Integrated Management of Pregnancy and Childbirth

Standards for Maternal and Neonatal Care

Department of
Making Pregnancy Safer

World Health
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Introduction

What are the Standards for Maternal and Neonatal Care?

The *Standards for Maternal and Neonatal Care* consists of a set of user-friendly leaflets that present World Health Organization (WHO) key recommendations on the delivery of maternal and neonatal care in health facilities, starting from the first level of care. Facilities at higher levels of care should also have these standards in place as a minimum (essential) care for all mothers and babies; in addition, they should have standards for the care of women and newborns in need of obstetric and special care. The *Standards for Maternal and Neonatal Care* are part of the WHO Integrated Management of Pregnancy and Childbirth Care (IMPAC) Package, which provides guidance for assisting countries to improve the health and survival of women and their newborn babies during pregnancy, childbirth and the postnatal period.

Why implement the Standards for Maternal and Neonatal Care?

Studies clearly indicate that countries with high maternal, perinatal and neonatal mortality have inadequate and poor quality health services and this can be associated with reduced utilization of health care services. As such, increased emphasis is being placed on the need for standards of care, as well as mechanisms which address the barriers to provision and use of quality care. Evidence also suggests that explicit, evidence-based guidelines improve the process and outcomes of health care when appropriately implemented. Experience from countries indicates that the characteristics of the guidelines, the process used in their development and a clear implementation strategy supported by effective monitoring and supervision influence the impact of practice guidelines.

What is the purpose of the Standards for Maternal and Neonatal Care?

The purpose of the *Standards for Maternal and Neonatal Care* is to assist programme managers and health care providers to:

- develop evidence-based national and sub-national standards on maternal and neonatal health care;
- introduce standards setting and a quality improvement process at facility level as a means to improve access and quality of maternal and neonatal health services;
- provide effective maternal and neonatal health services;
- use existing resources to achieve the optimal health care outcomes; and
- improve individuals', families' and community's satisfaction and utilization of maternal and neonatal health services.

How are the Standards for Maternal and Neonatal Care structured?

Overall the *Standards for Maternal and Neonatal Care* include the most relevant topics that need to be addressed for ensuring quality maternal and neonatal health services. They are grouped in six sections: five sections focus on clinical standards, where as the sixth encompasses health service delivery standards that are crucial to ensure the provision of quality maternal and neonatal care.

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The Standards for Maternal and Neonatal Care currently comprise the following sections:

- General standards of care for healthy pregnancy and childbirth
- Standards for safe care in childbirth and the immediate postpartum period
- Standards for postnatal care
- Standards of care for managing major complications in pregnancy, childbirth and after birth
- Standards of care for managing major complications in the newborn
- Health service delivery standards

How is each of the Standards for Maternal and Neonatal Care structured?

While presented in a package, each standard is structured to be self-standing, complete with all the elements needed for implementation. This format is meant to facilitate country use by encouraging a stepwise implementation of the standards according to country needs and availability of resources. In addition, such a format should allow for more effective updating. The section on efficacy and effectiveness of the proposed recommendations in each of the standards will be periodically updated as new evidence is gathered.

The key elements common to all standards are:

- the *title*, which identifies the standard;
- the *standard statement*, which is based on the best available evidence, feasibility and cost effectiveness;
- the *aim,* which indicates the public health intent and goal of implementing the standard;
- a section titled *requirements*, which indicates a checklist form the conditions that need to be in place to implement the standard;
- a section called *applying the standard,* which briefly explains what the health provider (for the first five sections) or the health manager (for the section on health service delivery standards) must do to implement the standard;
- a section focusing on *audit*, with suggested input, process and outcome indicators to be used to monitor the correct implementation and impact of the standard;
- a narrative part called *rationale*, which comprises two sections, namely the *burden of suffering* of the condition that the standard addresses, and the *efficacy and effectiveness* section which describes the importance of the recommendations and the evidence in support of the standard;
- a *table of evidence,* which summarizes the most important results of the available evidence;
- a list of *references* used to develop the standard; and
- a list of *links and additional readings,* which will assist the users in implementing the standards.

How were the Standards for Maternal and Neonatal Care developed?

In order to appropriately reflect the diversity of expert opinion and disciplinary perspectives, a systematic, participatory process was used in the development of these standards, in accordance with WHO Guidelines for Guidelines (http://whqlibdoc.who.int/hq/2003/EIP_GPE_EQC_2003_1.pdf). Draft standards were developed by WHO technical staff in the *Making Pregnancy Safer (MPS) Department* and the *Department of Reproductive Health and Research*. These drafts were then shared with other relevant departments for ensuring technical accuracy and consistency with other WHO programmes, and with WHO Regional Offices and MPS country focal persons, to gather input on their applicability in different contexts. Additional inputs have been requested from external experts and institutions throughout the entire development process.

The standards which are included in this guideline are only limited to those for which there is extensive experience or scientific evidence to support the recommendation. Three guiding principles were used in the selection of the topics:

1. public health relevance, as major causes of maternal, fetal or neonatal mortality and/or morbidity;
2. feasibility of implementation at first level facilities in settings with limited resources, both from the health service delivery and community perspective;
3. cost implications, such as cost-effectiveness (where information was available).

To develop the standards, a systematic process and methodology for gathering and summarizing the evidence was developed. The search for evidence followed a sequential process, beginning with higher level evidence, and including observational studies whenever hard evidence (randomized controlled trials or systematic reviews) were not available. For the Clinical Standards the following sources were used: Medline, Embase, and Cinhal (Silverplatter platform), the Cochrane Library, Medline and the WHO Reproductive Health Library, WHO publications based on technical working groups and expert reviews, and a number of articles and websites based on reference lists review and WHO guidelines. For the Health Service Delivery Standards the search included: PubMed, Sciencedirect, EconLit, Interscience, Popline, IDEA, and ECONbase, as well as the databases of relevant organizations, departments, and institutions, such as the World Health Organization, World Bank, Save the children and others as identified by the standards development sub-group.

A table summarizing the evidence complements each standard by presenting the analysis of the studies retrieved, their quality, the population considered in the studies including the specific baseline risk and an estimate of the efficacy of the intervention for major outcomes (benefits and harms). The level of evidence presented in the clinical standards is based on the SIGN methodology which uses a scale from 1 to 4 as shown in the table below.

Levels of evidence

1++	High quality meta analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well conducted meta analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1 -	Meta analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
2++	High quality systematic reviews of case-control or cohort studies High quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal
2+	Well conducted case control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal
2 -	Case control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g. case reports, case series
4	Expert opinion

Given the nature of the Health Service Delivery Standards, the studies mostly fell in categories 3 and 4. Therefore, the decision was made by the technical consultation team to use an alternative system scale for this group of standards. The scale is rated from 1 to 5 (1 = not very relevant and 5 = very relevant evidence as it relates to the standard). Each standard is completed by a list of references used in its development and a list of links and additional readings which can be used to facilitate the implementation and auditing process.

These standards were developed under the overall guidance of a Steering Group which has overseen the work of a Development Advisory Group, organized in three sub-groups on maternal, neonatal and health service delivery issues respectively. The development process included extensive consultations with relevant WHO departments (including Child and Adolescent Health and Development; Stop TB; Roll Back Malaria; HIV/AIDS, Nutrition

for Health and Development; Immunization, Vaccines and Biologicals; Essential Drugs and Medicines Policy; Essential Health Technologies; Health Systems Policy and Operations; and Human Resources for Health), WHO Regional Offices, professional organizations (International Confederation of Midwives and International Federation of Gynaecology and Obstetrics), the UNFPA, and experts and individuals from developing as well as developed countries.

For which audience are the Standards for Maternal and Neonatal Care intended?

The Standards for Maternal and Neonatal Care should be of interest to:

- policy-makers;
- programme managers and health planners at national, district and facility levels,
- maternal and neonatal health professionals;
- NGOs, including private sector health organizations, involved or interested in the provision of maternal and neonatal health services; and
- community organizations interested in improving maternal and neonatal health care practices.

Given the differences between countries in relation to the categories of health workers providing maternal and neonatal care, and rather than measure on a specific health care cadre, this document focuses more on the skills and services required to ensure that maternal and neonatal ill health conditions are possibly prevented and properly identified and managed. For the majority of cases and particularly in relation to routine maternal and neonatal care, the health care provider with these skills will better correspond to the skilled attendant*. However, it must be considered that a proportion of women and babies might require specialized care and consequently knowledge and skills of health care providers that are beyond those of the skilled attendant and that are not covered by this document.

How can the Standards for Maternal and Neonatal Care be utilized?

The *Standards for Maternal and Neonatal Care* are intended to be generic standards, which can be adapted and implemented according to the needs, financial and health systems capacities in different countries. They can be used individually or as a package. They are cross-referenced with each other for ease of use.

The standards can be used at the national and sub-national level to establish or to update current norms in line with the latest available evidence. Ideally, most of these standards should be in place to ensure quality maternal and neonatal health services. However, country users may wish to implement them in a stepwise manner (incrementally), for example, beginning with implementation only a few at one time, and then gradually scaling up to implement additional standards.

The standards can serve to further develop guidelines as well as design training curricula for the skilled attendants and other health care providers of maternal and neonatal care. They can also be used in the adaptation process of the *Pregnancy Childbirth Postpartum and Newborn Care practice guide,* the *Manual for Complications in Pregnancy and Childbirth,* the *Manual for Newborn Problems,* and other relevant WHO guidelines.

* The term "skilled attendant" in the document refers exclusively to people with midwifery skills (for example midwives, doctors and nurses) who have been trained to proficiency in skills necessary to manage normal births and diagnose, manage or refer obstetric and neonatal complications. Skilled attendants may practice in hospitals, clinics, health units, homes, or in any other service setting. Skilled attendants must be registered and/or legally licensed to practise. *(Making Pregnancy Safer: the critical role of the skilled attendant. A joint statement by WHO, ICM and FIGO. Geneva 2004)*

At the facility level, the *Standards for Maternal and Neonatal Care* can represent a useful tool for facilitating a systematic approach to evaluate and improve the care provided by maternal and neonatal health services. They can be the vehicle for introducing clinical audits which are the systematic review of the quality of care based on standards of care agreed upon by all the relevant health providers, or focus on a broader quality improvement process within the health facility.

It is envisaged that the process of setting standards, using standards to audit clinical practice and implementing agreed changes will contribute to improving provider's performance and clinical practice. It is intended that the *Standards for Maternal and Neonatal Care* will assist to enhance both health providers' and managers' awareness of quality of care and of their role to ensure best practices in communities with maternal and neonatal health services.

The WHO Making Pregnancy Safer Department intends to assist countries in adapting and implementing the *Standards for Maternal and Neonatal Care* as one of the key MPS strategies to influence policy decisions and improve health service provision towards the reduction of maternal and neonatal mortality and morbidity, thus contributing to the achievement of MDG4 and MDG5.

The *Standards for Maternal and Neonatal Care* will be updated as scientific evidence and experience in their use accumulates and will be modified to support the implementation of better maternal and neonatal services in countries.

Development Process

1. Introduction

In accordance with WHO's mandate and comparative advantage, the Department of Making Pregnancy Safer (MPS) has developed generic standards for maternal and neonatal care, with the purpose of providing countries and the international community with a tool for establishing evidence-based national standards of care. Where appropriate, MPS will assist countries and partners to develop and implement their own standards based on this generic tool. This work is one of the strategies to improve health service provision for women and newborn babies and complements other Integrated Management of Pregnancy and Childbirth (IMPAC) clinical and managerial tools.

2. Process

2.1 Overall process

In order to appropriately reflect the diversity of expert opinion and disciplinary perspectives, a systematic consultative process was used in the development of these standards. A *Steering Committee* and a *Standards Development Advisory Group* were established, whose composition and functions are described in Section 3. Drafts standards were developed internally by the technical staff in MPS in consultation with additional experts from the Department of Reproductive Health and Research (RHR) and experts external to WHO. These drafts were then shared with other relevant departments, including Child and Adolescent Health and Development (CAH); Stop TB; Global Malaria Programme (GMP); HIV/AIDS; Nutrition for Health and Development (NHD); Immunization, Vaccines and Biologicals (IVB); Technical Cooperation for Essential Drugs and Traditional Medicine (HTP/TCM); Essential Health Technologies; Health Policy, Development and Services (HDS); and Human Resources for Health (HRH) for ensuring technical accuracy and consistency with other WHO programmes. Starting from their early development stage the drafts were also shared with WHO Regional offices and Making Pregnancy Safer country focal points, to gather input on their applicability in different contexts. Additional inputs have been requested from external experts and institutions throughout the entire development process.

The Clinical Standards were reviewed in a technical consultation in Geneva,14-16 October 2002, where as the Health Service Delivery Standards were reviewed in a technical consultation in Geneva, 26-28 October 2004.

2.2 Methodology

In the selection of the list of topics for the standards, the following principles have been used:

- public health relevance as a major cause of maternal, fetal or neonatal mortality and/or morbidity;
- feasibility of implementation at first level facilities in settings with limited resources, both from the health service delivery and community perspective;
- cost implications, such as cost-effectiveness (where information was available).

After having agreed on the standards' framework and having defined the list of standards based on established guiding principles, the following process was applied for the development of each standard:

- Refinement of the questions to be addressed in each standard.
- Undertaking of a systematic review, critically appraise, synthesize and grade the evidence. All evidence, including that on safety, to be clearly laid out in an evidence table. Meta-analysis to be done when the data permitted.
- Development of model standard recommendations, including criteria for the implementation of the standard and suggested indicators for audit, and description of the application in different scenarios.
- Peer review held by widely circulating the standard to experts, professional organizations, regional offices and target audiences in countries.
- Dissemination plans made, including plans for contextualisation and evaluation, within an agreed standard setting framework.
- Completion of documentation of the standard development process.
- Submission to the Steering Group for reviewed approval of draft version, a well as to the Director of the Department for final approval.

2.3 Source of evidence

To develop the standards, a systematic process and methodology for gathering and summarizing the evidence was developed. The search for evidence followed a sequential process, beginning from higher level evidence (systematic review, randomized controlled trials) and included observational studies whenever randomized controlled trials or systematic reviews were not available.

The basic search strategy was developed using the National Library of Medicine medical Subject Headings (MeSH) key word nomenclature developed for each of the databases used. The initial search was performed in The Cochrane Library using the identified term both as a MeSH and as a free term. Clinical evidence was always consulted as a second step to update the Cochrane search results. When insufficient evidence was found, a further step was designed to search in MEDLINE (and then to duplicate the search in EMBASE and CINHAL). Selection was limited to human subjects. No time limits were applied. Three different specific search filters, as developed by Scottish Intercollegiate Guidelines Network (SIGN), were used to progressively identify Systematic review and Metanalysis, Randomized Controlled Trial and all other studies. The filters are more sensitive and less specific than the ones developed and used by the Cochrane Collaboration. For the purpose of our search higher sensitivity was preferred; and a second phase based on hand selection of all the studies retrieved was successively performed.

Finally, a free search was performed in Tripdatabase to identify any further important article. When the same authors or group of authors published more than one article on the same topic