

Evaluating the quality of care for
severe pregnancy complications

The WHO near-miss approach for maternal health



World Health
Organization

Evaluating the quality of care for
severe pregnancy complications

The WHO near-miss approach for maternal health

WHO Library Cataloguing-in-Publication Data :

Evaluating the quality of care for severe pregnancy complications: the WHO near-miss approach for maternal health.

1.Pregnancy complications. 2.Maternal health services. 3.Pregnancy outcome. 4.Maternal mortality. 5.Infant mortality. I.World Health Organization.
ISBN 978 92 4 150222 1 (NLM classification: WQ 240)

© World Health Organization 2011

All rights reserved. Publications of the World Health Organization are available on the WHO web site (www.who.int) or can be purchased from WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel.: +41 22 791 3264; fax: +41 22 791 4857; e-mail: bookorders@who.int).

Requests for permission to reproduce or translate WHO publications – whether for sale or for noncommercial distribution – should be addressed to WHO Press through the WHO web site (http://www.who.int/about/licensing/copyright_form/en/index.html).

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

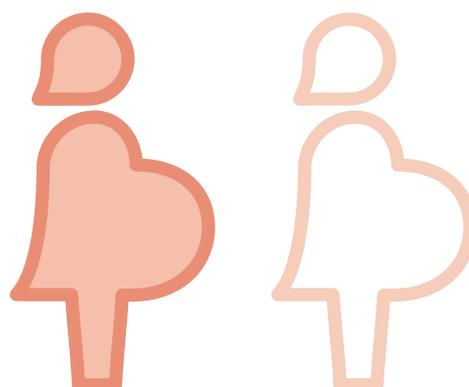
The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

Printed by the WHO Document Production Services, Geneva, Switzerland

TABLE OF CONTENTS

Acknowledgements	2
Abbreviations	3
Executive summary	4
1. Introduction	5
2. Implementing the WHO near-miss approach	7
3. Expected results	15
4. Application of the near-miss approach at the health district or health system level	15
5. Dissemination of the findings and beyond	16
References	17
Annex 1. The near-miss criteria glossary	19
Annex 2. Sample data collection form	21
Annex 3. Dummy tables and interpretation	23



Acknowledgements

This document was prepared by João Paulo Souza (WHO), Lale Say (WHO), Robert Pattinson and Ahmet Metin Gülmezoglu (WHO) in collaboration with Linda Bartlett, Jon Barret, José Guilherme Cecatti, Bukola Fawole, Anoma Jayathilaka (WHO Sri Lanka), Pisake Lumbiganon, Rintaro Mori, Idi Nafiou and Mohamed Cherine Ramadan on behalf of the WHO Working Group on Maternal Mortality and Morbidity Classifications and the WHO Multicountry Survey on Maternal and Newborn Health Research Group. WHO is grateful to the staff of the Family Health Bureau, Sri Lanka Ministry of Health, and members of the Brazilian Network for Surveillance of Severe Maternal Morbidity for their inputs into the document. Thanks are also due to Antonio Francisco Oliveira Neto and Özge Tunçalp for their comments on the earlier versions of this document. As a derivative product of the WHO Multicountry Survey on Maternal and Newborn Health research protocol, this document was externally reviewed by Olufemi T. Oladapo and field tested in Brazil, Ghana and Iraq. This work was funded by USAID and the UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP). Jitendra Khanna (WHO) edited this document prior to publication.

WHO Working Group on Maternal Mortality and Morbidity Classifications

The following individuals participated in the activities of the WHO Working Group on Maternal Mortality and Morbidity Classifications: Jon Barret, Linda Bartlett, Nynke van den Broek, José Guilherme Cecatti, Veronique Filippi, Rogelio Gonzalez, Ahmet Metin Gülmezoglu (WHO), Anoma Jayathilaka (WHO Sri Lanka), Affette McCaw-Binns, Robert C Pattinson, Mohamed Cherine Ramadan, Cleone Rooney, João Paulo Souza (WHO), Lale Say (WHO), Mary Ellen Stanton, and Buyanjargal Yadamsuren.

The WHO Multicountry Survey on Maternal and Newborn Health Research Group

The WHO Multicountry Survey on Maternal and Newborn Health Research Group comprises regional and country coordinators of the study, external advisers, and WHO staff: Anthony Armson, Vicente Bataglia, Katherine Ba-Thike (WHO), Eduardo Bergel (WHO), Liana Campodonico, Guillermo Carroli, José Guilherme Cecatti, Nomita Chandhiok, Kannitha Cheang (WHO Cambodia), Caroline Crowther, Cristina Cuesta, Bukola Fawole, Daniel Giordano, Ahmet Metin Gülmezoglu (WHO), Bernardo Hernandez, Hoang Thi Bang (WHO Viet Nam), Carol Hogue, Kapila Jayaratne, Anoma Jayathilaka (WHO Sri Lanka), Malinee Laopaiboon, Gunilla Lindmark, Pisake Lumbiganon, Matthews Mathai (WHO), Syeda Batool Mazhar, Mario Merialdi (WHO), Suneeta Mittal, Rintaro Mori, Yvonne Mugerwa, Mir Lais Mustafa, Idi Nafiou, Juan Manuel Nardin, Alberto Narváez, Isilda Neves, Nguyen Thi My Huong (WHO), Eduardo Ortiz-Panozo, Laxmi Raj Pathak, Robert Pattinson, Deepthi Perera, Ricardo Pérez-Cuevas, Zahida Qureshi, Tung Rathavy, Zenaida Recidoro, Malabika Roy, Pang Ruyan, Lale Say (WHO), Naveen Shrestha, João Paulo Souza (WHO), Mary Ellen Stanton, Surasak Taneepanichsku, Nguyen Viet Tien, Ganchimeg Togoobaatar, Eliette Valladares, Maria Julia Vaz Grave, Wang Yan, Jean-José Wolomby-Molondo, Buyanjargal Yadamsuren, Khalid Yunis, and Nelly Zavaleta.

Abbreviations

ICD	International Classification of Diseases
ICU	intensive care unit
INR	international normalized ratio
LB	live birth
HELLP	haemolysis, elevated liver enzymes, low platelet count
HRP	UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction
MD	maternal death
MI	mortality index
MNM	maternal near-miss
MNMR	maternal near-miss ratio
PPH	postpartum haemorrhage
SMO	severe maternal outcome
SMOR	severe maternal outcome ratio
UNDP	United Nations Development Programme
UNFPA	United Nations Population Fund
USAID	United States Agency for International Development
WHO	World Health Organization
WLTC	women with life-threatening conditions



Executive summary

In any setting, women who develop severe acute complications during pregnancy share many pathological and circumstantial factors. While some of these women die, a proportion of them narrowly escape death. By evaluating these cases with severe maternal outcomes (both “near-miss” cases and maternal deaths), much can be learnt about the processes in place (or lack of them) for the care of pregnant women. This guide is intended to be used by health-care workers, programme managers and policy-makers who are responsible for quality of maternal health care within a health-care facility or the health system. It presents the WHO maternal near-miss approach for monitoring the implementation of critical interventions in maternal health care and proposes a systematic process for assessing the quality of care.

The WHO near-miss approach is a standardized method which is implemented in three steps in a cyclical manner: (1) baseline assessment (or reassessment); (2) situation analysis; and (3) interventions for improving health care. The baseline assessment can be performed in individual health-care centres or a health district and then scaled up to the entire health system.

Identifying all eligible women is key to successful implementation of this approach. To ensure that all eligible women are identified and included in the audit, the team implementing the near-miss approach must develop a sound plan based on the types and characteristics of the participating facility (or facilities). Data for the assessment are extracted from appropriate patient records. For each woman, data are collected on the occurrence of selected severe pregnancy-related complications and severe maternal outcomes, use of critical/key interventions, and admission to intensive care unit.

The near-miss approach yields results that inform policy decisions for improving the quality of maternal health care in individual health-care facilities. The results include, among others, local rates and patterns of maternal mortality and morbidity, strengths and weaknesses in the referral system, and use of clinical and other health-care interventions.

To assess the quality of maternal health care in a district health system, all facilities that admit women for delivery or treat those with complications related to pregnancy should be included in the assessment. In the secondary and tertiary health-care facilities included in the health district assessment, the procedures described in the guide for individual health-care facilities should be followed.

It is recommended that the near-miss approach should be conducted in the three above-mentioned steps to continuously improve maternal health care. This standardized approach to assessment of quality of care is designed to enable comparability of data over time from different settings, and even across countries.

Findings of assessments undertaken with the WHO near-miss approach should be made public. Such information has considerable advocacy value for promoting policy actions and mobilizing professional and civil societies to improve the quality of care for pregnant women. Publication of good-quality data can also help to attract funding from international donors for improving services for maternal and perinatal health. Moreover, WHO and other agencies can use such information in systematic reviews, which can lead to a better global picture of maternal health-care needs and related guidance.

1. Introduction

Progress in the reduction of maternal mortality – a key Millennium Development Goal – has been slow in most countries that have high maternal mortality ratios, and solutions to this global problem are urgently needed (1). In this context, WHO and others have recommended that all deliveries should be attended by a skilled health-care worker so that effective interventions can be implemented to prevent and manage any complications that arise during childbirth (2). This has led more and more countries to adopt policies designed to encourage greater numbers of women to deliver in health-care facilities. However, given the lack of financial resources and skilled health-care professionals in many low- and middle-income countries, there is a risk that such policies may lead to overloading of health-care facilities, which could have serious implications for the overall quality of care provided by those facilities. In addition, for many low- and middle-income countries, the model of facility-based care for all births is still unrealistic and unaffordable in the short to medium term. A more feasible and cost-effective approach might be to aim at reducing delays in the provision of effective care (including community-based actions) for all pregnant women with complications (3).

In any setting, women who develop severe acute morbidity during pregnancy share many pathological and circumstantial factors related to their condition. While some of these women die, a proportion of them narrowly escape death. By evaluating these cases with severe maternal outcomes (both “near-miss” cases and maternal deaths), much can be learnt about the processes in place (or lack of them) to deal with maternal morbidities (4–6). In 2007, WHO established a technical working group comprising obstetricians, midwives, epidemiologists and public health-care professionals to develop a standard definition and uniform identification criteria for maternal near-miss cases. With a view to achieving a reasonable balance between the burden of data collection and useful information, this working

group targeted the identification of only very severe cases – i.e. primarily those presenting with features of organ dysfunctions. The near-miss identification criteria developed by the technical working group have been tested and validated as being able to provide robust and reliable data. Detailed information about the near-miss concept and its development is published elsewhere (7,8).

The WHO technical working group also developed a set of indicators for the assessment of quality of care within a health-care facility or the health system. They also provide information on intra-facility performance and on the extent to which the health system as a whole is successful in reducing delays for women in accessing a health-care facility or referral hospital (7). In order to ensure that the evaluation of quality of care with the near-miss approach is comprehensive, a set of process indicators has been developed or adapted based on the concept of criterion-based clinical audit, which is considered to be a feasible and beneficial method of auditing the quality of maternal health care (9). These process indicators assess the gap between the actual use and optimal use of high-priority effective interventions in the prevention and management of severe complications related to pregnancy and childbirth.

1.1 Purpose of the guide and audience

This guide is intended for health-care workers, programme managers and policy-makers who are responsible for the quality of maternal health care within a health-care facility or of the entire health system. It presents a standard approach for monitoring the implementation of critical interventions in maternal health care and proposes a systematic process for assessing the quality of care. In its entirety, the included methods and related processes constitute the WHO maternal near-miss approach. This approach has been suggested for routine use in national health-care programmes to evaluate and improve the

quality of care provided within the health system (8). Implementation of this approach in health services will serve to:

- determine the frequency of severe maternal complications, maternal near-miss cases and maternal deaths;
- evaluate a health-care facility's or the health-system's performance (depending on the health-care level at which the approach is implemented) in reducing severe maternal outcomes;
- determine the frequency of use of key interventions for the prevention and management of severe complications related to pregnancy and childbirth; and
- raise awareness about, and promote reflection of, quality-of-care issues and foster changes towards the improvement of maternal health care.

1.2 Underlying assumptions and principles

This generic guide is based on the concept of criterion-based clinical audit. The principles that guided its development include ease of use, actionable results and cost-effectiveness. The guide is founded on the assumption that all maternal deaths involve at least one life-threatening condition (organ dysfunction). It is further assumed that a substantial proportion of women with one or more life-threatening conditions are those who have severe pregnancy-related complications (e.g. severe postpartum haemorrhage, severe pre-eclampsia, eclampsia, sepsis or ruptured uterus) or receive critical interventions (e.g. blood transfusion, laparotomy, admission to intensive care unit).

While it is a useful tool for the assessment of quality of maternal health care in the health system, the maternal near-miss approach was primarily developed for use in individual health-

care facilities. Ideally, it should be used as part of a comprehensive intervention for strengthening district health systems, specifically contributing to monitoring the quality of care, assessing the implementation of key interventions, informing the mechanisms of referral, and strengthening all levels of health-care services.

In selecting the variables for assessing the quality of maternal health care, a conscious effort has been made to include only the most essential ones. The WHO technical working group felt that variables that are traditionally collected as part of sociodemographic or epidemiological assessments, such as maternal age and parity, may not necessarily be useful for quality of care assessments. The group also felt that the greater the number of variables the greater would be the burden on those collecting the data and thereby potentially compromising the quality of information. However, for more extensive evaluations, specific tailoring of variables to suit local requirements is possible. While this guide is primarily designed for assessing the quality of care provided by individual health-care facilities, it is necessary to note that, if in a health district a substantial proportion of deliveries take place in the community (i.e. over 20% of all deliveries occurring outside of a health facility), information will need to be collected direct from the community to complement the data collected in the health-care facility.

The ultimate purpose of the near-miss approach is to improve clinical practice and reduce preventable morbidity and mortality through the use of best evidence-based practices. Hence, this guide should be used in conjunction with evidence-based clinical guidelines (e.g. WHO guidelines) along with guidance for local adaptation of the guidelines (see for example reference 10).

2. Implementing The WHO Near-Miss Approach

The complete WHO near-miss approach is best implemented in three steps: (1) baseline assessment (or reassessment); (2) situation analysis; and (3) interventions for improving health care. This document focuses on steps 1 and 2, although the step 3 is included in the conceptual framework presented in Figure 1. This approach can be implemented in individual health-care facilities, within a health district or across the entire health system. The procedures employed in implementing the approach in individual health-care facilities are described below. Section 4 presents additional guidance for implementing the approach within a district health system.

2.1 Implementing the approach within a health-care facility

2.1.1 Definition of terms used in the WHO near-miss approach

This section provides essential operational definitions used in the near-miss approach. A near-miss criteria glossary is presented in Annex 1.

Severe maternal complications are defined as “potentially life-threatening conditions”. This is an extensive category of clinical conditions, including diseases that can threaten a woman’s life during pregnancy and labour and after termination of pregnancy. A summary list of potentially life-threatening conditions has been produced by the WHO Working Group on Maternal Deaths and Morbidity Classifications (7). In the present guide, five potentially life-threatening conditions are used as part of the inclusion criteria set: severe postpartum haemorrhage, severe pre-eclampsia, eclampsia, sepsis/severe systemic infection, and ruptured uterus. Diseases or conditions that may be relevant to a severe maternal outcome but are not part of the chain of events leading to that severe maternal outcome should be specified under **contributory/associated conditions** (11) (for more details see Section 2.1.4).

Critical interventions are those that are required in the management of life-threatening and potentially life-threatening conditions. In this guide, blood transfusion, interventional radiology and laparotomy (including hysterectomy and other emergency surgical interventions in the abdominal cavity, but excluding caesarean section) fall into this category.

Admission to intensive care unit is defined as admission to a unit that provides 24-hour medical supervision and is able to provide mechanical ventilation and continuous vasoactive drug support.

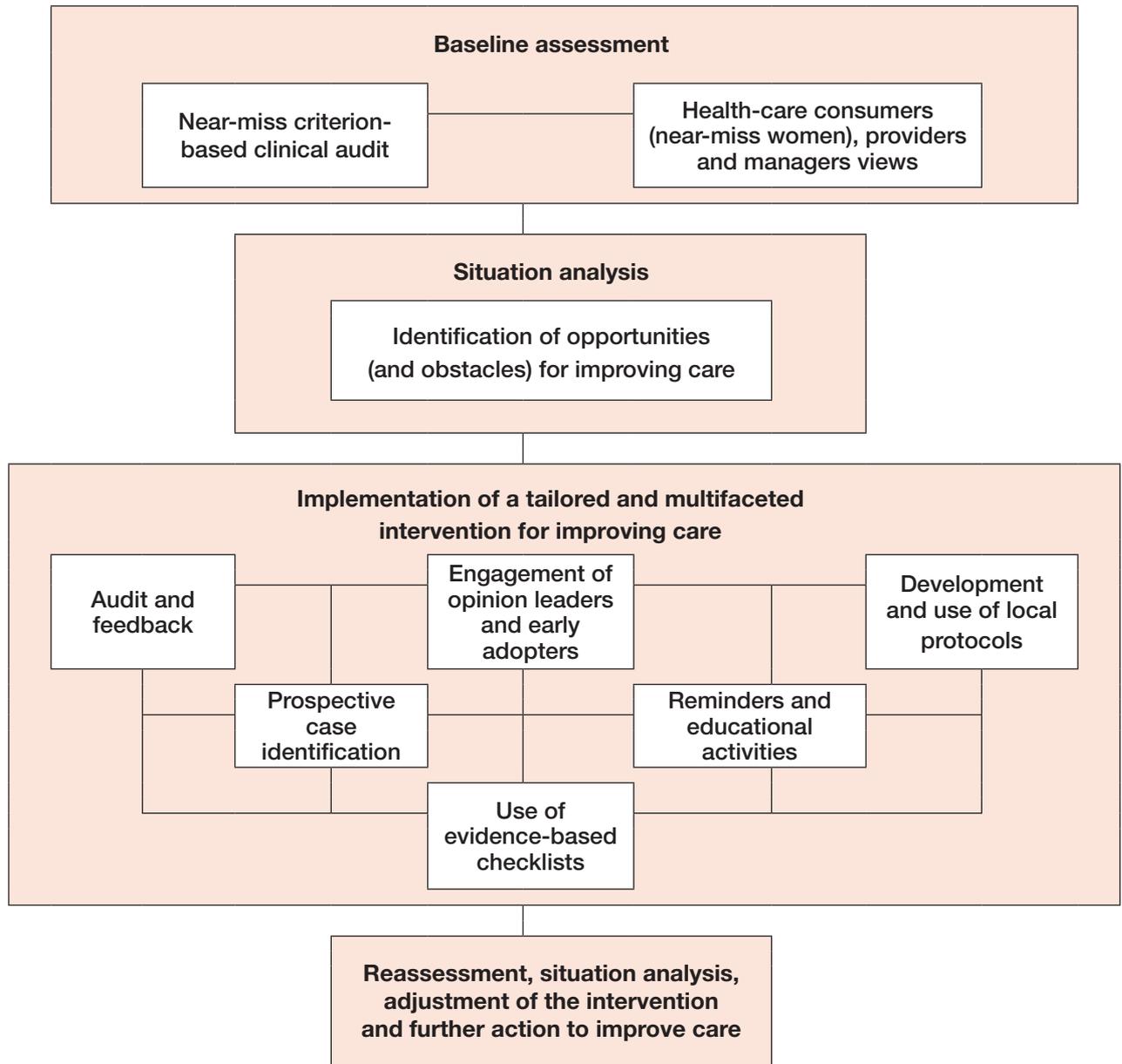
Maternal death is defined as death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and the site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes (12).

A **maternal near-miss** case is defined as “a woman who nearly died but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy” (7,11). In practical terms, women are considered near-miss cases when they survive life-threatening conditions (i.e. organ dysfunction).

Severe maternal outcomes are maternal near-miss cases and maternal deaths.

Process indicators are those that assess the processes of health care. In this guide, process indicators are those that assess the use of key interventions for the prevention and management of severe complications. Data on the use of key interventions provide information on the implementation status of evidence-based recommendations.

Sentinel units are structures in the facility that are likely to provide care to women with severe complications related to pregnancy, childbirth or postpartum (e.g. maternal high-risk wards, high-dependency or intensive care units, surgical recovery room, emergency or facility-arrival room, blood bank, postabortion care units, and others).

Figure 1. The near-miss approach conceptual framework

2.1.2 Inclusion criteria

The first step in implementing the near-miss approach is to systematically identify women with severe complications of pregnancy. In order to simplify data collection and data handling, only the essential information needed to produce meaningful results is collected for women with severe **pregnancy-related** complications.

Box 1 presents the inclusion criteria for the baseline assessment. Women who are pregnant, in labour, or who delivered or aborted up to 42 days ago arriving at the facility with any of the listed conditions or those who develop any of those

conditions during their stay at the health-care facility would be eligible. Women that develop those conditions unrelated to pregnancy (i.e. not during pregnancy or 42 days after termination of pregnancy) are not eligible. Women who are already dead when they are brought to the health-care facility or those who die on arrival at the facility should be included because they are likely to represent cases involving a major delay in accessing care. The eligibility is not restricted by gestational age at which complications occurred (i.e. women having abortions or ectopic pregnancies and presenting with any of the inclusion criteria are eligible).

Box 1. Inclusion criteria for baseline assessment of quality of care

Severe maternal complications

- Severe postpartum haemorrhage
- Severe pre-eclampsia
- Eclampsia
- Sepsis or severe systemic infection
- Ruptured uterus
- Severe complications of abortion

Critical interventions or intensive care unit use

- Admission to intensive care unit
- Interventional radiology
- Laparotomy (includes hysterectomy, excludes caesarean section)
- Use of blood products

Life-threatening conditions (near-miss criteria)

- Cardiovascular dysfunction
 - Shock, cardiac arrest (absence of pulse/heart beat and loss of consciousness), use of continuous vasoactive drugs, cardiopulmonary resuscitation, severe hypoperfusion (lactate >5 mmol/l or >45 mg/dl), severe acidosis (pH <7.1)
- Respiratory dysfunction
 - Acute cyanosis, gasping, severe tachypnea (respiratory rate >40 breaths per minute), severe bradypnea (respiratory rate <6 breaths per minute), intubation and ventilation not related to anaesthesia, severe hypoxemia (O_2 saturation <90% for ≥60 minutes or PAO_2/FiO_2 <200)

- Renal dysfunction
 - Oliguria non-responsive to fluids or diuretics, dialysis for acute renal failure, severe acute azotemia (creatinine ≥300 µmol/ml or ≥3.5 mg/dl)
- Coagulation/haematological dysfunction
 - Failure to form clots, massive transfusion of blood or red cells (≥5 units), severe acute thrombocytopenia (<50 000 platelets/ml)
- Hepatic dysfunction
 - Jaundice in the presence of pre-eclampsia, severe acute hyperbilirubinemia (bilirubin >100 µmol/l or >6.0 mg/dl)
- Neurological dysfunction
 - Prolonged unconsciousness (lasting ≥12 hours)/coma (including metabolic coma), stroke, uncontrollable fits/status epilepticus, total paralysis
- Uterine dysfunction
 - Uterine haemorrhage or infection leading to hysterectomy

Maternal vital status

- Maternal death

2.1.3 Plan for ensuring identification of all eligible women

Identifying all eligible women is vital for this approach. To ensure that all eligible women are identified and included in the assessment, the team implementing the near-miss approach must develop a sound plan based on the types and characteristics of participating facility. In primary-care facilities or small health-care units, the staff could be encouraged to make spontaneous notifications. The staff will, however, need to be sensitized about the importance of identifying all eligible women. In this regard the use of reminders (as a checklist in medical records) and wallcharts (about the study and inclusion criteria) can be helpful.

In secondary or tertiary care facilities, the plan to identify all eligible women should include periodic visits (preferably daily) to obstetric wards, delivery rooms, emergency rooms and other sentinel units (e.g. intensive care units) by study team members or other designated individuals. Staff that work in sentinel units should be sensitized appropriately, for example through individual and group discussions, reminders and wallcharts. In this context, early adopters (e.g. registrars) and opinion leaders may be enlisted to create a critical mass of people performing spontaneous notifications. In large general hospitals, periodic visits to the morgue to screen all deaths of women of reproductive age may be helpful in identifying maternal deaths that may have occurred in departments other than that of obstetrics and gynaecology.

2.1.4 Data collection and data management

Data for the near-miss criterion-based clinical audit are extracted from appropriate patient records. These records are usually kept by the facilities included in the audit. In case of doubt about individual cases, or incomplete data in the patient records, relevant facility staff should be contacted.

For each woman data should be collected on the occurrence of selected severe pregnancy-related complications and severe maternal outcomes,

use of critical/key interventions, and admission to intensive care unit. In addition, all relevant dates should be noted along with the referral process followed, condition of the woman on arrival at the facility, whether the woman had the complication before, during or after delivery, mode of delivery, pregnancy outcome, and underlying and contributing causes of severe maternal outcomes. The minimum set of variables for which data need to be collected is presented in a sample data collection form in Annex 2. In this form, the last group of variables is entitled “Contributory/associated conditions”. While four items (anaemia, HIV infection, previous caesarean section, and prolonged/obstructed labour) are pre-listed in that group, up to four additional locally relevant variables can be added in the local manual of operations. These could include conditions such as influenza-like disease, malaria, dengue fever, and neonatal death during the first week of life.

Data collected from each facility should include the total number of deliveries and total number of live births at the facility during the data collection period. Descriptive data on the facility (e.g. level of care, information about the catchment area, essential information on available resources) should also be documented.

A database should be constituted. Freely available software solutions and electronic spreadsheets could be used to store and manage the collected data (19, 20).

The following procedures should be considered in order to ensure that high-quality data are obtained.

1. Prepare a local protocol for the near-miss assessment by adapting this guide to local factors and context. In this regard the following should be kept in mind:
 - a. Adding new variables should be avoided. A careful examination of all additional variables must be performed because more variables will increase the complexity of data collection and may affect the reliability of the information.

- b. Emphasis should be placed on the more severe cases, avoiding unnecessary expansion of inclusion criteria.
2. Prepare a local operations manual describing all the steps necessary for the implementation of the local protocol in the facility.
3. Appropriate measures should be planned and undertaken to train the staff involved in the activity in terms of: use of the local protocol, manual of operations, and activity-related glossary; how to identify the eligible population; the role of sentinel units; and how to retrieve the required information from the facility records and facility staff.
 - a. Special attention should be paid to women with life-threatening conditions and maternal deaths. Frequently, in the same woman, several life-threatening conditions may be present. A maternal death is generally preceded by one or more than one life-threatening conditions. Recording all life-threatening conditions present in both maternal deaths and near-miss cases helps to identify the pattern of intensive support needed by women with severe complications arriving at the health-care facility.
4. After data collection, visual checking should be done before data entry in order to identify missing data and any out of range values.
5. Double entry of data should be considered to reduce typing mistakes.
6. A logbook should be maintained containing confidential information of the women included in the assessment (i.e. woman's identification code in the facility, name and other confidential information). The logbook must be kept in a safe place by the data collector to enable identification of individual records in case of need for data checks or when queries arise.
7. Discrepancies in data should be solved as soon as they are identified.
8. It is recommended to undertake random, periodic cross-checks of entered data, with double data extraction and data entry of at least 5% of the cases. Those responsible for data collection and data entry should prepare logbooks by documenting the problems encountered in service delivery. Contents of these logbooks should be discussed periodically by those responsible for quality of care at the facility.
9. As hospital records are the main source of information for this evaluation, an effort to optimize the quality of these records should be carried out (e.g. embedding the sample data collection form or parts of it as part of the routine hospital records).

2.1.5 Sample size and timeline

The minimum sample size for producing near-miss and process indicators has not been formally established. However, the prevalence of severe maternal outcomes (i.e. maternal deaths plus near-miss cases divided by the number of women giving birth within a given time period) may be used to estimate the sample size that could produce meaningful results. This prevalence of severe maternal outcomes may vary depending on several factors, but it is generally expected to be around 7.5 cases/1000 deliveries. Box 2 presents the expected number of cases with severe maternal outcomes according to the total number of deliveries investigated. Based on previous assessments, it would be desirable to obtain samples containing at least 20 cases with severe maternal outcomes. Smaller samples should be avoided as they may give imprecise results. The minimum period of data collection will vary according to the characteristics of the women receiving obstetrics care at the health-care facility and the annual number of deliveries. From a practical standpoint budgetary and other constraints may affect the duration of data collection.

Box 2. Expected number of all eligible women and women with severe maternal outcome (range) according to the total number of deliveries investigated^a

Number of deliveries	1000	2000	4000	10000
Expected number of all eligible women	37 (15–75)	75 (37–300)	150 (75–300)	375 (187–750)
Expected number of women with severe maternal outcomes	7 (3–15)	15 (7–30)	30 (15–60)	75 (37–150)

^aSee Box 1 for eligibility criteria.

Box 3. Maternal near-miss indicators

Maternal near-miss (MNM) refers to a woman who nearly died but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy.

Maternal death (MD) is the death of a woman while pregnant or within 42 days of termination of pregnancy or its management, but not from accidental or incidental causes.

Live birth (LB) refers to the birth of an offspring which breathes or shows evidence of life.

Severe maternal outcome refers to a life-threatening condition (i.e. organ dysfunction), including all maternal deaths and maternal near-miss cases.

Women with life-threatening conditions (WLTC) refers to all women who either qualified as maternal near-miss cases or those who died (i.e. women presenting a severe maternal outcome). It is the sum of maternal near-miss and maternal deaths (WLTC = MNM + MD).

Severe maternal outcome ratio (SMOR) refers to the number of women with life-threatening conditions (MNM + MD) per 1000 live births (LB). This indicator gives an estimate of the amount of care and resources that would be needed in an area or facility [SMOR = (MNM + MD)/LB].

MNM ratio (MNMR) refers to the number of maternal near-miss cases per 1000 live births (MNMR = MNM/LB). Similarly to the SMOR, this indicator gives an estimation of the amount of care and resources that would be needed in an area or facility.

Maternal near-miss mortality ratio (MNM : 1 MD) refers to the ratio between maternal near-miss cases and maternal deaths. Higher ratios indicate better care.

Mortality index refers to the number of maternal deaths divided by the number of women with life-threatening conditions expressed as a percentage [MI = MD/(MNM + MD)]. The higher the index the more women with life-threatening conditions die (low quality of care), whereas the lower the index the fewer women with life-threatening conditions die (better quality of care).

Perinatal outcome indicators (e.g. perinatal mortality, neonatal mortality or stillbirth rates) in the context of maternal near-miss could be useful to complement the quality-of-care evaluation.

Box 4. Operational definitions of severe maternal complication, selected evidence-based recommendations and process indicators

Operational definitions	
Severe postpartum haemorrhage	Genital bleeding after delivery, with at least one of the following: perceived abnormal bleeding (1000 ml or more) or any bleeding with hypotension or blood transfusion.
Severe pre-eclampsia	Persistent systolic blood pressure of 160 mmHg or more or a diastolic blood pressure of 110 mmHg; proteinuria of 5 g or more in 24 hours; oliguria of <400 ml in 24 hours; and HELLP syndrome or pulmonary oedema. Excludes eclampsia.
Eclampsia	Generalized fits in a patient without previous history of epilepsy. Includes coma in pre-eclampsia.
Severe systemic infection or sepsis	Presence of fever (body temperature >38°C), a confirmed or suspected infection (e.g. chorioamnionitis, septic abortion, endometritis, pneumonia), and at least one of the following: heart rate >90, respiratory rate >20, leukopenia (white blood cells <4000), leukocytosis (white blood cells >12 000).
Uterine rupture	Rupture of uterus during labour confirmed by laparotomy.

Standard care and process indicator^a	
Prevention of postpartum haemorrhage	
Standard care	All women should receive 10 IU of oxytocin just after delivery for the prevention of postpartum haemorrhage (13).
Process indicator	The number of women who received a single dose of oxytocin for the prevention of postpartum haemorrhage divided by the number of all women giving birth (vaginal delivery + caesarean section)
Treatment of postpartum haemorrhage	
Standard care	All women with postpartum haemorrhage should receive oxytocin (14).
Process indicator	The number of women with postpartum haemorrhage who received therapeutic oxytocin divided by the number of all women with postpartum haemorrhage.
Eclampsia	
Standard care	All women with eclampsia should receive magnesium sulfate (15).
Process indicator	The number of women with eclampsia who received magnesium sulfate divided by the number of all women with eclampsia.
Prevention of severe systemic infections or sepsis	
Standard care	All women having a caesarean section should receive prophylactic antibiotics (16).
Process indicator	The number of women having a caesarean section and receiving prophylactic antibiotics divided by the number of all women having caesarean sections.
Treatment of severe infections and sepsis	
Standard care	All women with severe systemic infections or sepsis should receive intravenous antibiotics (17).
Process indicator:	The number of women with severe systemic infections or sepsis who received antibiotics divided by the number of all women with severe systemic infections or sepsis.
Fetal lung maturation	
Standard care	All women delivering a live preterm fetus should receive corticosteroids for fetal lung maturation (18).
Process indicator	The number of women having a live birth after 3 hours of hospital stay and receiving corticosteroids for fetal lung maturation divided by all women having a live birth after 3 hours of hospital stay.

^aLower proportions of women receiving appropriate interventions indicate opportunities to improve care, whereas higher proportions indicate better quality of care.

Annual cycles of quality of care assessment and improvement would be desirable. A possible timeline for this activity would be around four months for the initial assessment, two months for analysing the obtained data and preparing a plan for improving clinical practice, and six months for implementing the interventions for health-care improvements. One year after the initial assessment, a new cycle of activities could be initiated with a reassessment, which would be followed by further improvements of quality of care. Alternatively, data collection could progress continuously after the initial assessment, concomitantly with activities to improve the quality of care. Importantly, the initial assessment should not be an end in itself, but the initial step towards strengthening the health system and improving the quality of care. Information obtained from near-miss women, health-care providers and managers could complement the near-miss criterion-based clinical audit as described in Figure 1, though this document does not cover this additional component.

2.1.6 Situation analysis

The situation analysis is based on near-miss and process indicators. The near-miss indicators are presented in Box 3, along with their definitions and the instructions for calculating the indicators. Box 4 presents operational definitions of severe maternal complications, selected evidence-based recommendations and process indicators. The collected data could be presented as shown in the dummy tables before starting to infer conclusions from the data. Annex 3 presents examples of dummy tables and provides guidance on interpretation of the findings.

2.1.7 Mode of implementation

The WHO maternal near-miss approach is designed to be implemented in health services as a routine activity for improving quality of care. Severe adverse events committees, maternal mortality committees, or other similar groups are ideal as the platform for the implementation of this approach in health-care facilities. The use of such groups where they exist, or establish-

ment of new ones for the purpose of the near-miss approach, can stimulate action for change and contribute to the long-term sustainability of actions to improve quality of care. It is nevertheless fundamental to have one person in charge of coordination of all activities related to the implementation of the approach within each participating facility. It is recommended that the person appointed to lead the implementation of the approach should have good clinical knowledge of severe maternal complications and the capacity to lead and motivate the facility staff to change practices.

2.1.8 Ethical considerations

The basic near-miss approach requires no direct interaction with patients. All needed data are extracted from health-facility records without any patient identification. Since no information is obtained direct from patients, no patient interviews are required. Staff at a participating health-care facility may be required to clarify doubts about individual cases during data collection or when the required information is missing. Confidential information about the identity of individual participants (i.e. individual participant identification number, name, facility registry code and hospital arrival date) is kept undisclosed by the data collector in a separate logbook, which is used only to complete forms in case of doubts or missing data. Given the above precautions and that individual participants are not approached direct for data collection, obtaining informed consent from individual patients is regarded as unnecessary. However, appropriate institutional authorization should be obtained. The privacy officer (or the professional overseeing activities related to access to individual patients' health information) should be also involved, if such a position exists at the health-care facility. Research projects using similar approaches have been approved by WHO and other ethical review committees (21, 22). The full near-miss approach, as conceptualized in Figure 1, and including interviews and other interventions may have other ethical requirements to be addressed by the appropriate ethical review committee.

2.1.9 Post assessment follow-up

In principle, no follow-up of individual women identified as near-miss cases is required. However, depending on the findings of the assessment, health facilities may need to take several follow-up actions to improve the quality of care. After the initial assessment, steps should be taken to implement measures informed by the evaluation. After that, employing the same procedures, the same health-care facilities should be re-assessed either periodically or continuously. Over time, repeated cycles of assessments and improvements will equip health service managers with knowledge about the effects of policies introduced in health services for the improvement of quality of health care.

3. Expected results

The expected results include, among others, understanding local patterns of maternal mortality and morbidity, strengths and weaknesses in the referral system, and the use of clinical and other health-care interventions. When the assessment is scaled up to the district or national level, it can produce a reliable picture of the strengths and shortcomings of the health system in dealing with pregnancy-related complications. A particular advantage of the approach is that it uses a standardized methodology, which when applied correctly, can produce consistently reliable and comparable results over time for varied geographical areas. Results of the near-miss assessment also provide the opportunity to evaluate, among other things, whether the best evidence-based practices are being used in the health-care facility. Data on cases with life-threatening conditions being managed at the health-care facility can be used to foster a culture of early identification of complications and better preparedness for acute morbidities.

4. Application of the near-miss approach at the health district or health system level

The primary unit for the implementation of the near-miss approach is the individual health-care facility. If the assessment is planned within a health district, all health-care facilities in that district that provide services to pregnant women will need to be included in the study. In secondary and tertiary health-care facilities in the district, the procedures described above for implementation of the approach in individual health-care facilities should be followed.

In applying the approach within a health district an important assumption is made: within a community, women who experience acute organ dysfunction related to pregnancy and who are unable to reach a health-care facility in time will not survive (i.e. the survival rate is likely to be minimal, less than 5%). Based on this assumption, the quality of community-based care within the health district can be evaluated through the number of maternal deaths in the community and the proportion of women arriving at a health-care facility with severe maternal outcomes.

Depending on the extent of maternal deaths occurring outside the health-care facilities included in the audit, reliable estimations of maternal deaths within a geographical area (e.g. a health district) during a specific time period is likely to be challenging. In contrast, determining the proportion of women arriving at a health-care facility already with severe maternal outcomes is feasible and provides information about the occurrence of the first (delay in recognizing a condition as a complication and delay in seeking help) and second (delay in reaching a health-care facility once the decision to seek care has been made) delays in the health district.

In primary health-care facilities in a district under evaluation, the burden of case identification and data collection is expected to be minimal because few women with severe complications are likely to be seen in individual facilities. However, such facilities would be involved in making referrals to higher-level facilities and records of all referrals eligible for inclusion in the assessment need to be maintained at the primary-level facilities. For instance, the nurse on duty at a primary-care facility could be made responsible for recording in a logbook all potentially eligible cases. If the above strategy is followed, the facility staff should be required to alert the nurse on duty about the arrival of a potentially eligible case so that it gets entered into the logbook; the facility coordinator should be required to check the logbook weekly. Reminders and wallcharts showing the eligibility criteria could be used to sensitize the staff and raise awareness about eligible cases. A district-wide coordination mechanism will need to be instituted for successful implementation of the maternal near-miss approach, including the identification of all relevant cases.

An alternative to the district-level implementation of the near-miss approach could be to implement it within a network of selected sentinel health-care facilities – for example: in all or a selection of high-volume facilities; in a selection of facilities with varying volumes; or at facilities at various care levels (primary care, first-level referral, tertiary) covering several geographical areas within a country. Implementation of the approach in sentinel hospitals could inform health system managers about the quality of care provided within that network (as a subset of the entire health system). This may be a less complicated arrangement which could result in the strengthening of sentinel hospitals. It could also be the first step towards a gradual/step-wedged implementation of the maternal near-miss approach in the entire health system.

5. Dissemination of the findings and beyond

Once the findings of assessments undertaken with the WHO near-miss approach have been discussed within individual health-care facilities, they should be made public. This should be followed by dissemination of appropriately designed policy briefs and presentations to policy-makers and administrators. Such information has considerable advocacy value and its wide dissemination can help promote policy actions and mobilize professional and civil societies to improve the quality of care for pregnant women. Publication of good-quality data can also help to attract funding for improving services for maternal and perinatal health. Moreover, WHO and other agencies can use such scientific papers in systematic reviews, which can lead to a better global picture of maternal health-care needs and related guidance.

Beyond the conduct of the near-miss approach, multifaceted tailored approaches may be needed to improve the quality of care within the health system (Figure 1). In selected areas and facilities, these approaches can include the implementation of evidence-based guidelines and the use of reminders, opinion leaders' endorsement, and continued audit and feedback to achieve behavioural and process changes (23,24).

References

- World Health Organization, UNICEF, UNFPA and The World Bank. *Trends in maternal mortality: 1990 to 2008*. Geneva: World Health Organization, 2010
- Campbell OM, Graham WJ, Lancet Maternal Survival Series Steering Group. Strategies for reducing maternal mortality: getting on with what works. *The Lancet*, 2006,368:1284–1299.
- Freedman LP et al. Practical lessons from global safe motherhood initiatives: time for a new focus on implementation. *The Lancet*, 2007, 370:1383–1391.
- Pattinson RC, Hall M. Near misses: a useful adjunct to maternal death enquiries. *British Medical Bulletin*, 2003, 67:231–243.
- Say L et al. WHO systematic review of maternal morbidity and mortality: the prevalence of severe acute maternal morbidity (near miss). *Reproductive Health*, 2004, 1(1):3 (DOI:10.1186/1742–4755–1-3).
- Cecatti JG, et al. Research on severe maternal morbidities and near-misses in Brazil: what we have learned. *Reproductive Health Matters*, 2007, 15:125–133.
- Say L et al., WHO working group on Maternal Mortality and Morbidity Classifications. Maternal near miss—towards a standard tool for monitoring quality of maternal health care. *Best Practice & Research Clinical Obstetrics & Gynaecology*, 2009,23:287–296.
- Pattinson R et al. WHO maternal death and near-miss classifications. *Bulletin of the World Health Organization*, 2009, 87:734–734A.
- Graham WJ. Criterion-based clinical audit in obstetrics: bridging the quality gap? *Best Practice & Research Clinical Obstetrics & Gynaecology*, 2009, 23(3):375–388.
- Introducing WHO's sexual and reproductive health guidelines and tools into national programmes: principles and process of adaptation and implementation*. Geneva, World Health Organization, 2007.
- Report on the World Health Organization Working Group on the Classification of Maternal Deaths and Severe Maternal Morbidities. Geneva, World Health Organization, 2009.
- International statistical classification of diseases and related health problems. Tenth revision, Volume 2*. Geneva, World Health Organization, 1993.
- WHO recommendations for the prevention of postpartum haemorrhage*. Geneva, World Health Organization, 2007.
- WHO Guidelines for the management of postpartum haemorrhage and retained placenta*. Geneva, World Health Organization, 2009.
- Duley L et al. Magnesium sulfate and other anticonvulsants for women with pre-eclampsia. *Cochrane Database of Systematic Reviews*, 2007; Issue 4. Art. No.: CD000025 (DOI: 10.1002/14651858.CD000025).
- Smaill F, Hofmeyr GJ. Antibiotic prophylaxis for cesarean section. *Cochrane Database of Systematic Reviews*, 2007; Issue 4. Art. No.: CD000933 (DOI: 10.1002/14651858.CD000933).
- Dellinger RP et al.; International Surviving Sepsis Campaign Guidelines Committee; American Association of Critical-Care Nurses; American College of Chest Physicians; American College of Emergency Physicians; Canadian Critical Care Society; European Society of Clinical Microbiology and Infectious Diseases; European Society of Intensive Care Medicine; European Respiratory Society; International Sepsis Forum; Japanese Association for Acute Medicine; Japanese Society of Intensive Care Medicine; Society of Critical Care Medicine; Society of Hospital Medicine; Surgical Infection Society; World Federation of Societies of Intensive and Critical Care Medicine. Surviving Sepsis Campaign: international guidelines for management of severe sepsis and septic shock: 2008. *Critical Care Medicine*, 2008, 36:296–327.
- Roberts D, Dalziel S. Antenatal corticosteroids for accelerating fetal lung maturation for women at risk of preterm birth. *Cochrane Database of Systematic Reviews*, 2007, Issue 4. Art. No.: CD004454 (DOI: 10.1002/14651858.CD004454.pub2).
- Lauritsen JM, Ed. EpiData data entry, data management and basic statistical analysis system. Odense, Denmark, EpiData Association, 2000–2008 (available at: <http://www.epidata.dk>).

20. Epi-Info. Atlanta, GA, Centers for Diseases Control and Prevention (available at: <http://wwwn.cdc.gov/epiinfo>).
21. Souza JP et al. The World Health Organization Multicountry Survey on Maternal and Newborn Health: study methods. *BMC Health Services Research*, 2011.
22. Cecatti JG et al.; Brazilian Network for Surveillance of Severe Maternal Morbidity. Brazilian network for the surveillance of maternal potentially life threatening morbidity and maternal near miss and a multidimensional evaluation of their long-term consequences. *Reproductive Health*, 2009, 6:15.
23. Althabe F et al. Guidelines Trial Group. A behavioral intervention to improve obstetrical care. *New England Journal of Medicine*, 2008, 358:1929–1940.
24. Rogers, E.M. *Diffusion of innovations*. Fifth edition. New York, Free Press, 2003.

Annex 1. The near-miss criteria glossary

Acute severe azotemia	creatinine ≥ 300 $\mu\text{mol/l}$ or ≥ 3.5 mg/dl .
Cardiac arrest	Sudden absence of pulse and loss of consciousness.
Cardiopulmonary resuscitation	A set of emergency procedures including chest compressions and lung ventilation applied in cardiac arrest victims.
Failure to form clots	The clinical inability to form clots/disseminated intravascular coagulation. Clinically, absence of clotting from the IV site or suture after 7–10 minutes. It can be assessed by the bedside clotting test (failure of a clot to form after 7 minutes or a soft clot that breaks down easily suggest coagulopathy) or other laboratory tests (acute thrombocytopenia ($< 50\,000$ platelets), low fibrinogen (< 100 mg/dl), prolonged prothrombin time (> 6 s, PT 1.5 times normal), or elevated D-dimer (> 1000 ng/ml)). The bedside clotting test is a clinical test to assess the clotting status (Instructions: (1) Take 2 ml of venous blood into a small, dry, clean, plain glass test-tube (approximately 10 mm \times 75 mm); (2) Hold the tube in your closed fist to keep it warm ($+37^\circ\text{C}$); (3) After 4 minutes, tip the tube slowly to see if a clot is forming. Then tip it again every minute until the blood clots and the tube can be turned upside down; (4) Failure of a clot to form after 7 minutes or a soft clot that breaks down easily suggests coagulopathy).
Gasping	A terminal respiratory pattern. The breath is convulsively and audibly caught.
Hysterectomy	In the maternal near-miss context, surgical removal of the uterus following infection or haemorrhage.
Life-threatening condition	A severe health condition usually associated with organ dysfunction. In the maternal near-miss context, a condition that can only result in a near-miss case or in a maternal death.
Massive transfusion	Transfusion of considerable amount of blood or red cells, i.e. transfusion of ≥ 5 units of blood or red blood cells.
Maternal near-miss	A woman who nearly died but survived a complication that occurred during pregnancy, childbirth or postpartum up to 42 days
Metabolic coma	loss of consciousness and the presence of glucose plus ketoacids in urine.
Oliguria non-responsive to fluids or diuretics	A urinary output < 30 ml/h for 4 hours or < 400 ml/24 h non-responsive to fluids or diuretics.
Prolonged unconsciousness	Any loss of consciousness lasting more than 12 hours, involving complete or almost complete lack of responsiveness to external stimuli. A state compatible with Coma Glasgow Scale < 10 .
Severe acidosis	a blood pH < 7.1 .
Severe acute hyperbilirubinemia	Bilirubin > 100 $\mu\text{mol/l}$ or > 6.0 mg/dl .
Severe acute thrombocytopenia	An acute reduction in the number of platelets in the blood to $< 50\,000$ platelets/ml.
Severe bradypnea	Respiratory rate less than six breaths per minute.
Severe hypoperfusion	Lactate > 5 mmol/l or 45 mg/dl .

Severe hypoxemia	Oxygen saturation <90% for ≥ 60 minutes or $\text{PaO}_2/\text{FiO}_2 < 200$. The $\text{PaO}_2/\text{FiO}_2$ index is the relation between the arterial oxygen saturation (PaO_2) and the fraction of inspired oxygen (FiO_2). Arterial oxygen saturation is determined by performing an arterial blood gasometry. The inspired oxygen fraction may vary according with patient need and should be recorded at the moment of blood collection for the gasometry. It can be precise (for instance during mechanical ventilation, 0.21–1.00) or estimated (without oxygen supplementation, 0.21; oxygen nasal catheter, 0.25; facial oxygen mask, 0.25–1.0).
Severe tachypnea	Respiratory rate of more than 40 breaths per minute.
Shock	A persistent systolic blood pressure <80 mmHg or a persistent systolic blood pressure <90 mmHg with a pulse rate at least 120 bpm.
Total paralysis	The complete or partial paralysis of both sides of the body. Usually, an extreme neuromuscular global weakness associated with critical illness. This conditions is also known as critical illness polyneuromyopathy
Uncontrollable fit	Refractory, persistent convulsions. Status epilepticus.
Use of continuous vasoactive drugs	The continuous use of any dose of dopamine, epinephrine or norepinephrine. In the context of vasoactive drugs infusion, continuous use refers to the uninterrupted infusion of a solution containing a vasoactive drug. It is opposed to the intermittent or in bolus injection of a vasoactive drug.

Annex 3. Dummy tables and interpretation

This annex presents suggested dummy tables for the compilation and interpretation of the data. Table 1 covers the morbidities that became the reason for including the affected women in the audit. Scrutiny of data in this table will allow identification of the pattern of organ dysfunction among those who died and those who survived the severe pregnancy-related complications. One practical implication of the information summarized in Table 1 is that it can point to the types of vital support that may need to be provided – for example, if more deaths occurred due to respiratory distress, then special attention will need to be dedicated to respiratory support. Such information is critical for planning the provision of emergency/intensive maternal health care.

Table 2, complements the information collected in Table 1, as it relates to the underlying and contributory causes of severe maternal morbidity. In Table 2, information on causes of severe maternal morbidity is stratified by group: all women in the audit; only near-miss cases; and only maternal deaths. Such information may have implications for anticipating the long-term consequences of severe complications among those who survived them, and contributes to the understanding of risk factors (e.g. anaemia or previous caesarean sections). Table 2 also includes information about locally specified conditions (e.g. malaria, dengue or other locally relevant conditions).

Table 3 compiles information about the end of pregnancy and the perinatal outcomes. In this table, the relationship between maternal near-miss, maternal deaths, mode of delivery/termination of pregnancy and perinatal outcomes is explored.

Table 4 records data on the near-miss indicators and presents a broader perspective of the women who receive care in the facilities in the assessment. In order to be consistent with the maternal mortality ratio, the total number of live births that took place in the health-care facilities during the data collection period (source population) is recorded and used in further calculations. The severe maternal outcome ratio (SMOR) and

the maternal near-miss ratio are outcome indicators that provide an assessment of how frequently those conditions occurred in the source population. These near-miss indicators provide an estimate of the complexity of care that is required by the population served by the health-care facilities in the assessment. For example, higher ratios (e.g. over 10 cases per 1000 live births) indicate that a substantial proportion of cases will require more complex interventions in order to survive their complications. The mortality index and the maternal near-miss mortality ratios provides an estimate of performance; if there is a high mortality index (e.g. over 20%) the quality of care provided to severe cases may need to be reviewed. If the recorded mortality rate is low (e.g. less than 5%), it can be interpreted that the health-care facilities/health system are performing well in dealing with complex and severe cases. Table 4 also stratifies the information with regard to at what stage the severe maternal outcome was identified. This has important implications for the health system because if a very large proportion (e.g. over 70%) of women is reaching the facility already with a severe maternal outcome, it indicates that first and second delays may be an issue. In addition, by examining especially the cases in which a severe maternal outcome occurs during hospital stay, both in terms of SMOR and mortality index, a more specific assessment of intrahospital care can be made.

Table 5 evaluates the use intensive care. By looking at the overall rate of admission to intensive care unit (ICU), one can have the first impression of the availability of ICU beds. Very low rates (e.g. less than 0.5%) may indicate a shortage of ICU beds. High rates (e.g. over 3%–5%) can indicate overuse/unnecessary use of ICU facilities. Of course, the conclusion depends on the profile of the population and the care offered. If the facility being assessed is a primary or secondary health-care facility, a low rate of ICU use could be explained by the lesser complexity of cases that are cared for in those facilities. On the contrary, if the audit was done at a tertiary or higher order facility that receives many cases with complications, higher rates of ICU admission use could be

perfectly justified. The other indicators included in Table 5 are useful to understand better the overall situation. Women presenting with organ dysfunction are severely ill and are most likely to benefit from intensive monitoring and care in an ICU. Hence, a high proportion (e.g. over 70%) of women with severe maternal outcomes are expected to be admitted to an ICU; if that is not the case, shortage of ICU beds for obstetric patients may be an issue in that specific health system. On the other hand, a low proportion (e.g. less than 30%) of severe maternal outcomes among all women admitted to ICU during pregnancy, childbirth or post partum, may indicate that a substantial proportion of women are being admitted just for monitoring, which should be considered by the health system in the context of optimization of resources (e.g. more and other severely ill patients could be sent to that unit or the number of ICU beds available for obstetric patients in that unit could be revised). Finally, the last indicator in this table is the proportion of maternal deaths assisted without ICU admission. If there is a substantial proportion (e.g. over 10%) of maternal deaths taking place without intensive care, shortage of ICU beds could certainly be an issue. It is important to note that the figures presented in Tables 4 and 5 should be considered as crude references. Targets and references for the near-miss indicators and process indicators including ICU use should be set locally.

Table 6 covers other process indicators related to specific conditions. For each condition, the target population is identified, and the proportion of that target population receiving the recommended evidence-based intervention examined. For example, among all women that had eclampsia, what is the proportion that received magnesium sulfate? Based on current evidence, only a negligible proportion of women with eclampsia would present actual contraindications for magnesium sulfate. Hence, the expected use of the intervention should be nearly 100%. If a gap is identified (e.g. use of the first option recommended intervention below 95%), it should be interpreted as an opportunity to improve care. In the Table 6, the only process indicator that does not follow

this logic is the proportion of women having a laparotomy for ruptured uterus after 3 hours of hospital stay. The rationale behind this indicator is that all women that arrive at the hospital with obstructed labour or uterine rupture should be operated within 3 hours of hospital stay. Any laparotomy for uterine rupture taking place after 3 hours of hospital stay indicates a delay in addressing obstructed labour/uterine rupture. This table also relates each specific target population to a SMOR and mortality-related index. For instance, a population of preterm infants with low use of corticosteroids for fetal lung maturation and high early neonatal mortality indicates an important opportunity to improve care.

Table 1. Morbidity conditions in the audited sample of women with potentially life-threatening conditions and severe maternal outcomes

Morbidity conditions	Number	Percentage
1. Women with potentially life-threatening conditions		
1.1 Women with severe complications		
Severe postpartum haemorrhage		
Severe pre-eclampsia		
Eclampsia		
Sepsis or severe systemic infection		
Ruptured uterus		
Other complications associated with severe maternal outcome		
1.2. Women undergoing critical Interventions		
Use of blood products		
Interventional radiology		
Laparotomy		
Admission to intensive care unit		
2. Organ dysfunction in maternal near-miss cases		
Cardiovascular dysfunction		
Respiratory dysfunction		
Renal dysfunction		
Coagulation/haematologic dysfunction		
Hepatic dysfunction		
Neurologic dysfunction		
Uterine dysfunction/hysterectomy		
Multiple organ dysfunction		
3. Organ dysfunction in maternal deaths		
Cardiovascular dysfunction		
Respiratory dysfunction		
Renal dysfunction		
Coagulation/haematologic dysfunction		
Hepatic dysfunction		
Neurologic dysfunction		
Uterine dysfunction/hysterectomy		
Unspecified organ dysfunction		
Multiple organ dysfunction		

Table 2. Underlying causes of life-threatening conditions and severe maternal outcomes

Underlying causes and associated conditions	Women with potentially life-threatening conditions		Maternal near-miss cases		Maternal deaths	
	Total number		Total number		Total number	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
1. Underlying causes						
Pregnancy with abortive outcome						
Obstetric haemorrhage						
Hypertensive disorders						
Pregnancy-related infection						
Other obstetric disease or complication						
Medical/Surgical/Mental disease or complication						
Unanticipated complications of management						
Coincidental conditions						
Unknown						
2. Contributory causes/associated conditions						
Anaemia						
HIV infection						
Previous caesarean section						
Prolonged / obstructed labour						
Other locally specified						
Other locally specified						
Other locally specified						
Other locally specified						

Table 3. End of pregnancy and pregnancy outcome

Pregnancy outcome	Potentially life-threatening conditions		Maternal near-miss cases		Maternal deaths	
	Number	%	Number	%	Number	%
1. End of pregnancy						
Vaginal delivery						
Caesarean Section						
Complete abortion						
Curettage/vacuum aspiration						
Medical methods for uterine evacuation						
Laparotomy for ectopic pregnancy						
Other/unknown						
Women still pregnant at discharge from hospital or at death						
2. Caesarean section rate ^a						
3. Preterm births						
4. Stillbirths						
5. Perinatal deaths ^b						

^aCaesarean deliveries divided by all deliveries.

^bFetal deaths + intrahospital early neonatal mortality.

Table 4. Severe maternal outcomes and near-miss indicators

Outcomes	Near-miss indicators
1. All live births in the population under surveillance	
2. Severe maternal outcomes (SMO) cases (number)	
Maternal deaths (<i>n</i>)	
Maternal near-miss cases (<i>n</i>)	
3. Overall near-miss indicators	
Severe maternal outcome ratio (per 1000 live births)	
Maternal near-miss ratio (per 1000 live births)	
Maternal near-miss mortality ratio	
Mortality index	
4. Hospital access indicators	
SMO cases presenting the organ dysfunction or maternal death within 12 hours of hospital stay (SMO12) (number)	
Proportion of SMO12 cases among all SMO cases	
Proportion of SMO12 cases coming from other health facilities	
SMO12 mortality index	
5. Intrahospital care	
Intrahospital SMO cases (number)	
Intrahospital SMO rate (per 1000 live births)	
Intrahospital mortality index	

Table 5. Intensive care use

Intensive care use	Unit
Total number of women giving birth	
ICU admission rate	
ICU admission rate among women with SMO	
SMO rate among women admitted to ICU	
Proportion of maternal deaths assisted without ICU admission	

Table 6. Process and outcome indicators related with specific conditions

Indicators	Number	Percentage
1. Prevention of postpartum haemorrhage		
Target population: women giving birth in health-care facilities		
Oxytocin ^a use		
Use of any uterotonic (including oxytocin)		
2. Treatment of severe postpartum haemorrhage		
Target population: women with severe PPH		
Oxytocin ^a use		
Ergometrine		
Misoprostol		
Other uterotonics		
Any of the above uterotonics		
Tranexamic acid		
Removal of retained products		
Balloon or condom tamponade		
Artery ligation		
Hysterectomy		
Abdominal packing		
Proportion of cases with SMO		
Mortality		
3. Anticonvulsants for eclampsia		
Target population: women with eclampsia		
Magnesium sulfate ^a		
Other anticonvulsant		
Any anticonvulsant		
Proportion of cases with SMO		
Mortality		
4. Prevention of caesarean section related infection		
Target population: women undergoing caesarean section		
Prophylactic antibiotic during caesarean section		
5. Treatment for sepsis		
Target population: women with sepsis		
Parenteral therapeutic antibiotics ^a		
Proportion of cases with SMO		
Mortality		
6. Ruptured uterus		
Target population: women with ruptured uterus		
Laparotomy		
Laparotomy after 3 hours of hospital stay		
Proportion of cases with SMO		
Mortality		
7. Preterm birth		
Target population: women having a preterm delivery after 3 hours of hospital stay		
Corticosteroids for fetal lung maturation ^a		
Early neonatal mortality		

^aPrimary indicator, based on the first option evidence-based intervention for the target population.

For more information, please contact:

Department of Reproductive Health and Research
World Health Organization
Avenue Appia 20, CH-1211 Geneva 27, Switzerland
Fax: +41 22 791 4171
E-mail: reproductivehealth@who.int
www.who.int/reproductivehealth



**World Health
Organization**

ISBN 978 92 4 150222 1



9 789241 502221