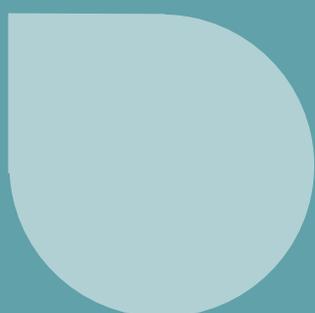
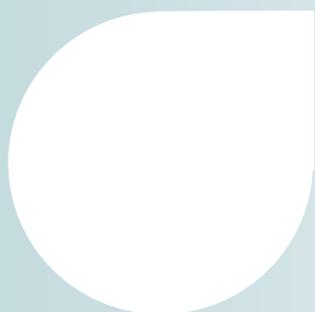


WHO recommendations on **mechanical methods** **for induction of labour**



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Acronyms and abbreviations

ANC	antenatal care
AROM	artificial rupture of membranes
DOI	declaration of interests
ERG	Evidence Review Group
ESG	Evidence Synthesis Group
EtD	Evidence-to-Decision
FIGO	International Federation of Gynecology and Obstetrics
GDG	Guideline Development Group
GRADE	Grading of Recommendations Assessment, Development and Evaluation
GSG	Guideline Steering Group
HRP	UNDP-UNFPA-UNICEF-WHO-World Bank Special Programme of Research, Development and Research Training in Human Reproduction
ICM	International Confederation of Midwives
MPH	maternal and perinatal health
MPH-GDG	WHO Maternal and Perinatal Health Guideline Development Group
NGO	nongovernmental organization
PICO	population (P), intervention (I), comparator (C), outcome (O)
QES	qualitative evidence synthesis
RCT	randomized controlled trial
RevMan	Review Manager 5 software
SDG	Sustainable Development Goal
UNDP	United Nations Development Programme
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WHO	World Health Organization

Executive summary

Introduction

In 2019, the Executive Guideline Steering Group (GSG) for the World Health Organization (WHO) maternal and perinatal health recommendations prioritized updating three then-current WHO recommendations on induction of labour at term or beyond (i.e. the timing of induction of labour), the use of mechanical methods for induction of labour and the use of outpatient settings for induction of labour.¹ This decision was based on new evidence on these subjects that had become available. The updated recommendations in this document on mechanical methods for induction of labour supersede the previous WHO recommendations on this topic in the 2011 publication *WHO recommendations for induction of labour*.

Target audience

The primary audience for these recommendations includes health professionals who are responsible for developing national and local health-care guidelines and protocols and health workers involved in the provision of care to women and their newborns during pregnancy, labour and childbirth; this includes midwives, nurses, general medical practitioners and obstetricians. The primary audience also includes managers of maternal and child health programmes, and relevant staff in ministries of health and educational and training institutions, in all settings.

Guideline development methods

Updating these recommendations was guided by standardized operating procedures in accordance with the process outlined in the WHO handbook for guideline development, second edition. The recommendations were developed and updated using the following steps: (i) identification of priority questions and outcomes; (ii) retrieval of evidence;

(iii) assessment and synthesis of evidence; (iv) formulation of the recommendations; and (v) planning for the dissemination, implementation, impact evaluation and future updating of the recommendations.

The scientific evidence supporting the recommendations was synthesized using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach. Updated systematic reviews were used to prepare the evidence profiles for the priority questions for each of the three thematic areas relating to induction of labour. For the recommendations in this guideline, the priority question was: In pregnant women at or beyond term, do mechanical methods (alone or in combination with pharmacological methods), compared with other types of induction methods or no intervention, improve maternal and perinatal outcomes? WHO convened a meeting on 21–22 October 2021 at which the Guideline Development Group (GDG) members reviewed, deliberated and achieved consensus on the strength and direction of the recommendations. Through a structured process, the GDG reviewed the balance between the desirable and undesirable effects and the overall certainty of the supporting evidence, values and preferences of stakeholders, resource requirements and cost-effectiveness, equity, acceptability and feasibility.

Recommendations

Following the review of the Evidence-to-Decision (EtD) frameworks, the GDG formulated the two updated recommendations presented in the box below. To ensure that the recommendations are correctly understood and applied in practice, guideline users should refer to the remarks, which summarize the deliberations of the GDG and specify the conditions under which the recommendations are applicable, as well as to the summary of supporting evidence available in the EtD framework (Web Annex).² In addition, implementation considerations are presented in the section following the recommendations in the full document.

¹ The updated recommendations on induction of labour at term or beyond, and outpatient settings for induction of labour are presented in separate publications, available at <https://apps.who.int/iris/bitstream/handle/10665/363138/9789240052796-eng.pdf> and <https://apps.who.int/iris/bitstream/handle/10665/363141/9789240055810-eng.pdf>, respectively.

² The Web Annex is available at: <https://apps.who.int/iris/bitstream/handle/10665/363146/9789240055803-eng.pdf>

RECOMMENDATION 1. Balloon catheter is recommended for induction of labour (low-certainty evidence).

Remarks:

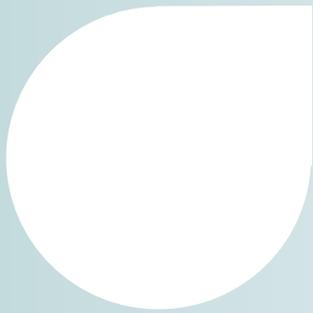
- There are multiple induction methods, both pharmacologic and mechanical.³ The choice of induction method should be discussed in the context of antenatal care, and taking into consideration the values and preferences of the woman; the potential for fetal risks; and the availability and accessibility of the different methods in the particular setting.
- As an induction method, the use of a balloon catheter for induction of labour may be particularly useful in situations where it would be beneficial to avoid uterine hyperstimulation, or when the use of prostaglandins is contraindicated.

RECOMMENDATION 2. The combination of balloon catheter plus oxytocin is recommended for induction of labour (low-certainty evidence).

Remarks:

- The GDG notes that most of the studies included in the systematic review defined the combination of balloon catheter plus oxytocin as concurrent use of balloon catheter and oxytocin, although the (sequential) use of balloon catheter followed by oxytocin is also in common use.
- In general, there is a lack of evidence on combined methods; therefore, the GDG identified several research priorities.

³ WHO recommendations for induction of labour. Geneva: World Health Organization; 2011 (<https://apps.who.int/iris/handle/10665/44531>).



Introduction

1.1 Background

The World Health Organization (WHO) envisions a world where “every pregnant woman and newborn receives quality care throughout the pregnancy, childbirth and postnatal period” (1). High-quality maternal health care for women is a necessary step towards the achievement of the health targets agreed in the Sustainable Development Goals (SDGs) and the targets and indicators of WHO’s Thirteenth General Programme of Work, particularly those for achieving universal health coverage (2, 3).

High-quality health care is essential for the prevention of morbidity and mortality in pregnancy and childbirth, and could reduce the profound inequities and inequalities in maternal and perinatal health globally (2, 4). Ensuring accessibility and acceptability of interventions to improve maternal health is consistent with international human rights laws, which include fundamental commitments of States to enable women and adolescent girls to survive pregnancy and childbirth as part of their enjoyment of sexual and reproductive health and rights, and living a life of dignity (4).

To provide good-quality care and maximize maternal and perinatal outcomes, once a woman’s pregnancy has reached term gestation, health practitioners must balance the risks and benefits of continued gestation or induction of labour. Induction of labour is only recommended when there are clear indications that continuing with a pregnancy poses greater risk to the mother or baby than the risk of inducing labour (5).

WHO general principles for performing labour induction state (5, 6):

- Wherever induction of labour is carried out, facilities should be available for assessing maternal and fetal well-being.
- Women receiving oxytocin, misoprostol or other prostaglandins should never be left unattended.
- Wherever possible, induction of labour should be carried out in facilities where caesarean sections can be performed.

Induction of labour may be initiated by pharmacologic or mechanical methods. Mechanical methods of labour induction are used to dilate the cervix, and include a range of procedures and devices. Mechanical methods have been used for induction of labour for decades, although more recently these have been replaced or supplemented by pharmacological methods (7). Despite this, mechanical methods have continued to be used in many obstetric settings as they are relatively low cost, and are not generally associated with some of the serious side-effects that may occur with the use of pharmacological methods.

1.2 Rationale and objectives

WHO has established a new process for prioritizing and updating maternal and perinatal health (MPH) recommendations, whereby an international group of independent experts – the Executive Guideline Steering Group (GSG) – oversees a systematic prioritization of MPH recommendations in most urgent need of updating. Recommendations are prioritized for updating on the basis of changes or important new uncertainties in the underlying evidence base on the effects (benefits and harms), the values placed on outcomes, resource use and cost-effectiveness, equity, acceptability and feasibility, or the factors affecting implementation.

In 2019, the Executive GSG for the WHO MPH recommendations prioritized updating the existing WHO recommendations on induction of labour at term or beyond (i.e. the timing of induction of labour), the use of mechanical methods for induction of labour, and the use of outpatient settings for induction of labour. This decision was based on new evidence on these subjects that had become available since the publication of the previous WHO recommendations in 2011 and 2018 (5, 6).

These updated recommendations were developed in accordance with the standards and procedures in the *WHO handbook for guideline development*, including the synthesis of available research evidence; use of the

Grading of Recommendations Assessment, Development and Evaluation (GRADE),⁴ application of the WHO-INTEGRATE framework; and formulation of recommendations by a Guideline Development Group (GDG) composed of international experts and stakeholders (8–11). The recommendations in this document, on the use of mechanical methods for induction of labour, thus supersede the previous 2011 WHO recommendations on this topic, as substantially more evidence became available (5).⁵ The primary aim of these recommendations is to improve the quality of care and outcomes for women whose pregnancies have reached term or gone beyond term. This document describes the evidence reviewed and the factors taken into considerations by the GDG to inform the updated recommendations on the use of mechanical methods for induction of labour.

1.3 Target audience

The primary audience includes health professionals who are responsible for developing national and local health-care guidelines and protocols and health workers involved in the provision of care to women during labour and childbirth, including midwives, nurses, general medical practitioners and obstetricians. The primary audience also includes managers of maternal and child health programmes, and relevant staff in ministries of health and educational and training institutions, in all settings.

These recommendations will also be of interest to pregnant women, as well as members of

professional societies involved in the care of pregnant women, staff of nongovernmental organizations (NGOs) concerned with promoting people-centred maternal care and implementers of maternal and perinatal health programmes.

1.4 Scope of the recommendations

These recommendations were framed using the population (P), intervention (I), comparator (C), outcome (O) (PICO) format. The priority question for these recommendations in PICO format was:

In pregnant women at or beyond term (P), do mechanical methods (alone or in combination with pharmacological methods) (I), compared with other types of induction methods or no intervention (C), improve maternal and perinatal outcomes (O)?

Problem: Perinatal risks associated with post-term pregnancy

Perspective: Clinical practice recommendation – population perspective

Population: Pregnant women at or beyond term

Intervention: Labour induction with mechanical methods (alone or in combination with pharmacological methods)

Comparator: Other types of induction methods or no intervention

Outcomes: See Annex 2

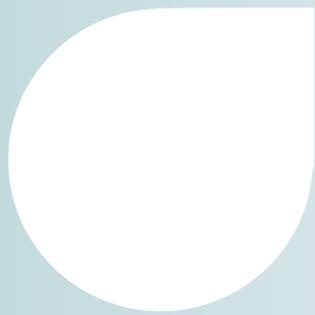
1.5 Persons affected by the recommendations

The population affected by the recommendations includes all pregnant women.⁶

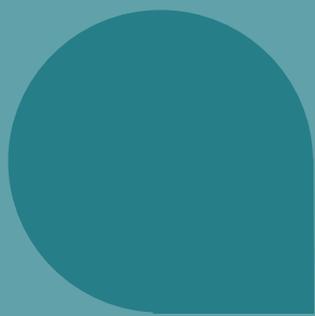
⁴ Further information is available at: <http://www.gradeworkinggroup.org/>.

⁵ The updated recommendations on induction of labour at term or beyond, and outpatient settings for induction of labour are presented in separate publications, available at <https://apps.who.int/iris/bitstream/handle/10665/363138/9789240052796-eng.pdf> and <https://apps.who.int/iris/bitstream/handle/10665/363141/9789240055810-eng.pdf>, respectively.

⁶ Throughout this guideline, to be concise and to facilitate readability, the term “woman” is used to refer to pregnant women and others/ gender-diverse people who can get pregnant. While a majority of persons who are or can get pregnant are cisgender women, who were born and identify as female, transgender men and other gender-diverse people may have the reproductive capacity to become pregnant.



Methods



The recommendations were developed using standardized operating procedures in accordance with the process described in the *WHO handbook for guideline development, second edition (12)*. In summary, the process included: (i) identification of the priority question and critical outcomes; (ii) retrieval of evidence; (iii) assessment and synthesis of evidence; (iv) formulation of the recommendations; and (v) planning for the dissemination, implementation, impact evaluation and updating of the recommendations.

Following the “living guideline” approach adopted by the WHO Maternal and Perinatal Health (MPH) Unit, the full complement of recommendations and the evidence base underlying those recommendations are reviewed at regular intervals by the WHO MPH Executive Guideline Steering Group (GSG) (13).

In 2019, the GSG identified the recommendations on the use of mechanical methods for the induction of labour as high priority for updating. This decision was made in response to new evidence from many more women than the evidence base for the 2011 guideline, allowing for more nuanced analyses of mechanical methods. Six main groups of experts and stakeholders were involved in this process, with their specific roles as described below.

2.1 Contributors to the guideline

2.1.1 Executive Guideline Steering Group (GSG)

The Executive GSG is an independent panel of 14 external experts and relevant stakeholders from the six WHO regions: the African Region, the Region of the Americas, the Eastern Mediterranean Region, the European Region, the South-East Asia Region and the Western Pacific Region. The Executive GSG advises WHO on the prioritization of new and existing PICO questions in maternal and perinatal health for development or updating of recommendations.

2.1.2 WHO Steering Group

The WHO Steering Group, comprising WHO staff members from the Department of Sexual

and Reproductive Health and Research and the Department of Maternal, Newborn, Child and Adolescent Health and Ageing, managed the process of updating the recommendations. The WHO Steering Group drafted the key recommendation questions in PICO format, engaged the systematic review teams and guideline methodologists (i.e. the Evidence Synthesis Group [ESG]), as well as the members of the GDG and the External Review Group (ERG) (see below). In addition, the WHO Steering Group supervised the retrieval and syntheses of evidence, organized the GDG meetings, drafted and finalized the guideline document, and will also manage the guideline dissemination, implementation and impact assessment. The members of the WHO Steering Group are listed in Annex 1.

2.1.3 Guideline Development Group (GDG)

The WHO Steering Group identified a pool of approximately 50 experts and stakeholders from the six WHO regions to constitute the WHO Maternal and Perinatal Health Guideline Development Group (MPH-GDG). This pool consists of a diverse group of experts skilled in the critical appraisal of research evidence; implementation of evidence-informed recommendations; guideline development methods; and clinical practice, policy and programmes relating to maternal and perinatal health; it also includes consumer representatives. The members of the MPH-GDG are identified in a way that ensures geographic representation and gender balance, and that there are no perceived or real conflicts of interest. The members' expertise cuts across thematic areas within maternal and perinatal health.

From the MPH-GDG pool, 16 external experts and relevant stakeholders were invited to participate as members of the GDG for updating the recommendations on all three thematic areas for induction of labour (timing, mechanical methods, outpatient settings). Those selected from the MPH-GDG pool of experts were a diverse group with expertise in perinatal research; guideline development methods; gender, equity and rights; clinical practice, policy and programmes; and included consumer

representatives relating to all three of the thematic areas.

The GDG members were also selected in a manner that ensured geographic representation and gender balance and that there were no significant conflicts of interest. The GDG appraised the evidence that was used to inform the recommendations, advised on the interpretation of this evidence, formulated the final recommendations based on the drafts prepared by the WHO Steering Group, and reviewed and reached a unanimous consensus on the recommendations in the final document. The members of the GDG are listed in Annex 1.

2.1.4 Evidence Synthesis Group (ESG)

WHO convened an ESG composed of guideline methodologists and systematic review teams to conduct or update systematic reviews, appraise the evidence and develop the Evidence-to-Decision (EtD) frameworks. Systematic reviews on the effects of the interventions for each of the three thematic areas (timing, mechanical methods and outpatient settings for induction of labour) were updated, supported by the Cochrane Pregnancy and Childbirth Group. A literature review for qualitative evidence on the values, preferences, costs, feasibility and impact on equity was undertaken by Cochrane Australia.⁷ The WHO Steering Group reviewed and provided input into the reviews and worked closely with the review authors and the guideline methodologists to appraise the evidence. Evidence on effectiveness was appraised using the GRADE methodology. Representatives of the Cochrane Pregnancy and Childbirth Group and the guideline methodologists attended the GDG meeting to provide an overview of the available evidence and GRADE tables, and to respond to technical queries from the GDG members. Evidence

on the qualitative aspects of the intervention was evaluated using the criteria of the WHO-INTEGRATE framework (11). The authors of the literature review on qualitative evidence attended the GDG meeting to provide an overview of the qualitative evidence and to respond to queries from the GDG. The members of the ESG are listed in Annex 1.

2.1.5 External partners and observers

External partners and observers included representatives from the United States Agency for International Development (USAID), the International Confederation of Midwives (ICM) and the International Federation of Gynecology and Obstetrics (FIGO). These organizations, with their history of collaboration with WHO in the dissemination and implementation of maternal and perinatal health guidelines, were identified as potential implementers of the recommendations. The list of observers who participated in the GDG meetings is included in Annex 1.

2.1.6 External Review Group (ERG)

The ERG included four technical experts with interests and expertise in the management of labour. The group was geographically diverse and gender balanced, and the members reported no significant conflicts of interest. The experts reviewed the final documents to identify any factual errors and commented on the clarity of language, contextual issues and implications for implementation. They ensured that the decision-making processes had considered and incorporated contextual values and the preferences of persons affected by the recommendations, health professionals, health practitioners and policy-makers. It was not within the remit of this group to change the recommendations that were formulated by the GDG. Members of the ERG are listed in Annex 1.

⁷ Murano M, Chou D, Costa do Nascimento ML, Turner T. Using the WHO-INTEGRATE evidence to decision framework to develop induction of labour recommendations. *Health Res Policy Syst.* 2022 (in press).

2.2 Identification of priority questions and outcomes

For the thematic area addressed in this guideline – mechanical methods for induction of labour – the priority outcomes were aligned with those on this topic from the 2011 *WHO recommendations for induction of labour* (5). These outcomes were initially identified through a search of scientific databases for relevant, published systematic reviews and a prioritization of outcomes by the GDG for the guideline. In recognition of the importance of women’s experiences of care, two additional outcomes – maternal well-being and maternal satisfaction – were included in this update to ensure that evidence synthesis and recommendation decision-making by the GDG were driven by outcomes that are important to women and to ensure that the final set of recommendations would be woman-centred. All the outcomes were included in the scope of this document for evidence searching, retrieval, synthesis, grading and formulation of the recommendations. The list of priority outcomes is provided in Annex 2.

2.3 Evidence identification and retrieval

Evidence to support this update was derived from several sources by the ESG working in collaboration with the WHO Steering Group.

Evidence on the effectiveness and safety of mechanical methods for induction of labour is from a Cochrane systematic review updated in 2019 (14). The updated review includes 113 trials, with data on relevant outcomes from 105 studies (with a total of 22 373 women), as compared with the previous review which included 71 studies with 9722 women. The trials were carried out in hospital settings across the world (including in low- and middle-income countries), including: Australia, Brazil, Canada, Czech Republic, Denmark, Egypt, Finland, France, India, Islamic Republic of Iran, Israel, Italy, Jordan, Netherlands, Nigeria, Norway, Pakistan, the Russian Federation, Rwanda, Singapore, Sri Lanka, South Africa, Sweden, Tunisia, Turkey, the United Kingdom of Great Britain and Northern Ireland, and the United States of

America. The earliest trial was published in 1981, although the majority were published after 2000. Most studies included both nulliparous and multiparous women, and most studies excluded those with a history of caesarean section. The majority of studies only recruited women at term (gestational age 37 weeks or more).

The review examined four broad types of interventions:

- balloon catheter versus other interventions (other mechanical or pharmacologic, or mixed);
- laminaria tent versus other interventions;
- extra-amniotic infusion versus other interventions; and
- any mechanical method combined with another (non-mechanical) intervention versus other interventions.

The updated review includes a total of 22 different comparisons, 18 of which are of relevance to this guideline recommendation. The update excludes studies comparing mechanical methods with placebo or no treatment, and comparisons with misoprostol are limited to only low-dose misoprostol (14).

This systematic review was the primary source of evidence of effectiveness for these recommendations. Randomized controlled trials (RCTs) relevant to the key questions were screened by the review authors and data on their outcomes and comparisons were entered into Review Manager 5 (RevMan) software. The RevMan file was retrieved from the Cochrane Pregnancy and Childbirth Group and customized to reflect the key comparisons and outcomes (those that were not relevant to the recommendations were excluded). The RevMan file was then exported to GRADE profiler software (GRADEpro) and GRADE criteria were used to critically appraise the retrieved scientific evidence (8). Finally, evidence profiles (in the form of GRADE Summary of Findings tables) were prepared for comparisons of interest, including the assessment and judgements of each outcome and the estimated risks (see Web Annex).

2.3.1 Evidence on values, resource use and cost-effectiveness, equity, acceptability and feasibility

Evidence on values, acceptability and feasibility were obtained by combining the findings of a qualitative evidence synthesis (QES) with additional primary papers.⁸ The systematic review provided information on women's and providers' perspectives and experiences relating to pregnancy and childbirth. The evidence on resource use and cost-effectiveness was very limited. As the review was based on a small number of primary studies involving trials conducted in high-income settings, the conclusions should be viewed as extremely tentative. No direct evidence on equity was identified; therefore, the GDG based their decisions on the general findings of the 2015 WHO report on inequality (15).

2.4 Certainty assessment and grading of the evidence

The GRADE approach (8–10) was used to assess the certainty of the evidence on effects. The certainty for each outcome was rated as “high”, “moderate”, “low” or “very low” based on a set of established criteria (see Box 2.1). The final rating was dependent on the factors briefly described below.

Study design limitations: The risk of bias was first examined at the level of each individual study and then across the studies contributing to the each outcome. For RCTs, certainty was first rated as “high” and then downgraded by one (“moderate”) or two (“low”) levels, depending on the minimum criteria met by the majority of the studies contributing to each outcome.

Inconsistency of the results: The consistency across the results for a given outcome was assessed by exploring the magnitude of differences in the direction and size of effects observed in different studies. The certainty of evidence was not downgraded when the directions of the findings were similar and confidence limits overlapped, whereas it was downgraded when the results were in different directions and confidence limits showed minimal or no overlap.

Indirectness: The certainty of evidence was downgraded when there were serious or very serious concerns regarding the directness of the evidence – that is, whether there were important differences between the research reported and the context for which the recommendation was being prepared. Such differences were related, for instance, to populations, interventions, comparisons or outcomes of interest.

BOX 2.1. Certainty of evidence assessments are defined according to the GRADE approach

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect.

Very low certainty: We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.

⁸ Murano M, Chou D, Costa do Nascimento ML, Turner T. Using the WHO-INTEGRATE evidence to decision framework to develop induction of labour recommendations. Health Res Policy Syst. 2022 (in press).

Imprecision: Imprecision refers to the degree of uncertainty around the estimate of the effect. As this is often a function of sample size and number of events, studies with relatively few participants or events – and thus wide confidence intervals around effect estimates – were downgraded for imprecision.

Publication bias: The certainty rating could also be affected by perceived or statistical evidence of bias to underestimate or overestimate the effect of an intervention as a result of selective publication based on study results. Downgrading evidence by one level was considered where there was strong suspicion of publication bias.

The findings of the qualitative reviews (qualitative evidence) were appraised for eligibility and quality (rather than certainty) using a two-step process, informed by the Enhancing transparency in reporting the synthesis of qualitative research (ENTREQ) statement (16). As for certainty, quality was also rated as “high”, “moderate”, “low” or “very low”. Findings from individual cost-effectiveness studies were reported narratively (17–19).

2.5 Formulation of the recommendations

The WHO Steering Group supervised and finalized the preparation of GRADE Summary of Findings tables and narrative evidence summaries in collaboration with the ESG using the GRADE EtD framework (see Web Annex). EtD frameworks include explicit and systematic consideration of evidence on prioritized interventions in terms of specified domains: effects, values, resources, equity, acceptability and feasibility. For the priority questions, judgement was made on the impact of the intervention on each domain to inform and guide the decision-making process. Using the EtD framework template, the WHO Steering Group and ESG created summary documents for each priority question covering evidence on each domain, as follows.

- **Effects:** The evidence on the priority outcomes was summarized in this domain to answer the questions: “What are the

desirable and undesirable effects of the intervention?” and “What is the certainty of the evidence on effects?” Where desirable effects (benefits) clearly outweighed undesirable effects (harms) for outcomes that are highly valued by women, or vice versa, there was a greater likelihood of a clear judgement in favour of or against the intervention, respectively. Uncertainty about the net benefits or harms, or small net benefits, usually led to a judgement that did not favour the intervention or the comparator. The higher the certainty of the evidence of 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 led to a recommendation against the intervention. Where the intervention showed evidence of potential harm and was also found to have evidence of important benefits, depending on the level of certainty and the likely impact of the harm, such evidence of potential harm was more likely to result in a context-specific recommendation, with the context explicitly stated within the recommendation.

- **Values:** This domain relates to the relative importance assigned to the outcomes associated with the intervention by those affected, how such importance varies within and across settings, and whether this importance is surrounded by any uncertainty. The question asked was: “Is there important uncertainty or variability in how much women value the main outcomes associated with the intervention?” When the intervention resulted in benefits or outcomes that most women consistently value (regardless of setting), this was more likely to lead to a judgement in favour of the intervention. This domain, together with the “effects” domain (see above), informed the “balance of effects” judgement.
- **Resources:** For this domain, the questions asked were: “What are the resources associated with the intervention?” and “Is the intervention cost-effective?” A judgement in favour of or against the intervention was

likely where the resource implications were clearly advantageous or disadvantageous, respectively.

- **Equity:** This domain encompasses evidence or considerations as to whether or not the intervention would reduce or increase health inequities. Therefore, this domain addressed the question: “What is the anticipated impact of the intervention on equity?” The intervention was likely to be recommended if its proven (or anticipated) effects reduce (or could reduce) health inequities among different groups of women and their families.
- **Acceptability:** For this domain, the questions were: “Is the intervention acceptable to women and health workers?” and “Is the intervention in accordance with universal human rights standards and principles?” The lower the acceptability, the lower the likelihood of a judgement in favour of the intervention.
- **Feasibility:** The feasibility of implementing this intervention depends on factors such as the resources, infrastructure and training requirements, and the perceptions of health workers responsible for administering it. The question addressed was: “Is it feasible for the relevant stakeholders to implement the intervention?” Where major barriers were identified, it was less likely that a judgement would be made in favour of the intervention.

For each of the above domains, additional evidence of potential harms or unintended consequences are described in the EtD framework (see the Additional considerations subsections in Web Annex). Such considerations were derived from studies that might not have directly addressed the priority question but provided pertinent information in the absence of direct evidence. These were extracted from single studies, systematic reviews or other relevant sources.

The WHO Steering Group provided the EtD framework (including evidence summaries, GRADE Summary of Findings tables and other documents related to the recommendations) to GDG members two weeks in advance of the

GDG meeting. The GDG members were asked to review and provide comments electronically on the documents before the virtual GDG meeting. During the GDG meeting on 21–22 October 2021, the GDG members collectively reviewed the EtD framework and any comments received through preliminary feedback, and formulated the recommendations. The purpose of the meeting was to reach consensus on the recommendations and the specific context, based on explicit consideration of the range of evidence presented in the EtD framework and the judgement of the GDG members. The GDG members were collectively required to select one of the following categories for the recommendations.

- **Recommended:** This category indicates that the intervention should be implemented.
- **Not recommended:** This category indicates that the intervention should not be implemented.
- **Recommended only in specific contexts (“context-specific recommendation”):** This category indicates that the intervention is applicable only to the condition, setting or population specified in the recommendation and should only be implemented in these contexts.
- **Recommended only in the context of rigorous research (“research-context recommendation”):** This category indicates that there are important uncertainties about the intervention. With this category of recommendation, implementation can still be undertaken on a large scale, provided it takes the form of research that addresses unanswered questions and uncertainties related both to effectiveness of the intervention or option, and its acceptability and feasibility.

2.6 Management of declarations and conflicts of interests

WHO has a robust process for management of conflicts of interests, which requires that experts serving in an advisory role disclose any circumstances that could give rise to actual

or ostensible conflicts of interest (financial or non-financial). According to the WHO guidelines for declaration of interests (DOI), all experts must declare their interests prior to participation in WHO guideline development processes and meetings (20). All potential GDG members were therefore required to complete a standard WHO DOI form, which was reviewed by the WHO Steering Group before confirming the experts' invitations to participate. Two GDG members declared interests (prior involvement in research support), and the WHO Steering Group subsequently applied the criteria as outlined in the WHO handbook for guideline development (12) and determined that these declared interests were not serious enough to affect their objective judgement in the process of developing the guideline and recommendations. These two experts were only required to openly declare such conflicts of interest at the beginning of the GDG meeting, and no further actions were taken. All findings from the DOI statements received were managed in accordance with the WHO procedures to ensure the work of WHO and the contribution of its experts is objective and independent. Annex 3 shows a summary of the DOI statements and how conflicts of interest declared by invited experts were managed by the WHO Steering Group.

2.7 Decision-making during the GDG meetings

During the meeting, the GDG reviewed and discussed the evidence summary and sought clarification as needed. In addition to evaluating the balance between the desirable and undesirable effects of the intervention and the overall certainty of the evidence, the GDG applied additional criteria based on the GRADE EtD framework to determine the direction and strength of the recommendations. These criteria included stakeholders' values, resource implications, equity, acceptability and feasibility.

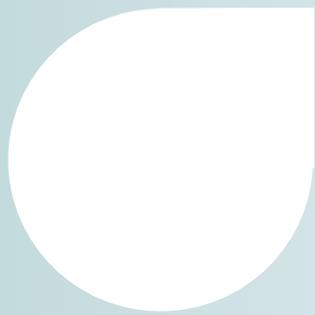
Considerations were supported by evidence from a literature search where available, or were based on the experience and opinions of the GDG members. EtD tables were used to describe and synthesize these considerations (see Web Annex).

Decisions were made based on consensus, defined as the agreement by three quarters or more of the participants. None of the GDG members expressed opposition to the recommendations.

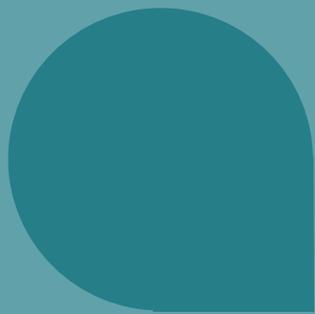
2.8 Document review and preparation

Prior to the online GDG meeting, the WHO Steering Group prepared a draft version of the GRADE evidence profiles, the evidence summary and other relevant documents, and made these available to the GDG members in advance, as described above. During the GDG meeting, these documents were modified in line with the participants' deliberations and remarks. Following the meeting, members of the WHO Steering Group drafted a full guideline document to accurately reflect the deliberations and decisions of the participants. The draft document was sent electronically to the GDG and the ERG for their final review and approval.

Following review and approval by GDG members, the final document was sent for peer review to four external independent experts (comprising the ERG) who were not involved in the GDG. The ERG members were tasked with identifying any factual errors, any lack of clarity, contextual issues and implications for implementation, and were also asked to determine if the recommendations made were aligned with stakeholder interests. The WHO Steering Group evaluated the inputs of the peer reviewers and any modifications made by the WHO Steering Group to the document at that time consisted only of the correction of factual errors along with the editing process to improve language, style and address any lack of clarity.



Recommendations and supporting evidence



This section presents the two updated recommendations on the timing of induction of labour that were formulated by the GDG, followed by the corresponding narrative summary of the evidence. To ensure that the

recommendations are correctly understood and appropriately implemented in practice, additional remarks reflecting the summary of the discussion by the GDG are included with the recommendations.

RECOMMENDATION 1. Balloon catheter is recommended for induction of labour (*low-certainty evidence*).

Remarks:

- There are multiple induction methods, both pharmacologic and mechanical (5). The choice of induction method should be discussed in the context of antenatal care, and taking into consideration the values and preferences of the woman; the potential for fetal risks; and the availability and accessibility of the different methods in the particular setting.
- As an induction method, the use of a balloon catheter for induction of labour may be particularly useful in situations where it would be beneficial to avoid uterine hyperstimulation, or when the use of prostaglandins is contraindicated.

RECOMMENDATION 2. The combination of balloon catheter plus oxytocin is recommended for induction of labour (*low-certainty evidence*).

Remarks:

- The GDG notes that most of the studies included in the systematic review defined the combination of balloon catheter plus oxytocin as concurrent use of balloon catheter and oxytocin, although the (sequential) use of balloon catheter followed by oxytocin is also in common use.
- In general, there is a lack of evidence on combined methods; therefore, the GDG identified several research priorities (see section 5).

3.1 Summary of the evidence

• Effects (desirable and undesirable)

The evidence on the effectiveness and safety of mechanical methods for the induction of labour was derived from a Cochrane systematic review updated in 2019 (14). The review included 113 trials, with data on relevant outcomes from 105 studies (with a total of 22 373 women). The evidence is summarized in GRADE tables presented as part of the EtD framework in the Web Annex.

The review examined four broad types of interventions:

- balloon catheter versus other interventions (other mechanical or pharmacologic, or mixed);

- laminaria tent versus other interventions;
- extra-amniotic infusion versus other interventions; and
- any mechanical method combined with another (non-mechanical) intervention versus other interventions.

Of the 22 comparisons made, 18 of them were relevant to the PICO for this guideline and were presented to the GDG.

Values and preferences

Considering the risks and benefits of induction using mechanical methods, the GDG considers it unlikely that there would be important variability in how women value the outcomes of interest (see Annex 2). During induction of labour women value the ability to move about

freely and to have privacy and a sense of security. This allows them to feel more in control and to maintain their dignity. Feeling secure was enhanced by having a support person present, systems which enabled this support to continue from induction to delivery, and by having rapid access to the clinical expertise and equipment that might be needed.⁹

Resource use and costs

The resources required to implement recommendations on induction of labour are primarily the costs of training skilled health personnel. Evidence for resource use and costs is very limited. The GDG was presented with the findings from two trial-based primary economic studies which were conducted in high-income settings (17, 19) and one model-based economic study (21). Together, these papers described aspects of cost, resource use, budget impact and value for money, when considering induction of labour.

Equity

The equity domain was discussed at length by the GDG members as they formulated these recommendations. It is likely that women from low- and middle-income settings, or from disadvantaged groups within a high-income setting, may also experience greater barriers to participation in health-care decision-making about labour induction than indicated in the qualitative evidence synthesis (QES) findings (16).⁹

Acceptability

The evidence for acceptability of methods for induction of labour was derived from a synthesis of a published QES and additional primary studies (22–28). When there is a recognized need to avert harm to the baby, labour induction is widely acceptable to women. Acceptability varies according to women's trust in their health-care provider, their perception of birth as a natural process, their need for

certainty, and the duration of waiting. There is limited evidence available on the acceptability of labour induction to clinicians. Health practitioners report lack of clear evidence on the risks and benefits of labour induction to guide their decision-making. They were particularly concerned about neonatal safety and the potential for medical litigation, and were uncertain about the optimal timing for induction and the risks of caesarean birth following induction (29).

Feasibility

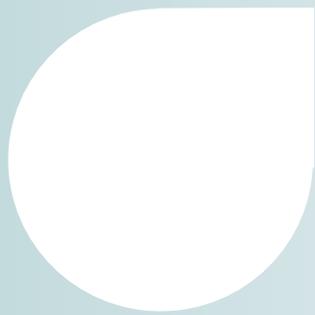
The feasibility of implementing these recommendations was considered by the GDG. WHO general principles for performing labour induction state (5, 6):

- Wherever induction of labour is carried out, facilities should be available for assessing maternal and fetal well-being.
- Women receiving oxytocin, misoprostol or other prostaglandins should never be left unattended.
- Wherever possible, induction of labour should be carried out in facilities where caesarean sections can be performed.

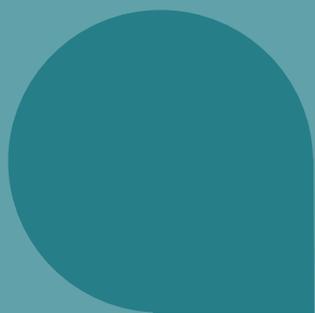
Performing induction of labour safely requires availability of appropriate medicines or mechanical devices, monitoring equipment and access to facilities for safe caesarean section. Inconsistent supply or lack of medicines, medical equipment and appropriate facilities may be an issue in some settings.

Note: The EtD table – which summarizes the balance between the desirable and undesirable effects and the overall certainty of the supporting evidence, values and preferences of stakeholders, resource requirements, cost-effectiveness, equity, acceptability and feasibility that were considered by the GDG in determining the strength and direction of the recommendations – is presented in the EtD framework (Web Annex).

⁹ Murano M, Chou D, Costa do Nascimento ML, Turner T. Using the WHO-INTEGRATE evidence to decision framework to develop induction of labour recommendations. *Health Res Policy Syst.* 2022 (in press).



Dissemination, adaptation and implementation of the recommendations



The dissemination and implementation of these recommendations are to be considered by all stakeholders involved in the provision of care for pregnant women at the international, national and local levels. There is a vital need to increase women's access to maternal health care at the community level and to strengthen the capacity at all levels of health-care facilities to ensure they can provide high-quality services and information to all women giving birth. It is therefore crucial that these recommendations be translated into care packages and programmes at country, health-care facility and community levels, where appropriate.

4.1 Dissemination

The recommendations will be disseminated through WHO regional and country offices, WHO advisory groups, ministries of health, country and regional technical advisory groups, professional organizations, WHO collaborating centres, other United Nations agencies and NGOs, among others. These recommendations will also be available on the WHO website. Updated recommendations are also routinely disseminated during meetings or scientific conferences attended by WHO maternal and perinatal staff.

This document will be translated into the six United Nations languages and disseminated through the WHO regional offices. Technical assistance will be provided to any WHO regional office willing to translate the full recommendations into any of these languages.

4.2 Adaptation

National and subnational subgroups may be established to adapt and implement these recommendations based on an existing strategy. This process may include the development or revision of existing national guidelines or protocols based on the updated recommendations.

The successful introduction of evidence-based policies (relating to the updated recommendations) depends on well planned

and participatory consensus-driven processes of adaptation and implementation. These processes may include the development or revision of existing national or local guidelines and protocols, often supported by ministries of health, United Nations agencies, local professional societies and other relevant leadership groups. An enabling environment should be created for the use of these recommendations, including changes in the behaviour of health practitioners to enable the use of evidence-based practices.

In the context of humanitarian emergencies, the adaptation of recommendations should consider integration and alignment with other response strategies. Additional considerations to the unique needs of women in emergency settings, including their values and preferences, should be taken into account. Context-specific tools and toolkits may be required in addition to standard tools to support the implementation of these updated recommendations by stakeholders in the context of humanitarian emergencies.

4.3 Implementation considerations

The successful introduction of these recommendations into national programmes and health services depends on well planned and participatory consensus-driven processes of adaptation and implementation. The adaptation and implementation processes may include the development or revision of existing national guidelines or protocols. Recommendations should be adapted into documents and tools that are appropriate for different locations and contexts, to meet the specific needs of each country and health service. Modifications to the recommendations, where necessary, should be justified in an explicit and transparent manner.

An enabling environment should be created for the implementation of these recommendations, including education to support behaviour change among skilled health personnel providing care during childbirth (30), to facilitate the use of evidence-based practices.

To implement these recommendations, the following should be considered:

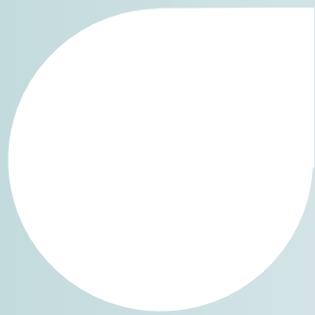
- To ensure accurate assessment of gestational age prior to induction, clear policies concerning the provision of early ultrasounds are required. Health workers in antenatal care (ANC) settings require training and supportive supervision on how to perform dating ultrasounds.
- Health professionals will require training to counsel women on the benefits and side-effects of different methods for induction of labour. Women should be adequately counselled and engaged in shared decision-making when considering the indications for induction of labour and the methods for induction.

Health worker shortages in low- and middle-income country settings may mean that staff are required to attend to much higher numbers of women on the labour ward than in other settings. Providing the necessary level of support, assessment and monitoring in these settings may be challenging and the impact may be reduced capacity among health

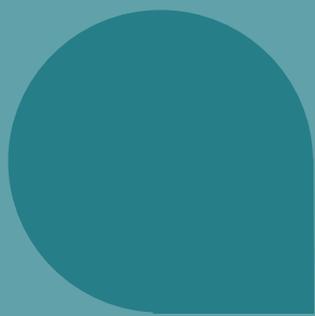
workers to monitor as frequently as needed or to respond quickly to emergencies (31).

- A higher number of induction deliveries are attended by medical doctors than non-induction deliveries (32). This has implications for the distribution and productivity of medical doctors, particularly in under-resourced settings.
- Performing induction of labour safely requires availability of appropriate medicines and/or mechanical devices, monitoring equipment and access to facilities for safe caesarean section. Inconsistent supply or lack of medicines and medical equipment and availability of appropriate facilities may be an issue in some settings.

In order to ensure that implementation of labour induction does not reinforce existing inequities or inequalities, the system should support all women (i) to have access to full and timely information; (ii) to use their own social networks to assist them to understand the information if needed; and (iii) to ensure a woman's health-care provider is aware of her needs, values and preferences (32).



Research priorities



The GDG noted the following evidence and research gaps.

- It is uncertain if any method of induction has comparative advantages. Further analysis – such as a network meta-analysis – may provide additional insights in synthesizing the available evidence.
- Additional research into different combinations of methods is needed, such as combinations with multiple Foley bulbs, the concurrent or sequential use of oxytocin. Future research projects should carefully document whether the actual use of oxytocin is concurrent or sequential.

The GDG acknowledges that there is planned or ongoing research relevant to some of the identified research priorities. Since there is no certainty that the planned or ongoing research will give conclusive results, the research topics

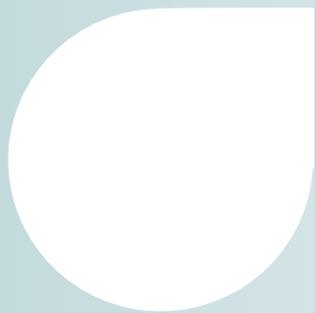
below were identified as research priorities. Potential PICO questions are suggested below.

Problem: Perinatal risks associated with post-term pregnancy

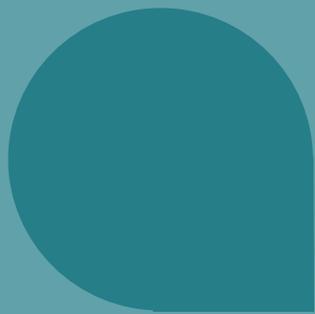
Perspective: Clinical practice recommendation – population perspective

PICO question: In pregnant women at or beyond term (P), does labour induction with combinations of mechanical methods (I), compared with labour induction with other combinations of mechanical methods, with or without pharmacologic agents (C), improve maternal and perinatal outcomes (O)? (See Annex 2 for outcomes.)

PICO question: In pregnant women at or beyond term (P), does labour induction with concurrent use of mechanical methods and oxytocin (I), compared with labour induction with mechanical methods followed by oxytocin (sequential use) (C), improve maternal and perinatal outcomes (O)? (See Annex 2 for outcomes.)



Applicability issues



6.1 Anticipated impact on the organization of care and resources

Implementing these evidence-based recommendations requires health workers to identify and provide counselling to those women with pregnancies that have reached or gone beyond term. Health worker shortages may also reduce the feasibility of performing ANC ultrasound scans and other risk assessments (15, 31). The GDG noted that updating training curricula and providing training on accurate gestational age assessment would increase the impact and facilitate implementation of these recommendations.

A number of factors may hinder the effective implementation and scale-up of these recommendations. These factors may be related to the behaviours of patients (women or families) or health workers, and to the organization of care or health-service delivery.

As part of efforts to implement these recommendations, health system stakeholders should consider the need to ensure (33, 34):

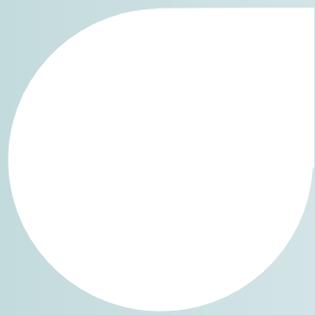
- one scan before 24 weeks of gestation for accurate estimation of gestational age;
- post-term pregnancy risk assessment; and
- schedule planning that allows for adequate time to provide information and counselling in ANC clinics.

6.2 Monitoring and evaluating guideline implementation

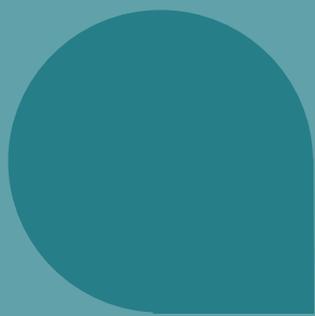
The implementation and impact of these recommendations will be monitored at the health service, country and regional levels, as part of broader efforts to monitor and improve the quality of maternal and newborn care. The WHO document *Standards for improving quality of maternal and newborn care in health facilities* (35) provides a list of prioritized input, output and outcome measures that can be used to define quality-of-care criteria and indicators, and that should be aligned with locally agreed targets. In collaboration with the monitoring and evaluation teams of the WHO Department of Sexual and Reproductive Health and Research and the WHO Department of Maternal, Newborn, Child and Adolescent Health and Ageing, data on country- and regional-level implementation of the recommendations can be collected and evaluated in the short-to-medium term to assess their impact on national policies of individual WHO Member States.

Information on recommended indicators can also be obtained at the local level by interrupted time series or clinical audits. In this context, the GDG suggests the following indicators be considered.

- The proportion of pregnant women who have an ultrasound prior to 24 weeks of gestation.
- The proportion of pregnant women who have a documented indication for undergoing induction of labour.



Updating the recommendations



The Executive GSG convenes annually to review WHO's current portfolio of maternal and perinatal health recommendations and to help WHO prioritize new and existing questions for recommendation development and updating. Accordingly, these recommendations will be reviewed along with other recommendations for prioritization by the Executive GSG. If new evidence that could potentially impact the current evidence base is identified, the recommendations may be updated. If no new reports or information are identified, the recommendations may be revalidated.

Following publication and dissemination of the updated recommendations, any concerns about the validity of the recommendations will be promptly communicated to the guideline implementers, along with information about plans to update the recommendations.

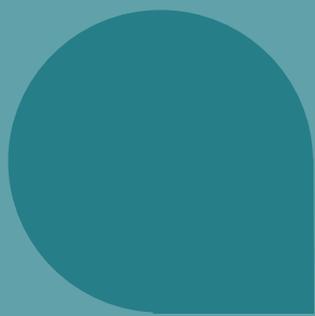
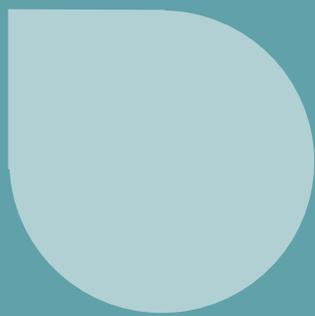
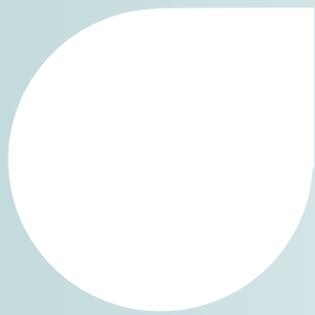
WHO welcomes suggestions regarding additional questions for future inclusion in the process of updating the recommendations. Please email your suggestions to srhmph@who.int.

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Annex 2. Priority outcomes used in decision-making

Priority outcomes (0):

Critical outcomes:¹⁰

Maternal

- Vaginal delivery not achieved within 24 hours
- Caesarean section
- Uterine hyperstimulation with fetal heart rate changes
- Postpartum haemorrhage
- Uterine rupture
- Severe maternal morbidity or death.

Fetal/neonatal

- Apgar score less than 7 at 5 minutes
- Admission to a neonatal intensive care unit
- Neonatal encephalopathy
- Severe neonatal morbidity
- Disability in childhood
- Perinatal death.

Important outcomes:

Maternal

- Cervix unfavourable or unchanged after 24 hours
- Oxytocin augmentation
- Epidural rate
- Uterine hyperstimulation without fetal heart rate changes
- Instrumental vaginal birth
- Meconium-stained amniotic fluid
- Maternal side-effects (all)
- Nausea
- Vomiting
- Diarrhoea
- Maternal well-being
- Women not satisfied with the care related to induction of labour (maternal satisfaction)
- Caregiver not satisfied with the care related to induction of labour.

¹⁰ These outcomes reflect the outcomes used in the 2011 *WHO recommendations for induction of labour* (available at: <https://apps.who.int/iris/handle/10665/44531>). An outcome ranked as 7 or more was considered “critical”, and an outcome ranked 4–6 was considered “important” (on a scale of 1 to 9, from not important to critical). The outcomes “maternal well-being” and “maternal satisfaction” have been added as part of this update.

Annex 3. Summary and management of declared interests from GDG members and reviewers

Name	Expertise contributed to guideline development process	Declared interest	Management of conflict of interest
Edgardo Abalos	Content expert and end-user	None	Not applicable
Niveen Abu Rmeileh	Content expert and end-user	None	Not applicable
Ebunoluwa Adejuyigbe	Content expert and end-user	None	Not applicable
Melania de Amorim	Content expert and end-user	None	Not applicable
Shabina Ariff	Content expert and end-user	None	Not applicable
Michel Boulvain	Content expert and end-user	None	Not applicable
Maria Laura Costa	Content expert and end-user	None	Not applicable
Christine East	Content expert and end-user	Research support, including grants, collaborations, sponsorships, and other funding	The conflict was not considered serious enough to affect GDG membership or participation in the technical consultation. The conflicts were disclosed prior to discussion.
Lynn Freedman	Content expert and end-user	None	Not applicable
Justus Hofmeyer	Content expert and end-user	None	Not applicable
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Jiji Mathews	Content expert and end-user	None	Not applicable
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Jim Neilson	Content expert and end-user	None	Not applicable
Hiromi Obara	Content expert and end-user	None	Not applicable
Andrew Weeks	Content expert and end-user	Research support and consulting, including service as a technical or other advisor	The conflict was not considered serious enough to affect GDG membership or participation in the technical consultation. The conflicts were disclosed prior to discussion.
Leanne Jones	Content expert and methodologist	None	Not applicable
Frances Kellie	Content expert and methodologist	None	Not applicable
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