

WHO
recommendations
**non-clinical
interventions
to reduce
unnecessary
caesarean
sections**



World Health
Organization

WHO recommendations
non-clinical interventions
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Acronyms and abbreviations

CERQual

Confidence in the Evidence from Reviews of Qualitative research

CI

Confidence Interval

CRT

Cluster-Randomized Trial

DECIDE

Developing and Evaluating Communication strategies to support Informed Decisions and practice based on Evidence

DOI

Declaration Of Interest

EPOC

Effective Practice and Organisation of Care group (a Cochrane Review Group)

ERG

External Review Group

FIGO

International Federation of Gynecology and Obstetrics

GDG

Guideline Development Group

GRADE

Grading of Recommendations Assessment, Development and Evaluation

GREAT

Guideline-driven, Research priorities, Evidence synthesis, Application of evidence and Transfer of knowledge

nRCT

non-Randomized Controlled Trial

OL

Opinion Leader education

PICO

Population, Intervention, Comparator, Outcome

PFMT

Pelvic Floor Muscle Training

RCT

Randomized Controlled Trial

RD

Risk Difference

RR

Risk Ratio

TWG

Technical Working Group

UNFPA

United Nations Population Fund

UNICEF

United Nations Children's Fund

USAID

United States Agency for International Development

VBAC

Vaginal Birth After Caesarean

WHO

World Health Organization

Executive summary

Introduction

Caesarean section is a surgical procedure that can effectively prevent maternal and newborn mortality when used for medically indicated reasons. Caesarean section rates have increased steadily worldwide over the last decades. This trend has not been accompanied by significant maternal or perinatal benefits. On the contrary, there is evidence that, beyond a certain threshold, increasing caesarean section rates may be associated with increased maternal and perinatal morbidity. Caesarean birth is associated with short- and long-term risks that can extend many years beyond the current delivery and affect the health of the woman, the child and future pregnancies. High rates of caesarean section are associated with substantial health-care costs.

The factors contributing to the rise in caesarean section rates are complex, and identifying interventions to address them is challenging. Factors associated with caesarean births include changes in the characteristics of the population such as increase in the prevalence of obesity and of multiple pregnancies, and increase in the proportion of nulliparous women or of older women. These changes are unlikely, however, to explain the large increases and wide variations in caesarean section rates across countries. Other non-clinical factors such as women increasingly wanting to determine how and when their child is born, generational shifts in work and family responsibilities, physician factors, increasing fear of medical litigation, as well as organizational, economic and social factors have all been implicated in this increase.

The sustained, unprecedented rise in caesarean section rates is a major public health concern. There is an urgent need for evidence-based guidance to address the trend. Clinical interventions that could help to reduce caesarean section rates have been addressed in previously published WHO guidelines. Until now, there have been no global guidelines on non-clinical interventions (defined as interventions applied independently of a clinical encounter between a health-care provider and a patient in the context of patient care). The objective of this guideline is to provide evidence-based recommendations on non-clinical interventions specifically designed to reduce caesarean

section rates. (Interventions not specifically designed to reduce caesarean section rates are not included, even if they may incidentally reduce caesarean section rates.)

Target audience

The primary audience for this guideline includes health-care professionals responsible for developing regional, national and local health protocols and policies, as well as obstetricians, midwives, nurses, general medical practitioners, managers of maternal and child health programmes and public health policy-makers in all settings and countries.

Guideline development methods

This guideline was developed in accordance with standard procedures set out in the *WHO handbook for guideline development*.

Evidence on the effectiveness of interventions was derived from an updated Cochrane review of 29 studies. Judgements about values, acceptability, equity, resource implications and feasibility of interventions were informed by three systematic reviews of 49 qualitative studies. The certainty of evidence on safety and effectiveness outcomes was assessed using Grading of Recommendations Assessment, Development and Evaluation (GRADE). Confidence in the qualitative findings was assessed using Confidence in the Evidence from Reviews of Qualitative research (CERQual). The framework for Developing and Evaluating Communication strategies to support Informed Decisions and practice based on Evidence (DECIDE) was used to integrate and present research evidence (benefits and harms of interventions) and relevant considerations (values, acceptability, equity, resource implications and feasibility) to the Guideline Development Group (GDG).

The GDG convened in September 2017 in Geneva, Switzerland, to review the summarized evidence and formulate recommendations. The members of the GDG made three types of recommendation:

1. Recommended: The benefits of implementing this option outweigh the possible harms. This option can be implemented, including at large scale.

2. Context-specific recommendation

- ◆ **Recommended only in the context of rigorous research:** This option indicates that there are important uncertainties about an intervention. In such instances, the implementation can still be undertaken at a large scale, but only as research that is able to address unanswered questions and uncertainties related both to the effectiveness of an intervention and its acceptability and feasibility.
- ◆ **Recommended only with targeted monitoring and evaluation:** This option indicates uncertainty about the effectiveness or acceptability of an intervention, especially regarding particular contexts or conditions. Interventions classified as such can be considered for implementation (including at large scale), provided they are accompanied by targeted monitoring and evaluation.

3. Not recommended: This option should not be implemented.

interventions targeted at health organizations, facilities or systems. The recommendations are intended to inform the development of national and subnational policies and protocols to reduce caesarean births. They should be implemented alongside other proven interventions to improve the quality of care for mothers and newborns during childbirth. The recommendations are summarized in Table 1.

Recommendations

This guideline targets settings with high rates of caesarean birth, where large numbers of caesarean sections are assumed to be unnecessary. The proportion of unnecessary caesarean sections was not reported in the included studies, however. It is therefore unclear whether the observed changes in caesarean section rates had been accounted for exclusively by those considered unnecessary. Given this uncertainty, caution should be exercised when interpreting the recommendations in this guideline.

The GDG made five recommendations on non-clinical interventions to reduce caesarean births. The recommendations are grouped according to the target of intervention: (a) interventions targeted at women, (b) interventions targeted at health-care professionals and (c)

Table 1: Summary list of recommendations on non-clinical interventions to reduce unnecessary caesarean sections

A. INTERVENTIONS TARGETED AT WOMEN

Recommendation 1. Health education for women is an essential component of antenatal care. The following educational interventions and support programmes are recommended to reduce caesarean births only with targeted monitoring and evaluation.

(Context-specific recommendation, Low-certainty evidence)

- ◆ **Childbirth training workshops** (content includes sessions about childbirth fear and pain, pharmacological pain-relief techniques and their effects, non-pharmacological pain-relief methods, advantages and disadvantages of caesarean sections and vaginal delivery, indications and contraindications of caesarean sections, among others).
- ◆ **Nurse-led applied relaxation training programme** (content includes group discussion of anxiety and stress-related issues in pregnancy and purpose of applied relaxation, deep breathing techniques, among other relaxation techniques).
- ◆ **Psychosocial couple-based prevention programme** (content includes emotional self-management, conflict management, problem solving, communication and mutual support strategies that foster positive joint parenting of an infant). "Couple" in this recommendation includes couples, people in a primary relationship or other close people.
- ◆ **Psychoeducation** (for women with fear of pain; comprising information about fear and anxiety, fear of childbirth, normalization of individual reactions, stages of labour, hospital routines, birth process, and pain relief [led by a therapist and midwife], among other topics).

When considering the educational interventions and support programmes, no specific format (e.g. pamphlet, videos, role play education) is recommended as more effective.

(Low- to moderate-certainty evidence)

B. INTERVENTIONS TARGETED AT HEALTH-CARE PROFESSIONALS

Recommendation 2.1. Implementation of evidence-based clinical practice guidelines combined with structured, mandatory second opinion for caesarean section indication is recommended to reduce caesarean births in settings with adequate resources and senior clinicians able to provide mandatory second opinion for caesarean section indication.

(Context-specific recommendation, High-certainty evidence)

Recommendation 2.2. Implementation of evidence-based clinical practice guidelines, caesarean section audits and timely feedback to health-care professionals are recommended to reduce caesarean births.

(Recommended, High-certainty evidence)

C. INTERVENTIONS TARGETED AT HEALTH ORGANIZATIONS, FACILITIES OR SYSTEMS

Recommendation 3.1. For the sole purpose of reducing caesarean section rates, collaborative midwifery-obstetrician model of care (i.e. a model of staffing based on care provided primarily by midwives, with 24-hour back-up from an obstetrician who provides in-house labour and delivery coverage without other competing clinical duties) is recommended only in the context of rigorous research. This model of care primarily addresses intrapartum caesarean sections.

(Context-specific recommendation, Low-certainty evidence)

Recommendation 3.2. For the sole purpose of reducing unnecessary caesarean sections, financial strategies (i.e. insurance reforms equalizing physician fees for vaginal births and caesarean sections) for health-care professionals or health-care organizations are recommended only in the context of rigorous research.

(Context-specific recommendation, Very low-certainty evidence)

1. Introduction

1.1 Background

A caesarean section is a surgical procedure that can save the lives of mothers and babies when certain complications arise during pregnancy or labour. In parallel with the significant improvements in clinical obstetric care and increased safety in the surgical procedures, the use of caesarean has risen in low-, middle- and high-income countries (1–3). This is despite a lack of evidence showing benefits of caesarean delivery for women or infants who do not require the procedure, and is in spite of some studies showing that higher rates could be linked to negative consequences in maternal and child health (4,5). These risks are higher in women with limited access to comprehensive obstetric care, and they require careful consideration in settings that lack the facilities and capacity to conduct surgery safely or to treat surgical complications.

As with any surgery, caesarean section is associated with short- and long-term risks. These can extend many years beyond the current delivery and affect the health of the woman, the child and future pregnancies. Caesarean section increases the likelihood of requiring a blood transfusion, the risks of anaesthesia complications, organ injury, infection, thromboembolic disease and neonatal respiratory distress, among other short-term complications (6,7). Caesarean section has been associated in the long term with an increased risk of asthma and obesity in children, and complications in subsequent pregnancies, such as uterine rupture, placenta accreta, placenta praevia, ectopic pregnancy, infertility, hysterectomy and intra-abdominal adhesions, with the risk of these morbidities progressively increasing as the number of previous caesarean deliveries increases (7–10).

According to the latest data from 150 countries, currently 18.6% of all births occur by caesarean section, ranging from 1.4% to 56.4% (11). Latin America and the Caribbean currently have the highest caesarean section rates (40.5%), followed by North America (32.3%), Oceania (31.1%), Europe (25%), Asia (19.2%) and Africa (7.3%). Trend analysis based on data from 121 countries shows that between 1990 and 2014, the global average caesarean section rate almost tripled (from 6.7% to

19.1%) with an average annual rate of increase (AARI) of 4.4%. The largest absolute increases occurred in Latin America and the Caribbean (by 19.4 percentage points, from 22.8% to 42.2%), followed by Asia (by 15.1 points, from 4.4% to 19.5%), Oceania (by 14.1 points, from 18.5% to 32.6%), Europe (by 13.8 points, from 11.2% to 25%), North America (by 10 points, from 22.3% to 32.3%) and Africa (by 4.5 points, from 2.9% to 7.4%). This steady and unprecedented rise in the use of caesarean section in the last decades has resulted in global concern, debate and a call for action from the scientific, public health and medical communities, particularly in view of the 2015 World Health Organization (WHO) statement on caesarean section rates (12,13).

1.2 WHO statements on caesarean section rates

For nearly 30 years, the international health-care community has considered the ideal rate for caesarean section to be between 10% and 15%. This has been based on the following statement by a panel of reproductive health experts at a meeting organized by the World Health Organization in 1985, in Fortaleza, Brazil: “[T]here is no justification for any region to have a rate higher than 10–15%” (14). The panel’s conclusion was drawn from a review of the limited data available at the time, mainly from northern European countries that demonstrated good maternal and perinatal outcomes with this rate of caesarean section.

In April 2015, WHO released a new statement summarizing the results of systematic reviews and analysis of the available data on caesarean births. In light of the evidence, the panel of experts convened by WHO concluded in the statement that, at population level, caesarean section rates higher than 10% were not associated with reductions in rates of maternal and newborn mortality (12,13). The statement notes, however, that the association between caesarean section rates and other relevant outcomes such as stillbirths, maternal and perinatal morbidity, paediatric outcomes and psychological or social well-being could not be determined due to the lack of data on these outcomes at

the population level. The scarcity of data is a limitation of this evidence that needs to be borne in mind when interpreting the WHO statement.

Although the ideal or optimal caesarean rate is unknown, WHO emphasizes that caesarean section is effective in saving maternal and infant lives, but only when it is used for medically indicated reasons. Ultimately, every effort should be made to provide caesarean sections to women in need, rather than striving to achieve a specific rate.

This is the first WHO guideline on non-clinical interventions to reduce unnecessary caesarean sections – i.e. those performed in the absence of medical indications (15,16). Non-clinical interventions in this guideline refer to those interventions applied independently of a clinical encounter between a particular provider and patient in the context of patient care (Annex 1). No guidelines on this topic have been published previously by WHO.

1.3 Why this guideline is needed

The rise in caesarean section rates is a universal problem. It affects low-, middle- and high-income countries, although the consequences of unnecessary caesarean sections may be different across settings and countries, depending on the human or financial resources available, and the capacity to perform caesarean section safely and to manage associated complications.

The causes of the increase are multiple. Changes in the characteristics of the population such as the increase in the prevalence of obesity, or the increases in the proportion of nulliparous woman, older women or in multiple births, have been cited to contribute to the rise. These factors are unlikely, however, to explain the large increases observed and the wide variations between countries (17,18). Other factors such as differences in style of professional practice, increasing fear of medical litigation, and organizational, economic, social and cultural factors have all been implicated in this trend (19–21).

Concerned with the potential medical and epigenetic consequences of this situation, clinicians, hospital administrators, policy-makers and governments are in need of evidence-based guidance to address the increasing use of caesarean section without medical indication. Unlike for clinical interventions, there are no

previous WHO guidelines on non-clinical interventions to reduce caesarean births. The objective of this guideline is to provide evidence-based recommendations on non-clinical interventions specifically designed to reduce caesarean section rates. (Interventions not specifically designed to reduce caesarean section rates are not included, even if they may incidentally reduce caesarean section rate.)

We expect this guideline to form the basis for developing national and subnational policies by WHO Member States as well as to help clinicians and other health-care professionals to reduce rates of unnecessary caesarean sections. Effective implementation of this guideline will contribute to achievement of the United Nation's Sustainable Development Goal 3 ("Ensure healthy lives and promote well-being for all at all ages") (22) by improving the quality of care during childbirth and reducing complications, disability and death associated with caesarean births, particularly in settings that lack the facilities and/or capacity to properly conduct safe surgery.

1.4 Target audience

The primary audience for this guideline includes health-care professionals responsible for developing regional, national and local health protocols and policies, as well as obstetricians, midwives, nurses, general medical practitioners, managers of maternal and child health programmes and public health policy-makers in all settings and countries.

2. Methods

2.1 WHO Steering Group

The Steering Group, comprising WHO staff members from the Departments of Reproductive Health and Research, and Maternal, Newborn, Child and Adolescent Health, oversaw the entire guideline development process. The group drafted the initial scope of the guideline (including key recommendation questions in the PICO format [population, intervention, comparator, outcome], and identified members of the Technical Working Group (TWG; comprising guideline methodologists and the systematic review team), the Guideline Development Group (GDG) and the External Review Group (ERG). The Steering Group also oversaw evidence retrieval and synthesis, preparation of evidence-to-decision tables – using Grading of Recommendations Assessment, Development and Evaluation (GRADE) (23) and Developing and Evaluating Communication strategies to support Informed Decisions and practice based on Evidence (DECIDE) (24) approaches, and organization of the GDG meeting. It drafted the recommendations and finalized the guideline document, and will manage the guideline's publication and dissemination. Members of the Steering Group are listed in Annex 2.

2.2 Guideline Development Group

The Steering Group identified 20 external experts and stakeholders from the six WHO regions to form the GDG. This was a diverse group of individuals with expertise in research, guideline development, health policy, clinical matters and reproductive health programmes. The group also included representatives of agencies that advocate for women's rights, including the right to respectful quality of care during childbirth. The members were identified in a way that ensured geographic representation and gender balance and no important conflicts of interest. A short biography of the members was published on the WHO Department of Reproductive Health and Research website for public review and comments prior to the GDG meeting held in September 2017.

Selected members of the GDG participated in the scoping meeting (April 2016), and provided input into

the scope of guideline, PICO questions and outcomes. The group also provided comments on the evidence summaries and evidence-to-decision tables, and formulated and approved the final guideline document before its submission to the WHO Guidelines Review Committee for approval. Members of the GDG are listed in Annex 2.

2.3 External Review Group

The ERG included six technical experts and other stakeholders with interests in evidence-based maternal and newborn care. The criteria for the selection of this group included geographical balance, gender representation and no conflicts of interest. The group peer reviewed the final guideline document for any errors of fact and commented on the clarity of the language, contextual issues and implications for implementation. The group also assessed whether the guideline decision-making processes considered and incorporated relevant contextual values and pv of persons affected by the recommendations (pregnant women and their families, health-care professionals and policy-makers). The ERG did not make any changes to the recommendations formulated by the GDG. Members of the ERG are listed in Annex 2.

2.4 Technical Working Group

The TWG comprised guideline methodologists and systematic review teams. Two health system researchers (both also editors of the Cochrane Effective Practice and Organisation of Care [EPOC] group) served as guideline methodologists.

Evidence on the effectiveness of non-clinical interventions to reduce unnecessary caesarean section was derived from a Cochrane review maintained by the Cochrane EPOC Group (25). The guideline methodologists collaborated with the review authors and WHO Steering Group to update the review and prepare GRADE evidence tables. The guideline methodologists also reviewed and synthesized case studies to identify contextual factors

likely to affect adoption and scale-up of the caesarean interventions examined.

Evidence on barriers and facilitators to the use of non-clinical interventions to reduce unnecessary caesarean section was derived from three systematic reviews of qualitative studies (26–28). The preparation of these reviews, including GRADE and the assessment of Confidence in the Evidence from Reviews of Qualitative Research (CERQual) (29) was commissioned from researchers from the University of Central Lancashire, United Kingdom.

The WHO Steering Group worked closely with the TWG to prepare DECIDE evidence-to-decision tables (see section 2.11) for the GDG meeting. The DECIDE framework is a tool that has been developed to help decision-makers to consider a range of relevant factors during guideline development (including benefits and harms of interventions, values and preferences, resource implications, equity, acceptability and feasibility). Members of TWG are listed in Annex 2.

2.5 External partners and observers

Representatives of the International Federation of Gynecology and Obstetrics (FIGO), International Confederation of Midwives (ICM), United Nations Population Fund (UNFPA) and United States Agency for International Development (USAID) were invited to the final guideline development meeting to serve as observers (see Annex 2). All these organizations are potential implementers of this guideline with a history of collaboration in guideline dissemination and implementation with the WHO Departments of Reproductive Health and Research, and Maternal, Newborn, Child and Adolescent Health.

2.6 Identifying priority questions and outcomes

The WHO Steering Group commissioned a scoping review of interventions to reduce caesarean rates in 2015. This review aimed to (i) map key concepts in the research area, (ii) map the range of available evidence (regardless of quality) to inform guideline development

as a preliminary exercise prior to the targeted systematic review, and (iii) define the scope of the targeted systematic review (i.e. eligible participants, interventions, comparators and outcomes).

The scoping literature search, conducted in six electronic databases (Cochrane Library, PubMed, Embase, LILACS, CINAHL, EBSCO), identified 11 relevant systematic reviews published between 2001 and January 2016. These included five Cochrane (30–34) and six non-Cochrane reviews (35–40), which reported the findings of 99 unique studies conducted in 32 different, mostly high-income countries. The 99 studies examined 151 components of interventions intended to reduce caesarean rates, many of which were repeated in more than one study. There were 21 distinct components, which were grouped into four main domains (education, management of labour, regulatory/administrative and others) (Web annex 1).

Based on these initial steps, the Steering Group convened a scoping meeting in Geneva, Switzerland, in April 2016 to identify priority questions and define the scope of the guideline in terms of key “background” and “foreground” questions and outcomes. Background questions relate to information that helped to put the recommendations into context. Foreground questions relate to questions that helped to guide the review of the evidence that informed the recommendations. The scoping team prioritized the following with respect to these questions.

Background questions

- ◆ What is the prevalence of the use of caesarean as a mode of delivery worldwide and what are the trends in the last decades?
- ◆ What is the standard definition for unnecessary caesarean?
- ◆ What is the relative contribution of healthy women (term, singleton, cephalic pregnancies with or without a previous caesarean) to the overall caesarean rate?
- ◆ What are the potential complications and burden of unnecessary caesarean?

Foreground questions and priority outcomes

The population of interest comprised:

- ◆ women seeking antenatal, labour and delivery care in health-care facilities (term, singleton, cephalic pregnancies with or without a previous caesarean);
- ◆ families of pregnant women;
- ◆ health-care professionals who work with expectant mothers (midwives, nurses and physicians);
- ◆ health-care facilities that provide maternity care to pregnant women; and
- ◆ communities and advocacy groups involved in maternity care.

The scoping and consultation process led to the identification of 12 key questions and priority outcomes (Annex 1).

2.7 Related guidelines

WHO statements related to current guideline

In April 2015, WHO released a statement on caesarean section rates indicating that, at population level, caesarean rates higher than 10% were not associated with any reductions in the rates of maternal and newborn mortality (12,13). The statement advises against the use of this threshold at the hospital level since by definition it is intended only for populations, normally defined by geopolitical boundaries. As the caesarean rates in health-care facilities vary widely according to the characteristics of the women served (obstetric case mix), it would be inappropriate to propose a unique threshold at this level.

Because the effects of caesarean on important outcomes (such as maternal, perinatal and neonatal morbidity, and psychological or social well-being) are still not well defined, the statement does not attempt to recommend any ideal or optimal caesarean rates at the population level.

Related recommendations from published WHO guidelines

All relevant guidelines approved by the WHO Guidelines Review Committee (41) were searched to identify recommendations relevant to the reduction of caesarean births. Five guidelines published between 2012 and 2018 were identified (42–46). These guidelines and recommendations are listed in Annex 3.

Relevant guidelines produced by external organizations

In spite of the increasing rates of caesarean and their potential non-medical nature, there are currently no formal guidelines on non-clinical interventions applicable to a global audience. Available statements from external organizations have placed more emphasis on clinical interventions. In 2011, the United Kingdom's National Institute for Health and Care Excellence (NICE) recommended the following interventions to reduce caesareans (47):

- ◆ involvement of consultant obstetricians in the decision-making process for caesarean;
- ◆ external cephalic version for breech presentation at 36 weeks (exceptions include women in labour, women with a uterine scar or abnormality, fetal compromise, ruptured membranes, vaginal bleeding and medical conditions);
- ◆ continuous labour support from women with or without prior training in childbirth;
- ◆ induction of labour beyond 41 weeks of gestation;
- ◆ fetal blood sampling before caesarean for abnormal cardiotocograph in labour if it is technically possible and there are no contraindications; and
- ◆ use of a partogram with a four-hour action line for women in spontaneous labour with an uncomplicated singleton pregnancy at term.

NICE's update in 2013 added that auditing using the Robson classification may result in reduced caesarean rates (48).

interventions are presented in Annex 1. The preparatory work for the guideline was organized according to three work streams shown in Box 1.

2.8 Focus and approach

The focus of this guideline is non-clinical interventions for reducing unnecessary caesareans. Details of these

BOX 1. WORK STREAMS FOR PREPARATION OF THE GUIDELINE

WORK STREAM	DECIDE DOMAIN	DATA SOURCE	CERTAINTY OF EVIDENCE
Update of Cochrane review on effectiveness and safety of non-clinical interventions to reduce unnecessary caesarean	<ul style="list-style-type: none"> • Benefits and harms • Resource requirements • Cost-effectiveness 	<ul style="list-style-type: none"> • Randomized controlled trials • Non-randomized controlled trials • Controlled before-and-after studies • Interrupted time series studies • Cohort studies 	GRADE
Qualitative synthesis of barriers and facilitators to the use of non-clinical interventions to reduce unnecessary caesareans, targeted at: <ul style="list-style-type: none"> • women, communities or the public • health-care professionals • health organizations, facilities or systems 	<ul style="list-style-type: none"> • Values and preferences • Acceptability • Resource implications • Equity • Feasibility 	Qualitative studies	GRADE-CERQual
Synthesis of implementation considerations for non-clinical interventions to reduce unnecessary caesareans: <ul style="list-style-type: none"> • contextual and health system factors likely to affect adoption and scale up of proven interventions to reduce unnecessary caesareans 	<ul style="list-style-type: none"> • Values and preferences • Acceptability • Resource requirements • Feasibility 	<ul style="list-style-type: none"> • Large-scale programme evaluations of interventions • Pre-post studies of health-system changes relevant to interventions • Country case studies of relevant interventions • Overviews of reviews of health system implementation, care delivery arrangements and financial strategies 	Not assessed

2.9 Evidence identification and retrieval

Three main types of evidence were considered.

a. Evidence on effectiveness and safety of non-clinical interventions to reduce unnecessary caesareans

Evidence on this aspect was derived from an update of a Cochrane review of randomized controlled trials (RCTs), non-randomized controlled trials (nRCTs), controlled before-and-after studies and interrupted time series studies (25). Relevant cohort studies were also considered for prioritized interventions that were not addressed by standard EPOC study designs. The search strategies used to identify relevant studies, and the study inclusion and exclusion criteria are described in the review.

b. Evidence on barriers and facilitators to the use of non-clinical interventions to reduce unnecessary caesareans

Evidence on this aspect was derived from three systematic reviews of qualitative studies.

Qualitative synthesis of non-clinical interventions to reduce unnecessary caesareans, targeted at women, communities or the public, exploring (26):

- ◆ women's, communities' and the public's views and experiences with non-clinical interventions to reduce unnecessary caesareans;
- ◆ factors (values and beliefs, expectations, and quality of human relationships) that determine the success or failure of specific non-clinical interventions to reduce unnecessary caesareans; and
- ◆ how targeted interventions to reduce unnecessary caesareans influence women's preferences, their decision-making processes and their assessments of actual birth methods.

Qualitative synthesis of non-clinical interventions to reduce unnecessary caesareans, targeted at health-care professionals, exploring (27):

- ◆ health-care professionals' views, perceptions and uses of educational interventions aimed at improving adherence to evidence-based clinical practices to reduce caesareans;
- ◆ health-care professionals' views of the perceived benefits, barriers, facilitators and disadvantages of a policy of second opinion for caesareans to reduce their rates; and
- ◆ health-care professionals' views as to how audit, feedback and peer-review can reduce caesarean rates.

Qualitative synthesis of non-clinical interventions to reduce unnecessary caesareans, targeted at organizations, facilities or systems exploring implementation-related factors, including barriers and facilitators, feasibility and meaningfulness (28). Specifically:

- ◆ stakeholders' views of different types of nurse/midwife and physician staffing interventions to reduce unnecessary caesareans;
- ◆ stakeholders' views and experiences of interventions to change the physical environment of labour to reduce unnecessary caesareans;
- ◆ stakeholders' views of interventions in which predetermined caesarean rates are set at physician, hospital or regional level;
- ◆ stakeholders' views about the barriers, facilitators and ethical considerations of financial strategies to reduce unnecessary caesareans;
- ◆ views and experiences of stakeholders on the use of legal liability interventions for reducing unnecessary caesareans; and
- ◆ stakeholders' views of the most important factors in organizational cultures that are committed to reducing unnecessary caesareans.

The reviews included studies that used qualitative designs (e.g. ethnography, phenomenology) or mixed-method designs for data collection (e.g. focus group interviews, individual interviews) and analysis (e.g. thematic analysis, grounded theory).

Targeted search strategies were developed for each review, drawing on guidelines developed by the Cochrane Qualitative and Implementation Methods Group for searching qualitative evidence (49,50) and related literature on strategies for optimizing identification of qualitative studies in MEDLINE (51), Embase (52), CINAHL (53) and PsycINFO (54).

Details of the search strategies and study inclusion and exclusion criteria are described in the individual reviews (26–28).

c. Evidence on implementation considerations for non-clinical interventions to reduce unnecessary caesareans

Implementation factors included context-specific factors (barriers and enablers) that may have an impact on the adoption and scale-up of non-clinical interventions to reduce unnecessary caesareans (e.g. resource needs and practicality of implementation within existing practice setting or routines).

Evidence on these factors was derived from large-scale programme evaluations and country case studies of interventions to reduce unnecessary caesareans (55–57). Even if these studies provide no proof of effectiveness because they have not yet been rigorously tested according to current internationally accepted methodological standards, we deemed it important to broaden the scope to gain a comprehensive understanding of factors likely to influence adoption and scale-up of included interventions. Additional data on implementation factors were sourced from Cochrane EPOC overviews of systematic reviews of health system implementation, care delivery arrangements and financial strategies (58–60).

Multiple searches were conducted to identify relevant evidence:

- ◆ PubMed (using search strategies combining relevant MeSH (Medical Subject Headings) and free-text terms);

- ◆ PDQ-Evidence;
- ◆ Citation pearls (e.g. using the “related citation” feature in PubMed); and
- ◆ Professional organization and health agency websites: Agency for Healthcare Research and Quality (AHRQ), American College of Obstetricians and Gynecologists (ACOG), Institute for Clinical Systems Improvement (ICSI), International Federation of Gynecology and Obstetrics (FIGO), National Institute for Health and Care Excellence (NICE), Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), Royal College of Obstetricians and Gynaecologists (RCOG) and Society for Maternal–Fetal Medicine (SMFM).

2.10 Quality assessment and synthesis of the evidence

Evidence on the effectiveness and safety of non-clinical interventions to reduce unnecessary caesareans

The assessment of risk of bias in the studies included in the Cochrane review (RCTs, nRCTs, controlled before-and-after studies and interrupted time series studies) was performed using the Cochrane EPOC criteria (61). For RCTs, nRCTs and controlled before-and-after studies, the key domains assessed included: random sequence generation, allocation concealment, similarity of baseline characteristics and outcome measures, blinding of study personnel and participants, completeness of outcome data, freedom from reporting bias and other sources of bias (such as contamination). The risk-of-bias domains assessed in interrupted time series studies are outlined in the EPOC tool (61).

The risk of bias for cohort studies was assessed using the “Risk Of Bias In Non-randomized Studies – of Interventions” (ROBINS-I) tool (62). Key domains assessed in ROBINS-I include risk of bias due to: confounding, selection of participants, classification of interventions, deviations from intended interventions, missing data, measurement of outcomes and selection of the reported results.

The certainty of the evidence (also known as the quality of the evidence or confidence in the estimate of effect) for each outcome was assessed using GRADE (23). According to GRADE, high-quality evidence starts with RCTs while low-quality evidence comes from observational studies. The certainty of the evidence from RCTs can be downgraded in consideration of five factors: risk of bias, study limitations, directness and consistency of results, precision of effect estimates and publication bias. The certainty of the evidence from observational studies can be upgraded in consideration of three factors: magnitude of effect, dose-response gradient and influence of residual plausible confounding. Based on the highlighted factors, the certainty of the evidence for each outcome is rated as high, moderate, low or very low. GRADE assessments were undertaken by the guideline methodologist in collaboration with the review authors. Details of the GRADE assessments are presented in Web annex 3.

Results of individual studies were described narratively (differences in study designs and interventions precluded meta-analysis). The effects of the interventions and the certainty of the evidence are presented in Web annex 3.

Evidence on barriers and facilitators to the use of non-clinical interventions to reduce unnecessary caesareans

The quality of studies included in the reviews of qualitative studies was assessed using a validated set of criteria developed by Walsh and others (63,64). This includes an assessment of the study scope and purpose, design, sampling strategy, analysis, interpretation, researcher reflexivity, ethical dimensions, relevance and transferability. Studies are allocated a grade from A to D as follows.

- ◆ **Grade A:** no or few flaws. The study credibility, transferability, dependability and confirmability is high.
- ◆ **Grade B:** some flaws, unlikely to affect the credibility, transferability, dependability and/or confirmability of the study.
- ◆ **Grade C:** some flaws that may affect the credibility, transferability, dependability and/or confirmability of the study.

- ◆ **Grade D:** significant flaws that are very likely to affect the credibility, transferability, dependability and/or confirmability of the study.

The GRADE-CERQual tool (29) was used to assess confidence in the findings of reviews of qualitative studies. The tool considers the following four components.

- ◆ **Methodological limitations of included studies:** the extent to which there are problems in the design or conduct of the primary studies that contributed evidence to a review finding.
- ◆ **Relevance of the included studies to the review question:** the extent to which the body of evidence from the primary studies supporting a review finding is applicable to the context (perspective or population, phenomenon of interest, setting) specified in the review question.
- ◆ **Coherence of the review finding:** the extent to which the review finding is well grounded in data from the contributing primary studies and provides a convincing explanation for the patterns found in these data.
- ◆ **Adequacy of the data contributing to a review finding:** an overall determination of the degree of richness and quantity of data supporting a review finding.

GRADE-CERQual assessments were undertaken independently by two researchers from the University of Central Lancashire, United Kingdom.

Data synthesis was undertaken by drawing on the principles of meta-ethnography (65). Meta-ethnography is based on the constant comparative technique, in which the analysis is built up study by study using the principles of confirmation (“reciprocal analysis”) and disconfirmation (“refutational analysis”).

2.11 Formulation of the recommendations

The DECIDE framework was used to guide the formulation of recommendations (24). DECIDE is an evidence-to-decision tool that allows explicit and systematic consideration of evidence on interventions in terms of six domains: effects, values, resources, equity, acceptability and feasibility. For each priority question, judgements are made on the impact of the intervention against each of these domains, to inform guideline recommendations.

- ◆ **Effects of interventions:** Where benefits clearly outweigh harms for outcomes that are highly valued by decision-makers (pregnant women and their families, health-care professionals), there is a greater likelihood of a clear judgement in favour of the intervention – and vice versa, clearly against the intervention where harms clearly outweigh benefits for valued outcomes. Uncertainty about the net benefits or harms and small net benefits will most likely lead to a judgement that neither favours the intervention nor the comparator. The higher the certainty of the evidence on benefits across outcomes, the higher the likelihood of a judgement in favour of the intervention. In the absence of evidence of benefits, evidence of potential harm will lead to a recommendation against the option. Where evidence of potential harm is found for interventions that are also found to have evidence of important benefits, depending on the level of certainty and likely impact of the harm, such evidence of potential harm is more likely to result in a context-specific recommendation for the intervention (where the context is explicitly stated within the recommendation).
- ◆ **Values and preferences:** The relative importance assigned to the prioritized outcomes of the intervention by those affected by them, and how such importance varies within and across settings. The more the uncertainty or variability in these values and preferences, the more the likelihood of a conditional recommendation, while less uncertainty or variability in these values and preferences warrants a strong recommendation. For this guideline, the values and preferences of persons directly affected by the recommendations (women at risk of delivering by caesarean without a medical indication and their families, and health-care professionals) were considered in determining the strength of the recommendations. Evidence from a systematic review of studies on women's views, beliefs and experiences with the caesarean interventions examined informed this judgement.
- ◆ **Resource implications:** Evaluation of the cost of options available to service users and health systems in different settings, as well as the cost-effectiveness of the intervention being considered. A strong recommendation in favour or against the intervention is likely where the resource implications are clearly advantageous or disadvantageous, whereas a conditional recommendation may be justified if the resource implications are uncertain. The most relevant resources in the context of this guideline include costs of implementing the interventions (e.g. educational materials, meetings, in-service training, mass media communication). Evidence on resource use and costs was derived from the Cochrane review update, qualitative reviews and overviews of reviews.
- ◆ **Acceptability:** Whether an intervention is acceptable both to women and health-care providers. Qualitative evidence from the systematic reviews on women's and providers' views and experiences informed judgements for this domain. The lower the acceptability, the lower the likelihood of a judgement in favour of the intervention.
- ◆ **Feasibility:** This is influenced by factors such as the resources available, infrastructure and training. Where barriers exist, it is less likely that a judgement will be made in favour of the intervention. Judgements about the feasibility of targeted interventions

were informed by evidence identified from systematic reviews and by the experiences and opinions of the GDG members.

- ◆ **Equity:** Consideration of whether an intervention will reduce health inequities (i.e. differences in effectiveness for disadvantaged populations within countries, such as low-income groups, less educated, rural populations). An intervention is likely to be recommended if it will reduce health inequities among different groups of women and their families. This domain was informed by findings from systematic reviews as well as by the opinions and experiences of the GDG members.

Using the DECIDE framework, the guideline methodologists in collaboration with the Steering Group prepared evidence-to-decision tables for each priority question, covering evidence on each of these six domains. The evidence-to-decision tables, evidence summaries and GRADE evidence tables were sent in batches to the GDG members two to four weeks prior to the face-to-face consultative meeting. The GDG members were asked to review and comment on these materials before the GDG meeting.

At the face-to-face meeting (held in September 2017 at the WHO headquarters in Geneva, Switzerland), GDG members collectively reviewed the evidence-to-decision tables and the draft recommendations, and reached consensus on each recommendation, based on explicit consideration of domains within the evidence-to-decision tables. The GDG also identified important considerations for guideline implementation, monitoring and evaluation, and research gaps.

The GDG made three types of recommendation (Box 2):

- ◆ Recommended
- ◆ Context-specific recommendations
 - only in the context of rigorous research
 - only with targeted monitoring and evaluation
 - only in other specific contexts
- ◆ Not recommended.

BOX 2. TYPES OF RECOMMENDATIONS

RECOMMENDATION	EXPLANATION
Recommended	<p>The benefits of implementing this option outweigh the possible harms. This option can be implemented, including at large scale.</p>
Context-specific recommendation	<p>The benefits of implementing this option outweigh the possible harms in specific circumstances. The specific circumstances are outlined for each recommendation. This option can be implemented under one of these specific circumstances.</p> <p>Only in the context of rigorous research.</p> <ul style="list-style-type: none"> • Such interventions should be implemented only in the context of rigorous research. Implementation may still be large-scale, providing it takes the form of research that is able to address unanswered questions. • Unanswered questions may relate both to the effectiveness of an intervention and its acceptability and feasibility. To assess an intervention’s <i>effectiveness</i>, research should at least compare what happens to people who are exposed to one option with those who are not, and should include a baseline assessment. These groups should be as similar to one another as possible to ensure that the effect of the intervention is assessed rather than the effect of other factors. Randomized controlled trials are the most effective way to do this but if these are not possible, interrupted time series analyses or controlled before-and-after studies should be considered. • Where the unanswered question or uncertainty is linked to the <i>acceptability</i> or <i>feasibility</i> of the intervention, research should include well conducted studies using qualitative methods for data collection and for data analysis (as well as quantitative designs such as surveys). These methods are likely to lead to valuable information regarding the perceptions of those who were interviewed or surveyed, but policy-makers should be aware that such studies are unable to generate the kind of data that can be used to estimate the <i>effectiveness</i> of an option. <p>Only with targeted monitoring and evaluation.</p> <ul style="list-style-type: none"> • Such interventions can be considered for implementation, including at large scale, but should be accompanied by targeted monitoring and evaluation. Such monitoring and evaluation should focus on specific issues where there are concerns and when little or no information is available, for example, about specific risks or harms. • Information about monitoring and evaluation may be obtained from a range of sources, including routine data (e.g. on health-care utilization or service costs) and survey data (e.g. health and demographics).
Not recommended	<p>This option should not be implemented.</p>

2.12 Decision-making during the GDG meeting

The GDG meeting was held in September 2017 at the WHO headquarters in Geneva, Switzerland. The GDG members discussed the evidence summarized in the evidence-to-decision tables for each guideline question and then considered the relevant draft recommendation. After discussing each question, the draft recommendation and justification were revised as needed. The final adoption of recommendations was made by consensus (i.e. full agreement of all GDG members).

The GDG group elected not to make recommendations on the following four interventions because they were not specifically designed to reduce unnecessary caesareans in the identified studies (i.e. the interventions were not tailored to specific determinants of caesarean practices and were not tested in specific populations with high baseline rates of caesarean):

- ◆ midwife-led continuity model of care (66)
- ◆ continuous one-to-one intrapartum support (67)
- ◆ simulation-based obstetrics and neonatal emergency training (68)
- ◆ physical activity-based interventions (69)

2.13 Declarations of interests by external contributors

Standard procedures recommended in the *WHO handbook for guideline development* (70) were applied to identify, manage and report potential conflicts of interest of contributors to the guideline.

All GDG, TWG and External Review Group members were asked to declare, in writing at the time of the invitation to participate in the guideline development, any competing interests (whether academic, financial or other). The standard WHO form for declaration of interest (DOI) was completed and signed by each expert and sent electronically to the responsible technical officer. The WHO Steering Group reviewed all the DOI forms before finalizing experts' invitations to participate. All experts

were instructed to notify the responsible technical officer of any change in relevant interests during guideline development, in order to update and review conflicts of interest accordingly. In addition, experts were requested to submit an electronic copy of their curriculum vitae along with the completed DOI form. The WHO Steering Group reviewed signed DOI forms and curricula vitae, and determined whether conflicts of interest existed. Where any conflict of interest was declared, the Steering Group determined whether it was serious enough to affect the individual's ability to make objective judgements about the evidence or recommendations. To ensure consistency, the Steering Group applied the criteria for assessing the severity of a conflict of interest in the *WHO handbook for guideline development* (70).

All findings from the received DOI statements were managed in accordance with the WHO DOI guidelines on a case-by-case basis. Where a conflict of interest was not considered significant enough to pose any risk to the guideline development process or reduce its credibility, the expert was required only to declare such a conflict at the GDG meeting and no further action was taken. No participation in the guideline development process was allowed if a conflict of interest was deemed serious enough to bias or reduce the credibility of the recommendations. At the GDG face-to-face meeting, members were required again to state any conflicts of interest openly to the entire group. A summary of the DOI statements and information on how conflicts of interest were managed are presented in Annex 4.

2.14 Document preparation and peer review

Following the final GDG meeting, the guideline methodologists and the responsible WHO technical officer prepared a draft of the full guideline document. Members of the Steering Group provided comments on the draft guideline document before it was sent to the GDG members for further comments. The document was revised based on the feedback received from the GDG and then sent to the External Review Group for peer review. The External Review Group members were asked to review the final draft guideline to identify errors of fact, comment on clarity of language, and consider issues of implementation, adaptation and context. The Steering Group evaluated the input of the peer reviewers

for inclusion in the guideline document and made further revisions to the guideline draft as needed. After the GDG meetings and external peer review, further modifications to the guideline by the Steering Group were limited to corrections of factual error and improvements in language to address any lack of clarity. The revised final version was returned to the GDG for its final approval.

2.15 Presentation of guideline content

A summary of the recommendations is presented in Table 1 within the executive summary of this guideline. For each recommendation, a narrative description of the evidence on effects, values, acceptability, feasibility, resource requirements, equity and other considerations reviewed during the GDG meeting is presented in section 3: Evidence and recommendations. Implementation of the guideline recommendations (including applicability issues) is discussed in section 4. The remaining sections are 5: Research implications, 6: Dissemination, and 7: Updating the guideline. The guideline was evaluated using the AGREE-II appraisal instrument to ensure it met international quality standards and reporting criteria (71).

3. Evidence and recommendations

With an overall aim of reducing caesarean births, this guideline targets settings with high rates, where large numbers of caesarean sections are assumed to be unnecessary. However, the proportion of births by unnecessary caesarean sections was not reported in the included studies. It was unclear, for example, whether caesarean section rates reported following educational interventions were due to unnecessary caesarean sections (or whether caesarean section would have been appropriate for women who had vaginal births). Given this uncertainty, caution should be exercised when interpreting the recommendations in this guideline.

The GDG made five recommendations on non-clinical interventions to reduce unnecessary caesarean sections. They should be implemented alongside other proven interventions to improve the quality of care for mothers and newborns during childbirth (42–46).

The recommendations are grouped according to the target of intervention:

- a.** interventions targeted at women
- b.** interventions targeted at health-care professionals
- c.** interventions targeted at health organizations, facilities or systems.

Evidence on the effectiveness of interventions was derived from an updated Cochrane review of 29 studies – 19 randomized controlled trials, 1 controlled before-and-after study and 9 interrupted time series studies (25). Most of the studies (20 studies) were conducted in high-income countries. None of the studies was done in a low-income country. The studies were conducted in 16 different countries:

- ◆ North America (seven studies in the United States and two studies in Canada)
- ◆ Europe (three studies in Finland and one study each in Portugal, Sweden and the United Kingdom)

- ◆ Latin America (one study in Chile and one multicentre study each in Argentina, Brazil, Cuba, Guatemala and Mexico)
- ◆ Western Asia (six studies in the Islamic Republic of Iran)
- ◆ East Asia (two studies in China and two studies in Taiwan [China])
- ◆ Oceania (two studies in Australia).

Caesarean section rates in the control groups (or prior to intervention in interrupted time series studies) ranged from 6.3% (72) to 73.3% (73). Descriptions of the interventions, their effect estimates and certainty ratings (Grading of Recommendations Assessment, Development and Evaluation; GRADE) are summarized in Web annexes 2 and 3.

Evidence from three systematic reviews of qualitative studies (26–28) informed judgements about values, resource implications, equity, acceptability and feasibility. Overall, 49 studies (reported in 52 papers) were included in the three reviews.

- ◆ Twelve studies were included in the review of women's, communities' and the public's views and experiences with non-clinical interventions to reduce unnecessary caesareans (26). The studies were conducted in seven different countries (Australia, Brazil, Canada, Norway, Taiwan [China], the United Kingdom and the United States). Eleven studies were from high-income countries and one was from a middle-income country.
- ◆ Seventeen studies were included in the review of health-care professionals' views and experiences with non-clinical interventions to reduce unnecessary caesareans (27). The studies were conducted in 17 different

countries (Australia, Canada, China, Ethiopia, Finland, Germany, Ireland, the Islamic Republic of Iran, Italy, Kenya, the Netherlands, Nicaragua, Sweden, Uganda, the United Kingdom, the United Republic of Tanzania and the United States). Nine studies were from high-income countries, six from middle-income countries and two from low-income countries.

- ◆ Twenty-five studies (28 papers) were included in the review of non-clinical interventions to reduce unnecessary caesareans, targeted at organizations, facilities or health systems (28). The studies were conducted in 17 different countries (Bangladesh, Benin, Burkina Faso, Canada, Chile, China, Ghana, the Islamic Republic of Iran, Japan, Lebanon, Mali, Mexico, Morocco, Nicaragua, Senegal, the United Kingdom and the United States). Nine studies were from high-income countries, 11 from middle-income countries and five from low-income countries.

Details of the findings and the CERQual assessment are presented in Web annex 4.

The GDG did not make recommendations for seven pre-specified guideline questions, for which no eligible studies were identified. (These questions have been proposed for further research; further details are presented in Box 3.)

A. INTERVENTIONS TARGETED AT WOMEN

3.1. Non-clinical educational interventions

RECOMMENDATION 1

Health education for women is an essential component of antenatal care. The following educational interventions and support programmes are recommended to reduce caesarean births only with targeted monitoring and evaluation.

(Context-specific recommendation, Low-certainty evidence)

- ◆ childbirth training workshops
- ◆ nurse-led applied relaxation training programme
- ◆ psychosocial couple-based prevention programme
- ◆ psychoeducation for women with fear of childbirth

REMARKS

Educational interventions and support programmes referred to in the included studies comprise the following, all delivered during the antenatal period.

- ◆ **Childbirth training workshops.**
 - Training comprised three four-hour weekly sessions in groups of 30 members.
 - Content included childbirth fear and pain, pharmacological pain-relief techniques and their effects, non-pharmacological pain-relief methods, advantages and disadvantages of caesarean and vaginal delivery, and indications and contraindications of caesareans, among other topics.
- ◆ **Nurse-led applied relaxation training programme.**
 - Programme comprised seven 90-minute group education sessions over seven weeks led by a nurse, under the supervision of a clinical psychologist.
 - Content included group discussion of anxiety and stress-related issues in pregnancy and the purpose of applied relaxation and deep breathing techniques, among other relaxation techniques.
- ◆ **Psychosocial couple-based prevention programme.**
 - The psychosocial programme consisted of nine classes, with four weekly classes conducted during the second or third trimester of pregnancy and four weekly classes conducted within the first six months postpartum.
 - Classes focused on emotional self-management, conflict management, problem solving, communication and mutual support strategies that foster positive joint parenting of an infant.
 - “Couple” in this recommendation includes couples, people in a primary relationship or other close people.
- ◆ **Psychoeducation for women with fear of childbirth.**
 - The psychoeducative group therapy was led by four different psychologists with special group therapeutic skills in pregnancy-related issues. Six group sessions were held during pregnancy and one was held with the newborns six to eight weeks after delivery.
 - Each two-hour session consisted of a focused topic and a 30-minute guided relaxation exercise using an audio recording developed for this purpose. This relaxation exercise guided the participants through stages of imaginary delivery in a relaxed state of mind with positive, calming and supportive suggestions.
 - The topics covered included information about fear and anxiety, fear of childbirth, normalization of individual reactions, stages of labour, hospital routines, the birth process, and pain relief (led by a therapist and midwife), among others.
- ◆ When considering the educational interventions and support programmes targeted at women to reduce caesarean births, no specific format (e.g. pamphlet, videos, role play education) is recommended as more effective. (Low- to Moderate-certainty evidence)
- ◆ Further information on the educational interventions and support programmes is presented in Web annex 2.

The following are according to the systematic review of qualitative studies (26).

- ◆ Women think that learning new information about birth can be empowering. Women want educational tools (childbirth training workshops, booklets, decision-aids) and welcome multiple formats (although information on paper is ultimately needed for reflection with family, friends and health-care professionals).
- ◆ The content of educational materials should not provoke anxiety and needs to be consistent with advice from health-care professionals and provide the basis for more informed dialogue with them.
- ◆ Women want emotional support alongside the communication of facts and figures about birth.

Summary of evidence and considerations

Description of included studies

Evidence on non-clinical educational interventions targeted at women was derived from 15 RCTs (72–86) included in the Cochrane review update: 12 trials compared specific educational interventions with usual practice and three trials compared different formats of educational interventions. Most studies were done in high-income countries (Australia, Canada, Finland, Sweden, the United Kingdom and the United States; 9 studies). Six studies were done in middle-income countries (China, the Islamic Republic of Iran). There were no studies from low-income countries.

Eight studies included only nulliparous women (72,73,75,77–80, 84). Four studies included only women with a previous caesarean (81,82,85,86). The remaining three studies included a mixed population of women (74,76,83).

Four of the educational interventions were studied in groups of women with fear of childbirth – psychoeducation (78), intensive group therapy (cognitive behavioural therapy and childbirth psychotherapy) (83), psychoeducation by telephone (76), and role play education versus standard education using lectures (84). The nurse-led applied relaxation training programme (80) was studied in women with high levels of anxiety. The remaining interventions were studied in women (or couples) with no specific health condition.

A narrative synthesis of the effect of the interventions was undertaken (the heterogeneity in the examined educational interventions precluded meta-analysis).

The following educational interventions were assessed.

Education, birth preparation classes and support programmes

Nulliparous women

- ◆ Antenatal education on natural childbirth preparation with training in breathing and relaxation techniques (72).

- ◆ Childbirth training workshop (73).
- ◆ Psychosocial couple-based prevention programme (75).
- ◆ Pelvic floor muscle training (PFMT) exercises with telephone follow-up (77).
- ◆ Psychoeducation for women with fear of childbirth (78).
- ◆ Prenatal education for partners of pregnant women (79).
- ◆ Nurse-led applied relaxation training programme (80).

Mixed population of women (nulliparous and multiparous women with or without previous caesarean sections)

- ◆ Antenatal education programme for physiological childbirth (birth preparation training) (74).
- ◆ Psychoeducation by telephone for women with fear of childbirth (76).
- ◆ Intensive group therapy (cognitive behavioural therapy and childbirth psychotherapy) for women with fear of childbirth (83).

Women with a previous caesarean section

- ◆ Computer-based decision aids (information programme, decision analysis) (81).
- ◆ Decision-aid booklet (82).

Women in the control group received routine maternity care in accordance with local protocols. PFMT with telephone follow-up was compared with PFMT without telephone follow-up.

Different formats of educational interventions

Nulliparous women

- ◆ Role-play education (versus standard

education using lectures) for women with fear of childbirth (84).

- ◆ Psychoeducation for women with fear of childbirth (RR 1.33, 95% CI 1.11 to 1.61; 371 women, *Low-certainty evidence*) (78).

Women with a previous caesarean section

- ◆ Interactive decision aid (versus educational brochures) (85).
- ◆ Individualized prenatal education and support programme (versus written information in a pamphlet) (86).

There were no differences in caesarean section rates between routine maternity care and the following interventions.

- ◆ PFMT with telephone follow-up (versus PFMT without telephone follow-up) (RR 0.87, 95% CI 0.37 to 2.04; 90 women, *Low-certainty evidence*) (77).

Descriptions of the interventions are summarized in Web annex 2, Table 1.

- ◆ Psychoeducation for women with fear of childbirth (RR 0.70, 95% CI 0.49 to 1.01; 371 women, *Low-certainty evidence*) (78).

Effects of the interventions (Web annex 3, Table 1)

Education, birth preparation classes and support programmes

Nulliparous women

Three interventions were found to reduce caesarean section rates.

- ◆ Childbirth training workshop (mothers alone versus control: risk ratio [RR] 0.55, 95% confidence interval [CI] 0.33 to 0.89; couple versus control: RR 0.59, 95% CI 0.37 to 0.94; 60 women, *Low-certainty evidence*) (73).
- ◆ Psychosocial couple-based prevention programme (odds ratio 0.36, 95% CI 0.15 to 0.86; 147 women, *Low-certainty evidence*) (75).
- ◆ Nurse-led applied relaxation training programme (RR 0.22, 95% CI 0.11 to 0.43; 104 women, *Low-certainty evidence*) (80).

- ◆ Antenatal education on natural childbirth preparation with training in breathing and relaxation techniques (elective caesarean: RR 0.95, 95% CI 0.58 to 1.56; emergency caesarean: RR 0.91, 95% CI 0.67 to 1.23; 977 women, *Moderate-certainty evidence*) (79).

The effect of prenatal education for partners of pregnant women on caesarean births is uncertain (79).

Mixed population of women (nulliparous and multiparous women with or without previous caesarean sections)

There were no differences in caesarean section rates between routine maternity care and the following interventions.

- ◆ Intensive group therapy (cognitive behavioural therapy and childbirth psychotherapy) for women with fear of childbirth (RR 0.90, 95% CI 0.65 to 1.24; 176 women, *Low-certainty evidence*) (63).
- ◆ Antenatal education programme for physiological childbirth (RR 1.03, 95% CI 0.72 to 1.49; 150 women, *Moderate-certainty evidence*) (74).

Two interventions were found to increase rates of vaginal births.

- ◆ Childbirth training workshop (mothers alone versus control: RR 2.25, 95% CI 1.16 to 4.36; couple versus control: RR 2.13, 95% CI 1.09 to 4.16; 60 women, *Low-certainty evidence*) (73).

The effect of psychoeducation sessions by telephone for women with fear of childbirth on caesarean births is uncertain (76).

Women with a previous caesarean section

There were no differences in caesarean section rates between routine maternity care and the following interventions:

- ◆ Computer-based decision aids (information programme, decision analysis) (information group versus usual care group, elective caesarean: RR 0.98, 95% CI 0.82 to 1.18, 478 women; emergency caesarean: RR 1.09, 95% CI 0.77 to 1.55, 478 women; decision analysis group versus usual care group, elective caesarean: RR 0.83, 95% CI 0.68 to 1.02, 473 women; emergency caesarean: RR 1.05, 95% CI 0.74 to 1.50, 473 women; *Moderate-certainty evidence*) (81).
- ◆ Decision-aid booklet (absolute change from baseline 26.2%, versus control 22.6%; 227 women, *Moderate-certainty evidence*) (82).

Limited data were available on the effect of the interventions on maternal and neonatal mortality and morbidity.

Different formats of educational interventions

Data from three studies comparing different formats of educational intervention showed little or no differences in rates of caesarean section or vaginal birth after caesarean (VBAC) between formats:

Nulliparous women

- ◆ Role play versus standard education using lectures for women with fear of childbirth (caesarean: RR 0.66, 95% CI 0.39 to 1.12; 67 women, *Low-certainty evidence*) (84).

Women with a previous caesarean section

- ◆ Interactive decision aid versus educational brochures (VBAC: 41% versus 37%; number of participants unclear, *Low-certainty evidence*) (85).
- ◆ Individualized prenatal education and support programme versus written information in

a pamphlet (VBAC: RR 1.08, 95% CI 0.97 to 1.21; 1275 women, *Moderate-certainty evidence*) (86).

Maternal and neonatal morbidity and mortality (where reported) were similar between study groups.

Values (Web annex 4, Table 1)

A qualitative evidence synthesis of women's views and experiences with non-clinical educational interventions to reduce unnecessary caesarean (26) informed this domain. Most of the evidence came from studies conducted in high-income countries. The findings show that women and communities want educational booklets, workshops and decision aids conveying their lived experiences of birth (including the physical demand of labour and the social and emotional impact of vaginal birth and caesarean section) (*High confidence in high-income countries; Moderate confidence all countries*). Some women experience important gaps in information relating to specific birth choices, particularly in relation to home birth and VBAC). Women also want educational provision to include greater acknowledgment of labour and vaginal birth as an important and valuable life experience.

Resources

One RCT compared the cost in Finland of group psychoeducation with that of conventional care for women with fear of childbirth (87). There were no differences between the groups in total direct costs (€3786 per woman in the psychoeducation group versus €3830 per woman in the control group).

MAIN RESOURCE REQUIREMENTS

RECOMMENDATION	DESCRIPTION
Staff	<ul style="list-style-type: none"> • Health-care personnel to conduct birth preparation classes, training workshops and support programmes. • Periodic in-service training for course facilitators.
Training	<ul style="list-style-type: none"> • Locally adapted information, education and communication materials to support training and support programmes (e.g. booklets or pamphlets in local languages).
Infrastructure	<ul style="list-style-type: none"> • Physical space (a venue) to hold training and counselling sessions (or a telephone if conducted this way).
Monitoring and evaluation	<ul style="list-style-type: none"> • Health information system required for routine data collection to monitor the impact of training and support programmes.

Cost-effectiveness

No research evidence was identified on the cost-effectiveness of educational interventions.

Equity (Web annex 4, Table 1)

No direct evidence was identified on the impact on equity of implementing educational interventions.

Indirect evidence from the qualitative review of women’s views and experiences (26) shows that women want multiple modes and formats of educational intervention (*Moderate confidence*) with different women having different levels of literacy, comprehension or requisite skills and access to electronic resources (including printing facilities). Women who have experience of electronic educational interventions report an unmet need for printed copies to reflect on, revisit and share during subsequent discussions with family, friends and health-care professionals. The five studies contributing to this domain were all from high-income countries (Taiwan [China], the United Kingdom and the United States) (26).

Further evidence from the qualitative review indicates that women and communities have wide-ranging views

on the use of appropriate language, figures and tables to communicate information across intervention formats. The importance of health literacy (in respect of familiarity with medical terms) and readability considerations – including Simple Measurement of Gobbledygook (SMOG), a widely used formula to determine how easy written health education materials are to read and comprehend (88) – were reported in the design of some interventions. Video content was largely welcomed where it facilitated the visualization of positive, actual birth experiences. In one study, however, most women did not distinguish the usefulness of the video intervention over the standard information leaflet provided by the hospital, although two women did comment on the video’s relevance for women with low levels of literacy. Many women could see the benefits of computer-based interventions, but ease of use was problematic for some, and pregnant women in particular still wanted information in paper format too.

Additional considerations

In settings where the majority of women are in contact with the health system or where prenatal education is provided through community health workers, educational interventions may increase equity. On the other hand, in settings where access is a barrier to antenatal care, prenatal education may decrease equity.

In the case of educational interventions targeting partners, women who are separated/divorced, and single mothers, may not benefit from these interventions.

Acceptability (Web annex 4, Table 1)

Findings from the qualitative review (26) show that women like learning new information about birth (*High confidence in high-income countries; Moderate confidence in all countries*) with the content and design of interventions opening up new ways of thinking about caesarean section, labour and vaginal birth for women.

Some women were surprised by the actual number of caesarean sections performed. The new knowledge and support communicated can be empowering for women (*Moderate confidence*), although they also desire emotional support alongside the communication of facts and figures about birth (*Moderate confidence*), because some women experience educational intervention content as anxiety provoking (*Moderate confidence*). Use of a decision aid and follow-up by a midwife helped to mediate pregnant women's concerns in one study, but in another study midwives who failed to take women's concerns seriously added to their fears.

Further evidence from the qualitative review (26) shows that educational interventions are only one component informing women's and communities' views and decision-making about birth (*Moderate confidence*). Women are exposed to a multiplicity of information sources before, during and after pregnancy. Some women use decision aids as a springboard for seeking more information. Learning from the birth stories of families and friends is widespread, as is gleaning information from the media and actively seeking it from the Internet.

Face-to-face interactions with health-care professionals were experienced as the most important influence on actual birth method. Although women want all modes and formats of educational interventions in preparation for birth (*Moderate confidence*), intervention content is most useful when it (*Moderate confidence*):

- ◆ complements clinical care
- ◆ is consistent with advice from health-care professionals

- ◆ provides a basis for more informed, meaningful dialogue between women and care providers.

Additional considerations

No research evidence was found relating to acceptability among partners. Issues may include problems with the investment of time or with a lack of opportunity to be released from work to attend sessions, and social stigma in cultures where men are not traditionally included in pregnancy and birth.

Feasibility (Web annex 4, Table 1)

Findings from the qualitative review (26) show that women are aware of how the organization of care and information impacts on the actual choices available to them (*Moderate confidence*), with a few women, from different settings, reporting having to fight for their preferred birth method (vaginal or caesarean). This is likely to affect the feasibility of the women being able to enact their choices no matter what educational intervention they receive. Women's attitudes towards involvement in decision-making vary (*Moderate confidence*). Some women are highly motivated to be involved in decision-making, others are uncertain of their role, and still others want a health-care professional to make the decision about birth method for them. This may impact on the feasibility for funders/providers of supporting sessions or resources that meet the needs of all women in a range of diverse local contexts.

Additional considerations

In settings where educational sessions are provided in locations that are difficult to access, or expensive in terms of transportation, or where "under the counter" payments are demanded for services, it may not be feasible for some women to access the sessions (89).

No research evidence was found relating to the feasibility of involving partners in educational interventions. Issues may include problems with the investment of time or with a lack of opportunity to be released from work to attend sessions, and difficulty or expense of travel to the venue.

Summary of Guideline Development Group’s judgements

RECOMMENDATION 1. NON-CLINICAL EDUCATIONAL INTERVENTIONS TARGETED AT WOMEN COMPARED WITH USUAL PRACTICE

DOMAIN	JUDGEMENT						
Desirable effects	Do not know	⊕ Varies		Trivial	Small	Moderate	Large
Certainty of the evidence of desirable effects	No included studies			Very low	⊕ Low	Moderate	High
Undesirable effects	Do not know	Varies		Large	Moderate	Small	⊕ Trivial
Certainty of the evidence of undesirable effects	No included studies			⊕ Very low	Low	Moderate	High
Balance of effects	Do not know	Varies	Favours usual practice	Probably favours usual practice	Does not favour educational interventions or usual practice	⊕ Probably favours educational interventions	Favours educational interventions
Values				Important uncertainty or variability	Possibly important uncertainty or variability	⊕ Probably no important uncertainty or variability	No important uncertainty or variability
Resources required	Do not know	⊕ Varies	Large costs	Moderate costs	Negligible costs or savings	Moderate savings	Large savings
Certainty of the evidence of required resources	⊕ No included studies			Very low	Low	Moderate	High
Cost-effectiveness	Do not know	Varies	Favours usual practice	Probably favours usual practice	Does not favour educational interventions or usual practice	⊕ Probably favours educational interventions	Favours educational interventions
Equity	Do not know	Varies	Reduced	Probably reduced	Probably no impact	⊕ Probably increased	Increased
Acceptability	Do not know	Varies		No	Probably No	⊕ Probably Yes	Yes
Feasibility	Do not know	Varies		No	Probably No	⊕ Probably Yes	Yes

RECOMMENDATION 1. DIFFERENT MODES OR FORMATS OF NON-CLINICAL EDUCATIONAL INTERVENTIONS TARGETED AT WOMEN

DOMAIN	JUDGEMENT						
Desirable effects	Do not know	Varies		☑ Trivial	Small	Moderate	Large
Certainty of the evidence of desirable effects	No included studies			Very low	☑ Low	Moderate	High
Undesirable effects	Do not know	Varies		Large	Moderate	Small	☑ Trivial
Certainty of the evidence of undesirable effects	No included studies			Very low	☑ Low	Moderate	High
Balance of effects	Do not know	Varies	Favours usual practice	Probably favours usual practice	☑ Does not favour a specific mode or format	Probably favours a specific mode or format	Favours a specific mode or format
Values				Important uncertainty or variability	☑ Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability
Resources required	Do not know	☑ Varies	Large costs	Moderate costs	Negligible costs or savings	Moderate savings	Large savings
Certainty of the evidence of required resources	☑ No included studies			Very low	Low	Moderate	High
Cost-effectiveness	☑ Do not know	Varies	Favours usual practice	Probably favours usual practice	Does not favour a specific mode or format	Probably favours a specific mode or format	Favours a specific mode or format
Equity	Do not know	☑ Varies	Reduced	Probably reduced	Probably no impact	Probably increased	Increased
Acceptability	Do not know	Varies		No	Probably No	☑ Probably Yes	Yes
Feasibility	☑ Do not know	Varies		No	Probably No	Probably Yes	Yes

B. INTERVENTIONS TARGETED AT HEALTH-CARE PROFESSIONALS

3.2. Implementation of evidence-based clinical practice guidelines combined with mandatory second opinion for caesarean indication

RECOMMENDATION 2.1

Implementation of evidence-based clinical practice guidelines combined with structured, mandatory second opinion for caesarean section indication is recommended to reduce unnecessary caesarean sections in settings with adequate resources and senior clinicians able to provide mandatory second opinion for caesarean indication.

(Context-specific recommendation, High-certainty evidence)

REMARKS

- ◆ The GDG emphasized that this recommendation is for settings with adequate resources and senior clinicians (obstetrician-gynaecologists) able to provide mandatory second opinion for caesarean indication.
- ◆ The GDG noted that, although the effect size for this intervention is small, it might still translate into important impact on caesarean section rates, particularly in settings with adequate resources and high caesarean section rates.
- ◆ The following were components of the clinical practice guideline plus mandatory second opinion intervention.
 - Clinical practice guidelines were prepared as decision flow charts for six primary indications for caesarean section. The guidelines were developed by the investigators of the included study (90).
 - Mandatory second opinion was provided by the attending physician before caesarean section. The physician providing the second opinion had to be a person with clinical qualifications equal to or higher than those of the attending physician, working at the same hospital, selected by the obstetrics department and who agreed to follow the clinical guideline.
- ◆ Clinical practice guidelines in this recommendation refers to those implemented in the included study (90)¹ and the relevant WHO guidelines listed in Annex 3.

Summary of evidence and considerations

Brazil, Cuba, Guatemala and Mexico) (90) and one interrupted time series study (Taiwan, China) (91).

Description of included studies

Evidence on the effect of a policy of second opinion for caesarean indication was available from one multicentre cluster-randomized trial (CRT; conducted in Argentina,

1. The guidelines for dystocia, intrapartum fetal distress, previous caesarean section and breech presentation had the format of decision-making flow charts. For other maternal and fetal indications, general recommendations were provided. A seventh guideline for "other indications" was also developed for causes not included in the main six (e.g. maternal request).

The multicentre trial assessed the effect of implementation of evidence-based clinical practice guidelines with mandatory second opinion (mandatory second opinion for non-emergency caesarean sections given by another obstetrician with the same or higher professional status than the attending physician). The control group received routine delivery care.

The interrupted time series study assessed the effect of peer review, including pre-caesarean consultation, mandatory secondary opinion for all caesarean sections and post-caesarean surveillance (cases presented to the department).

Descriptions of the interventions are summarized in Web annex 2, Table 2.

Effects of interventions (Web annex 3, Table 2)

High-certainty evidence shows that implementation of evidence-based clinical practice guidelines combined with mandatory second opinion slightly reduces caesarean section rates (overall caesarean sections: risk difference, RD -1.9, 95% CI -3.8 to -0.1; 34 hospitals attending 149 276 births) (90).

High-certainty evidence shows that implementation of evidence-based clinical practice guidelines combined with mandatory second opinion has little or no effect on maternal and perinatal outcomes (90).

- ◆ Maternal deaths (1.1 deaths per 10 000 live births in intervention hospitals versus 1.6 deaths per 10 000 live births in control hospitals; no further details provided in the trial report).
- ◆ Operative vaginal births (RD -0.1, 95% CI -1.4 to 1.2).
- ◆ Maternal postpartum admission to intensive care unit or referral (RD 0.0, 95% CI -0.4 to 0.4).
- ◆ Neonatal mortality (RD -0.1, 95% CI -0.4 to 0.3).
- ◆ Perinatal mortality (RD -0.3, 95% CI -1.0 to 0.3).
- ◆ Stillbirths (RD -0.1, 95% CI -0.6 to 0.3).
- ◆ Neonatal admission to intensive care unit for more than one day (RD -0.7, 95% CI -2.1 to 0.8).

The effect of peer review, including pre-caesarean consultation, mandatory secondary opinion for all caesarean sections and post-caesarean surveillance on caesarean section, is uncertain (the certainty of evidence was judged as very low) (91).

Details of the results can be found in Web annex 3, Table 2.

Values (Web annex 4, Table 2)

The studies contributing to this domain were from high-income countries (Australia, Canada, Finland, Ireland, the United Kingdom and the United States) and middle-income countries (China, the Islamic Republic of Iran and Nicaragua) (27). The findings show that health-care professionals have varying beliefs about labour and vaginal birth being normal physiological processes versus inherently pathological ones (*Moderate confidence*). A key mechanism for teams facilitating care that could help women to deliver vaginally was the presence of a shared belief in vaginal birth.

Health-care professionals' beliefs about what constitutes necessary and unnecessary caesarean (*Low confidence*), and beliefs about the evidence base surrounding caesarean indication (*Moderate confidence*) are relevant to the importance professionals attach to reducing the rates of unnecessary caesarean. While some health-care professionals report that caesarean rates are determined by factors beyond their control, there is no clear consensus between health-care professionals as to what constitutes a definite clinical indication for caesarean across time (e.g. breech presentation), place (i.e. availability and access) or parity (i.e. women with a previous caesarean), with health-care professionals drawing on different evidence to support their underpinning belief about vaginal birth as normal or as inherently pathological.

The extent to which health-care professionals value lowering caesarean rates locally is also influenced by:

- ◆ fear of blame and recrimination – including fear of litigation for not intervening (*Moderate confidence*);

- ◆ the value they attach to personal financial reward associated with caesarean (*Moderate confidence*);
- ◆ any preference for caesarean as a convenient, efficient birth method that can be scheduled (*Moderate confidence*); and
- ◆ their beliefs about women (*High confidence*), including shifts in beliefs about women’s preparedness for labour and to give birth vaginally, lack of antenatal education, sedentary lifestyles and increasing rates of obesity.

One interview study (92) assessed Brazilian doctors’ perspectives on the second-opinion strategy before a caesarean section. Participants comprised 72 doctors from the hospitals included in the CRT of guideline implementation and mandatory second opinion (90), and 70 doctors from control hospitals. The great majority of those interviewed from both intervention and control hospitals considered this strategy feasible in public hospitals (87% and 95% respectively) but not in private hospitals (64% and 70% respectively). Among those doctors from intervention hospitals who did not consider it feasible (13%), the main reason, mentioned by 29% of them, was that in most public hospitals there are not two obstetrician-gynaecologists on duty at the same time; the next most frequent reason (14%) was that there were not enough personnel and there was a lack of hierarchical structure.

Resources

No direct research evidence was identified on the impact on resource use (costs) of guidelines plus mandatory second opinion.

MAIN RESOURCE REQUIREMENTS

RECOMMENDATION	DESCRIPTION
Staff	<ul style="list-style-type: none"> • Remuneration for additional senior clinicians required to provide mandatory second opinion. • Regular on-site supervision by senior staff.
Training	<ul style="list-style-type: none"> • In-service training on clinical practice guidelines. • Training is generally expensive (costs include remuneration for trainers and facilitators, per diems, adaptation of training materials/job aides).
Infrastructure	<ul style="list-style-type: none"> • Physical space (a venue) for training. • Implementation of mandatory second opinion requires a clear hierarchical structure (often lacking among consultant obstetrician-gynaecologists).
Monitoring and evaluation	<ul style="list-style-type: none"> • Health information system required for routine data collection to monitor the impact of implementing guidelines plus mandatory second opinion.

Cost-effectiveness

No research evidence was identified on the cost-effectiveness of evidence-based clinical practice guidelines combined with mandatory second opinion.

Equity

No direct evidence was identified on the impact on equity of implementing evidence-based clinical practice guidelines combined with mandatory second opinion.

Poor adherence to evidence-based clinical practice guidelines often impacts more on disadvantaged populations (58). Resources needed for mandatory second opinion may be less easily available in disadvantaged populations.

Acceptability (Web annex 4, Table 2)

Findings from the qualitative review (27) indicate that across high-, middle- and low-resource settings, some health-care professionals believe there is a need to reduce unnecessary caesareans and were receptive to change (*Moderate confidence*). Across different settings, health-care professionals acknowledge that concerted action to reduce unnecessary caesareans is challenging but achievable, and, for some, intrinsically rewarding where there is mutual respect, accountability and shared responsibility in supporting women to achieve a vaginal birth.

Further evidence from the CRT (90) indicates good acceptability:

“The intervention was well accepted by both women and physicians. More women in the second opinion group than controls realized that their situation was consulted with another physician, although we cannot exclude chance as an explanation. Most women felt better with the idea of a second opinion, and no differences were observed between the study groups. 91% of the physicians in the intervention hospitals would recommend the mandatory second opinion to be used in public institutions, if it was proven effective at the expected level.”

Feasibility (Web annex 4, Table 2)

Findings from the qualitative review (27) indicate that barriers to implementation of proven interventions to reduce caesarean section rates are multifactorial.

The barriers include some health-care professionals' reluctance to change based on lack of training, skills or experience (*Low confidence*), particularly in high- and middle-income countries where high caesarean rates mean younger generations of clinicians have less knowledge of labour and vaginal birth.

Another important factor is the current organization of care (*Moderate confidence*) across all resource settings where human resource and facilities to support labour and vaginal birth are perceived as lacking. Health-care professionals, predominantly from low- and middle-income countries, but also from some high-income countries, expressed concerns that lack of human and technological resources makes guideline recommendations unworkable in practice.

Dysfunctional teamwork within the medical profession, including the marginalization of midwives (*Moderate confidence*) is another barrier. Unsupportive medical hierarchies, lack of communication between maternity and theatre staff, and sometimes difficult relationships between obstetricians, midwives and family doctors were all discussed in all settings. In middle- and high-income settings, some midwives and obstetricians spoke passionately about the marginalization of midwives and their exclusion from guidelines as counterproductive.

Beliefs about the need for high-level infrastructure to offer safe vaginal birth after caesarean section (VBAC) (*Moderate confidence*) are also a barrier to guideline implementation. However, where this infrastructure is available it is not always made accessible. In high-income countries where 24-hour obstetrical and anaesthesia cover is available, some health-care professionals report women are still refused a trial of labour. Health-care professionals who are supportive of VBAC report being flexible in their interpretation of guidelines and facilitative in their use of available technologies to avoid unnecessary caesarean.

Additional evidence on feasibility of implementing guidelines and mandatory second opinion can be found in the resources domain above for Recommendation 2.1.

Summary of Guideline Development Group’s judgements

RECOMMENDATION 2.1. IMPLEMENTATION OF EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES COMBINED WITH MANDATORY SECOND OPINION FOR CAESAREAN INDICATION COMPARED WITH USUAL PRACTICE

DOMAIN	JUDGEMENT						
Desirable effects	Do not know	Varies		Trivial	☑ Small	Moderate	Large
Certainty of the evidence of desirable effects	No included studies			Very low	Low	Moderate	☑ High
Undesirable effects	Do not know	Varies		Large	Moderate	Small	☑ Trivial
Certainty of the evidence of undesirable effects	No included studies			Very low	Low	Moderate	☑ High
Balance of effects	Do not know	Varies	Favours usual practice	Probably favours usual practice	Does not favour guidelines plus mandatory second opinion or usual practice	☑ Probably favours guidelines plus mandatory second opinion	Favours guidelines plus mandatory second opinion
Values				Important uncertainty or variability	☑ Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability
Resources required	Do not know	Varies	Large costs	☑ Moderate costs	Negligible costs or savings	Moderate savings	Large savings
Certainty of the evidence of required resources	☑ No included studies			Very low	Low	Moderate	High
Cost-effectiveness	☑ Do not know	Varies	Favours usual practice	Probably favours usual practice	Does not favour guidelines plus mandatory second opinion or usual practice	Probably favours guidelines plus mandatory second opinion	Favours guidelines plus mandatory second opinion
Equity	Do not know	Varies	Reduced	Probably reduced	Probably no impact	☑ Probably increased	Increased
Acceptability	Do not know	Varies		No	Probably No	☑ Probably Yes	Yes
Feasibility	Do not know	☑ Varies		No	Probably No	☑ Probably Yes	Yes

3.3. Implementation of evidence-based clinical practice guidelines combined with audit and feedback

RECOMMENDATION 2.2

Implementation of evidence-based clinical practice guidelines, caesarean section audits and timely feedback to health-care professionals are recommended to reduce unnecessary caesarean sections.

(Recommended, High-certainty evidence)

REMARKS

- ◆ The following were components of the evidence-based clinical practice guidelines² and audit and feedback intervention.
 - Onsite training in evidence-based clinical practice, facilitation of implementation by a local opinion leader (obstetrician-gynaecologist) and supportive supervision.
 - Audits of indications for caesarean births and provision of feedback to physicians and nurses involved in the decision-making process for deliveries. The audits were conducted by a local audit committee comprising two obstetrician-gynaecologists, one general practitioner and one nurse.
- ◆ The evidence supported audits of indications for caesarean sections; however, the GDG emphasized the need to assess all aspects of caesarean sections in audits (such as underlying health-care professional factors, women factors (e.g. maternal request) and organizational factors).
- ◆ Qualitative evidence (27) indicates that lack of training, skills or experience is a barrier to change and thus it is important that interventions have a training component tailored to local needs.
- ◆ Clinical practice guidelines in this recommendation refers to those implemented in the included study (93) and the relevant WHO guidelines listed in Annex 3.

Summary of evidence and considerations

Description of included studies

Evidence on the effect of audit and feedback and peer review was available from two cluster-randomized

controlled trials (CRTs), both from Canada (93, 94), and three interrupted time series studies, from Chile (95), Islamic Republic of Iran (96) and the United States (97).

One of the two CRTs (83) assessed the effect of a multifaceted intervention comprising implementation of evidence-based clinical practice guidelines (on-site training, facilitation by a local opinion leader [obstetrician-gynaecologist], supervision), audits of indications for caesarean delivery and provision of feedback to health-care professionals. Control hospitals received usual care. The second of the two CRTs (94) assessed the effect of physician education by a local opinion leader (physician) and audit with feedback as methods of encouraging

2. The guidelines were based on the Advances in Labour and Risk Management (ALARM) programme. Topics covered in the ALARM clinical practice guidelines and algorithms include: induction and stimulation of labour, fetal health surveillance, assisted vaginal delivery, prolonged pregnancy (> 42 weeks), active management of labour, partogram use, VBAC, breech and multiple pregnancy delivery. The training programme also sensitized participants to social, economic, organizational, cultural and legal factors contributing to the rise of the caesarean rate in Quebec. The training was provided by certified instructors from the Society of Obstetricians and Gynaecologists of Canada (SOGC).

compliance with guidelines that recommended clinical action to increase trial of labour and vaginal birth rates in women who have had previous caesarean sections.

The interventions assessed in the interrupted time series studies were audit and feedback using the Robson classification (95), audit and feedback and financial incentive (96), and audit and feedback combined with 24-hour coverage by a dedicated physician on the premises to manage labour and complications (97) (Web annex 2, Table 2). The effect of these strategies on caesarean section rates is uncertain (the certainty of evidence was judged as very low).

Details of the results can be found in Web annex 3, Table 2.

Effects of interventions (Web annex 3, Table 2)

Implementation of guidelines combined with audit and feedback

High-certainty evidence shows that implementation of guidelines combined with audit and feedback slightly reduces caesarean section rates in women with low-risk pregnancies (risk difference, RD: -1.7%, 95% CI -3.0 to -0.3; 16 intervention hospitals, 11 478 births at baseline, 10 067 births post-intervention; 16 control hospitals, 14 717 births at baseline, 13 019 births post-intervention).

High-certainty evidence shows that implementation of guidelines combined with audit and feedback slightly reduces assisted vaginal delivery (RD -1.1%, 95% CI -2.2 to -0.1). The intervention has little or no effect, however, on episiotomy (in women who attempted labour) (RD 0.1%, 95% CI -2.0 to 2.7), major maternal morbidity (RD 0.03%, 95% CI -0.11 to 0.23) and minor maternal morbidity (RD 0.3%, 95% CI -1.2 to 1.8).

High-certainty evidence shows that implementation of guidelines combined with audit and feedback slightly reduces major neonatal morbidity (RD -0.7%, 95% CI -1.3 to -0.1), minor neonatal morbidity (RD -1.7%, 95% CI -2.6 to -0.9), intrapartum and neonatal deaths (RD -0.06%, 95% CI -0.08 to -0.03%), major trauma (RD -0.23%, 95% CI -0.40 to -0.01) and use of invasive mechanical ventilation (RD -0.38%, 95% CI -0.60 to -0.09).

Audit and feedback and local opinion leader education

High-certainty evidence shows that the use of local opinion leader education (OL) as a method to implement guidelines reduces rates of elective caesarean (OL: 53.7%, 95% CI 46.5 to 61.0; control: 66.8%, 95% CI 61.7 to 72.0). There were no differences, however, between audit and feedback (AF) and control in rates of elective caesarean (AF: 69.7%, 95% CI 62.4 to 77.0; control: 66.8%, 95% CI 61.7 to 72.0). Comparisons of unscheduled caesarean rates revealed no differences between study groups (AF: 18.6%, 95% CI 13.9 to 23.2; OL: 21.4%, 95% CI 16.8 to 26.1; control: 18.7%, 95% CI 15.4 to 22.1%).

The proportion of women who had vaginal births was higher in the opinion leader education group compared with the control group (OL: 25.3%, 95% CI 19.3 to 31.2; control: 14.5%, 95% CI 10.3 to 18.7). There were no differences between AF and control groups on this outcome (AF: 11.8%, 95% CI 5.8 to 17.7; control: 14.5%, 95% CI 10.3 to 18.7).

There was no difference between study groups in the proportion of women with a previous history of caesarean section offered trial of labour (AF: 21.4%, 95% CI 13.9 to 29.0; OL: 38.2%, 95% CI 30.6 to 45.7; control: 28.3%, 95% CI 23.0 to 33.7).

Limited data were available on maternal complications (ruptured uterus, dehiscence of uterus) and stillbirths.

Details of the results can be found in Web annex 3, Table 2.

Values (Web annex 4, Table 2)

See the values domain in Recommendation 2.1.

Resources

See the cost-effectiveness domain in the present recommendation.

MAIN RESOURCE REQUIREMENTS

RECOMMENDATION	DESCRIPTION
Staff	<ul style="list-style-type: none"> • Remuneration for additional health-care personnel required to perform audit and feedback and peer review of caesarean section practices.
Training	<ul style="list-style-type: none"> • In-service training, including suitably trained facilitators, required to implement clinical guidelines. • Training is generally expensive (costs include remuneration for trainers and facilitators, per diems, locally adapted training materials and job aides).
Infrastructure	<ul style="list-style-type: none"> • Physical space (a venue) for training.
Monitoring and evaluation	<ul style="list-style-type: none"> • Health management information system for routine data collection to monitor the impact of implementing the guidelines combined with audit and feedback.

Cost-effectiveness

Economic evaluation of the guidelines plus audit and feedback intervention (98) showed that the strategy resulted in per-patient reductions of 0.005 caesareans (95% CI -0.015 to 0.004, $P = 0.09$) and \$ 180 (95% CI -\$ 277 to -\$ 83, $P < 0.001$). Women with low-risk pregnancies experienced statistically significant reductions in caesarean rates and costs; changes for the high-risk subgroup were not significant. The intervention was dominant (i.e. effective in reducing caesareans and less costly than usual care) in 86.08% of simulations. It reduced costs in 99.99% of simulations. Cost reductions were driven by lower rates of neonatal complications in the intervention group (-\$ 190, 95% CI -\$ 255 to -\$ 125, $P < 0.001$). The authors estimated that, given 88 000 annual births in the study area (Quebec), a similar intervention could save \$ 15.8 million (range \$ 7.3 to \$ 24.4 million) annually. (All costs are reported in 2013 Canadian dollars).

Equity

No research evidence was identified on the impact on equity of implementing guidelines combined with audit and feedback.

Poor adherence to guidelines often impacts more on disadvantaged populations (58). Resources needed for audit and feedback may be less easily available in disadvantaged populations.

Acceptability

No research evidence was identified on the acceptability of implementing guidelines combined with audit and feedback.

Feasibility

See the feasibility domain in the section on Recommendation 2.1.

Summary of Guideline Development Group's judgements

RECOMMENDATION 2.2. IMPLEMENTATION OF EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES COMBINED WITH AUDIT AND FEEDBACK COMPARED WITH USUAL PRACTICE

DOMAIN	JUDGEMENT						
Desirable effects	Do not know	Varies		Trivial	☑ Small	Moderate	Large
Certainty of the evidence of desirable effects	No included studies			Very low	Low	Moderate	☑ High
Undesirable effects	Do not know	Varies		Large	Moderate	Small	☑ Trivial
Certainty of the evidence of undesirable effects	No included studies			Very low	Low	Moderate	☑ High
Balance of effects	Do not know	Varies	Favours usual practice	Probably favours usual practice	Does not favour guidelines plus audit and feedback or usual practice	Probably favours guidelines plus audit and feedback	☑ Favours guidelines plus audit and feedback
Values				Important uncertainty or variability	☑ Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability
Resources required	Do not know	☑ Varies	Large costs	Moderate costs	Negligible costs or savings	Moderate savings	Large savings
Certainty of the evidence of required resources	☑ No included studies			Very low	Low	Moderate	High
Cost-effectiveness	Do not know	Varies	Favours usual practice	Probably favours usual practice	Does not favour guidelines plus audit and feedback or usual practice	☑ Probably favours guidelines plus audit and feedback	Favours guidelines plus audit and feedback
Equity	Do not know	Varies	Reduced	Probably reduced	Probably no impact	☑ Probably increased	Increased
Acceptability	Do not know	Varies		No	Probably No	☑ Probably Yes	Yes
Feasibility	Do not know	Varies		No	Probably No	☑ Probably Yes	Yes

C. INTERVENTIONS TARGETED AT HEALTH ORGANIZATIONS, FACILITIES OR SYSTEMS

3.4. Collaborative midwifery-obstetrician model of care in which the obstetrician provides in-house labour and delivery coverage, 24 hours a day, without competing clinical duties.

RECOMMENDATION 3.1

For the sole purpose of reducing caesarean section rates, collaborative midwifery-obstetrician model of care (i.e. a model of staffing based on care provided primarily by midwives, with 24-hour back-up from an obstetrician who provides in-house labour and delivery coverage without other competing clinical duties) is recommended only in the context of rigorous research.

(Context-specific recommendation, Low-certainty evidence)

REMARKS

- ◆ The collaborative midwifery-obstetrician staffing model comprised a midwife and an obstetrician being present in-house 24 hours a day, working collaboratively to provide primary labour care for all private and public patients (99). This staffing model was compared with labour care provided by an on-call private physician or a covering partner.
- ◆ This recommendation is based on evidence from one interrupted time series study conducted in the United States (99). There are uncertainties about the effectiveness, feasibility and acceptability of the intervention in other settings. Thus, the intervention should be implemented only in the context of well designed studies examining the impact on caesarean sections and exploring the acceptability to key stakeholders and the feasibility of implementation.
- ◆ This model of care primarily addresses intrapartum caesarean sections.

The following are according to the systematic review of qualitative studies (27).

- ◆ Dysfunctional teamwork within the medical profession and lack of communication are important barriers that need to be addressed in the context of fostering change.
- ◆ Marginalization of midwives recurs across settings and acts as an important barrier to reducing caesareans. Collaborative staffing models can address this issue.

Summary of evidence and considerations

Description of included studies

Evidence on the effect of a collaborative midwifery-obstetrician care model was available from one interrupted time series study conducted in the United States (99). This study examined the association between expanded access to collaborative midwifery and obstetrician services and caesarean section rates in a community hospital between 2005 and 2014. Privately insured women changed from a private practice model to one that included 24-hour midwifery and obstetrician coverage in 2011. In the private practice model, labour and delivery care was provided by a private physician (obstetrician) or a covering partner who took calls while at home or in the office and, in general, managed labour remotely.

Description of the intervention can be found in Web annex 2, Table 3.

Effects of interventions (Web annex 3, Table 3)

Low-certainty evidence suggests that collaborative midwifery-obstetrician care model may reduce the rate of primary caesareans and increase the VBAC rate: the rate

of primary caesareans among privately insured women decreased by 7% in the year after the expansion and by 1.7% per year thereafter; the VBAC rate increased from 13.3% before, to 22.4% afterwards.

Values (Web annex 4, Table 2)

See the values domain in Recommendation 2.1.

Resources

No research evidence was identified on the impact on resource use (costs) of the collaborative midwifery-obstetrician care model.

If the model requires a shift from privately funded sources (personal, employment or insurance-based) all the extra costs of the new scheme will be borne by the public health-care system. If the comparison is with on-call physician care provided by the public sector rather than the private sector, the resources required for a collaborative midwifery-obstetrician care model may still be high, especially in settings that currently have no or limited access to skilled birth attendants for labour and birth. The subsequent need for training, supervision, resources and support could limit scale-up in low-resource settings.

MAIN RESOURCE REQUIREMENTS

RECOMMENDATION	DESCRIPTION
Staff	<ul style="list-style-type: none"> Remuneration for additional staff required to provide midwifery and obstetric care.
Training	<ul style="list-style-type: none"> Training for existing or new staff who are moving to a midwifery-obstetrician model.
Infrastructure	<ul style="list-style-type: none"> If obstetric staff provide on-site cover 24 hours a day, there will be resource requirements for overnight accommodation and associated living costs. If staff are off-site, there may be additional travel costs for call-ins.
Monitoring and evaluation	<ul style="list-style-type: none"> Health information system for routine data collection to monitor the impact of introducing a collaborative midwifery-obstetrician model of obstetric care.

Cost-effectiveness

No research evidence was identified on the cost-effectiveness of the midwifery-obstetrician care model.

Equity

No research evidence was identified on the impact on equity of the collaborative midwifery-obstetrician care model.

Acceptability (Web annex 4, Table 2)

The studies contributing to this domain were from 10 different countries: the high-income countries Australia, Canada, Finland, the Netherlands, the United Kingdom and the United States; the middle-income countries China, the Islamic Republic of Iran and Nicaragua; and the low-income country, the United Republic of Tanzania (27). The findings show that among health-care professionals' beliefs about the clinical encounter and autonomous decision-making is the view that, where teams have a shared approach, informed decision-making is more likely to happen irrespective of who makes the final decision, and everyone involved is reassured by the process. On this basis, the collaborative midwifery-obstetrician care model could be acceptable.

In many settings, there was a shared belief in the need to reduce unnecessary caesareans, and there was receptiveness to change. In European settings, health-care professionals experienced interventions targeted to reduce unnecessary caesareans as most acceptable where this vision was shared within and between multidisciplinary groups. In Denmark, Norway, Sweden and the United Kingdom, health-care professionals from organizations that achieved success in reducing rates had positive attitudes towards critical self-reflection (including audit, second opinion and continuing medical education) and felt supported by colleagues and opinion leaders. Across settings with different levels of resources, health-care professionals acknowledged that concerted action to reduce unnecessary caesarean was challenging but achievable and intrinsically rewarding where there was respect, accountability and shared responsibility to support women in achieving a vaginal birth. Collaborative multidisciplinary staffing models are likely to be

acceptable where they increase a sense that these benefits are achieved.

Dysfunctional teamwork, within and between professional groups, including the marginalization of midwives, was seen as an important barrier to reducing unnecessary caesareans. Unsupportive medical hierarchies, lack of communication between maternity and theatre staff, and difficult relationships between obstetricians, midwives and family doctors were often mentioned. Some midwives and obstetricians spoke passionately about the marginalization of midwives and their exclusion from birth as counterproductive. Given that collaborative midwifery-obstetrician models, by definition, address some of these issues, they are likely to be acceptable to most staff.

Feasibility (Web annex 4, Table 2)

Qualitative evidence (27) indicates a reluctance of health-care professionals to change, based on lack of training, skills or experience. Some health-care professionals spoke about how pre- and post-registration training has ill-equipped the next generation for a reduction in caesarean rates as they have little experience, competency or confidence in normal labour and vaginal birth. Others reported wanting specific training on recommendations to make them more acceptable in practice. The feasibility of implementing a collaborative midwifery-obstetrician model with the aim of reducing unnecessary caesareans may depend in part on the capacity of local resources and leadership to overcome these factors.

Summary of Guideline Development Group's judgements

RECOMMENDATION 3.1. COLLABORATIVE MIDWIFERY-OBSTETRICIAN MODEL OF CARE COMPARED WITH LABOUR AND DELIVERY CARE PROVIDED BY AN ON-CALL PRIVATE PHYSICIAN OR A COVERING PARTNER

DOMAIN	JUDGEMENT						
Desirable effects	Do not know	Varies		Trivial	☑ Small	Moderate	Large
Certainty of the evidence of desirable effects	No included studies			Very low	☑ Low	Moderate	High
Undesirable effects	☑ Do not know	Varies		Large	Moderate	Small	Trivial
Certainty of the evidence of undesirable effects	☑ Not assessed by included studies			Very low	Low	Moderate	High
Balance of effects	Do not know	Varies	Favours private model of care	Probably favours private model of care	Does not favour collaborative midwifery-obstetrician model of care or private model of care	☑ Probably favours collaborative midwifery-obstetrician model of care	Favours collaborative midwifery-obstetrician model of care
Values				Important uncertainty or variability	☑ Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability
Resources required	Do not know	☑ Varies	Large costs	Moderate costs	Negligible costs or savings	Moderate savings	Large savings
Certainty of the evidence of required resources	☑ No included studies			Very low	Low	Moderate	High
Cost-effectiveness	☑ Do not know	Varies	Favours usual practice	Probably favours usual practice	Does not favour collaborative midwifery-obstetrician model of care or private model of care	Probably favours collaborative midwifery-obstetrician model of care	Favours collaborative midwifery-obstetrician model of care
Equity	Do not know	☑ Varies	Reduced	Probably reduced	Probably no impact	Probably increased	Increased
Acceptability	Do not know	Varies		No	Probably No	☑ Probably Yes	Yes
Feasibility	Do not know	☑ Varies		No	Probably No	Probably Yes	Yes

3.5. Financial strategies for health-care professionals or health-care organizations

RECOMMENDATION 3.2

For the sole purpose of reducing unnecessary caesarean sections, financial strategies (i.e. insurance reforms equalizing physician fees for vaginal births and caesarean sections) for health-care professionals or health-care organizations are recommended only in the context of rigorous research.

(Context-specific recommendation, Very low-certainty evidence)

REMARKS

- ◆ Financial strategies examined in the included studies comprised insurance reforms equalizing physician fees for vaginal births and caesarean sections.
- ◆ The GDG noted that only two interrupted time series studies assessed this intervention, conducted in countries with different health-care systems and resource capacities (Taiwan [China], the United States) – applicability in other settings is therefore uncertain. The certainty of evidence for caesarean section outcome was judged as very low in both studies (the effect on caesarean section rates is therefore uncertain). Despite these uncertainties, the GDG noted that financial incentive remains a major determinant of caesarean births in all settings.
- ◆ Given the uncertainties in the impact of financial strategies and their importance in caesarean births, the GDG recommended the implementation of financial strategies equalizing physician fees for vaginal births and caesarean sections only in the context of rigorous research examining the impact on caesarean births and exploring their acceptability to key stakeholders and the feasibility of their implementation.

Summary of evidence and considerations

Description of included studies

Evidence on financial strategies for health-care professionals was derived from two interrupted time series studies that assessed the effect of insurance reforms equalizing physician fees for vaginal births and caesarean sections (100, 101).

In the first study (conducted in the United States) (100), caesarean section rates were calculated from data on 11 767 births in the 12 months before and after the reform. In the second study (in Taiwan, China) (101), the National Health Insurance fee for a vaginal birth was raised in May 2005 to the level of that for a caesarean section birth,

preceded by the fee rise in April 2003 for VBAC to the level of caesarean section fee.

Descriptions of the interventions are summarized in Web annex 2, Table 4.

Effects of interventions (Web annex 3, Table 4)

The effect of both strategies on caesarean section rates is uncertain (the certainty of evidence was judged as very low). None of the studies reported other maternal or neonatal outcomes.

Details of the results can be found in Web annex 3, Table 4.

Values (Web annex 4, Table 3)

Findings from the qualitative review (27) indicate that some health-care professionals are outspoken about the economic incentives for caesareans, particularly in private health-care facilities. This included doctors in China, the Islamic Republic of Iran, Nicaragua and the United Republic of Tanzania, as well as midwives in the Islamic Republic of Iran and the United States. Some doctors considered caesareans to involve more work, which justified the payment, others blamed the system, while still others reported personally valuing the extra income. Some doctors and midwives were critical of the insufficient monetary reward to staff by comparison for labour and vaginal birth.

Further qualitative evidence (28) suggests that in high- and middle-income countries, health-care professionals have varying attitudes towards the value of caesarean section. Some claimed a lack of awareness of any ill-effects of caesarean or of awareness of their facility’s caesarean rate, others acknowledged their rates were high and that risks existed, but considered them “ignorable”, while some expressed specific concerns about anaesthetic risks, surgical complications, recovery times, costs and longer-term consequences for women. Women in Ghana were aware that access to a health insurance scheme that gave them free maternity care could benefit them if they needed a caesarean, but also that this could lead to an increase in caesarean rates and, for some women, increased morbidity.

Across a number of studies (28), fee-reduction policies were associated with a variable effect on appropriate use of caesarean dependent on local philosophies of maternity care, inter-professional and interpersonal relationships, staff motivation to work with women or with the organization, or simply for an income, and the expectations and demands of local women, families and communities. The unintended consequences of an increase in caesareans subsequent to reducing fees included longer-term iatrogenic damage to women’s health that is not covered by fee exemption.

Feasibility (Web annex 4, Table 3)

The implementation of strategies to limit indications for caesarean accepted by insurance companies in the Islamic Republic of Iran was met with scepticism about the power of insurance companies, with concerns that women who need a caesarean may no longer get one, and with concerns of an increase in the misreporting of indications for caesarean to satisfy amended insurance criteria (28). Insurance reform in China was not believed to be as influential on caesarean rates as women’s views of the advantages of caesarean.

Resources

No research evidence was identified on the impact on resource use of insurance reforms equalizing physician fees for vaginal births and caesarean sections.

MAIN RESOURCE REQUIREMENTS

RECOMMENDATION	DESCRIPTION
Staff	<ul style="list-style-type: none"> Physician remuneration for increased vaginal delivery fees
Training	<ul style="list-style-type: none"> None
Infrastructure	<ul style="list-style-type: none"> None
Monitoring and evaluation	<ul style="list-style-type: none"> Health information system for routine data collection to monitor the impact of financial reform equalizing physician fees for vaginal births and caesarean sections

Equity

No research evidence was identified on the impact on equity of insurance reforms equalizing physician fees for vaginal births and caesarean sections.

Increasing physician fees for vaginal births may result in the unintended consequence of increasing inequity in access to skilled care at birth among disadvantaged groups (e.g. households unable to meet high physician fees). This is particularly likely in settings where the increased physician fees are not covered by the government or the national health insurance programme.

No research evidence was identified on additional considerations (cost-effectiveness, acceptability) for financial strategies. The effect on these outcomes of the financial strategies studied is therefore uncertain. Further research is needed to investigate these issues.

Summary of Guideline Development Group’s judgements

RECOMMENDATION 3.2. INSURANCE REFORMS EQUALIZING PHYSICIAN FEES FOR VAGINAL BIRTHS AND CAESAREAN SECTIONS VERSUS USUAL PRACTICE

DOMAIN	JUDGEMENT						
Desirable effects	⊕ Do not know	Varies		Trivial	Small	Moderate	Large
Certainty of the evidence of desirable effects	No included studies			⊕ Very low	Low	Moderate	High
Undesirable effects	⊕ Do not know	Varies		Large	Moderate	Small	Trivial
Certainty of the evidence of undesirable effects	⊕ Not assessed by included studies			Very low	Low	Moderate	High
Balance of effects	⊕ Do not know	Varies	Favours usual practice	Probably favours usual practice	Does not favour insurance reforms equalizing fees or usual practice	Probably favours insurance reforms equalizing fees	Favours insurance reforms equalizing fees
Values				Important uncertainty or variability	⊕ Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability
Resources required	Do not know	Varies	⊕ Large costs	Moderate costs	Negligible costs or savings	Moderate savings	Large savings
Certainty of the evidence of required resources	⊕ No included studies			Very low	Low	Moderate	High
Cost-effectiveness	⊕ Do not know	Varies	Favours usual practice	Probably favours usual practice	Does not favour insurance reforms equalizing fees or usual practice	Probably favours insurance reforms equalizing fees	Favours insurance reforms equalizing fees
Equity	⊕ Do not know	Varies	Reduced	Probably reduced	Probably no impact	Probably increased	Increased
Acceptability	⊕ Do not know	Varies		No	Probably No	Probably Yes	Yes
Feasibility	Do not know	Varies		No	⊕ Probably No	Probably Yes	Yes

4. Implementation of the recommendations

4.1 Applicability issues

A number of factors (barriers) may hinder the effective implementation and scale-up of the recommendations in this guideline. These factors may be related to the behaviours of patients (women or families), the behaviour of health-care professionals, to the organization of care, health service delivery or to financial arrangements. The barriers and potential strategies to addressing these

factors are summarized in Box 4. The barriers were identified from case studies and systematic reviews exploring factors affecting the implementation of interventions to reduce caesarean section rates (55–57). Additional barriers were identified from qualitative reviews undertaken for this guideline (26–28) and Cochrane overviews of reviews of health system implementation, care delivery arrangements and financial strategies (58–60).

BOX 4. BARRIERS, AND IMPLEMENTATION STRATEGIES TO OVERCOME THEM, FOR WHO RECOMMENDATIONS NON-CLINICAL INTERVENTIONS TO REDUCE UNNECESSARY CAESAREAN SECTIONS

BARRIER OR CONSTRAINT	PROPOSED IMPLEMENTATION STRATEGY
Patient factors (women, families, community)	
Lack of understanding of the value of recommended practices among women seeking maternity care, families or communities.	<ul style="list-style-type: none"> • Community-level sensitization activities should be undertaken to disseminate information about the risks of unnecessary caesarean sections and the benefits of adhering to recommended practices.
Health-care professional factors	
Resistance of health-care providers to changing their entrenched caesarean section practices; lack of understanding of the value of newly recommended interventions.	<ul style="list-style-type: none"> • Involve local opinion leaders; identify champions to promote the implementation of the recommendation. • Provide information or education that helps the targeted health-care professionals to fit the recommended behaviour into their current practice. • Involve training institutions and professional bodies in the introduction of the guideline so that pre-service and in-service training curricula can be updated with the recommendations. • Successful implementation strategies should be documented and shared as examples to other implementers.
Lack of clear hierarchical structure among senior clinicians (obstetrician-gynaecologists) may hinder the implementation of mandatory second opinion for caesarean section indication.	<ul style="list-style-type: none"> • Develop local case-specific protocols to ensure timely and appropriate senior clinician review for caesarean section indication. • Organize teams in which roles are defined and they have a shared goal.

<p>Patients may make demands that hinder adherence.</p>	<ul style="list-style-type: none"> • Provide tailored patient education materials. • Train targeted health-care professionals to provide patient education.
<p>There may be financial incentives that hinder adherence (e.g. higher pay for caesarean section compared with vaginal births).</p>	<ul style="list-style-type: none"> • Remove or modify financial incentive.
<p>Dysfunctional teamwork among health-care professionals (e.g. lack of communication between maternity and theatre staff, and sometimes difficult relationships between obstetricians, midwives and family doctors).</p>	<ul style="list-style-type: none"> • Organize teams in which roles are defined and they have a shared goal.
<p>Health-care organization or system factors</p>	
<p>Lack of human resources with the necessary expertise and skills to implement, supervise and support recommended practices (e.g. birth preparation classes and support programmes, senior clinicians to provide second opinion for caesarean section indication).</p>	<ul style="list-style-type: none"> • Redistribute health-care resources; task shifting. • Pragmatic consideration of what is feasible; gradual change; shifting resources from elsewhere in the health-care budget; increasing the health-care budget. • Strategic long-term planning and budgeting to provide the necessary resources.
<p>Lack of physical space (e.g. a venue for birth preparation classes and counselling sessions, training workshops).</p>	<ul style="list-style-type: none"> • Adapt implementation strategies to work within the constraints of the existing systems. • Strategic long-term planning and budgeting to provide the necessary resources.
<p>Lack of essential supplies (locally adapted information, education and communication materials to support training, and support programmes, e.g. booklets or pamphlets in local languages).</p>	<ul style="list-style-type: none"> • Devise strategies to improve supply chain management according to local requirements, such as developing protocols for obtaining and maintaining the stock of supplies. • Adapt implementation strategies to work within the constraints of the existing systems.
<p>Lack of health information management systems designed to document and monitor recommended practices (e.g. electronic records, registers).</p>	<ul style="list-style-type: none"> • Provide appropriate incentives to record the needed information. • Strategic long-term planning and budgeting to provide the necessary resources for health information management systems.
<p>Guideline factors</p>	
<p>Inconsistency with existing national guidelines or protocols.</p>	<ul style="list-style-type: none"> • Explain to the targeted users the reasons for conflicting recommendations.
<p>Recommendation may not be congruous with customs or norms in the contexts where they are being implemented.</p>	<ul style="list-style-type: none"> • Provide information or education on the benefits of adhering to recommended practices.

4.2 Monitoring and evaluating the impact of the guideline

The implementation and the impact of the recommendations can be monitored at the health-service, regional and country levels based on clearly defined criteria and indicators that are associated with locally agreed targets. The WHO *Standards for improving quality of maternal and newborn care in health facilities (102)* provide lists of prioritized input, output and outcome measures, which can be used to define quality-of-care criteria and indicators with locally agreed targets. In collaboration with the monitoring and evaluation teams of the WHO Departments of Reproductive Health and Research, and Maternal, Newborn, Child and Adolescent Health, data on country- and regional-level implementation of the recommendations will be collected to evaluate their impact on the national policies of individual WHO Member States.

5. Research implications

The Technical Working Group and Steering Group identified areas where further studies are needed based on four broad considerations:

1. uncertainty in the effects of the interventions due to evidence of very low or low certainty;
2. concerns with the applicability of the evidence (particularly as most interventions were assessed in single studies; the interventions would benefit from replication in other settings);
3. lack of studies for predefined guideline questions; and

4. promising interventions not specifically designed to reduce caesarean births that would benefit from examination in areas with high caesarean section rates (e.g. continuous one-to-one intrapartum support).

Additional research questions were proposed by the Guideline Development Group (GDG) during the face-to-face consultative meeting. In particular, the GDG emphasized that future intervention trials should be preceded with formative research to define locally relevant determinants of caesarean births. Prioritized research gaps are summarized in Box 5.

BOX 5. RESEARCH GAPS FOR WHO RECOMMENDATIONS NON-CLINICAL INTERVENTIONS TO REDUCE UNNECESSARY CAESAREAN SECTIONS

FUTURE RESEARCH SHOULD FOCUS ON THE FOLLOWING AREAS
Population
Healthy women seeking antenatal, labour and delivery care in health-care facilities (term, singleton, cephalic pregnancies with or without a previous caesarean).
Settings
<ul style="list-style-type: none"> • All areas with high or increasing caesarean section rates. • All settings where women receive maternity or delivery care (community, home, clinics, hospitals, birth centres).
Study designs
<ul style="list-style-type: none"> • Pragmatic randomized controlled trials or cluster-randomized trials (involving clusters of practices, hospitals, birth centres, labour units). Where these are not feasible, interrupted time series designs should be used. • Studies should be sufficiently powered (include adequate sample sizes) for primary and secondary outcomes. • Studies should include sufficient sample sizes to allow assessment of intervention effect by factors such as parity, socioeconomic status, staffing patterns, practice setting (private versus public) and geographical region (urban versus rural), among others. • Multi-site studies are encouraged to increase the sample size and generalizability of findings. • Mixed-methods studies integrating quantitative and qualitative data within a single investigation are encouraged. The qualitative component can help to provide insight into effects of interventions to reduce caesarean births.

Interventions

Multifaceted (rather than single-component) interventions tailored to local determinants (barriers and facilitators) of caesarean section practices are recommended.

The certainty of evidence for caesarean section outcome was low to very low for the following interventions. Further studies are needed to address the uncertainty in the effect of these interventions.

Educational interventions targeted at women

- Education, birth preparation classes and support programmes.
- Psychoeducation by telephone.
- Prenatal education for partners of pregnant women.
- Different formats of educational interventions (decision support tools).

Interventions targeted at health-care professionals

- Audit and feedback using the Robson classification.

Interventions targeted at health organizations, facilities or systems

- Insurance reforms equalizing physician fees for vaginal births and caesarean sections.
- Collaborative midwifery-obstetrician model of care.

Although not specifically designed to reduce caesarean births, the following interventions, examined in related reviews, showed benefits in reducing caesarean births and/or increasing spontaneous vaginal births. Further studies are required to confirm the observed benefits in areas with high caesarean section rates.

- Midwife-led continuity models of care (66).
- Continuous one-to-one intrapartum support (by nurse-midwives, lay companions and doulas) (67).
- Simulation-based obstetrics and neonatal emergency training (68).
- Physical activity-based interventions (69).

No eligible studies on the following prespecified interventions were identified. Studies evaluating the effects of these interventions (preferably as components of multifaceted strategies) are needed.

- Use of opinion leaders (dissemination of information or advocacy) with support or campaigns from local or international opinion leaders (role models, leadership persons, public celebrities).
- Public dissemination of caesarean section rates (informing the public about caesarean section rates by releasing performance data (e.g. for individual physicians or hospitals) in written or electronic form).

<ul style="list-style-type: none"> • Financial strategies for health-care professionals or organizations: pay for performance (target payments), payment for 24-hour shifts (not for number of procedures), additional payment if caesarean section rate during shifts is maintained below a predefined threshold. • Goal-setting for caesarean section rates (setting a specific predetermined goal for caesarean rate). • Policies that limit financial or legal liability in the case of litigation of health-care professionals or organizations (tort reforms). • Changing the physical or sensory environment of labour and delivery (adding or altering equipment or layout; place of birth – planned home versus hospital births). • Strategies to change the organizational culture (including various components of organizational culture – e.g. shared values, behaviours, norms, traditions, sense-making – which may shape and/or contribute to the overall environment of an organization).
<p>Outcomes</p>
<ul style="list-style-type: none"> • Limited data were available from the included studies on maternal mortality and morbidity (e.g. chorioamnionitis, endometritis, wound complications), neonatal mortality and morbidity, maternal birth experience and satisfaction with care, resource use, costs and equity. Future studies should address these outcomes to facilitate the full assessment of the desirable and undesirable effects of interventions to reduce caesarean births. • Studies should address both short-term and long-term maternal outcomes (e.g. urinary incontinence, obstetric fistula, utero-vaginal prolapse) and infant outcomes (e.g. breastfeeding, childhood disability).
<p>Methodological considerations</p>
<p>Classification of caesarean section</p>
<ul style="list-style-type: none"> • The studies included in the systematic reviews measured and reported caesarean sections in different ways (overall, elective, emergency, intrapartum). This made the synthesis and interpretation of findings across studies difficult. Research to develop a unified system for classifying and reporting caesarean sections would be useful – in line with the CoRe Outcomes in Women’s and Newborn health (CROWN) initiative (103).
<p>Taxonomy of interventions to reduce caesarean sections</p>
<ul style="list-style-type: none"> • Given the broad range of interventions intended to reduce caesarean sections (targeting women, community, public, health-care professionals, health-care organizations, facilities and systems), there is a need to develop a comprehensive typology of these interventions. This would aid categorization, comparison and synthesis in systematic reviews and related research.
<p>Reporting interventions</p>
<ul style="list-style-type: none"> • Studies should fully describe components of interventions (including standard care) to help implementation and replication. Use of the template for intervention description and replication (TIDieR) checklist is recommended (104).

6. Dissemination

This guideline is available online and as a printed publication. Online versions are at the WHO Reproductive Health Library,³ which has over 5000 subscribers, and the websites of the WHO Departments of Reproductive Health and Research, and Maternal, Newborn, Child and Adolescent Health. Print versions will be distributed to WHO regional and country offices, ministries of health, WHO collaborating centres, nongovernmental partners and professional associations, using a distribution list maintained by the WHO Department of Reproductive Health and Research.

Technical meetings will be held within the WHO Departments of Reproductive Health and Research and Maternal, Newborn, Child and Adolescent Health to share the recommendations and derivative products with the teams responsible for policy and programme implementation.

The guideline was launched at the website of the WHO Department of Reproductive Health and Research.⁴ The website currently has over 3000 subscribers, including clinicians, programme managers, policy-makers and health service users from all around the world.

The executive summary and recommendations will be translated into the six United Nations languages and disseminated through the WHO regional offices and during meetings organized by or attended by staff of the WHO Department of Reproductive Health and Research. A policy brief summarizing the recommendations and implementation-related issues will be developed for policy-makers and programme managers. To increase awareness of the guideline, the recommendations will also be published as a commentary in a peer-reviewed journal, in compliance with WHO's open-access and copyright policies.

The WHO Department of Reproductive Health and Research, in collaboration with nongovernmental partners and professional associations, will support national and subnational working groups to adapt and

implement the guideline. This process will include the development or revision of existing national guidelines or protocols in line with this guideline. The GREAT Network⁵ (Guideline-driven, Research priorities, Evidence synthesis, Application of evidence, and Transfer of knowledge) strategy can be used to bring together relevant stakeholders to identify the priorities, barriers and facilitators to guideline implementation, and to support stakeholders to develop guideline implementation strategies tailored to their local contexts. This includes technical support for local guideline implementers in the development of training manuals, flow charts and quality indicators as well as participation in stakeholders' meetings.

3. Available at: <http://extranet.who.int/rhl>

4. Available at: <http://www.who.int/reproductivehealth>

5. Available at: <http://greatnetworkglobal.org>

7. Updating the guideline

An Executive Guideline Steering Group (GSG) (105) for maternal and perinatal health recommendations convenes annually to review WHO's current portfolio of maternal and perinatal health recommendations, and to prioritize new and existing questions for the development or updating of recommendations. Accordingly, the recommendations included in this guideline will be regularly reviewed and prioritized as needed by the Executive GSG.

The WHO Steering Group will continue to follow the research developments in caesarean section, particularly those relating to questions for which no evidence was found and those that are supported by evidence of very low or low certainty, where new recommendations or a change in the published recommendations may be warranted. Decisions to make updates will also be informed by data on ongoing studies identified from trial registry searches. Following the publication and dissemination of the guideline, any appropriate concern about the validity of any recommendation will be promptly communicated to the guideline implementers in addition to informing plans to update the recommendation.

All technical products developed during the process of developing this guideline – including full reports of systematic reviews, corresponding search strategies and dates of searches, Cochrane RevMan files customized for critical and important outcomes, and the basis for quality rating of outcomes within the GRADE process – have been archived in the departmental shared folder for future reference and use. Where there are concerns about the validity of a recommendation based on new evidence, the systematic review addressing the primary question will be updated. Any new questions identified following the scoping exercise at the end of five years will undergo a similar process of evidence retrieval, synthesis and grading in accordance with the WHO standards for guideline development.

In conjunction with the Steering Group, WHO will periodically assess the currency of the recommendations and the need for new or updated guidance on the topic. This will be achieved by performing a scoping exercise among technical experts, health-care professionals, and

research and service users to identify controversial or priority areas where evidence-based guidance may be needed.

The WHO Departments of Reproductive Health and Research, and Maternal, Newborn, Child and Adolescent Health welcome suggestions regarding additional questions for inclusion in future updates of this guideline. Suggestions can be emailed to: reproductivehealth@who.int.

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Annex

Annex 1: Priority guideline questions and outcomes

P= POPULATION I = INTERVENTION C = COMPARATOR O = OUTCOME(S)

KEY QUESTION	EXAMPLE OF INTERVENTIONS
A. Interventions targeted at women, the community or the public	
<p>1. Do non-clinical educational interventions (e.g. educational games, materials, meetings) (I) reduce caesarean rates (O) in groups of low-risk women (P) compared with usual care (C)?</p> <p>1.1. Does the mode or format of communication affect the effectiveness of non-clinical education (e.g. information and communication technology, written, radio, television)?</p>	<ul style="list-style-type: none"> • Booklets on vaginal birth after caesarean section (VBAC) • Educational sessions on VBAC • Computer decision-aids on VBAC • Special childbirth classes to explain the active management of labour protocol • Birth preparation classes • Antenatal classes to reduce anxiety in nulliparous women • Antenatal nurse-led relaxation and breathing classes • Special classes for women with fear of birth
<p>2. Does the use of opinion leaders (I) reduce caesarean rates (O) in groups of low-risk women (P) compared with usual care (C)?</p>	<p>Dissemination of information or advocacy with support or campaigns from local or international opinion leaders to reduce unnecessary caesarean sections:</p> <ul style="list-style-type: none"> • role models • leadership persons • public celebrities
<p>3. Does public dissemination of caesarean rates (I) reduce caesarean rates (O) in groups of low-risk women (P) compared with usual care (C)?</p>	<p>Informing the public about caesarean rates by releasing performance data in written or electronic form</p>

B. Interventions targeted at the health-care professional

<p>4. Do educational interventions targeted at health-care professionals that aim to improve adherence to evidence-based clinical practice (I) reduce caesarean rates (O) in groups of low-risk women (P) compared with usual care (C)?</p>	<ul style="list-style-type: none"> • Education of nurses to focus on childbirth in group sessions during antenatal care (a type of “training the teacher” educational intervention) • Mailed educational material on trial of labour after caesarean section for physicians • Education of staff on management of labour using evidence-based clinical practice guidelines • Education of nurses, physicians and community about labour support • Community education strategy (presentations on VBAC, fetal distress, breech and other common indications for caesarean) for health-care professionals and laypeople • Workshops for physicians on strategies to reduce caesarean, with opportunities to share experiences
<p>5. Does the implementation of a policy of second opinion for caesarean indication (I) reduce caesarean rates (O) in groups of low-risk women (P) compared with usual care (C)?</p>	<p>Requirement of second opinion by an obstetrician on caesarean decisions</p>
<p>6. Does audit and feedback and peer review (I) reduce caesarean rates (O) in groups of low-risk women (P) compared with usual care (C)?</p>	<p>Summary of health workers’ performance over a specified period, given to them in a written, electronic or verbal format. The summary may include recommendations for clinical action</p>

C. Interventions targeted at the health organization, facility or system	
7a. Do different types of nurse/ midwife staffing models reduce caesarean rates (O) in groups of low-risk women (P) compared with usual care (C)?	<ul style="list-style-type: none"> • Midwife-led delivery units • Comparisons of providing care to groups versus to individual women (e.g. group prenatal care versus individual prenatal care)
7b. Do different types of physician staffing models reduce caesarean rates (O) in groups of low-risk women (P) compared with usual care (C)?	<ul style="list-style-type: none"> • 24-hour in-house physician • 24-hour in-house anaesthetist
8. Does changing the physical or sensory environment of labour and delivery (I) reduce caesarean rates (O) in groups of low-risk women (P) compared with usual care (C)?	<ul style="list-style-type: none"> • Changes to the physical or sensory health-care environment, by adding or altering equipment or layout, providing music, art • Place of birth (planned home versus hospital births)
9. Do targeted financial strategies for health-care professionals or health-care organizations (I) reduce caesarean rates (O) in groups of low-risk women (P) compared with usual care (C)?	<ul style="list-style-type: none"> • Pay for performance (target payments) • Incentives for career • Equalize payment for caesarean and vaginal delivery or higher payment for vaginal delivery than caesarean • Payment for 24-hour shifts, not for number of procedures • Financial penalties for exceeding certain caesarean rate • Additional payment if the caesarean rate during shifts is maintained below a predefined threshold
10. Does goal setting for caesarean rates (I) reduce caesarean rates (O) in groups of low-risk women (P) compared with usual care (C)?	Setting-specific predetermined goal for caesarean rate
11. Do policies that limit financial/legal liability in case of litigation of health-care professionals or organizations (I) reduce caesarean rate (O) in groups of low-risk women (P) compared with usual care (C)?	Policies limiting financial/legal liability in case of litigation
12. Do strategies to change the organizational culture (I) reduce caesarean rates (O) in groups of low-risk women (P) compared with usual care (C)?	Strategies include various components of organizational culture (e.g. shared values, behaviours, norms, traditions, sense-making) which may shape and/or contribute to the overall environment of an organization

PRIORITY OUTCOMES

CRITICAL OUTCOMES	IMPORTANT OUTCOMES
<ul style="list-style-type: none"> • Rate of caesarean section and rate of all other modes of delivery (spontaneous vaginal birth, caesarean section before labour, emergency caesarean section, instrumental vaginal birth) • Perineal/vaginal trauma (including second-, third or fourth-degree perineal tears, obstetric anal sphincter injury, vaginal tears, episiotomy, perineal suturing, postpartum perineal pain) • Birth trauma (fractured skull, haematoma, cerebral haemorrhage, fractured clavicle, facial paralysis, brachial plexus injury, scalp injury, facial skin lesions, retinal haemorrhage) • Perinatal asphyxia (low Apgar score at 5 minutes, cord blood acidosis, needed major resuscitation (respiratory support, intubation at birth), hypoxic ischaemic encephalopathy) • Maternal birth experience (including maternal satisfaction with care, women’s mental and psychological health assessment, rating of birth experience, or as defined by study authors) 	<ul style="list-style-type: none"> • Maternal morbidity (including febrile morbidity, peripartum infection, wound complication, postpartum haemorrhage, or as defined by authors) • Long-term infant outcomes (breastfeeding, childhood disability, mother-infant bonding/ separation) • Serious maternal morbidity (including organ failure, obstetric hysterectomy, sepsis, severe obstetric haemorrhage (ante partum or postpartum), uterine rupture, admission to intensive care or as defined by trial authors) • Long-term maternal outcomes (including urinary or faecal incontinence, obstetric fistula, utero-vaginal prolapse) • Health-care resource utilization (length of hospital stay, maternal readmission/rehospitalization, readmission/rehospitalization in neonatal period [up to 28 days], cost of care, referral for higher-level care)

Annex 2: External experts and World Health Organization staff involved in the preparation of this guideline

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Annex 3: Other World Health Organization guidelines with recommendations relevant to this guideline

GUIDELINE TITLE	YEAR OF PUBLICATION	WORLD HEALTH ORGANIZATION (WHO) DEPARTMENT RESPONSIBLE	RECOMMENDATION
WHO recommendations: intrapartum care for a positive childbirth experience	2018	Reproductive Health and Research	<p>Recommendation 3 A companion of choice is recommended for all women throughout labour and childbirth. <i>(Recommended)</i></p>
WHO recommendations: intrapartum care for a positive childbirth experience. Geneva: World Health Organization; 2018 (http://apps.who.int/iris/bitstream/handle/10665/260178/9789241550215-eng.pdf , accessed 1 June 2018).			
WHO recommendations on antenatal care for a positive pregnancy experience	2016	Reproductive Health and Research; Nutrition for Health and Development; Maternal, Newborn, Child and Adolescent Health	<p>Recommendation E2 Midwife-led continuity-of-care models (in which a known midwife or small group of known midwives supports a woman throughout the antenatal, intrapartum and postnatal continuum) are recommended for pregnant women in settings with well functioning midwifery programmes. <i>(Context-specific recommendation)</i></p>
WHO recommendations on antenatal care for a positive pregnancy experience. Geneva: World Health Organization; 2016 (http://apps.who.int/iris/bitstream/handle/10665/250796/9789241549912-eng.pdf , accessed 1 June 2018).			
WHO recommendations on health promotion interventions for maternal and newborn health	2015	Maternal, Newborn, Child and Adolescent Health	<p>Box A Continuous companionship during labour and birth is recommended for improving women's satisfaction with services. <i>(Strong recommendation, moderate quality of evidence)</i></p> <p>Continuous companionship during labour and birth is recommended for improving labour outcomes. <i>(Strong recommendation, moderate quality of evidence)</i></p>
WHO recommendations on health promotion interventions for maternal and newborn health. Geneva: World Health Organization; 2015 (http://apps.who.int/iris/bitstream/handle/10665/172427/9789241508742_report_eng.pdf , accessed 1 June 2018).			

<p>WHO recommendations for augmentation of labour</p>	<p>2014</p>	<p>Reproductive Health and Research; Maternal, Newborn, Child and Adolescent Health</p>	<p>Recommendation 12 Continuous companionship during labour is recommended for improving labour outcomes. <i>(Strong recommendation, moderate quality of evidence)</i></p>
<p>WHO recommendations for augmentation of labour. Geneva: World Health Organization; 2014 (http://apps.who.int/iris/bitstream/10665/112825/1/9789241507363_eng.pdf, accessed 1 June 2018).</p>			
<p>WHO recommendations: optimizing health worker roles to improve access to key maternal and newborn health interventions through task shifting</p>	<p>2012</p>	<p>Reproductive Health and Research; Maternal, Newborn, Child and Adolescent Health; Health Policy, Development and Services</p>	<p>Recommendation 5 Guidance question: Should lay health workers provide continuous support for the woman during labour, in the presence of a skilled birth attendant? Recommendation: We recommend this option.</p>
<p>WHO recommendations: optimizing health worker roles to improve access to key maternal and newborn health interventions through task shifting. Geneva: World Health Organization; 2012 (http://apps.who.int/iris/bitstream/handle/10665/77764/9789241504843_eng.pdf, accessed 1 June 2018).</p>			

Annex 4: Summary of the declarations of interest from the Guideline Development Group members and how they were managed

NAME	EXPERTISE	POTENTIAL CONFLICT OF INTEREST DECLARED	CONFLICT OF INTEREST AND MANAGEMENT
Dr Fernando Althabe	Obstetrics and gynaecology, evidence-based medicine, clinical trials, systematic reviews, guideline development	None	Not applicable
Dr Maria Regina Torloni	Obstetrics and gynaecology, systematic reviews, evidence-based medicine, medical education	None	Not applicable
Dr Tomas Pantoja	Family medicine, health management, evidence-based medicine, systematic reviews, health policy	None	Not applicable
Professor Pisake Lumbiganon	Obstetrics and gynaecology, clinical epidemiology, systematic reviews, evidence synthesis, guideline development using Grading of Recommendations Assessment, Development and Evaluation (GRADE)	None	Not applicable
Professor Rintaro Mori	Health policy, global health, maternal and child health, perinatal medicine, clinical epidemiology	None	Not applicable
Dr Aparajita Gogoi	Consumer (women) representation, health and human rights activism, campaign and advocacy for safe motherhood	None	Not applicable
Dr Tao Duan	Obstetrics and gynaecology	None	Not applicable

Professor Alexandre Dumont	Reproductive health, maternal health in developing countries, quality of care, health equity, implementation research, global health	Research support was received from the Centre de recherche du CHU Sainte-Justine, Montreal to conduct an intervention trial on non-medically indicated caesarean section in Burkina Faso	The conflict was not considered serious enough to affect Guideline Development Group (GDG) membership or participation in the technical consultation
Professor Elizabeth Sullivan	Maternal and perinatal health, perinatal epidemiology, systematic reviews, evidence synthesis, health equity, health services research	None	Not applicable
Dr Abedini Mehrandokht	Obstetrics and gynaecology, reproductive health	None	Not applicable
Dr Petr Velebil	Maternal and perinatal health, reproductive health, health policy	None	Not applicable
Professor Hany Abdel-Aleem	Obstetrics and gynaecology, reproductive health research (Robson classification), health policy and implementation	None	Not applicable
Dr Sadequa Shahrook	Maternal, neonatal and child health, systematic reviews, health policy, health services research, global health	None	Not applicable
Dr Karen Daniels	Health policy and systems research, evidence synthesis, social activism, qualitative research, consumer (women) representation	None	Not applicable
Professor William Stones	Obstetrics and gynaecology, reproductive health, maternal and child health, health service delivery, quality improvement, implementation science, global health	Received support in kind to attend scientific meetings from the International Federation of Gynecology and Obstetrics (FIGO) in connection with role as committee chair and member	The conflict was not considered serious enough to affect GDG membership or participation in the technical consultation
Dr Guillermo Carroli	Obstetrics and gynaecology, evidence-based medicine, clinical trials, systematic reviews, guideline development	None	Not applicable

Dr Sylvia Deganus	Obstetrics and gynaecology, safe motherhood and reproductive health, health policy	None	Not applicable
Dr Ana Langer	Reproductive health, paediatrics, neonatology, health policy	None	Not applicable
Dr Barbara Levy	Obstetrics and gynaecology, health policy	None	Not applicable



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