whether the enquiry will cover all or selected deaths in all circumstances, in health care facilities

only, or in a subset of each. The various approaches that could be adopted or adapted to suit local circumstances are shown in Table 6.1.

Table 6.1 Types of confidential enquiry

	All maternal deaths	Selected causes of maternal deaths
Deaths in both community and all health facilities	Option 1	Option 5
Deaths in all health facilities	Option 2	Option 6
Deaths in selected communities and health facilities	Option 3	Option 7
Deaths in selected health facilities	Option 4	Option 8

Options available

Investigate all maternal deaths

Option 1: This is what happens in the United Kingdom. This system will provide the most robust data and, if good vital statistics are available, can enable the true maternal mortality ratio to be established as well as providing a sound basis for clinical and other recommendations. All deaths from whatever cause occurring during pregnancy and up to one year after delivery are reported to the enquiry, including deaths from incidental causes, suicide and late deaths which occur between 42 days and one year after delivery. It requires comprehensive teams of assessors and a well-established enquiry system. It is not costly as it is well established and the need for complete participation by all health care workers is well accepted. It is also part of the training programme of obstetricians and midwives. Their participation is all the more secure because, due to its confidential basis and anonymous results, no health care worker in the past 50 years has ever been disciplined as a result of participating in the enquiry.

Option 2: This requires less intensive data collection as it is focused on health facilities where the hospital records and staff should be able to provide an account of the circumstances of the death. It can provide very useful data on the major causes of maternal mortality without the problem of obtaining community data and is thus less expensive than Option 1, but potentially valuable community and public health data will be excluded. This is the system in Malaysia and also the approach adopted by the United Kingdom confidential enquiries into suicide.

Option 3: If death rates are generally high or vary widely from community to community, then choosing to undertake an enquiry in a number of specific communities may be the most cost-effective approach from which general lessons may still be learnt. These enquiries will also include

community data. Professionals participating in these enquiries can then be used as local advocates for the introduction of wider enquiries later.

Option 4: This is a valuable approach if death rates are very high and there is an absence of available community data, or if there are significant problems in obtaining data from certain types of health care institution, such as private hospitals. As with option 3, the participating professionals can be used as advocates for the wider introduction of similar enquiries in other institutions later.

Investigate selected causes of death

Option 5: This approach, in which all deaths from specific causes are investigated in detail was the methodology used by the early United Kingdom of Great Britain and Northern Ireland enquiries and is possibly the most appropriate approach for countries which have available resources and high rates of death from remediable direct causes. The greatest reduction in maternal mortality is usually seen among these cases. However, it is still helpful to collect basic details on other causes of maternal mortality in order to monitor trends or refine the process, once well established.

Option 6: As with option 2, this approach has the benefit of limiting the enquiry to selected causes of death which occur within health facilities and may be appropriate for countries with very high death rates or lack of community data.

Options 7 and 8: These options are the minimum level that the confidential enquiry process can support, but may prove to be a useful first step or pilot study. In undertaking these types of enquiry, it is necessary to ensure that adequate numbers of cases are assessed upon which to draw general as well as specific conclusions.

Step 3: Plan data collection and determine the time frame for reporting and completion

Data collection

Chapter 3 details the type of data that should be considered for collection, as there is a tendency for data surveillance systems to collect too much data without a clear plan of what they will be used for in terms of outputs. All enquiries should develop a standardized maternal death notification form that takes the institutions and data collector through reporting the death in a systematic way and which asks the same questions on each aspect of care for every woman. Completing these forms can also act as a learning process for the individuals and institutions concerned. Regional assessors will have an additional form to complete which translates the information on the report form and the case notes into a standardized format, with specific fields or variables. Examples of these, which can be adapted for local use, are available from the existing enquiries and in the CD-ROM available with this guide on request.

Determine the time frame for reporting and completion of the report

It is important at the outset that a clear time scale be determined, to enable the local assessors to have firm deadlines for asking for case reports and to provide advance publicity that a report is expected. It is also important to be realistic about the time scale envisaged as it can take some time for the process to become established; also, the length of time taken to fulfil a first reporting cycle depends on the number of the cases likely to be assessed. Even after the assessments are completed, it can take time for the central committee to assess them and prepare a report. In general, most confidential enquiry reports are available a year after the end of the reporting cycle. In countries with lower numbers of maternal deaths, a three-year reporting period is used to allow for an adequate number of deaths upon which to base recommendations. In countries with higher maternal death rates, the reporting period could be shorter, but should not in general be less than one year: this will allow the process to become established.

Step 4: Set up regional teams of assessors and set up and train local coordinators

Regional assessors

Depending on the number of deaths to be assessed and the workload expected as a result, a number of regional teams of assessors or expert review committees will need to be established. These committees will review, anonymously, all the cases in their area and collate the findings and send them to the central steering committee. They do not need to know the names of the women or the health care workers. Neither do they have the authority to take disciplinary action. They are expected to assess the case and comment on the standard of care the woman received as judged against local best practice, any barriers she encountered in accessing the system, and point to remediable actions that might be taken in future. It is important that quality control issues be considered in order to ensure standardized and consistent review and reporting. These can be agreed through meetings between the assessors, by two assessors reviewing each case or by random reviews by independent assessors. However, the final level of quality control will take place when all the cases are reviewed together by the central enquiry committee prior to writing and publication of the report.

The members of these groups are usually health care professionals with an expertise in the area of health being reviewed. For example the United Kingdom of Great Britain and Northern Ireland regional committees consist of an obstetrician, midwife, pathologist, anaesthetist and family doctor. In Scotland, the assessors meet every six months to review all deaths, whereas in England, the system of assessment is done by post.

Set up and train local coordinators

Local coordinators are responsible for informing the regional or national enquiry team of a maternal death and for ensuring the report form is completed appropriately. In the United Kingdom of Great Britain and Northern Ireland, the local area Director of Public Health fulfilled this function but has recently been replaced by the local supervisors of midwives. The coordinator can be a particular person in each hospital; midwife or obstetrician, a superintendent or someone based in the local community health department. As not many maternal deaths will occur in each institution, the workload should not be heavy. Local coordinators need to ensure that all staff involved in the care of the women complete the relevant sections and that all other information requested is made available.

The local coordinator will be the only person in the enquiry process who knows the names of the women and the health care workers. Although these details are not shown on the report form, the local coordinator should maintain confidentiality and ensure that the record is securely kept when not in use. It is their responsibility to remove any possible identifying information from the report form before it is sent to the regional assessors for completion.

It is usually helpful to set up training days for both regional assessors and local coordinators to ensure a consistency of approach to data collection and analysis. Issues need to be considered within this context. Regular meetings of the assessors should be arranged to ensure standardized and consistent review and reporting, although the central committee will act as an overall further independent assessment panel. Random reviews by independent assessors can also be set up to verify findings.

Step 5: Regularly assess deaths, collate and analyse the findings and prepare recommendations for action

Regular case assessment

The regional assessors should send their reports on a three to six-monthly basis to the central maternal mortality review committee. Here, the data will be re-assessed, aggregated and ongoing analysis can start. Through this ongoing assessment the committee can also identify particular areas in which the enquiry process is not functioning as well as it should and institute remedial action.

During this process, the emerging findings often become apparent early on and if firm trends are identified, then preparation for guidelines and recommendations can start to be made prior to the publication of the report. It is more useful to publish a report which also contains firm guidelines and recommendations than to suggest these be developed in future. Furthermore, the nearer to the end of the reporting period the final report is produced, the more immediate impact it will have on local practice.

Data analysis

Both quantitative and qualitative analyses provide insights into the causes of maternal deaths. A combination of both can provide more insights into maternal deaths than either can provide alone. Quantitative analysis shows which groups of women may be at higher risk of maternal death, e.g. women from specific ethnic groups, places of residence or who have other characteristics in common. Qualitative analysis then provides more detailed information on the precise causes of death for individual women from the higher risk groups. Readers are strongly encouraged to read the relevant section in Chapter 3 which describes these methodologies in detail and gives useful sources of reference material.

What sort of recommendations to make

The action(s) taken to decrease pregnancy-related mortality will be determined by the findings of the review process and analysis. Interventions to improve maternal health and decrease pregnancy-related mortality fall into three types of strategies, namely:

- *Primary prevention strategies* preventing the condition from occurring,
- *Secondary prevention strategies,* which detect and treat conditions early in order to minimize the effects, and
- *Tertiary prevention strategies,* which treat conditions in an optimal fashion in order to reduce mortality and morbidity rates.

These strategies are discussed in detail in Chapter 3.

Individual country-level enquiries will be able to determine, from their own results, which mixture of these strategies to use in the first instance.

Not too many recommendations at once

In order to help focus the concentration of health care planners and professionals on the key issues to be addressed, it is important to keep the number of recommendations to a minimum. More sophisticated recommendations can be introduced at a later stage of the enquiry. Ensure the key recommendations are those that will achieve the greatest health gain in practice. In clinical areas, these will probably relate to the management of common obstetric complications arising in cases of direct deaths. Even in areas with a high prevalence of HIV infection, the greatest health gains will be achieved through improving the management of women with direct complications of pregnancy where simple interventions can have an immediate life-saving effect. As an example, the South African enquiry only made ten recommendations in its first report, but all were crucial for the improvement of maternal health.[10]

Step 6: Disseminate the findings and recommendations

The maternal death review committee should have planned formally how to disseminate the report, but remain alert to new possibilities. It is important to note that at the outset it will be impossible to define what the specific recommendations may be.

The committee should consider which groups and individuals can act on the findings of the report. These will include the Ministry of Health, public health physicians and health care planners, the professional groups involved in providing community and facility-based maternity care, consumer advocacy groups and representatives of specific faiths or cultural institutions who can also facilitate beneficial changes in local customs.

The format and dissemination of the report depends on the circumstances in which it will be produced. But it is important to get the key messages to those who can implement the findings and make a real difference towards saving women's lives. Large, expensive, very detailed reports are of no use if they cannot be widely disseminated. It may be that producing a comprehensive report for health care planners and policy-makers could be supplemented by the use of shorter "executive summaries" for health care workers. These summaries could be a simple newsletter or short booklet, preferably with an introduction written by the Minister of Health or leaders of health care professional organizations.

It may be that the maternal mortality committee may wish to publicize the report at a national event such as an official launch by the Minister of Health, with the involvement of the media, parliamentarians, health care professionals and consumer advocacy groups.

Step 7: Evaluation and refinement

Closing the audit loop and evaluating the uptake and impact of the recommendations, and modifying procedures accordingly, is the vital last step in any audit process. The key principles are discussed in Chapter 3. In the case of maternal deaths it is important to recognize that achieving significant reductions in overall mortality rates may take time, although local changes in practice can show quite rapid effects. Indeed, maternal mortality rates may appear to increase just after a confidential enquiry is started as case ascertainment improves. This is normal and an expectation for this should be built into the system.

In the United Kingdom, the enquiry identifies certain key auditable standards for maternity care, whose uptake is monitored by regular reviews. In 1996, an audit of recommendations of the 1991–1993 enquiry was undertaken in the United Kingdom's 295 maternity units, with a response rate of 100%.[11] The audit showed that the services planned to minimize maternal risk were improving—more maternity units were on acute hospital sites, with more intensive care units and blood banks on site, and although most units had local protocols for the management of severe complications,

in some instances, these were out of date. The results are therefore useful in reviewing practice and planning maternal health services. The most recent UKCEMD auditable standards are shown in Box 6.1.

Box 6.1—Auditable standards set by the United Kingdom CEMD for 2000-2002

Each unit should identify a lead professional to develop and regularly update local multidisciplinary guidelines for the management of obstetric problems. As a minimum, guidelines should be provided for the following:

- The identification of, and support for, women with higher risk pregnancies and who appear unsuitable for midwifery-led care.
- Follow-up procedures for women who regularly fail to attend for antenatal care.
- The management of women who are at risk of a relapse or recurrence of a serious mental illness.
- The management and local support strategies for women who disclose domestic violence.
- Multidisciplinary management for women with concurrent medical problems.
- The management of pre-eclampsia and eclampsia.
- The management of obstetric haemorrhage.
- The use of thromboprophylaxis.
- The use of antibiotics for caesarean section.
- The identification and management of ectopic pregnancy.

Clinical guidelines should be prominently placed in all antenatal and postnatal wards, the delivery suite, and in accident and emergency departments, and all guidelines given to all new members of staff.

The implementation of the guidelines should be subject to regular audit.

The views of women who book late or fail to attend should be sought in helping to provide more appropriate services in future. The views of all women who use the services should also be sought on a regular basis.

All staff should become familiar with the contents of the confidential enquiry report. Staff training, particularly in relation to audit and local guidelines, should be organized on a regular basis.

Case study 1: Confidential enquiries into maternal deaths in Malaysia[12]

A confidential system of enquiry into maternal deaths was introduced in Malaysia in 1991 in order to identify deficiencies in care and recommend remedial measures. It was based on the system used in England and Wales, but was modified to suit local needs. The hallmarks of the investigative process are confidentiality, comprehensiveness, timeliness and a non-punitive nature.

In public hospitals, the system requires a maternal death coordinator to review every death of a woman between 15 and 49 years of age and decide whether a maternal death investigation is required. The patient notes are examined to see if amenorrhoea had occurred. If a death occurs at home, the community health coordinator in the district concerned reviews the case and interviews family members. The coordinators present their findings to the obstetricians in the hospitals that provided care for the patient or to the relevant district medical officers. Deaths in private hospitals are reported by the police and investigated by district health staff. Although participation in the enquiry process is not compulsory for private hospitals, almost all cooperate to some degree.

The state Family Health Officer is initially contacted by telephone and subsequently in writing, and then passes the information on to the state review committee. This committee sends a confidential report on the cause of death, areas of suboptimal care, and necessary remedial actions to the National Technical Committee. This committee prepares an annual report, including recommendations aimed at reducing maternal mortality, and holds discussions on their implementation with various agencies. Issues of general concern are notified to quality assurance committees in the administrative regions, without reference to specific individuals or hospitals.

From 1991 through 1996, there were 1702 pregnancy-related deaths identified. Of these, 1186 (70%) were attributed to direct causes and 214 (13%) to indirect causes. The remaining deaths (17%) were attributed to fortuitous causes. The main causes of the maternal deaths were postpartum haemorrhage, hypertensive disorders of pregnancy, and obstetric pulmonary embolism.

After confidential enquiries were instituted in Malaysia, there was an apparent increase in the maternal mortality ratio, with a slight decrease being seen after implementation of the recommendations. This increase in the ratio was felt to be due to the more comprehensive reporting of maternal deaths.

The impact of the confidential enquiry in Malaysia has been felt in the curriculum and training components of all categories of health staff, especially nurses, in the development of protocols and training manuals, and in widespread publications and reports.

Case Study 2: Confidential enquiries into maternal deaths in South Africa[13]

South Africa introduced a confidential enquiry into maternal deaths in October 1997, when the Health Policy Act was amended such that all maternal deaths were regarded as notifiable events. The Minister of Health appointed a committee to manage the process with its terms of reference being to produce recommendations based on the findings of the confidential enquiries into maternal deaths such that their implementation would lead to a reduction in the maternal deaths in South Africa.

The system is primarily based on data collected from health institutions and is very similar to the UKCEMD system. When a maternal death occurs in an institution, a maternal death notification form is filled in at the local Maternal Mortality and Morbidity Meeting. The form along with a copy of the case notes is sent within seven days to the provincial Maternal, Child and Women's Health (MCWH) Units where a unique number is obtained from the national confidential enquiry secretariat; the case is anonymized and the form and case notes are sent to the provincial assessors. Each case is assessed by at least a doctor and a midwife and returned to the provincial unit within 30 days. The assessment form is forwarded to the national secretariat. In the national office the cases are collated into the different disease categories and given to the various 'chapter' heads responsible for writing the chapter on that disease category. Each maternal death is assessed with respect to avoidable factors, missed opportunities and substandard care relating to the patient and community, administrative factors and health workers. A national committee member reassesses a random sample of cases to ensure a high standard of case assessment. The data is collated, discussed with the assessors, provincial MCWH units and national department of health representatives and a final report produced with recommendations. The committee decided that the recommendations must concern the major causes of maternal death, they must be implementable within the resource constraints of South Africa and progress on their implementation must be measurable. The data are then destroyed.

The report is distributed to all institutions via the provincial MCWH units and regional workshops are held to inform all health workers involved in the care of pregnant women about the recommendations. An executive summary is produced which is posted independently to all doctors and midwives in the country. Pamphlets in all 11 official languages are produced for the general public with the essential health messages derived from the report. A comprehensive report is produced every three years, with interim reports being produced in the intervening years. The interim reports track changes in disease patterns and alert health authorities to new developments.

The first comprehensive report produced concerned the year 1998, and the subsequent report dealt with the years 1999-2001. Approximately 1000 maternal deaths are being reported annually. The proportion of direct causes of maternal death is decreasing because of an increase in the indirect causes of maternal death. Currently, almost 40% of maternal deaths are due to indirect causes and 60% due to direct causes. The most common cause of maternal death is non-pregnancy-related infections including AIDS, followed by complications of hypertension in pregnancy, obstetric haemorrhage and puerperal sepsis. The number of deaths due to AIDS is steadily increasing. However, the number of deaths due to abortion has declined over the years. This has coincided with the introduction of the Choice of Termination of Pregnancy Act in South Africa. The most common patient-related avoidable factors was the lack of initiation of antenatal care, the most common administrative problem was related to transport and the most common health worker related problem was lack of adherence to standard protocols.

The national committee has published policy and management guidelines for the common causes of maternal deaths and these have been distributed to all institutions. An independent organization has been asked to assess the implementation of the ten recommendations at the institutions and they have conducted a random survey of institutions for this purpose.

The CEMD system has been institutionalized in South Africa and the process simplified by using a specially designed programme that will allow for a more rapid turnover of data. The main focus in the next triennium will be to ensure the implementation of the recommendations and to

Authors

Gwyneth Lewis. Director of the United Kingdom Confidential Enquiries into Maternal Deaths. This chapter has been seen and discussed with Professor Robert Pattinson, Editor of the Confidential Enquiries into Maternal Deaths for South Africa.

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Reports and papers in French that may be of interest include:

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Bouvier-Colle MH. Enquêtes confidentielles avec comités d'experts : une méthode d'évaluation des soins. L'exemple de l'Obstétrique. *Revue d'Epidémiologique et de Santé publique* 2002; 50: 203-217.

7 Reviewing severe maternal morbidity: learning from survivors of life-threatening complications

Carine Ronsmans, Veronique Filippi

Key messages

- ✓ Cases of severe maternal morbidity or "near misses" occur in larger numbers than maternal deaths, and their review should enable more robust conclusions to be drawn concerning risk factors and remediable or avoidable factors.
- ✓ Apart from community-based verbal autopsies, any of the approaches described in this handbook can also be used to undertake a near-miss review.
- ✓ There is no right or wrong definition of a case of severe morbidity or "near miss". It is important that the definitions used in any review are appropriate to local circumstances to enable local improvements to be made in maternal care. The use of standardized case definitions is strongly recommended, as this will facilitate the comparison with standard treatment protocols and enhance quantitative comparisons between facilities or over time.
- ✓ Survivors live to tell stories. In these reviews, it is possible to speak to the woman to obtain her views about what happened and the care she received.
- ✓ The study of women who had life-threatening complications but whose lives were saved may be less threatening to health providers than the study of deaths.

Enquiries into maternal health care have long used maternal deaths as the starting point for investigation. Deaths are the most extreme adverse events in pregnancy, and viewing the circumstances leading to a maternal death highlights not only areas of clinical relevance, but also avoidable or remediable health sector, community or public health factors. Over the last decade, the identification of cases of severe maternal morbidity has emerged as a promising complement or alternative to the investigation of maternal deaths. In particular, cases at the very severe end of the morbidity spectrum—the near misses—are seen as a useful outcome measure for the evaluation and improvement of maternal health services.[1, 2]

Although obstetric complications are sometimes presented as a relatively easy alternative to maternal deaths, difficulties remain in their definition and identification, and there is still limited experience with the use of severe obstetric complications as a starting point for case reviews in developing countries. In this chapter, some insights are provided into the local definition and ascertainment of cases suitable for review. Two reviews are presented as examples.

The documentation of near-miss events is well developed in some industries, such as air transport, where incidents which could have had serious consequences are being studied to improve safety. Recent years have also seen the emergence of the term "near miss" for the evaluation of health services performance, particularly in obstetrics for the evaluation of the quality of obstetric care in large hospitals or at regional level in the low mortality context of the United Kingdom.[3, 4]

In developing countries, near-miss events were initially seen as a promising outcome measure for the evaluation of safe motherhood programmes at the population level.[5] In a study conducted in Benin it was hypothesized that, because women might be able to recall an event as severe as a near miss, interview-based surveys assessing the incidence of near miss might be a promising way forward in the evaluation of programmes at the population level. However, the study showed that women's recall of their childbirth experience was not sufficiently accurate for use in surveys.

Box 7.1—Improving obstetric care through near-miss case reviews: A feasibility study in Benin, Ghana, Ivory Coast and Morocco[a]

This collaborative research project was aimed at developing and implementing a strategy to improve obstetric care in referral hospitals by using a systematic review of near misses as a mechanism for the evaluation and improvement of the quality of obstetric care. The study took place in 12 referral hospitals in four African countries. The strategy of the case reviews involved:

- Establishing a near-miss enquiry committee in each country to facilitate the development, application and dissemination of the findings from the near-miss enquiries.
- Establishing hospital teams to conduct near-miss case reviews in their facilities.
- Identifying valid and reliable criteria for the definition and identification of near-miss events.
- Conducting in-depth enquiries in a subset of cases of near miss to document the nature of substandard care, to make recommendations concerning the improvement of clinical care and organizational procedures, and to implement the changes.
- Conducting a quantitative assessment of all reviewed near misses to document the magnitude and causes of near-miss morbidity in the hospitals.

On the other hand, the study revealed that near misses were a potentially useful starting point for audits and case reviews in developing countries.[1]

[a] The project started in November 1998 and finished in September 2001. The conclusions are reported in Filippi V et al. How to do (or not to do)...Obstetric audit in resource-poor settings: lessons from a multi-country auditing "near miss" obstetrical emergencies. *Health policy and planning* 2004; 19:57-66, and Sahel A et al. Des catastrophes obstétricales évitées de justesse : les near miss dans les hôpitaux marocains [Obstetric catastrophes barely avoided: near misses in Moroccan hospitals]. *Cahiers d'Etudes et de Recherches Francophones / Santé* 2001; 11:229–235.

For this reason, a multisite study in four countries in Africa was set up to explore ways in which near misses could be used as a trigger for in-depth investigation of the quality of care in hospitals as shown in Box 7.1. Similar efforts have taken place in Malaysia[6] and South Africa.[2, 7]

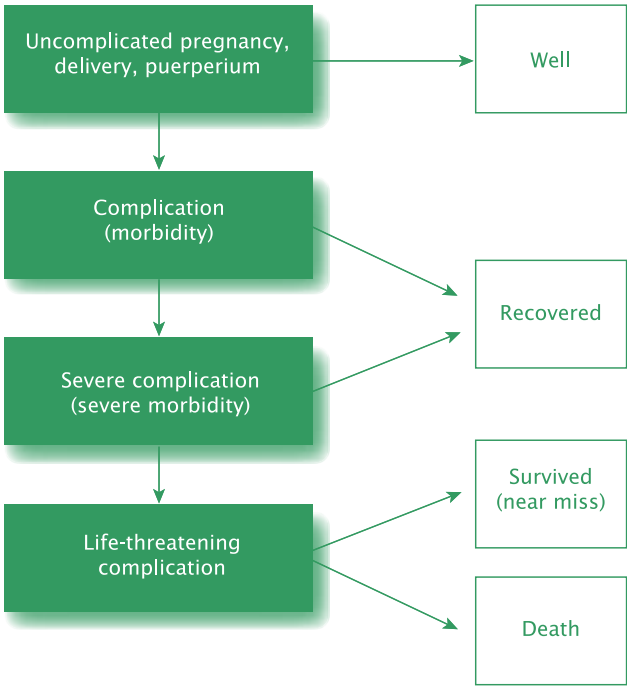
7.1 Explanation of the terminology used in this chapter

A number of terms are in use to describe incidents of severe maternal ill-health including life-threatening complications, severe maternal morbidity and near misses. These terms are often used interchangeably and can cause confusion.[3, 4, 8, 9]

Pregnancy as a continuum between good and poor health

Ill-health during pregnancy represents part of a continuum between the extremes of normal health and death. On this continuum, a pregnancy may be thought of as being uncomplicated, complicated (morbidity), severely complicated (severe morbidity) or life-threatening as shown in Figure 7.1. From life-threatening conditions the woman may recover, she may be temporarily or permanently disabled, or she may die. Therefore, a near miss represents one of two possible outcomes of a life-threatening complication: the woman either survives and becomes a near miss, or she dies and becomes a maternal death.

Figure 7.1 Pregnancy continuum between extremes of normal and death



As the underlying philosophy of undertaking these reviews is to learn lessons to determine how health care can best be improved, whether a case is described, for example, as a near miss or one of severe maternal morbidity

is of less importance than the commitment to review such cases, however they are locally defined. Since many of the references and examples given in this chapter relate to studies using the term "near miss", this term will be used here to cover any reviews relating to women who have survived severe problems related to their pregnancy. But it is stressed again that the key issue when planning a case review is to define *locally* usable and relevant definitions.

Definition of a near miss

There is no universally applicable definition of a near miss. The management (and hence definition) of a *near-miss* postpartum haemorrhage managed in an intensive care unit in a tertiary hospital in a developed country will be entirely different to that of a woman haemorrhaging in a district level facility with no blood supplies in a developing country. What is important is that the definition used in any review be appropriate to *local* circumstances to enable *local* improvements in maternal care.

In the Benin review, a near miss was defined as "a severe life-threatening obstetric complication necessitating an urgent medical intervention in order to prevent the likely death of the mother".[1, 10] The notion of urgent medical care was included because the study focused on acute conditions with immediate threat to the life of the woman.

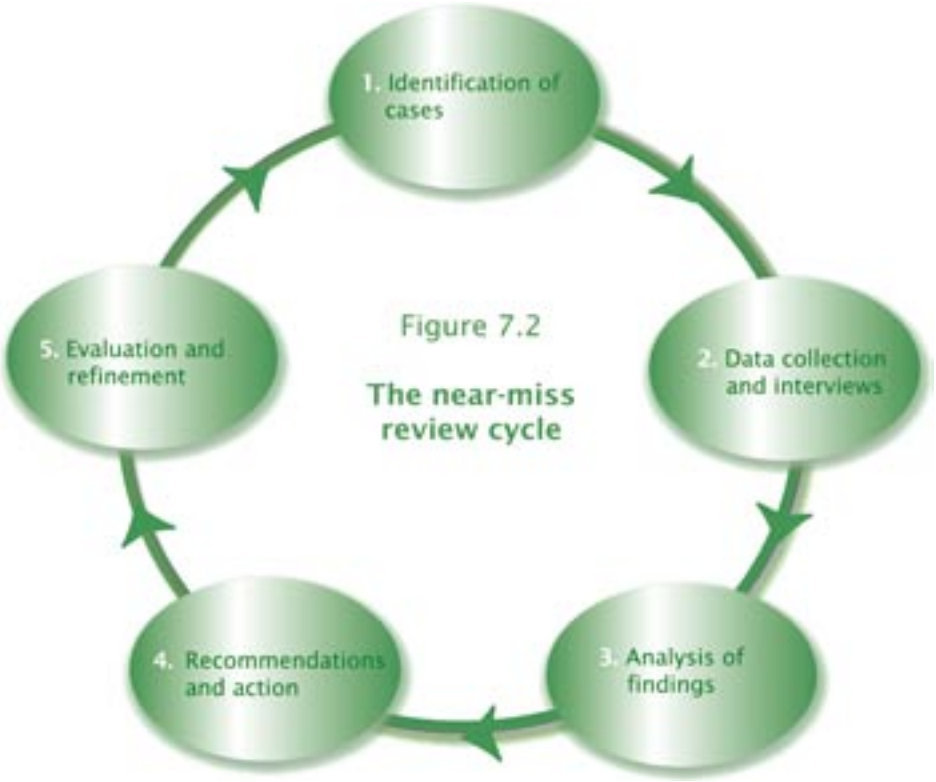


Figure 7.2

The near-miss review cycle

The West Africa Near-Miss Audit Network used the following definition for the case review of near misses: "any pregnant or recently delivered woman (within six weeks after termination of pregnancy or delivery), in whom

immediate survival is threatened and who survives by chance or because of the hospital care she receives." The notion of chance is an important one, as women may survive severe complications in the absence of medical care. This was also recognized in a study in South Africa by defining a near miss as "a very ill woman who would have died had it not been that luck and good care was on her side".[2]

What is a near-miss review?

Near-miss case reviews can be undertaken on individual cases or all cases occurring in one or more health facilities in conjunction with, or in addition to, *facility-based case reviews*, and are already being incorporated in the *confidential enquiry into maternal deaths* methodologies used in South Africa and Scotland, with other countries about to follow suit. Because cases are easier to identify within health facilities, such reviews are unlikely to be helpful in identifying avoidable factors in community-based settings.

Chapter 3, on practical issues for implementation, and the specific chapters relating to *facility-based case reviews*, *confidential enquiries* and *clinical audit* all supply further practical advice and steps which can be used to develop a near-miss review relevant for these approaches.

Once cases to review have been decided, the stages involved in the process of reviewing near misses are very similar to those generally presented as the classical steps of the surveillance cycle. These are to establish best local practice, compare local current and best practice, implement change and re-evaluate practice. The cycle is shown in Figure 7.2. As with all of the approaches in this manual, the ultimate purpose of near-miss case reviews is to improve maternal care. An example of the outcome of one such review is given in Box 7.2.

7.2 The advantages and disadvantages of near-miss reviews or other studies of severe morbidity

The advantages of a near-miss review include:

A more comprehensive analysis

As with maternal deaths, a severe obstetric complication can be the event triggering a case review[2, 11] or audit.[12] The main advantage of using near misses rather than deaths for audits or case reviews is that obstetric complications occur much more frequently than maternal deaths, enabling a more comprehensive quantitative analysis. In hospitals in Benin and South Africa, for example, near misses were between five and ten times more frequent than deaths.[1, 2] Depending on the definition used, this ratio can be as high as 117 near-miss cases per maternal death in developed countries.[13, 14]

Box 7.2—Actions taken based on a near-miss case review in Papua New Guinea[b]

Dr A was called by the intern to see a primigravida woman in labour because of delay in the second stage with a face presentation. He found that the cervix was fully dilated and that the head was in the pelvis. He delivered the woman using obstetrical forceps. The procedure was followed by some excessive vaginal bleeding (about 400–500 ml), but this seemed to settle on an oxytocin infusion. (The ventouse is the usual method of assisted delivery for vertex presentations in this obstetric service.)

During the night, ward nursing staff noticed that the woman continued to have a moderate vaginal blood loss. The next morning there was still a trickle of blood being passed, and examination revealed severe maternal pallor and a lacerated cervix. Under examination in the operating theatre, it was found that the cervical tear seemed to extend into the lower uterine segment posteriorly. A consultant was called and it was decided that a laparotomy was necessary. A rupture of the uterus was found that also involved the serosa of the rectum. There was more than one litre of blood in the peritoneal cavity. It was necessary to perform a total hysterectomy to control the bleeding.

After the operation, delivery records were reviewed to try and ascertain how the rupture could have occurred. The forceps delivery was noted, but there was no indication in the case notes that there had been any difficulty or immediate postpartum problem. However, a review of the labour ward register revealed that the case had been noted as a mentoposterior face presentation with rotational forceps extraction.

At a meeting the next day with the consultants, the trainee specialist (Dr A) who had performed the delivery was asked how he had managed to deliver a posterior face with forceps. Dr A said that he had managed to manually turn the head to the transverse position and had then applied curved obstetric forceps to complete the rotation and extract the head. Further discussion between Dr A and the consultant group concluded that:

1. When an unfamiliar procedure is to be attempted, the most experienced person available should be present for guidance and advice.
2. Curved forceps are not to be used for rotation of the fetal head.
3. Any abnormal postpartum bleeding needs to be investigated, particularly when it follows an instrumental delivery.
4. The standard protocol for delivery of a mentoposterior position is caesarean section. When an alternative management is thought to be appropriate in an individual case, then the decision to depart from standard management should be a matter of consensus involving the most senior person available at the time.

This is important for clinical audits, for which relatively large numbers of aggregate data are needed to measure the progress towards set criteria or targets. In general, the larger numbers of cases of severe complications will allow a more detailed quantification of risk factors and determinants than the relatively small numbers of maternal deaths.

Another possible advantage of morbidity over death in case reviews and audits is that some life-threatening complications may have arisen while the women were hospitalized, thus providing opportunities to observe and review the care that was given in the hospital. Some maternal deaths, on the

[b] Professor Glen Mola, Port Moresby General Hospital, Papua New Guinea

other hand, cannot be prevented in the hospital because women arrive too late and they die relatively early during their stay. Such cases may be less informative when the focus of the investigation is on in-hospital care, as with clinical audit.

Acceptability

In the context of case reviews, reviewing the outcome of severe obstetric morbidity has three other possible advantages. First, if the woman survived the life-threatening complication, discussing her case may be less threatening to providers than discussing maternal deaths, and the enquiry may be less likely to assign blame. And, since the woman survived, positive elements in the care may appear and staff may be congratulated for saving the woman's life. Second, as she survived, the woman, rather than her family members, can be interviewed about the quality of the care she received. This may reveal important aspects of the quality of care that might otherwise have been overlooked. The interview with the woman may also complement the information from records.

Finally, the involvement of health professionals in determining case definitions and in taking responsibility for the accuracy and completeness of the data on severe morbidity may in itself be a first step towards improvements in the quality of obstetric care.

The disadvantages of a near-miss review include:

Defining the cases to review

Unlike maternal deaths, defining life-threatening obstetric morbidity is not straightforward and agreeing on a local definition requires a concerted effort and support by all those involved in the review process. This is discussed in greater depth later in this chapter.

Not identifying cases in the community

Near-miss events can only be identified in health facilities and do not provide community data. Since the majority of these cases require hospital care to save the woman's life, hospital records are the most likely source of information on these complications. Although some have argued that cases can also be identified in the community because women can remember an event as distressing as a near miss, there is now substantial evidence that this is not the case. Studies assessing women's recall of obstetric morbidity have found ample disagreement between the woman's recall of her childbirth experience and medically diagnosed complications or near misses.[15, 16, 17] A task force meeting on the validation of women's reporting of obstetric complications concluded that, "estimation of the population prevalence of obstetric complications based on interview data collected in

national surveys are not likely to be valid or reliable."[18] While this does not mean that obtaining the community perspective on severe maternal illness is not possible, it does imply that life-threatening adverse events need to be identified in the hospital first, or the review risks interviewing cases which are not truly life-threatening.

In settings where relatively few women deliver in health facilities, even a national enquiry into near misses would not yield a representative picture of avoidable factors.

Case ascertainment

Case ascertainment may require reviewing a large number of registers and case notes in each facility and in settings with a high volume of severe morbidity events, selection of a sub-sample of cases might be required for in-depth case reviews. Selection criteria might include, for example, focusing on events which only occurred at night or weekends or reviewing only a specific type of complication.

Obtaining consent

The women whose cases are being reviewed have survived and if the review methodology proposes to interview the women in addition to reviewing the case notes, then their consent should be sought before interviewing them. This may also unfairly raise the women's concerns about the quality of care received and arouse unjustifiable distrust of the health care professionals who may well have saved their lives. Within the multisite study in Africa however, no such problems occurred. Exposure to the women's views by providers and administrators may well have been one of the most critical elements in inducing change towards better care. Mere awareness of what the woman had felt during her hospital stay, sometimes accompanied by deep shame about what had happened, and a feeling of gratefulness towards women who congratulated the hospital staff, all contributed to promoting better care.

7.3 Key principles

Reviews must be developed and conducted within the local health care context

The threshold above which an adverse obstetric event becomes life-threatening is specific to the context of the woman's general state of health and the facilities available to her. The probability of a woman dying depends not only on the woman's capacity to cope with a complication, but also on the access to and the quality of the care she receives. For example, a blood loss of 500 ml may not be life-threatening in a non-anaemic healthy woman, but might put the mother's life at risk if she is severely anaemic. Similarly, a placenta praevia will carry a high risk of death in a setting where it cannot be identified early through ultrasound, while early detection and intervention

in a setting with good antenatal and delivery services may prevent it from becoming severe. Another example is the partograph, a structured graphical representation of the progress of labour, which although improving the diagnosis of prolonged labour, is not yet widely used in many developing countries.

It is therefore vital to develop the case definitions required for survey within the context of prevailing local health problems and the availability of services.

All participants in the review must understand, agree and adopt the local context-specific definitions

Unlike a maternal death, maternal morbidity is not an unequivocal event, and opinions will vary, even among local clinicians, as to what represents a case for inclusion. Also, some diagnoses of severe obstetric complications may be particularly dependent on subjective physician factors. The equivocal nature of the definition of entities such as dystocia or prolonged labour, for example, is well known. [19, 20] Cephalopelvic disproportion (CPD) in particular is difficult to ascertain.[21] In the USA in the 1980s, there were six times more caesarean sections for CPD than in Ireland among women with a comparable risk status, but these differences were believed to reflect cultural factors rather than real differences in the epidemiology of CPD.[22]

Therefore, to ensure consistency in case reviews and valid analysis, the definitions chosen to be used in a near-miss review need be agreed between health professionals at the outset and be relevant to the local situation and practice.

7.4 Step-by-step process for undertaking a near-miss review

The steps for undertaking a *near-miss case review* are very similar to those required for undertaking any of the other specific approaches described in this manual. If the near-miss approach is to be adopted for a *facility-based case review* then the steps in Chapter 5 should be followed and, for a *confidential enquiry,* the steps in Chapter 7. If *clinical audit* is planned, then Chapter 8 describes the process more fully. Chapter 3 describes the processes common to all methodologies in more detail. However there are a few additional steps to consider when undertaking any type of near-miss review and these are described here.

The additional steps for *near-miss reviews* are:

1. Establish the purpose of the review and which of the methodologies to use.
2. Decide how to define a near miss in the context of the chosen review.
3. Develop a consensus on the threshold for the *near-miss* cases to be reviewed.
4. Develop a realistic and useable definition.
5. Consider how to identify cases.

Step 1: Establish the purpose of the review and which of the methodologies to use

If the purpose is to use life-threatening complications for monitoring or auditing progress against specific clinical standards (for example, in the context of clinical audit), the first requirement is that the complication be sufficiently common to allow quantitative analysis. Secondly, precise criteria for the identification and management of the complication need to be developed. A definition of pre-eclampsia specified as *hypertension and proteinuria,* for example, is too general, as it does not specify the levels of blood pressure or proteinuria above which specific interventions are needed. Preferably, the definition will incorporate some of the criteria against which targets have been set. For example, if one of the criteria is that all women with a diastolic blood pressure above 95 mm/Hg should receive antihypertensive treatment, then it would be useful to incorporate this level of blood pressure in the case definition of pre-eclampsia.

If the purpose is to learn qualitatively from adverse events, such as with facility-based case reviews or confidential enquiries, the definitions might be less stringent, as every case may yield some useful lessons. The use of standardized case definitions is strongly recommended, however, as this will facilitate the comparison with standard treatment protocols.

If the purpose is to highlight needs in health care resources and technical skills to manage cases appropriately, it may be useful to identify any organ system failure or dysfunction in addition to the obstetric complication. In Pretoria, where definitions were based on organ dysfunctions, the observation that hypovolaemia was the most common form of organ dysfunction highlighted the need to redirect the allocation of scarce resources to ensure effective management of such problems.[2]

If the aim is to study the appropriateness of intensive care admission, on the other hand, intensive care admission (regardless of cause) might be a good starting point. Even so, criteria of severity will have to be defined to assess whether the admission was justified.

Step 2: Decide how to define a near miss in the context of the chosen review

In the literature, one or a combination of three types of approaches has been proposed for reviewing and defining life-threatening obstetric complications and *near-miss* events. These approaches include definitions based on (a) management, (b) clinical signs and symptoms, and (c) organ systems. There are a number of possible approaches to this, and the most appropriate to use will depend on the local context.

Management-based definitions

Admission to an intensive care unit

In developed countries, most of the definitions of life-threatening obstetric complications and near-miss events are management-based. The

management criterion most commonly used is admission to intensive care, regardless of the medical reason for the admission.[3, 9, 23, 24, 25]

The main advantages of this definition are its simplicity and the ease of data collection, since the use of only one register may be required. In addition, this definition encompasses non-obstetric medical conditions that might become life-threatening and lead to death, for example, cerebral haemorrhage and hepatitis. The major disadvantage is that intensive care may only identify a subset of life-threatening conditions. In France, for example, most maternal deaths had been seen in intensive care units, while in Britain only a third of maternal deaths had received intensive care.[25, 26] Admission criteria to intensive care vary between countries, hospitals and clinicians, and the capacity and location of the intensive care units also influence the number of admissions to these units.[27] The definition of what constitutes an intensive care unit is in itself not clear and varies across hospitals,[9] and some hospitals may not have an intensive care unit. Because of such variations, comparisons across settings have to be interpreted with caution.

Major interventions

Other examples of management criteria used in the definition of life-threatening complications include the use of some major interventions such as emergency hysterectomy, caesarean section, blood transfusion, hospitalization for more than four days, and anaesthetic accidents.[2, 9, 10, 17, 28, 29]

In a study in Benin, for example, any woman with an obstetric haemorrhage necessitating a major intervention to stop the bleeding qualified as a near miss. Major interventions included hysterectomy, a blood transfusion of two litres or more for acute anaemia and coagulation defects, a manual revision of the uterus with extraction of placental fragments, a caesarean section, and a suture of the cervix or vagina.[10, 17] The main reason for this choice was that the interventions received were generally noted in the hospital records, while detailed clinical signs and symptoms were not.

The above management criteria are prone to the same disadvantages as intensive care, however, since indications for their use may not be standardized and will differ between settings. In South Africa,[2] for example, the definition of severe hypovolaemia proposed for use in the tertiary hospital (i.e. hypovolaemia requiring five or more units of whole blood or packed cells for resuscitation) had to be adapted for use in a rural district hospital. In the rural area, thresholds for transfusion were much higher and the volumes of blood given much lower. The definition for hypovolaemia adopted was hypovolaemia where, if available, one would transfuse four units of blood or packed cells for resuscitation (these women should be included even if blood was not available).[7] The latter illustrates that where blood is not routinely available, relying on the need for transfusion will clearly not work, and other, probably clinical, criteria will have to be used.

Definitions based on clinical signs and symptoms

Definitions based on clinical signs and symptoms are generally built around obstetric diagnoses or complications and tend to focus on the major causes of maternal mortality, such as haemorrhage, hypertensive disorders and sepsis. This approach is straightforward to interpret and has an immediate appeal for both clinicians and non-clinicians, particularly because the conditions listed tend to mirror the main causes of maternal death. In developing countries, data on broad diagnoses of complications might also be relatively easy to obtain from hospital registers.

However, developing definitions based on signs and symptoms for all types of complications can be a difficult task. The definitions will require the consensus of clinicians on criteria of severity, which can be difficult to obtain given the diversity of clinical experience.[29] The criteria will also depend on the means available to clinicians for making diagnoses. Finally, the criteria need to build on information that is routinely available in medical records to facilitate data extraction and verification.

The above points can be illustrated using the example of definitions for severe vaginal bleeding. In a European study, Bouvier-Colle and colleagues[30] based their definition of a life-threatening postpartum haemorrhage on the following signs and symptoms: blood loss greater than 1500 ml if measured, or haemorrhage leading to anomalies of coagulation. In a study in the United Kingdom of Great Britain and Northern Ireland, on the other hand, severe blood loss was defined as that exceeding 2000 ml.[4] In settings where the amount of blood loss is not routinely measured, other indicators of severe blood loss need to be sought. In Benin, for example, any postpartum haemorrhage associated with clinical signs of shock qualified as a near miss.[10] Clearly, there appears to be no consensus as to what constitutes life-threatening blood loss, and definitions will vary according to the context of the study. However, this should not prevent local definitions being used for the assessment of the quality of care at an individual facility level and to make appropriate recommendations.

Organ system-based definitions

An interesting approach to the definition of near miss is that based on organ systems.[2] A woman with organ failure or organ dysfunction (renal failure or cardiac decompensation, for example) during or within six weeks after pregnancy is very likely to die if she does not receive adequate care.[2] For example, a haemorrhage might become life-threatening if the bleeding leads to vascular (hypovolaemia), renal (oliguria) or coagulation dysfunction. Infection, on the other hand, might become life-threatening if the woman shows signs of respiratory, immunological or cerebral dysfunction.

The organ system-based definition approximates most closely the true definition of a life-threatening complication or a near miss in that only very severe end-points are selected. This approach does not entirely avoid the weaknesses outlined above, however, in that the criteria used to define organ

system failure or dysfunction may also rely on the management received (e.g. admission to intensive care or emergency hysterectomy). In addition, the diagnosis of organ failure could require technologies which may not be available in many developing country hospitals (for example, oxygen saturation measurement).

Step 3: Develop a consensus on the threshold for the near-miss cases to be reviewed

When it has been decided which cases to include, the next step is to define where, on the continuum shown in Figure 7.1, the starting point for a case review should be triggered. At what point lies the threshold of severity above which morbidity becomes severe or even life-threatening? Although this threshold is easy to define for some conditions (for example, few will disagree that a ruptured uterus is life-threatening), it is not straightforward for others (for example, what is the threshold for severe vaginal bleeding or for prolonged labour?).

Again, it is necessary to consider the context in which the review will be carried out. Some conditions might be life-threatening in certain contexts while not in others, and different clinical criteria (i.e. signs and symptoms) may need to be applied to define the life-threatening nature of the complication. As mentioned earlier, a severe haemorrhage may require a less stringent definition in a severely anaemic than in a healthy non-anaemic population. In addition, when management-based criteria are chosen, the resources available will need to be considered. For example, as noted above, where blood is not routinely available, relying on the need for transfusion will clearly not work, and other, probably clinical, criteria will have to be used.

In settings where audits and case reviews are done in more than one facility, efforts should be made to standardize case definitions across these facilities. Although this may not always be possible, it will certainly enhance comparisons between facilities.

Step 4: Develop a realistic and useable definition

A good operational definition should be easily understood and used by all staff concerned, and the data should be easy to extract from available registers or records. This implies that case definitions have to be designed with the quality of the records in mind. Although the efforts to define and review cases might in itself be a trigger for better record-keeping, an initial record review to ascertain the quality of the available information is essential before attempting to define a near miss. If the amount of blood loss is not routinely measured or noted in the records, for example, other criteria for severe blood loss have to be sought. Similarly, if the partograph is not routinely used, the definition of dysfunctional labour will have to rely on signs and symptoms that are noted in the records.

To take into account the variable quality of case records, it might be useful to provide a number of alternative case definitions rather than focusing on one. In Benin, for example, vaginal bleeding was qualified as life-threatening if the woman was in shock or when a major intervention was necessary to stop the bleeding. This choice was made because the signs of shock were not always noted in the records, even when shock had been present.[10,17]

Step 5: Consider how to identify cases

The problems with the community identification of cases have already been described. There are, therefore, two main ways to establish a case.

Registers

Within facilities, the data on obstetric complications often need to be collected from a series of registers and case notes, including admission, delivery, discharge, referral, intensive care and surgical registers.[31] Women with complications are likely to be admitted in different wards of the hospital, and tracing patients across different registers is not easy because many registers lack clear patient identification. Double counting may be a problem if more than one register needs to be consulted.

Existing registers often need modification to supply the required data. Most hospital registers record the type of delivery and obstetric interventions, but specifying the complications as indications for the interventions appears to be inadequate.[31, 32, 33] In Morocco, for example, 28% of major, potentially life-saving interventions had no record of the indication.[34] Missing information seems to be more likely for emergency admissions, which are also likely to represent more serious complications.

Regular staff reporting

If regular staff meetings are held, obstetric events can also be identified from a review of the case notes from these meetings[2] or, alternatively, a member of staff could be identified to regularly review the cases known in all departments of the facility and notify the study coordinator.

7.5 Variants of investigating severe maternal morbidity

This chapter has focused on the investigation of life-threatening obstetric morbidity because events close to the severe end of the morbidity spectrum are believed to reveal a large number of facets of the access to and quality of care. The event triggering an audit or a case review need not be as extreme, however, and reviewing routine care may be equally informative. A regular audit or case review of the use of the partograph, for example, might reveal deficiencies that need urgent action to prevent the occurrence of adverse events. Similarly, a review of the use of uterotonics might be particularly

relevant, since their use might be life-saving, but also harmful when used inappropriately.

Before embarking on large-scale case reviews or audits, it is important to think carefully about the topic of investigation and to select subjects that will highlight the areas where improvement is not only desirable but also feasible. Sometimes, the review of very specific topics, such as the use of the partograph or uterotonics, may be more likely to induce change than the review of problem areas encompassing the entire health system.

Finally, although interviewing women will provide valuable insights into their perception of events, hospital teams may decide against it either because the focus of the review is strictly technical or because it is not feasible or sustainable.

Box 7.3—A near-miss review in Benin, Ghana, Ivory Coast and Morocco

Rather than largely focusing on an aggregate analysis of deficiencies in care in a large number of cases, as in criterion-based clinical audit and maternal death case review, the emphasis in this project was on the participation of and interaction among all those providing and/or organizing obstetric care at each individual case review meeting. The active involvement of care providers and managers in the review process was not only expected to enhance ownership of the findings and accountability, but by encouraging a culture of self-criticism, it was hoped that this process would also bring about a more sustained effect on improvements in the quality of obstetric care.

It was agreed to use this approach because:

- Near misses are an important public health problem and were more common than deaths.
- Discussing near-miss cases was less threatening to providers than discussing maternal deaths. Since the woman survived, positive elements in the care may appear and staff may be congratulated for saving the woman's life.
- In near-miss case reviews, it is possible to speak to the woman. This is important because it is an opportunity to obtain the woman's point of view about the care she received. It also complements information from records.

Step 1 – Establishing criteria of near miss

This crucial step was carried out by each team during an in-country workshop. Near-misses definition criteria were selected on the basis of their frequency, the resource context in each of the countries, and the quality of patient records. The definitions were harmonized during an international workshop. Consensus was reached on the main clinical features of the near-miss events for five complications: hypertensive disorders of pregnancy, haemorrhage, infections, dystocia and anaemia.

Step 2 – Establishing best practice

This step was initiated during an in-country workshop attended by obstetricians, midwives, public health researchers, and policy-makers. Only a limited number of explicit treatment guidelines were established at this initial stage, however. The process of arriving at a subset of standard treatment criteria continued as the case reviews were ongoing. Over time, it was hoped that the case review itself would induce a shift from implicit rules of best practice to more explicit verifiable standards of obstetric care.

Step 3 – Developing a structure for individual case review meetings

Each hospital team established ground rules for running the meetings. Confidentiality and nonpunitive use of information were seen as paramount. Active involvement in the discussion of all those directly involved in the clinical care of the woman, hospital management, and representatives of support departments was strongly encouraged. These ground rules also included the venue, frequency and length of the meetings, identification of a moderator, facilitator and rapporteur, and definition of a format for presentations and final reports. Some of these rules were likely to evolve and change over time.

In addition, a broad framework to help with the systematic review of each case was developed. This framework consisted of a systematic checklist of questions that helped identify possible deficiencies in care.

For each case, the following three analyses were made:

1. The management of the woman, from arrival at the hospital to discharge (gate-to-gate), identifying those elements of care that went well and those that did not. Deficiencies in care were categorized under six headings: referral, admission, diagnosis, treatment, monitoring and further treatment, and discharge.

2. The factors or reasons that facilitated good care, and the factors or reasons that hindered or prevented good care being given. These were also categorized under six headings: staff, drugs, equipment, protocols, organization and administration, and patient and family.
3. The areas in the care process that could be improved, and what action or solutions were agreed for ensuring the best possible care for future obstetric emergencies.

Step 4 – Identifying cases and interviewing the women

Cases were identified from hospital registers and case notes. Because near-miss cases were extremely common in these hospitals, selection criteria had to be established, either to ensure that the reviewed cases were representative or to focus on a particular area of concern (for example, care given at night). After discharge, the woman was visited in her home and interviewed about the care she received in the hospital. To ensure the sustainability of the audit approach, these interviews were conducted by hospital social workers in Benin and Côte d'Ivoire. This information was incorporated in the discussion during case review.

Step 5 – Reviewing a number of near-miss cases

Each of the hospitals decided upon a number of regular review meetings. After extensive discussion of a case using the framework discussed in Step 3, the review team proposed solutions and recommendations for action, and individuals were assigned the responsibility to follow up on the actions proposed. A summary form was filled in at the end of the meeting, and the actions taken were reviewed at the next meeting.

Step 6 – Summarizing findings and resetting selection criteria and standards if required

After six months, an assessment of recurring patterns of deficiencies in care was made by a research assistant. These were then presented to the hospital teams and policy-makers during a workshop. The aim of this workshop was to revisit the case review process, including the selection of topics for review and the development of standard criteria.

Step 7 – Re-evaluating practice

This second round of reviewing the management of near misses was followed by a second assessment of the patterns of deficiencies in care.

How was this case review different from routine case reviews during staff meetings?
Doctors and other health personnel often meet in the morning to discuss cases that were admitted overnight or in the last 24 hours. The review of near misses presented here is different from this type of case review in that:

- The meetings were structured to follow an analytical framework, involved hospital managers and included ground rules of confidentiality and openness.
- For each particular illness to be reviewed, formal and explicit standard procedures of care were developed. Although this process takes time, it is hoped that the strict criteria for near miss and the recurrent acknowledgement of the need for standards during review meetings will facilitate the development of a number of relevant criteria of care.
- The near-miss review was not restricted to the clinical management of the patient (accuracy of diagnosis or appropriateness of treatment), but covered the entire process of care (administrative, managerial and clinical). In addition, the opinion of the patient about the care she received was taken into account.
- The emphasis of the case review was on finding solutions for the problems identified, rather than on problem description. During the meetings, the reasons for the problems were discussed, solutions were proposed, and suggested actions were monitored. This may be the most difficult aspect of the cycle, but without it, there would be no improvements in the delivery of care and hospital staff would lose confidence in the audit system.

Box 7.4—Case study 2: Severe obstetric haemorrhages in France. An example of auditing maternal morbidity cases

Eighty per cent of the maternal deaths due to haemorrhage are avoidable according to the National Committee for the Study of Maternal Mortality. Moreover, France has a higher maternal mortality rate due to haemorrhage than any other European country with similar levels of health care. To explore the adequacy of care and treatment for obstetric haemorrhage, a survey was carried out in 1995–1996 in three different administrative regions. All women living in the regions who were pregnant or had recently delivered were included. All severe obstetric haemorrhage cases were studied.

Step 1 – Establish criteria for severe haemorrhages

A haemorrhage occurring at the time of pregnancy outcome (birth, abortion, caesarean section, ectopic pregnancy) was defined as severe if blood loss: equalled 1500 ml or more, if measured, or required plasma expanders; equalled 2500 ml or more over 24 hours, or the equivalent expressed in packed cells; resulted in transfusion, hysterectomy or maternal death.

Step 2 – Structure for case review

An expert committee was appointed: five obstetricians (not related to the facilities whose cases were reviewed), two anaesthetists, two epidemiologists. The group established a framework for qualitative assessment.

Step 3 – Establish best practices

The criteria for evaluation of quality of care of severe haemorrhage were extracted from the international literature or from the clinical experience of the medical experts; these are shown in Table 7.2. Three categories of quality of care were defined:

- appropriate (all the criteria were met)
- totally inadequate (the majority of the criteria were not met)
- insufficient (only one or two criteria were not met, or the judgement of the experts was not clear-cut)

Step 4 – Identify cases and collect information

A questionnaire was completed retrospectively by trained investigators for each case and included: demographic items; medical and obstetric history; antenatal care during the pregnancy; delivery and the immediate postpartum period; type of anaesthesia and drugs used; medical or surgical treatment of the haemorrhage; transfusion administration of oxytocin or prostaglandin and the timing of these interventions.

Information was also collected on the organizational aspects of the obstetric facility relating to each patient: volume of annual deliveries; private or public status; staffing levels, including 24-hour on-site presence of anaesthetist and obstetrician consultants; on-site blood bank; on-site intensive care unit; guidelines for treating haemorrhage.

Step 5 – Review the life-threatening morbidity cases

The cases were anonymous. They were randomly allocated to teams of one obstetrician and one anaesthetist. The teams classified the cases and if there was no agreement, the case was discussed by the entire group of experts and a consensual decision was taken.

Summary of results

Of the 165 cases reviewed, 51% were vaginal deliveries, 19% operative vaginal deliveries and 30% caesarean deliveries. The leading cause of haemorrhage was uterine atony. Overall, 62% received appropriate care, 14 % received insufficient care and 24 % received totally inadequate care. The need for quicker, more efficient diagnosis/reaction was highlighted in several areas: between the delivery and the diagnosis of haemorrhage (more than 45 minutes in 21% of cases); between the diagnosis and manual placental delivery or performance of manual uterine exploration (more than 15 minutes in 49% of cases); and non-administration of prostaglandins when oxytocins had not been effective (85% of the cases). Finally, the significant factors associated with substandard care were the lack of a 24-hour on-site anaesthetist at the hospital and the low volume of deliveries in the facility.[33]

Table 7.2 Criteria for the near-miss study of haemorrhage adopted by the French study (Box 7.4)

Selected criteria	Justification
1. Time elapsed between delivery and diagnosis of the haemorrhage was less than 45 minutes?	Expert Group Consensus
2. After diagnosis of the haemorrhage, was manual placenta delivery or uterine exploration effected in less than 15 minutes?	Expert Group Consensus
3. Time elapsed in minutes between diagnosis of the haemorrhage and anaesthetic administration (in the absence of previous epidural).	Expert Group Consensus
4. In the case of manual placenta delivery, manual uterine exploration, or caesarean delivery, were prophylactic antibiotics administered?	Reference SFAR,[35] Smaill[36]
5. Was oxytocin administered within 15 minutes of observation of uterine atony?	Expert Group Consensus
6. Were prostaglandins administered within 20 minutes of determining the failure of oxytocin?	Reference Goffinet[37]
7. If haemoglobin fell below 7 g/dl, did colloid replacement take place or were blood products administered?	Reference SFAR/ANDEM[38]
8. If no treatment succeeded within 60 minutes of diagnosis of the haemorrhage or 120 minutes after delivery, was surgical or radiological intervention considered?	Expert Group Consensus

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[37] Goffinet F. Hémorragies de la délivrance : prise en charge en France et intérêt des prostaglandines [Haemorrhage during delivery: management in France and value of prostaglandins]. *Journal de Gynécologie, Obstétrique et Biologie de la Reproduction* (Paris) 1997; 26 Suppl 2:26–33.

[38] Société Française d'Anesthésie et Réanimation. Les apports d'erythrocytes pour la compensation des pertes sanguines en chirurgie de l'adulte. Texte résumé des recommandations. [Use of red blood cells for compensation of surgical blood loss in adult patients. Summary of recommendations]. Paris, SFAR-ANDEM, 1993.

8 Clinical audit-learning[a] from systematic case reviews assessed against explicit criteria

Colin Bullough, Wendy Graham

Key Messages

- ✓ Evidence-based medicine promotes the identification and implementation of good practice in clinical settings.
- ✓ The extent to which people implement good practice is never as good as they think it is.
- ✓ When conducting clinical audit, it is more helpful to focus on one or more detailed aspects of practice rather than trying to do everything at once.
- ✓ Improvements in practice can be made step by step.

The word "audit" is often used to refer to a wide range of methods for monitoring, investigating and reporting on health outcomes as well as the structure or the process of care. The term maternal death audit is similarly broad and is used to describe maternal death case reviews, confidential enquiries, and maternal death surveillance. "Clinical audit", however, has a more specific meaning and recently has been described as "a quality improvement process that seeks to improve patient care and outcomes by 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."[1] In this context, the word "clinical" applies to the work of doctors, midwives, nurses and other health professionals. Although a clinical audit tends to be used to investigate the structure and process of care, it can also be used to look at health outcomes.

Many people who have been involved in the process of audit believe that it has considerable potential to influence the quality of patient care.[2] This is certainly so in the United Kingdom, where the government and leaders of health professions have taken numerous steps to promote this approach. Clinical audit of selected topics was initiated by the UK government in 1989 as part of health service reforms and is now a key part of overall efforts to promote the provision of services that are clinically effective.[3] The professional bodies of both doctors and nurses have taken the lead in its promotion, but health workers from all disciplines and sectors are involved. The UK government has created a National Institute for Clinical Excellence that supports and coordinates a national development progamme

[a] This is sometimes also called "criterion-based clinical audit".

of clincal guidelines and clinical audit.[1] But, despite government support, it still remains a process where clinicians and health workers review their own work against agreed, evidence-based standards.[4]

There are two main types of audit as applied to maternal health. The first type—critical incident/adverse event audit—includes methods such as *confidential enquiries into maternal deaths* and *maternal death case reviews*. This methodology tends to focus on auditing outcomes (such as death or morbidity) rather than the structure or process of care, and usually does not evaluate the care the women received against predefined clinical criteria. The second type—*clinical audit,* involving assessment against explicitly agreed criteria—is the focus of this chapter. Some authors, such as ourselves, often refer to this technique as *criterion-based clinical audit* to ensure the distinction is perfectly clear.

8.1 The clinical audit cycle

It is implicit in clinical audit that the process seeks to improve clinical practice based on the audit findings. This improved practice can itself be measured against the agreed criteria and targets, and thus itself be subject to re-audit. In other words, clinical audits should involve a cycle in which the audit loop is ultimately closed, as illustrated schematically in Figure 8.1.

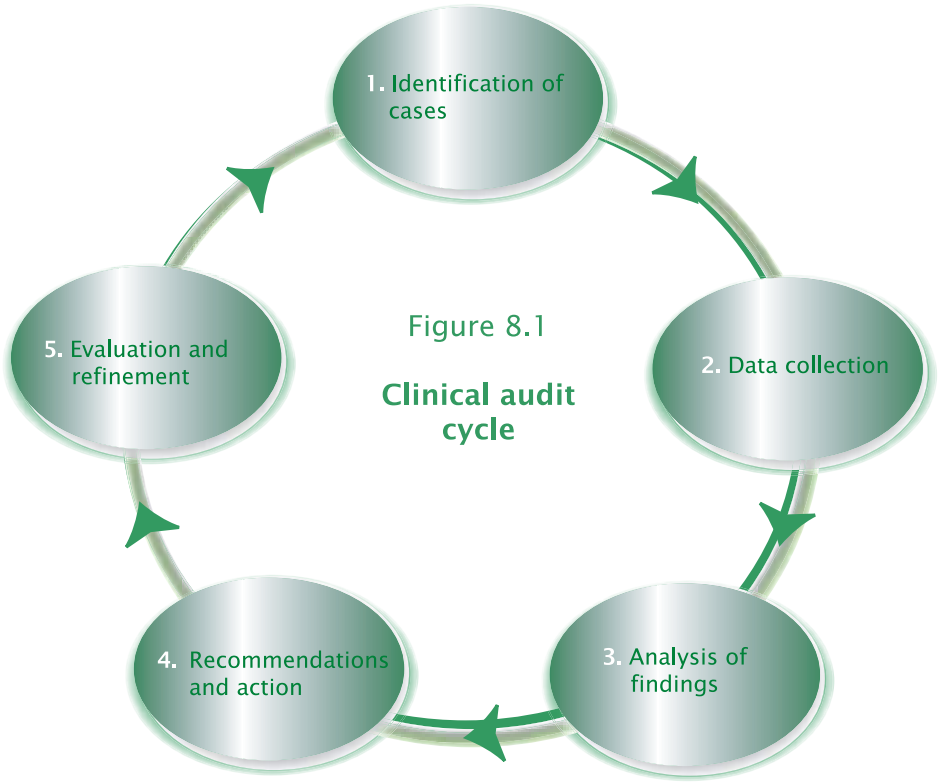

Figure 8.1

Clinical audit cycle

In this chapter, the main focus for the audit methodology described is the care provided to cases of severe maternal morbidity or "near misses". Using clinical audit to investigate health outcomes is a fairly new approach compared to the other methods described in this guide. It has not yet been

widely applied to the subject of maternal mortality or serious morbidity in developing countries.[5] This type of audit is, however, a potentially powerful way to improve the care of women who develop pregnancy complications.

8.2 Key principles

The terminology and concepts surrounding clinical audits require some introductory explanation. One of their distinctive features is that the very process of revealing that an agreed level of care is not being met also identifies the specific changes needed in clinical practice to improve the situation. Therefore, the emphasis in clinical audit is on directly improving the quality of care.

Topic selection

A clinical audit usually focuses on a topic that is part of the process of care. A narrow rather than a broad topic tends to be chosen. For example, "*blood transfusion in cases of obstetric haemorrhage"* would be selected rather than the wider topic of "*the overall management of obstetric haemorrhage*". A further example might be "*the use of antibiotics in the management of puerperal sepsis*" rather than "*the overall management of puerperal sepsis*". Here, however, we want to demonstrate that clinical audit can be applied to life-threatening obstetric complications and so make a direct contribution to the prevention of maternal deaths and morbidity.

Explicit criteria

A clinical audit involves the direct comparison of the care provided to particular cases against previously determined and agreed criteria of best practice in the management of those types of cases. Although the word *criteria* has a common sense or everyday meaning, here *clinical audit criteria* are defined specifically as succinct statements about optimal care.

The concept of best practice or evidence-based practice[4] may be unfamiliar to health professionals in some countries. In simple terms, this means that research evidence is used to specify the optimal management of common conditions and that clinicians agree to implement such management. This may not be something with which all clinicians feel comfortable so workshops and other means of raising awareness of this among professionals are usually necessary to enable the introduction of a clinical audit.

A set of criteria relating to a particular topic or complication does *not* necessarily prescribe all the elements of management, but rather encompasses those practices:[6]

- which are essential rather than optional,
- for which sound research evidence exists,

- which can be audited using case notes, and
- which are realistic practices given the capacity of a facility in terms of staff and resources.

In comparison, a clinical guideline or protocol would set out, step by step, all actions that should be taken in a given situation.

For example, criteria for the topic *"blood transfusion in cases of obstetric haemorrhage"* might include:

- All women who are estimated to have lost at least 1500 ml of blood postpartum should receive blood transfusion.
- Blood transfusion should begin within one hour of the decision to transfuse.
- A fluid balance chart should be maintained during blood transfusion.

In some instances of clinical audit, the comparison of practice against criteria includes every patient whose management comes within the selected specific topic area. It can thus be seen that, if this style of clinical audit is used for all causes of maternal death, it could take a long while to complete since many subtopics would need to be considered. These could include for example, blood transfusion, the use of antibiotics, and delay in getting a woman to the operating theatre.

Therefore, a more realistic approach is to concentrate on the major complications that lead to death, and to regard each of these as a topic for audit. Criteria are then selected which reflect best practice in the management of each type of life-threatening complication.[4] In a sense, such an approach is in fact a combination of clinical audit and adverse event audit, and an example of this is given later in this chapter.

Targets

One further concept requires explanation. C*linical audit* implies that the type and quality of care provided to individual patients are compared, not only with previously agreed *criteria,* but also with *targets*. An example of a criterion that has already been given is that *"blood transfusion will begin within one hour of the decision to transfuse.*" The target associated with this criterion might be that it will be achieved in 100% of cases. But in recognition of, for instance, a low staffing level and a high workload in the laboratory, a lower target of 80% might be set at a particular facility.

Time scale

Clinical audit involves a continuous, cyclical process. All cases occurring during an agreed period are reviewed, and the findings are aggregated and fed back to facility staff. The cycle of review and feedback should be repeated until the agreed targets have been met, and then a new topic or complication may be chosen.

Where it may be applied

Clinical audit can be carried out at any health facility where there are written patient records of clinical care, and where there are staff available to carry out the extraction of information from the records. It could potentially be conducted at the district, regional, or even national level, although most commonly it is carried out by individual health facilities.

Representativeness of findings

The results of a clinical audit are very specific to the facility where it was conducted: they are not easily transferable to other institutions without making assumptions about case-mix and level of resources. Indeed, audits carried out across several facilities will often present the results separately and anonymously for each.

Having explained and clarified the key concepts, it is possible to confirm that, in the context of these guidelines, clinical audit refers to the systematic critical analysis of the quality of care provided to cases of life-threatening obstetric complications occurring at a health facility.

8.3 The purpose of clinical audit

Health professionals and administrators use the results of a clinical audit of life-threatening complications to improve the care provided and so reduce case fatality among women with life-threatening complications. It should be emphasized that clinical audit is complementary to, rather than being an alternative to, *facility-based deaths review*. For example, an audit may alert clinicians to the need to revisit particular cases of maternal death, and equally, during a case review, new criteria may emerge for an audit. A description of the changed staff perceptions following the use of a criterion-based clinical audit in Jamaica and Ghana is given in Box 8.1.

As it is a confidential exercise, patients and relatives will not see the results of a clinical audit. This should reassure those with concerns that the endorsement of criteria may increase the risks of litigation. The confidential nature of audit is thus central to its continuing existence, with neither patient nor providers being individually identified.

Box 8.1—Changed perceptions following the use of criterion-based clinical audit[5]

The feasibility of conducting criterion-based clinical audit at district hospitals was studied as a collaborative research project in Jamaica and Ghana. A detailed account of this is included as a Case Study in Box 8.3. Here, mention will be made only of how the experience changed the way medical, nursing and administrative staff perceived several matters related to their work and practice.

An early requirement was the acceptance that nonclinical research assistants, often record clerks, could accurately and objectively record details of clinical practice. This was through use of data collection forms that required no clinical judgement for their completion, and consisted mostly of "yes / no" answers.

Next, staff learned that despite individual preferences it is possible for a group of experts to reach a consensus about what constitutes good practice. Then there was the need to reconcile the discrepancy between the fact that a questionnaire had shown that staff had a good awareness of best practice, but the evidence showed that it was not always put into practice. When it was questioned as to whether this just reflected poor patient record-keeping, it was necessary to reach an understanding that, if something was not recorded, it had to be assumed that it had not been done. As it was clearly stated in Ghanaian patois, "book no lie".

When clinical practice was again evaluated after an agreement on what standards and targets should be aimed for, feedback resulted in as much morale boosting commendation for good practice as recriminations for failures. By then it was accepted that the findings were a genuine reflection of practice—as someone said "like holding up a mirror to ourselves".

The final realization was that conducting a criterion-based clinical audit could result in improved clinical practice. Indeed, staff members were so encouraged by the experience that at dissemination meetings in both countries they recommended that the method should be widely adopted.

The feasibility of conducting clinical audit in developing countries

It may be thought that the resources required would make it difficult to conduct clinical audit in developing countries. But in an article on clinical audit,[7] Maher is able to describe nine examples of audit performed in Malawi. Dyke[8] has convincingly argued that it is not only desirable but also feasible to carry out audit in Papua New Guinea, and a surgical audit in Papua New Guinea has also been described.[9]

8.4 The advantages and disadvantages of clinical audit

The advantages of clinical audit include:

- As with the other approaches in this manual, the process of involving local staff in reflecting on their current practice and in setting targets is an effective mechanism for bringing about improvements in care. The participatory element of audit cannot be overemphasized.

- In addition, one common outcome of facility-based clinical audit is that staff proceed to develop multidisciplinary local protocols of clinical practice on the topics which were audited. These protocols often incorporate the criteria of good practice employed in the audit, or those modified as a result of the audit experience.

- In countries where complete professional commitment and resources allow, the outcomes of countrywide audits may lead to national clinical guideline development.

The disadvantages of clinical audit include:

- Clinical audit is limited to the clinical care in the health facility in which it is carried out and cannot be used to investigate issues in the community.

- Owing to the need for objective data collection and analysis, audit assistants (such as records staff) should ideally be available to find patient records and undertake the extraction of information.

8.5 Step-by-step process for conducting clinical audit at a health facility

This section provides a detailed description of how a clinical audit can be conducted at a health facility. In summary, the six steps of the process are:

1. Set up the audit process
2. Establish criteria of good practice and define cases
3. Measure current practice
4. Feedback findings and set local targets
5. Implement changes in practice where indicated
6. Re-evaluate practice and feedback

Step 1: Set up the audit process

It would be usual for the head of clinical service or the most senior midwife or doctor in obstetrics to initiate a clinical audit, but any health professional may take the lead with the consent of their colleagues. High-level managers of the facility must support the initiative. Clinicians, midwives, nurses, as well as laboratory and records staff also must be willing to collaborate. Government support can be very influential in promoting audit.[10]

A multiprofessional audit team needs to be identified, representative of the various cadres involved in the delivery of the service. The exact composition will be affected by the topics or complications chosen for the audit. For example, if "life-threatening obstetric haemorrhage" were selected as the topic for a clinical audit, then a member of the blood transfusion service would be invited to participate. But the team should not be too large, and everyone on the team should be expected to give up some time to the work. Above all, there must be at least one committed member of the clinical staff who is able to devote sufficient time to guiding the audit and presenting the results.

The actual data collection and analysis may be done by nonmedical audit clerks (e.g. medical record officers), but additional resources could be needed to fund data extraction if this cannot be done using existing staff. In some settings, there may be a national or regional audit office that can provide support to a health facility, for example, to assist in identifying criteria or in deciding specific actions to be taken to bring about change in practice.

The focus of an audit may be on a specific topic, such as drug use in cases of eclampsia, or on a specific complication, such as obstructed labour. The process of selection will usually be driven by senior obstetric or midwifery staff, and may emerge from conducting maternal death case reviews, or from earlier audits which revealed inadequate care.

After the initial phase has been completed within the facility, the remaining steps typically proceed as a cyclical process with five main elements, as depicted in Figure 8.1. This process concludes with the decision on whether or not to repeat the cycle.

Examples of the application of this cycle are provided in two of the case studies highlighted in this manual. The first case study, shown in Box 8.3, describes the use of criterion-based clinical audit of life-threatening obstetric complications to improve the quality of care in Ghana and Jamaica, and a field manual on criterion-based clinical audit derived from this experience is now available.[10] A second case study described in Box 7.1 in Chapter 7 shows how the same sorts of principles were applied in a near-miss study in Benin, Ghana, Ivory Coast and Morocco.

Step 2: Establish criteria of good practice and define cases

Identify guidelines and standards that can be used as a source of criteria of good practice

In some settings, there are national guidelines and standards that can be used. Alternatively, there are international standards published by agencies, such as the *World Health Organization's Integrated Management of Pregnancy and Childbirth (IMPAC)*[b] which can be used and adapted using local expert panels. In some situations, a systematic review of evidence on

the audit topic may already be available, and may be identified by using one of the other resources referenced in Box 8.2.

Box 8.2—Resources for information on evidence-based practice in obstetrics and midwifery

- *The Cochrane Library.* This source of systematic reviews and randomized controlled trials is available on CD-ROM from Update Software Ltd., Summertown Pavilion, Middle Way, Oxford OX2 7LG, UK. If access to the Internet is available, the latest information can be found at http://www.update-software.com

- *The WHO Reproductive Health Library (RHL) 6th edition.* This is available on CD-ROM from WHO. The RHL is aimed at developing countries and is distributed free of charge to people in those countries.[c] Otherwise, it is available for purchase from Update Software Ltd.

For those without computer facilities or access to the Internet, the obstetric element of the Cochrane Library is available in full as a two-volume publication *Effective Care in Pregnancy and Childbirth.* The size and cost of this limits availability, and the main conclusions are available in a more affordable publication—*A Guide to Effective Care in Pregnancy and Childbirth (Third Edition)* by Enkin M et al. from Oxford University Press (2000).

Specify which category of life-threatening complications or processes of care are to be audited and for what period

It would be usual to focus on the most common and serious category of complications in the first round of audit. The minimum number of cases that is likely to yield useful results is difficult to define for all settings. While there is no set number, in order to produce meaningful percentages of cases managed according to the criteria, in general at least 10 cases are desirable. However, investigators have to decide for themselves if conclusions should be reached and actions taken based on a smaller number, particularly given the seriousness of the cases being audited. How long it takes to collect this number of cases will vary according to the size and type of health facility.

For example, while every case of eclampsia or ruptured uterus might be considered life-threatening, the same would not be thought of every case of postpartum haemorrhage or of puerperal infection. To illustrate this, the working definition for cases of life-threatening primary postpartum haemorrhage in the audit conducted in Ghana and Jamaica[6] was:

[b] IMPAC is a comprehensive set of norms, standards and tools that can be adapted and applied at the national and district levels in support of country efforts to reduce maternal and perinatal morbidity and mortality. Available from the Department of Reproductive Health and Research, WHO, Geneva. Consult web site http://www.who.int/reproductive-health for further information.

[c] Available from Department of Reproductive Health and Research, WHO Geneva. Consult web site http://www.who.int/reproductive-health for further information.

Essential features

1. Genital tract bleeding within 24 hours of delivery.
2. Gestation of fetus > 24 weeks.

Additional features

At least one of the following:
1. Perceived blood loss of more than 1000 ml.
2. Clinical signs of shock (pulse >100/min, systolic blood pressure <100 mm/Hg).

Identify the practices to audit and formulate succinct criteria

In identifying local criteria or standards, use local expert opinion, including experts from other local, regional or national facilities, as felt appropriate.

A set of criteria relating to a particular topic or management of a complication would encompass those practices:

- that are essential rather than optional,
- for which sound research evidence exists,
- that can be audited using case notes,
- that are realistic given the capacity of the facility in terms of staff and resources.

Table 8.1 shows examples of criteria used for obstructed labour and uterine rupture in the Ghana and Jamaica case study described at the end of this chapter.

Step 3: Measure current practice

Collect data

- Draft the audit forms. These are developed from the criteria and used in order to establish whether or not good practice was followed in specific cases. The draft forms need to be tested and appropriate modifications made. Examples of audit forms that have been used in other studies are contained in the accompanying CD-ROM.

- Train the personnel who are going to extract data from patient records onto the audit forms.

Table 8.1 Criteria of best practice in the management of obstructed labour and uterine rupture used in the Ghana and Jamaica case study[6]

Life-threatening complication	Criteria
Obstructed labour	1. Prompt delivery of the fetus should occur within 3 hours (Ghana) or 2 hours (Jamaica) of diagnosis. 2. Urinary bladder should be drained. 3. An observation chart should be maintained (fluids, pulse, blood pressure). 4. IV access and hydration should be achieved. 5. Broad-spectrum antibiotics should be given. 6. Typing and cross-matching of blood should be carried out.
Uterine rupture	1. In suspected or diagnosed uterine rupture, emergency surgery should be performed within 2 hours (Ghana) or 1 hour (Jamaica). 2. Urinary bladder should be drained. 3. An observation chart should be maintained (fluids, pulse, blood pressure).

- Specify registers and other sources to identify relevant cases. Cases are usually initially identified from health facility registers, such as admission and discharge logs, delivery, operating theatre and emergency room registers, and mortuary records, or from listings kept by senior health professionals at the facility. It is important not to miss any maternal deaths outside the obstetric and gynaecology unit and women admitted postpartum. See Chapter 3 for the steps to be taken to limit selection biases in identifying cases.

- Retrieve case notes and calculate proportions of those not retrieved in order to gauge the possible magnitude of selection bias.

- Check that the cases agree with the definitions.

- Extract information onto the structured audit form. Routinely collected data should be used wherever possible, with additional data (such as laboratory reports) collected only if absolutely necessary. Patient records and other routinely maintained clinical records, such as nursing records, blood bank records and operating theatre log book entries, are primary sources of information. The confidentiality of the extraction process is crucial, usually with no mention being made of the names of the professionals providing the care. This maintains the essential spirit of audit as a non-punitive educational tool for improving the quality of care.

  In the first round of audit, the data required may not be recorded in patient records, although when questioned, staff may maintain that the procedure in question was carried out. This, of course, reflects poor recording. It has to be made clear that, for audit purposes, if a practice or procedure is not recorded, then it has to be assumed that it was not done.

Appropriate initial training and further refresher courses for the audit assistants are necessary for quality control of the data collection process. The data entries for a subset of cases should be periodically double-checked.

Synthesize data, interpret and draw conclusions

- Analyse data to find proportions of cases that met the criteria of good practice. This can be done by hand, but if a sizeable number of cases is being considered, it is worth putting the data into a simple computer database and then calculating the percentages. In the Ghana and Jamaica case study, EPI-INFO was used.[d] Conduct a questionnaire survey of relevant staff. In some settings, it may be helpful to also carry out a questionnaire survey of staff practices and knowledge. This will enable any deficiencies in care to be attributed to lack of knowledge versus lack of application of knowledge.

Step 4: Feedback findings and set local targets

- Initially, review the findings in detail with senior obstetric, midwifery and administrative staff and agree on key results.
- Present a summary of the key findings on current practice to all staff at hospital meetings. This involves staff first being encouraged to say to what extent they think the criteria are currently being met, and then showing them the proportions determined from the audit. This will usually reveal that the criteria are being met less often than the staff would wish, and so provides the stimulus to change.
- Reach a consensus on the proportion of cases that should be met for each criterion, and set realistic targets to be achieved by the next round of audit.
- Agree to make affordable and achievable changes in clinical practice and/or in service provisions that might help to meet the targets.
- Outside experts may be invited to participate in this step of the process.

Step 5: Implement changes in practice where indicated

Assuming that the results of the audit showed that some aspects of care were deficient, the next step to be taken is to identify the reasons for the deficiencies. Provided that the criteria were valid, then alternative reasons for falling short of the desired targets include:

[d] This software package is available free of charge from: www.cdc.gov/epo/epi/epiinfo.htm.

- The organization of care is deficient.
- Knowledge is inadequate.
- Skills are inadequate.
- Attitudes are inappropriate.

The reasons will often fall within the first three categories. Attitudes are inferred as inappropriate if the other three possible reasons are excluded.[11] For example, provider reluctance to give appropriate care to women who are HIV positive, despite adequate protective resources such as surgical gloves and the necessary knowledge and skills, can by default be attributed to inappropriate attitudes.

The changes and actions needed to meet the targets will be specific to the reasons identified and to the setting. They may include writing clinical protocols, conducting staff training sessions, and ensuring implementation of protocols through, for example, daily ward rounds or weekly review meetings. It may be that providing feedback of the results and specifying a period before practice is to be re-evaluated will, in itself, bring about change.

Step 6: Re-evaluate practice and feedback

The activities in this step are essentially the same as those in Step 3 (Measure current practice).

- Specify the time period needed to collect sufficient cases for the second round of audit.
- Confirm registers and other sources to pick up relevant cases.
- Retrieve case notes and calculate proportions of those not retrieved.
- Check that the cases comply with the definitions.
- Extract information onto the structured audit form.
- Analyse data to find proportions of cases that meet the criteria of good practice.
- Review findings with senior obstetric, midwifery and administrative staff.
- Present a summary of findings to all staff.
- Agree on further changes in clinical or administrative practice.
- Decide if there is value in carrying out a further round of the audit cycle. If so, this may begin at Step 2, by revising the criteria of good practice or developing new or additional ones. If the original criteria are to be maintained, then the process may begin at Step 4.

8.6 Other sources of information

Chapter 3 describes the general principles underlying the approaches in this manual, many of which will be relevant to clinical audit.

The National Institute for Clinical Excellence in the United Kindom of Great Britain and Northern Ireland has recently published a comprehensive

manual on the *Principles for best practice in clinical audit*,[1] which is available in book form or can be downloaded from the Internet at www.nice.org.uk.

The Royal College of Obstetricians and Gynaecologists (RCOG) of the United Kingdom of Great Britain and Northern Ireland have prepared a series of helpful practical booklets on how to "*Search for evidence*", "*How to develop guidelines*" and a new booklet "*Understanding audit*". Current RCOG guidelines for a number of conditions are also available. All can be downloaded free of charge from the RCOG web site at www.rcog.org.uk.

Helpful summaries of important principles are also contained in: Berg C et al., eds. *Strategies to reduce pregnancy-related deaths: from identification and review to action.* Atlanta, Centers for Disease Control and Prevention, 2001.

The following publications may be particularly helpful for developing countries:

Graham WJ et al. Criteria for clinical audit of the quality of hospital-based obstetric care in developing countries.[6]

Criterion-based audit manual. New York, NY, AMDD Columbia University, 2003 (internet communication of May 2003 at web site http: //cpmcnet.columbia.edu/dept/sph/popfam/amdd/resources.html)

Wagaarachchi et al. Conducting criterion-based clinical audit of obstetric care: a practical field guide.[10]

Box 8.3—Case study. Using criterion-based clinical audit to improve the quality of obstetric care: a feasibility study in Ghana and Jamaica, 1998-2000[5]

This collaborative research project assessed the use of criterion-based clinical audit as a means of measuring and improving the quality of obstetric care at the district hospital level. It focused on the assessment and management of the five major life-threatening obstetric complications—haemorrhage, eclampsia, genital tract infection, obstructed labour and uterine rupture.

The audit model was applied and evaluated in four district hospitals—two in Ghana (Goaso and Berekum) and two in Jamaica (St Ann's Bay and Spanish Town). All four hospitals act as first-level referral facilities for obstetric emergencies, with the annual number of deliveries ranging between 650 and 6500.

Steps in conducting the criterion-based clinical audit

Step 1—Set up the audit process

In this project, the Senior Medical Officer (SMO) at each hospital was initially approached by the in-country collaborators from the Ministry of Health in order to introduce the concept of criterion-based clinical audit. The requirements of the study in terms of staff time and for implementing any changes in clinical practice indicated by the audit were discussed. External funds to support audit assistants for the first round of the audit were to be made available, but the need for the hospital's own records staff to also participate was emphasized. A one-page summary sheet of the aims, objectives and timeframe of the project was distributed through the SMO to all hospital staff involved with maternity patients.

Step 2—Establish criteria of good practice and define cases

This crucial step involved a structured review of the literature, followed by three expert panel meetings to evaluate the criteria which emerged.[10] Panels were held in Scotland, Ghana and Jamaica. A final set of 37 criteria of best practice were agreed for the five life-threatening complications, together with working definitions of cases. Criteria for cases of life-threatening obstetric haemorrhage included

- the patient's haematocrit or haemoglobin should be established, and
- oxytocics should be used in the treatment of postpartum haemorrhage.

Although there are published standards that groups can adapt for their own use, this project sought to develop its own criteria. Once the criteria were established, the remaining four steps of the cycle occurred in each hospital.

Step 3—Measure current practice

A baseline assessment was made of current practice by reviewing patient records for cases of the five complications that had occurred over the previous 12 to 18 months. The review process first required that relevant life-threatening cases were identified from all sources, such as admission and discharge registers. Once patient records were retrieved, it was necessary to confirm that the woman met the case definition. Nonmedical audit assistants then extracted information from the patient records onto a structured form for each type of complication. The forms were used to record whether or not a particular best practice had been performed. Data from all forms were entered into a computer database and analysed using EPI-INFO. In addition, a questionnaire survey of all staff at the hospital was conducted to ascertain their reported practices and knowledge.

Step 4—Feed back the findings and set local targets

Two meetings were held with staff in each hospital for the project team to feed back the findings on current practices and knowledge. In the first meeting, a detailed review of all the results was undertaken with *senior* obstetric, midwifery and administrative staff. The second meeting was attended by *all* relevant staff, highlighting key areas for improvement and commending good practice. A one-page summary handout was distributed.
The purpose of both meetings was to encourage staff to identify occurrences of poor quality care in the management of the five types of life-threatening complications and to develop ways to avoid these, including setting realistic targets to aim for in the next round of audit. Most importantly, the changes had to be affordable.

Step 5—Implement changes in practice where indicated

A 12-month period was agreed for implementation. An example of change identified was the need to use magnesium sulfate in the treatment of eclamptic convulsions, rather than a combination of less effective drugs.

Step 6—Re-evaluate practice and continue feedback

The audit loop or cycle was closed by a second round of reviewing the management of the selected complications against the agreed criteria. The extent to which the set targets were met was again fed back to relevant staff, and a decision made on the value of a further round of the audit cycle.

Results

The cycle within each hospital (Steps 3–6) took 18 months to complete. The initial review of practice in each hospital was based on a total of 555 life-threatening complications. There were 18 maternal deaths among this series. Overall, patient records could be retrieved for 75%

of the complications identified through registers, ranging from 58% to 83% across the four hospitals. Only about a quarter of the complications appeared in more than one register, indicating that consulting just one source would have missed a large number of cases. The findings from the baseline assessment revealed generally good levels of staff knowledge of best practice in the management of the complications, but the evidence from the audit of patient records showed that this knowledge was not always being applied. Generally speaking, first-line management of these emergencies was good, but there were deficiencies regarding the subsequent monitoring and care of the women. There were also many deficiencies in record-keeping. At the first round of feedback meetings across all four hospitals some common mechanisms for achieving improvements were proposed. These included: a) availability of clinical protocols, b) reviews of supervisory structures and roles and responsibilities on the maternity wards, c) liaison with hospital administration regarding additional facilities for record storage, blood cultures, structured patient records and partographs, and d) meetings and training workshops to endorse the use of protocols and higher quality reporting in patient records.

The second review of practice in each hospital was based on a total of 342 life-threatening complications. In comparison with the findings in the initial review of practice on pooled data for all four hospitals, there were significant changes in the percentages of cases meeting criteria of best practice. A few examples of these are:

- In cases of obstetric haemorrhage, the proportion of women who underwent blood typing/cross-matching and haemoglobin estimation.
- Clinical monitoring of pulse and blood pressure to detect early deterioration after control of a major haemorrhage.
- Maintenance of fluid balance charts in patients with eclampsia.
- The proportion of patients treated with broad-spectrum antibiotics in cases of genital tract sepsis.

Lessons learned

A number of key lessons emerged on the use of criterion-based clinical audit in district hospitals:

- The importance of selecting criteria relevant to the local situation and drawing upon local expertise.
- The need to apply working definitions to ensure that cases are life-threatening.
- The importance of using multiple sources to find cases.
- The benefit of using nonmedical audit assistants, which desensitizes the review process and is more affordable and sustainable, with medical records staff potentially taking on this role on a permanent basis.
- The opportunity that audit provides for staff to receive feedback on their practice in an educational and non-punitive framework.
- The need to improve the quality of recording in patient records as well as the storage of records.

A field manual is now available describing criterion-based clinical audit based on this experience.[10]

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