WHO recommendations on the assessment of postpartum blood loss and use of a treatment bundle for postpartum haemorrhage



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Abbreviations

CERQual Confidence in the Evidence from Reviews of Qualitative Research

DOI declaration of interest

ERG External 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

HRP The UNDP-UNFPA-UNICEF-WHO-World Bank Special Programme of Research,

Development and Research Training in Human Reproduction (also known as the

Human Reproduction Programme)

ICM International Confederation of Midwives

LMIC low- and middle-income country

MCA [WHO Department of] Maternal, Newborn, Child and Adolescent Health and

Ageing

MIDIRS Midwives Information & Resource Service

MPH maternal and perinatal health

PICO population (P), intervention (I), comparator (C), outcome (O)

PPH postpartum haemorrhage

QES qualitative evidence synthesis

RCT randomized controlled trial

SDGs Sustainable Development Goals

SRH [WHO Department of] Sexual and Reproductive Health and Research

UNDP United Nations Development Programme

UNFPA United Nations Population Fund

UNICEF United Nations Children's Fund

WHO World Health Organization

Executive summary

Introduction

Global estimates indicate that there were 287 000 maternal deaths in 2020, most of which occurred in the world's least developed countries. Specifically, 87% of the world's maternal deaths occurred in sub-Saharan African and South Asian countries. Obstetric haemorrhage is the leading cause of maternal mortality, accounting for 27% of all maternal deaths occurring worldwide each year. Most of these deaths are due to postpartum haemorrhage (PPH). The World Health Organization (WHO) estimates that about 14 million women experience PPH each year. Steps towards reducing the incidence and impact of PPH would significantly contribute to reducing maternal mortality and morbidity. Likewise, an improvement in the overall quality of maternal health care to prevent and treat complications such as PPH is critical to attaining the health targets of the Sustainable Development Goals (SDGs).

To provide good-quality care, health workers, especially those in low- and middle-income countries with the greatest burden of maternal mortality and morbidities, need to be up to date on the latest scientific evidence and best practices, and have access to and be trained in the use of appropriate life-saving interventions.

In the context of poor identification of PPH, slow treatment, and inconsistent use of recommended interventions, WHO convened a group of over 130 stakeholders for the first Global Summit on Postpartum Haemorrhage (PPH Summit) in March 2023. The aim of the PPH Summit was to identify the major research, guideline, implementation and advocacy priorities that needed to be addressed to end preventable maternal deaths due to PPH between 2023 and 2030. This expert group, which represented diverse stakeholders, identified several clinical topics where WHO PPH guidelines are currently lacking, or where updates are required. The PPH Summit stakeholders also highlighted that the (then) forthcoming multi-country trial on the detection and treatment of PPH (including the use of a clinical care bundle) could have significant implications for WHO PPH guideline portfolio.

In May 2023, the findings of this trial, involving over 200 000 study participants, were published. The study reported a 60% reduction in the composite primary outcome of severe PPH, or laparotomy or maternal death from PPH. In the context of the WHO "living guidelines" approach in responding to new, impactful evidence, and the need for global action to combat PPH (the leading cause of maternal death), it is prudent to review all available data on the use of treatment bundles for PPH, to ensure that appropriate guidance is rapidly issued to Member States.

The trial evaluated a complex intervention comprising the detection of PPH and a PPH treatment bundle, supported by an implementation strategy. It is not possible to attribute the observed benefit to any one component of this complex intervention. As such, it is necessary to reconsider the available evidence on how PPH is detected. Thus, the evidence underpinning the 2012 WHO statement on the assessment of postpartum blood loss was also reconsidered, to ensure consistency across related WHO PPH recommendations.

What's new?

In 2012, the WHO recommendations for the prevention and treatment of postpartum haemorrhage (14) did not make a specific recommendation on blood loss assessment during the third stage of labour, stating that "There is insufficient evidence to recommend the measurement of blood loss over clinical estimation of blood loss". This statement was based on evidence that use of calibrated blood collection drapes alone compared to visual estimation alone had no clear effects on PPH-related health outcomes. WHO has not previously issued any recommendation that pertains to the use of care bundles for the treatment of PPH.

Review of the evidence in 2023 resulted in two recommendations in favour of (i) objective measurement of postpartum blood loss to improve the detection and treatment of PPH in women experiencing vaginal birth, and (ii) a standardized and timely approach to PPH management, consisting of objective quantification of blood loss and a treatment care bundle, supported by an implementation strategy in women experiencing vaginal birth.

Target audience

The primary audience for this document includes health-care professionals responsible for developing national and local health-care protocols and policies, as well as managers of maternal and child health programmes, and policy-makers in all settings. The recommendations will also be useful to those health workers directly providing care to women giving birth, such as obstetricians, midwives, nurses and general practitioners. The information in this document will also be useful for developing clinical tools for pre-service and in-service training of health workers and health system strengthening efforts to enhance their delivery of clinical care.

Recommendation development methods

The development of these recommendations was guided by standardized operating procedures in accordance with the process described in the *WHO handbook for guideline development*. 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.

Updated and de novo systematic reviews were used to prepare evidence profiles for the prioritized questions. The quality of the scientific evidence underpinning the recommendations was appraised using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) and the GRADE-Confidence in the Evidence from Reviews of Qualitative Research (GRADE-CERQual) approaches, for quantitative and qualitative evidence, respectively. The GRADE Evidence-to-Decision (EtD) framework – an EtD tool that includes intervention effects, values, resource use, equity, acceptability and feasibility criteria – was used to guide the formulation of recommendations by the Guideline Development Group (GDG), an international group of experts assembled for the consideration of these recommendations on 31 August and 1 September 2023.

Recommendations

The GDG issued one recommendation on the assessment of postpartum blood loss and one recommendation on the use of care bundles for PPH treatment. To ensure that the recommendations are correctly understood and applied in practice, the GDG provided additional remarks. Users of the recommendations should refer to these remarks, which are presented directly beneath the recommendations (section 3.1). The recommendations and remarks are also given in Table 1.

Table 1. Summary of recommendations and remarks

Recommendation 1 Recommended

For all women giving birth, routine objective measurement of postpartum blood loss is recommended to improve the detection and prompt treatment of postpartum haemorrhage. Methods to objectively quantify blood loss, such as calibrated drapes for women having vaginal birth, can achieve this.

Recommendation 2 Recommended

A standardized and timely approach to the management of postpartum haemorrhage (PPH), comprising an objective assessment of blood loss and use of a treatment bundle supported by an implementation strategy, is recommended for all women having a vaginal birth. The care bundle for the first-line treatment of PPH should include rapid institution of uterine massage, administration of an oxytocic agent and tranexamic acid, intravenous fluids, examination of the genital tract and escalation of care.

Remarks

Assessment of postpartum blood loss

- Visual estimation of postpartum blood loss is frequently inaccurate, meaning that PPH often
 goes unrecognized or is identified when it is too late to provide a life-saving intervention.
 Objective methods of quantifying blood loss, which are superior to visual estimation, are more
 likely to detect PPH. For women who have had a vaginal birth, most of the available evidence on
 postpartum blood loss measurement comes from the use of a calibrated drape.
- Blood loss measurement is particularly critical in the first few hours after birth. Women should
 also be regularly monitored for early warning signs of excessive blood loss (e.g. tachycardia or
 hypotension).
- To be effective, measurement of postpartum blood loss must be linked with a standardized treatment approach or protocol, and vice versa. Detecting PPH, in the absence of prompt initiation of treatment, is unlikely to improve a woman's health outcomes.
- The available studies have been conducted in women giving birth vaginally. However, the measurement of blood loss in women undergoing a caesarean section is also clinically important.
- The process for postpartum blood loss measurement should ensure that a woman's customary or cultural requirements, including choice of birth position, are respected and maintained.
- Birth-related bleeding risks and the signs and symptoms of excessive blood loss should be discussed with women across the birth continuum (including antenatally) to foster shared decision-making.
- There should be consideration and investments made into the development and use of sustainable and climate-friendly drapes.

Care bundle for the treatment of PPH

- All interventions included within the PPH treatment bundle are individually recommended in the existing 2012 and 2017 WHO PPH guidelines.
- In the context of this recommendation, the GDG emphasizes the need for a consistent use and interpretation of the term "bundle" as a clinical care bundle for the treatment of PPH. This should not be misconstrued with the usage of this term in other contexts.
- To ensure the maximal success of the PPH treatment bundle, early detection of PPH is a key and indissociable component of the first-response intervention. The available evidence on postpartum blood loss measurement is largely from trials that used calibrated drapes for women who had a vaginal birth (see Recommendation 1).
- Clinical judgement is important to guide PPH treatment decision-making. In a large trial, the treatment bundle was initiated when measured blood loss was 500 ml or greater, or when measured blood loss was 300 ml or greater with early warning signs of excessive blood loss (see Recommendation 1).
- The trial underlying this recommendation included multiple implementation and health system strengthening strategies that helped to achieve a high coverage in the consistent use of the treatment bundle. These included ensuring availability of the required human resources, strengthened by dedicated research staff, regular health-care facility-level audit and feedback, designated facility champions to oversee change, restocking of PPH trolleys or carry cases so that all necessary medicines and equipment were readily available in one place, and training for health workers.
- The PPH treatment bundle requires standardized and timely use of all included interventions.
 All bundle treatment interventions should ideally be initiated within the first 15 minutes after a
 diagnosis of PPH. However, health system readiness (e.g. availability of staff, equipment) varies
 across different settings. In the event that not all bundle interventions are available, available
 components should be initiated in a timely and standardized manner.
- In cases of refractory postpartum bleeding where a woman has received all interventions within the PPH treatment bundle yet continues to bleed prompt escalation to a higher-level health-care facility or a senior clinical provider capable of providing further management is critical. WHO has made recommendations on the treatment of refractory PPH.
- The GDG acknowledges that the evidence supporting a treatment bundle is largely from trials
 on vaginal birth, and does not have any clear evidence to refute that the findings would be
 different for a caesarean section. The individual PPH treatment interventions included in the
 PPH treatment bundle are also recommended by WHO for women undergoing a caesarean
 section (see the 2012 WHO recommendations for the prevention and treatment of postpartum
 haemorrhage [14]). However, the group acknowledged that additional research is required to
 confidently recommend bundle care for caesarean section births.
- National, regional, subregional and district-level health systems must be strengthened so that sufficient resources are available, ensuring the sustainability of treatment bundle implementation. Adequate numbers of staff and availability of commodities are essential to achieve the benefits of treatment bundles (for further details, see Chapter 4, section 4.2: Implementation considerations).
- The supporting evidence has largely been generated from studies conducted in secondary-level
 health-care facilities. However, prompt recognition and treatment of PPH for women who give
 birth in primary care settings, in the community or at home are equally relevant. Appropriate
 resources and health worker training integrated with setting-specific implementation strategies
 are necessary to facilitate this.
- Engagement with women and their communities is paramount to promote women's human rights and agency in their health, and foster their participation in shared decision-making around PPH treatment

1 Introduction

1.1Background

Global estimates indicate that there were 287 000 maternal deaths in 2020, most of which occurred in the world's least developed countries (1). Specifically, 87% of the world's maternal deaths occurred in sub-Saharan African and South Asian countries. Obstetric haemorrhage is the leading cause of maternal mortality, accounting for 27% of all maternal deaths occurring worldwide each year (2). Most of these deaths are due to postpartum haemorrhage (PPH). The World Health Organization (WHO) estimates that about 14 million women experience PPH each year (3). Steps towards reducing the incidence and impact of PPH would significantly contribute to reducing maternal mortality and morbidity. Likewise, an improvement in the overall quality of maternal health care to prevent and treat complications such as PPH is critical to attaining the health targets of the Sustainable Development Goals (SDGs) (4) and the targets and indicators of WHO's Thirteenth General Programme of Work (5), particularly those for achieving universal health coverage (UHC).

As a fundamental human right, women, including adolescent girls, are entitled to sexual and reproductive health and rights, including access to evidence-based care during pregnancy and childbirth (6). Similarly, it is the vision of WHO that "every pregnant woman and newborn receives quality care throughout pregnancy, childbirth and the postnatal period" (7). Thus, where there is evidence to support the effectiveness of a feasible intervention to reduce maternal and perinatal mortality and morbidity, it is essential that mothers and their babies have the opportunity to receive such care.

To provide good-quality care, health workers, especially those in low- and middle-income countries (LMICs) with the greatest burden of maternal mortality and morbidities, need to be up to date on the latest scientific evidence and best practices, and have access to and be trained in the use of appropriate life-saving interventions. Importantly, health managers, policy-makers and other stakeholders who make decisions on maternal and perinatal health (MPH) service delivery require updated guidance to inform policies and programmes. These efforts can collectively help to optimize quality of care for women and their babies during pregnancy, childbirth and the postnatal period.

Ensuring accessibility and acceptability of interventions to improve maternal and newborn health outcomes is consistent with international human rights laws, which include the fundamental commitments of States to enable women to survive pregnancy and childbirth, to assure their sexual and reproductive health rights, and to live a life of dignity. High-quality health care could reduce the profound inequities in maternal and newborn health globally and is essential for improving pregnancy and birth outcomes.

1.2 Rationale and objectives

Since 2017, the WHO Department of Sexual and Reproductive Health and Research (SRH) has applied the "living guidelines" approach to updating individual WHO recommendations (8). In this approach, a combination of regular literature surveillance and "intelligence gathering" on new and important evidence is regularly applied to WHO's portfolio of more than 400 MPH recommendations. These findings are periodically reviewed by an independent group of experts who identify the highest priority questions for updating or creating new recommendations. The living guideline approach was instrumental in rapidly producing the 2017 WHO recommendation on tranexamic acid for the treatment of postpartum haemorrhage

(9), as well as updated recommendations on uterotonics for PPH prevention in 2018 (10). In both instances, WHO's recommendations were produced rapidly in response to new, clinically important evidence from large multi-country trials. These guidelines have demonstrated the significant advantages of a "living guidelines" approach.

In 2017, WHO hosted a technical consultation of diverse experts to identify novel strategies for the prevention and treatment of PPH, resulting in a proposal for a "first-line PPH treatment" bundle and a "refractory PPH treatment bundle" for PPH that does not respond to first-line therapies (11). Both of these bundles were conceptualized as a collection of existing WHO-recommended therapies. However, the expert group acknowledged that there was a lack of direct evidence on the impact of such bundles on PPH-related outcomes.

In March 2023, WHO convened a group of over 130 stakeholders for the first Global Summit on Postpartum Haemorrhage (PPH Summit) (3). The aim of the PPH Summit was to identify the major research, guideline, implementation, and advocacy priorities that need to be addressed to end preventable maternal deaths due to PPH between 2023 and 2030. This expert group, which represented diverse stakeholders, identified several clinical topics where the WHO PPH guidelines are currently lacking, or where updates are more urgently required. The PPH Summit stakeholders also highlighted that the forthcoming large trial on the detection of PPH and use of the WHO-proposed PPH treatment bundle (E-MOTIVE trial) could have significant implications for WHO's PPH guideline portfolio.

In May 2023, the findings of the E-MOTIVE trial, involving over 200 000 study participants, were published (12). The study reported a 60% reduction in the composite primary outcome of severe PPH, or laparotomy or maternal death from PPH. In the context of WHO's "living guidelines" approach in responding to new, impactful evidence, and the need for global action to combat PPH (the leading cause of maternal death), it was considered prudent to review all available data on the detection of PPH and the use of care bundles for the treatment of PPH, to ensure that appropriate guidance was rapidly issued to Member States.

Care bundles are complex interventions consisting of a straightforward set of evidence-based practices – generally three to five – that, when performed collectively and reliably, have been proven to improve the processes of care and patient outcomes (13). A large multi-centre trial evaluated a complex intervention comprising the detection of PPH and a care bundle for the treatment of PPH, supported by an implementation strategy. The complex intervention had a positive impact. It is not possible to attribute the observed benefit to any one component of this complex intervention. WHO's prior recommendation (published in 2012) on the assessment of blood loss for detecting PPH indicated that there was insufficient evidence to recommend objective measurement of blood loss over clinical estimation (14, 15). As such, it is necessary to reconsider the available evidence on how PPH is assessed.

The recommendations were developed in accordance with the standards and procedures in the WHO handbook for guideline development (16), including the synthesis of available research evidence, use of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology,¹ and formulation of recommendations by a Guideline Development Group (GDG) consisting of international experts and stakeholders. WHO has not previously made recommendations on the topics of assessment of postpartum blood loss or care bundles for the treatment of PPH. The advice on the assessment of postpartum blood loss in this document supersedes the conclusion that "There is insufficient evidence to recommend the

¹ Further information is available at the GRADE Working Group website: http://www.gradeworkinggroup.org/

measurement of blood loss over clinical estimation of blood loss", which was published as part of the WHO recommendations on the prevention and treatment of postpartum haemorrhage in 2012 (14).

1.3 Target audience

WHO MPH recommendations are relevant to those providing care and support during pregnancy, labour, childbirth and postpartum periods, in any health-care setting.

The primary audience for these recommendations includes health-care professionals who are responsible for developing national and local health policies related to care during childbirth and the postpartum period, and those health workers directly providing care to women around the time of birth, including midwives, nurses, general medical practitioners and obstetricians, and managers of maternal and child health programmes, in all settings.

The recommendations will also be of interest to professional societies involved in the care of pregnant women, nongovernmental organizations concerned with the promotion of womancentred maternity care, and implementers of maternal and child health programmes.

1.4 Scope of the recommendations

The recommendations focus on the detection and treatment of PPH. The priority questions that guided evidence synthesis and decision-making for these recommendations are presented below using the population (P), intervention (I), comparator (C), outcome (O) (PICO) format.

Priority questions

- For women in the third stage of labour and up to 24 hours after delivery (P), does the use of any particular method to assess postpartum blood loss (I) compared to other method(s) of assessing postpartum blood loss (C) improve the detection of PPH and improve maternal and perinatal outcomes (O)?
- For women who experience PPH (P), does the use of a care bundle (I) compared to usual care or a care bundle with different components (C) improve maternal and perinatal outcomes (O)?

1.5 Persons affected by the recommendations

The population affected by the recommendations includes women giving birth and women experiencing PPH in low-, middle- and high-resource settings.

2 Methods

The recommendations were developed using the standardized operating procedures in accordance with the process described in the *WHO handbook for guideline development (16)*. In summary, the process included: (i) identification of the priority questions and outcomes; (ii) retrieval of the evidence; (iii) assessment and synthesis of the evidence; (iv) formulation of the recommendation; and (v) planning for the dissemination, implementation, impact evaluation and updating of the recommendations.

In 2023, developing WHO recommendations on the detection of PPH and treatment using care bundles was identified as a high priority. Six main groups participated in this process. Their specific roles are described in the following sections; members of each group are listed in Annex 1.

2.1Contributors to the guideline

2.1.1 WHO Steering Group

The WHO Steering Group, consisting of WHO staff members from the SRH and the WHO Department of Maternal, Newborn, Child and Adolescent Health and Ageing (MCA) managed the updating process. The WHO Steering Group drafted the key recommendation questions in PICO format and identified the systematic review teams and guideline methodologists, as well as members of the GDG and the External Review Group (ERG). In addition, the WHO Steering Group supervised the retrieval and syntheses of evidence, organized the GDG meeting, finalized the recommendation document and managed its dissemination, implementation and impact assessment.

2.1.2 Guideline Development Group (GDG)

For the development of these recommendations, a diverse group of individuals with expertise in research, clinical practice, policy and programmes, and guideline development methods relating to interventions for intrapartum and immediate postpartum care and service delivery, as well as patient and consumer representatives, were invited to participate as members of the GDG.

For the development of these recommendations, 15 external experts and relevant stakeholders were invited to participate as members of the GDG. These individuals were drawn from a pool of approximately 50 experts and relevant stakeholders who constitute the WHO MPH GDG. Those selected had expertise in research, guideline development methods, and clinical policy and programmes relating to improving the quality of care and outcomes for women giving birth, as well as a representative of the affected population.

GDG members were selected in a way that ensured geographical representation and gender balance and that there were no important conflicts of interest. Based on the documents prepared by the Steering Group, the GDG appraised and interpreted the evidence and formulated the final recommendations at meetings convened on 31 August and 1 September 2023. The group also reviewed and approved the final recommendation document.

2.1.3 Evidence Synthesis Group (ESG)

WHO convened an Evidence Synthesis Group (ESG) consisting of guideline methodologists and systematic review teams for the conduct or updating of systematic reviews, appraisal of

evidence and development of the Evidence-to-Decision (EtD) frameworks.

Technical experts from the Burnet Institute, Australia served as the guideline methodologists. The guideline methodologists oversaw the appraisal of evidence using the GRADE methodology (17).

Before planning for this guideline, a systematic review of qualitative evidence (qualitative evidence synthesis [QES]) on PPH prevention, detection and management was already under way (18). This was led by experts from the University of Melbourne, Australia who have extensive experience in qualitative evidence reviews and have led methodological research on the development of the Confidence in the Evidence from Reviews of Qualitative Research (CERQual) tool. In addition, the ESG initiated a new systematic review of economic evaluations for the prevention and treatment of PPH (19).

The Steering Group worked closely with the ESG to review the evidence and prepare the GRADE EtD frameworks. Members of the ESG attended the GDG meeting to provide an overview of the synthesized evidence and to respond to technical gueries from the GDG.

2.1.4 External partners and observers

Representatives of the United States Agency for International Development, the International Confederation of Midwives (ICM), the International Federation of Gynecology and Obstetrics (FIGO) and Unitaid participated in the GDG meeting as observers. These organizations collaborate with WHO departments in guideline dissemination and implementation and were identified as significant implementers of the recommendations.

2.1.5 External Review Group (ERG)

The ERG consisted of six technical experts with interest and expertise in the provision of evidence-based care to improve the quality care and outcomes for women giving birth. The group was gender-balanced and members were from five different WHO regions. Members had no significant conflicts of interest. Experts reviewed the final document 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-care professionals and policy-makers. It was not within the remit of this group to change the recommendations formulated by the GDG.

2.2 Evidence identification and retrieval

Evidence to support the update of the recommendation was derived from several sources by the systematic review teams working in collaboration with the WHO Steering Group.

2.2.1 Evidence on effectiveness

To inform the development of the recommendations, WHO commissioned an update of an existing systematic review on the assessment of postpartum blood loss and the development of a new systematic review on the effectiveness of care bundles in the treatment of PPH.

Methods to assess postpartum blood loss for the detection of PPH

Evidence on the effects of methods for the assessment of postpartum blood loss to detect PPH was derived from an update of an existing systematic review of randomized controlled trials (RCTs), last published in 2018 (20). The authors of the review conducted an updated search on

14 June 2023. This review previously included three trials (of which two contributed data). The update included four trials, of which three contributed data. The new data did not change the estimates or certainty of effect for the priority outcomes.

To inform the "Additional considerations" section of the EtD framework, the evidence synthesis team conducted a rapid review of available evidence on the diagnostic accuracy of different methods of assessing postpartum blood loss. The reference lists of seven published systematic reviews on the measurement of obstetric blood loss were searched, as well as citations recovered from a structured MEDLINE search. Eligible studies were those that compared any two methods of postpartum blood loss assessment, provided that diagnostic measures were available for PPH (500 ml or more) or severe PPH (1000 ml or more). Findings from eight eligible studies were reported.

Effectiveness of care bundles in the treatment of PPH

An external group of systematic reviewers was asked to prepare a review protocol with a clear PICO question and criteria for the identification of studies, including search strategies for different bibliographic databases, methods for assessing risk of bias and a data analysis plan (21). The WHO Steering Group and selected members of the ESG then reviewed and endorsed the protocol before the systematic review was conducted.

The search strategies used to identify the studies and the specific criteria for the inclusion and exclusion of studies were described in the systematic review protocol. Briefly, a comprehensive search of six electronic databases – MEDLINE, Embase, CINAHL, Midwives Information & Resource Service (MIDIRS), Global Index Medicus and the Cochrane Central Register of Controlled Trials – was conducted without date restrictions to identify studies that evaluated the effects of a care bundle (as defined by the Institute for Healthcare Improvement [13]) for the prevention or treatment of PPH, regardless of the health-care setting. Eligible studies were RCTs (whether individual, cluster or crossover studies), non-RCTs (where participants were allocated to different interventions using non-random methods), interrupted time series studies and before–after studies (whether controlled or uncontrolled).

For the purposes of these recommendations, the intervention of interest was the use of a care bundle for PPH treatment. An operational definition was used to assess study eligibility, which was based on the Institute for Healthcare Improvement's definition of a care bundle. Studies were potentially eligible if they evaluated an intervention that combined three or more interventions used concurrently or collectively (for further details, see the Evidence-to-Decision frameworks in Web Annexes A and B). Studies from low-, middle- and high-income countries were considered and no language restrictions were applied.

The development of the systematic review protocol was iterative, with the systematic reviewers and methodologists communicating with the WHO Steering Group to discuss challenges and agree on solutions.

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

Values, equity, acceptability and feasibility

A 2023 QES explored the perceptions and experiences of women, community members, lay health workers and skilled health workers with PPH experience or experience with preventing, detecting and managing PPH, in both community and health-care facility settings (18). This review was the primary source of evidence on acceptability, feasibility and equity.

Resource use and cost-effectiveness

Evidence on resource use and cost-effectiveness was based on a new systematic review of the literature (19). The review aimed to synthesize all available evidence on the cost-effectiveness of interventions to prevent, diagnose and treat PPH. Eligible studies were identified from specialist health economic databases (NHS Economic Evaluation Database and EconLit) and medical databases (PubMed, Embase, CINAHL and PsycInfo). Eligible studies were full economic evaluations that assessed cost-benefit, cost-effectiveness or cost-utility. For the purposes of these recommendations, we identified only those economic evaluations pertaining to postpartum blood loss measurement and care bundles for the treatment of PPH.

2.3 Quality assessment and grading of the evidence

2.3.1 Quality assessment of the primary studies included in the reviews

For the effectiveness reviews, all eligible randomized trials were assessed using either a research integrity assessment tool developed by Cochrane Pregnancy and Childbirth, or a separate tool adapted from the tool described by Weibel et al. (22). These tools are similar and aim to detect any potential issues related to study retraction, trial registration, ethical approval, author contributions, and plausibility of the methods (e.g. randomization) and study results.

For all trials judged to be trustworthy, two reviewers independently assessed the risk of bias of randomized trials using the revised Cochrane risk-of-bias tool for randomized trials (RoB 2). For non-randomized trials, the Risk Of Bias In Non-randomised Studies – of Interventions (ROBINS-I) tool for non-randomized trials. Any disagreement was resolved by discussion or by involving a third assessor.

For each included trial and each outcome, the domains of bias explored were: randomization process, identification or recruitment of individual participants within clusters, deviations from the intended interventions, missing outcome data, measurement of the outcome, selection of the reported results and overall bias.

For non-randomized trials, the domains of bias explored were: confounding, selection of participants into the study, classification of interventions, deviations from the intended interventions, missing data, measurement of the outcomes, selection of the reported results and overall bias.

The quality of studies included in the QES was assessed using an adapted version of the Critical Appraisal Skills Programme (CASP) tool. The following domains were included in the tool: aims, methodology, design, participant enrolment, data collection, data analysis, reflexivity, ethical considerations, results and research contribution. Assessments were reported in a "methodological limitations" table.

The cost–effectiveness systematic review used the extended Consensus on Health Economics Criteria list for assessing the quality of both trial-based and model-based studies.

2.3.2 Assessment of the certainty of the effectiveness evidence

For the effectiveness evidence, the certainty of evidence for a given outcome was rated using the standard GRADE approach based on consideration of study design limitations (risk of bias), inconsistency (heterogeneity or variability in results), indirectness (differences in study populations), imprecision (small study populations and few events) and publication bias (16). Tables summarizing the findings were prepared, which included the relative and absolute risk and an overall certainty rating for each outcome.

GRADE certainty of the evidence

The certainty of evidence for each outcome was rated as "high", "moderate", "low" or "very low" as defined by the GRADE methodology:

- **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 the effect.

2.3.3 Assessment of the certainty (confidence) of the qualitative evidence

The findings of qualitative studies included in the QES were appraised using the GRADE-CERQual tool (23). The GRADE-CERQual tool, which uses a similar conceptual approach to other GRADE tools, provides a transparent method for assessing and assigning the level of confidence that can be placed on the evidence from Reviews of Qualitative Research. The systematic review team used the GRADE-CERQual tool to assign a level of confidence to each review finding according to four components: methodological limitations of the individual studies; adequacy of the data; coherence; and relevance to the review question of the individual studies contributing to a review finding.

The confidence of the evidence for each review finding was rated as "high", "moderate", "low" or "very low" (23):

- **High confidence**: It is highly likely that the review finding is a reasonable representation of the phenomenon of interest.
- **Moderate confidence**: It is likely that the review finding is a reasonable representation of the phenomenon of interest.
- **Low confidence**: It is possible that the review finding is a reasonable representation of the phenomenon of interest.
- **Very low confidence**: It is not clear whether the review finding is a reasonable representation of the phenomenon of interest.

2.4 Formulation of the recommendations

The WHO Steering Group supervised the preparation and finalization of the summary of findings tables, which present evidence for each of the WHO prioritized outcomes (see Annex 2), and the narrative evidence summaries in collaboration with the ESG using the GRADE EtD framework (24). The EtD framework includes explicit and systematic consideration of evidence on the intervention in terms of specified domains, that is, effectiveness, values, resources, equity, acceptability and feasibility. Using the EtD framework template, the Steering Group and ESG created summary documents for each priority question covering the evidence on each domain. The certainty of the effectiveness evidence and confidence in the qualitative evidence were included under each domain (see Web Annexes A and B). For each priority question,

judgements were made on the impact of the intervention on each domain to inform and guide the decision-making process.

The WHO Steering Group provided the EtD frameworks, including the evidence summaries and summary of findings tables, to GDG members one week before the GDG meeting. GDG members were asked to review and electronically provide comments on the documents before the GDG meeting. During the online GDG meetings (31 August and 1 September 2023), under the leadership of the GDG chairperson, GDG members collectively reviewed and discussed the frameworks.

The purpose of the meeting was to formulate recommendations and reach a consensus on any recommendations, based on explicit consideration of the range of evidence presented in the EtD framework and the judgement of the GDG members.

In formulating the recommendations, the GDG used the recommended GRADE EtD frameworks and considered separately the synthesized evidence on the effectiveness of the intervention, values (outcome importance) of the stakeholders, resource use and cost–effectiveness of the intervention, acceptability and feasibility of the intervention, and the impact of the intervention on equity. For each of these domains, an appraisal of the certainty of evidence was performed using methods that were appropriate to the supporting evidence synthesis (e.g. GRADE or GRADE-CERQual). It was the view of the GDG that, as the certainty of the evidence was evaluated across several domains to arrive at the recommendation, and not just for evidence on the effectiveness of the intervention, this cannot be captured within a single "certainty" rating. Providing the certainty of evidence for effectiveness alone within the text of the recommendations does not adequately demonstrate consideration of all types of evidence and could potentially confuse the target audience.

The GDG classified the recommendation into one of the following categories:

- **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 with monitoring and evaluation: This category indicates that the
 intervention is recommended, with monitoring and evaluation if implementation is
 advised.
- Recommended only in the context of rigorous research ("research context recommendation"): This category indicates that there are important uncertainties about the intervention. In such instances, implementation can still be undertaken on a large scale, provided that it takes the form of research that addresses unanswered questions and uncertainties related both to the effectiveness of the intervention or option, and its acceptability and feasibility.

This classification approach has been used for the development of WHO MPH guidelines and updates of recommendations since 2016, spanning more than 90 individual recommendations. The approach was adopted in response to the feedback received from end users of MPH guidelines about the challenges of interpreting recommendations coupled

with specific evidence ratings. The GRADE Public Health Group has acknowledged that a key challenge for GRADE in public health is to identify how to reconcile the tension between the methodologically correct presentation of recommendations and the implications of strong versus conditional recommendations from the perspective of decision-makers (25).

2.5 Management of the declaration of interests

WHO has a robust process to protect the integrity of its normative work and to protect the integrity of the individual experts with whom it collaborates. WHO requires that experts serving in an advisory role disclose any circumstances that could give rise to actual or ostensible conflicts of interest. The disclosure and appropriate management of relevant financial and non-financial conflicts of interest of GDG members and other external experts and contributors are a critical part of guideline development at WHO. According to WHO regulations, all experts must declare their interests before participation in WHO guideline development processes and meetings according to the procedures for the declaration of interests (DOI) for WHO experts (16). All GDG members were therefore required to complete a standard WHO DOI form before engaging in the guideline development process and before participating in guideline-related meetings. Short biographies of the GDG members were also published on the SRH departmental website for 2 weeks for public review and comments before the first GDG meeting.

The WHO Steering Group reviewed all declarations before finalizing the experts' invitations to participate. Where any conflicts of interest were declared, the WHO Steering Group determined whether such conflicts were serious enough to affect an expert's objective judgement in the guideline and recommendation development process. To ensure consistency, the WHO Steering Group applied the criteria for assessing the severity of conflicts of interest as outlined in the WHO handbook for guideline development (16) to all participating experts. All findings from the DOI statements received were managed in accordance with WHO procedures to ensure that the work of WHO and the contribution of its experts is, actually and ostensibly, objective and independent. Where conflicts of interest were not considered significant enough to pose any risk to the guideline development process or to reduce its credibility, experts were only required to openly declare such conflicts of interest at the beginning of the GDG meeting and no further actions were taken. 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.

2.6 Decision-making during the GDG meetings

The GDG meetings were designed to allow participants to discuss the supporting evidence and to reach a consensus on the final wording of each recommendation. Consensus was defined as the agreement by three quarters or more of the GDG, provided that those who disagreed did not feel strongly about their position. No GDG member expressed opposition to the recommendations.

2.7 Document preparation and peer review

The WHO Steering Group made a draft version of the EtD framework available to the participants 1 week before the meeting for their comments. During the meeting, the framework was modified in line with the participants' deliberations and remarks. After the meeting, the WHO Steering Group worked with the guideline methodologists to prepare a full recommendation document to accurately reflect the deliberations and decisions of the participants. The draft document was sent electronically to GDG members for their final review

and approval. The final document was also sent for peer review to five external independent experts who were not involved in the development of the recommendations. The WHO Steering Group evaluated the inputs of the peer-reviewers for inclusion in this document. After the meetings and external peer reviews, the modifications made by the WHO Steering Group to the document consisted only of the correction of factual errors and edits to address any lack of clarity.

3 Recommendations and supporting evidence

The GDG issued two recommendations — one on the detection of PPH and one on the use of a standardized and timely approach to PPH treatment. This section outlines the recommendations corresponding to the priority questions. To ensure that the recommendations are correctly understood and appropriately implemented in practice, additional remarks reflecting the summary of the discussions by the GDG are included under the recommendations. The recommendations should be applied in conjunction with the implementation of the considerations.

The tables summarizing the findings and the EtD frameworks — presenting the balance between desirable and undesirable effects, values of stakeholders, resource requirements, cost–effectiveness, acceptability, feasibility and equity that were considered in formulating each recommendation — are presented separately in Web Annexes A and B.

3.1 Recommendations

Recommendation 1 Recommended

For all women giving birth, routine objective measurement of postpartum blood loss is recommended to improve the detection and prompt treatment of postpartum haemorrhage. Methods to objectively quantify blood loss, such as calibrated drapes for women having vaginal birth, can achieve this.

Recommendation 2 Recommended

A standardized and timely approach to the management of postpartum haemorrhage (PPH), comprising an objective assessment of blood loss and use of a treatment bundle supported by an implementation strategy, is recommended for all women having a vaginal birth. The care bundle for first-line treatment of PPH should include rapid institution of uterine massage, administration of an oxytocic agent and tranexamic acid, intravenous fluids, examination of the genital tract and escalation of care

Remarks

Assessment of postpartum blood loss

- Visual estimation of postpartum blood loss is frequently inaccurate, meaning that PPH often
 goes unrecognized or is identified when it is too late to provide a life-saving intervention.
 Objective methods of quantifying blood loss, which are superior to visual estimation, are more
 likely to detect PPH. For women who have had a vaginal birth, most of the available evidence on
 postpartum blood loss measurement comes from the use of a calibrated drape.
- Blood loss measurement is particularly critical in the first few hours after birth. Women should
 also be regularly monitored for early warning signs of excessive blood loss (e.g. tachycardia or
 hypotension).
- To be effective, measurement of postpartum blood loss must be linked with a standardized treatment approach or protocol, and vice versa. Detecting PPH, in the absence of prompt initiation of treatment, is unlikely to improve a woman's health outcomes.
- The available studies have been conducted in women giving birth vaginally. However, the measurement of blood loss in women undergoing a caesarean section is also clinically important.
- The process for postpartum blood loss measurement should ensure that a woman's customary or cultural requirements, including choice of birth position, are respected and maintained (26).
- Birth-related bleeding risks and the signs and symptoms of excessive blood loss should be

- discussed with women across the birth continuum (including antenatally) to foster shared decision-making.
- There should be consideration and investments made into the development and use of sustainable and climate-friendly drapes.

Care bundle for the treatment of PPH

- All interventions included within the PPH treatment bundle are individually recommended in WHO's existing 2012 and 2017 PPH guidelines (9, 14).
- In the context of this recommendation, the GDG emphasizes the need for a consistent use and interpretation of the term "bundle" as a clinical care bundle for the treatment of PPH. This should not be misconstrued with the use of this term in other contexts.
- To ensure the maximal success of the PPH treatment bundle, early detection of PPH is a key and indissociable component of the first-response intervention. The available evidence on postpartum blood loss measurement is largely from trials that used calibrated drapes for women who had a vaginal birth (see Recommendation 1).
- Clinical judgement is important to guide PPH treatment decision-making. In a large trial, the
 treatment care bundle was initiated when measured blood loss was 500 ml or greater, or when
 measured blood loss was 300 ml or greater with early warning signs of excessive blood loss (see
 Recommendation 1 and remarks).
- The trial underlying this recommendation included multiple implementation and health
 system strengthening strategies, which helped to achieve high coverage in the consistent use
 of the treatment bundle. These included ensuring availability of required human resources,
 strengthened by dedicated research staff, regular health-care facility-level audit and feedback,
 designated facility champions to oversee change, restocking of PPH trolleys or carry cases so that
 all necessary medicines and equipment were readily available in one place, and training for health
 workers.
- The PPH treatment bundle requires standardized and timely use of all included interventions. All bundle treatment interventions should ideally be initiated within the first 15 minutes after a diagnosis of PPH. However, health system readiness (e.g. availability of staff, equipment) varies across different settings. In the event that not all bundle interventions are available, available components should be initiated in a timely and standardized manner.
- In cases of refractory postpartum bleeding where a woman has received all interventions within the PPH treatment bundle yet continues to bleed prompt escalation to a higher-level health-care facility or a senior clinical provider capable of providing further management is critical. WHO has made recommendations on the treatment of refractory PPH (14).
- The GDG acknowledges that the evidence supporting the treatment bundle is largely from trials on vaginal births, and does not have any clear evidence to refute that the findings would be different for a caesarean section. The individual PPH treatment interventions included in the PPH treatment bundle are also recommended by WHO for women undergoing a caesarean section (see the 2012 WHO recommendations for the prevention and treatment of postpartum haemorrhage (14)). However, the group acknowledged that additional research is required to confidently recommend bundle care for caesarean section births.
- National, regional, subregional and district-level health systems must be strengthened so that sufficient resources are available, ensuring the sustainability of treatment bundle implementation. Adequate numbers of staff and availability of commodities are essential to achieve the benefits of treatment bundles (for further details, see Chapter 4, section 4.2: Implementation considerations).
- The supporting evidence has largely been generated from studies conducted in secondary-level
 health-care facilities. However, prompt recognition and treatment of PPH for women who give
 birth in primary care settings, in the community or at home are equally relevant. Appropriate
 resources and health worker training integrated with setting-specific implementation strategies
 are necessary to facilitate this.
- Engagement with women and their communities is paramount to promote women's human rights and agency in their health, and foster their participation in shared decision-making around PPH treatment.

4 Dissemination and implementation of the recommendations

The dissemination and implementation of these recommendations is 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 and strengthen the capacity at health-care facilities of all levels to ensure they can provide high-quality services to all women giving birth. It is therefore crucial that these recommendations be translated into care packages and programmes at the country and health-care facility levels, where appropriate. In particular, these recommendations will need to be incorporated into existing programmes and policies on the prevention, detection and treatment of PPH.

4.1 Dissemination and evaluation

An separate executive summary containing the recommendations, remarks, implementation considerations and research priorities will be prepared for public dissemination. The WHO Steering Group will also develop derivative tools to aid the understanding and adaptation of these recommendations to local contexts, including a policy brief on the early detection and treatment of PPH, an updated clinical algorithm and a toolkit for PPH prevention, detection and treatment.

The recommendations and derivative tools will be disseminated through WHO regional and country offices, ministries of health, professional organizations, WHO collaborating centres, other United Nations agencies and nongovernmental organizations, among others. The recommendations will be published on the WHO SRH Department website as part of the monthly WHO Human Reproduction Programme News. This site currently has over 8000 subscribers, including clinicians, health programme managers, policy-makers and service users from all around the world. Updated recommendations are also routinely disseminated during meetings and scientific conferences attended by WHO MPH staff.

The executive summary including the recommendations from this publication will be translated into the six United Nations languages for dissemination through the WHO regional and country offices and during meetings organized by, or attended by, staff of the WHO SRH Department and the WHO MCA Department. Technical assistance will be provided to any WHO regional office willing to translate these recommendations into any of the languages. In addition, the publication of journal articles presenting the recommendations and key implementation considerations will be considered in compliance with WHO's open access and copyright policies. Relevant WHO clusters, departments and partnerships, such as the Partnership for Maternal, Newborn and Child Health (PMNCH), will also be part of this dissemination process.

To ensure that these recommendations have an impact on MPH at the country level, coordinated action between international agencies, national departments of health and key MPH stakeholders is needed. National and subnational working groups should assess current national guidelines and protocols and determine whether the development of new guidelines or the updating of existing guidelines is required in line with these new WHO recommendations. WHO staff at the headquarters, regional and country levels, as well as international agency partners and international professional societies (e.g. FIGO and ICM), and national professional associations, can support national stakeholders in developing or revising existing national guidelines or protocols and optimizing their implementation.

In the context of humanitarian emergencies, the adaptation of the current recommendations should consider the 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 made. Context-specific tools and toolkits may be required in addition to standard tools to support the implementation of the recommendations in humanitarian emergencies by stakeholders.

4.2 Implementation considerations

As part of the recommendation development process, implementation considerations were developed. These may assist policy-makers, clinicians and other stakeholders to better prepare for implementation.

- The successful introduction of evidence-based policies related to the measurement of postpartum blood loss, and a standardized and timely approach to PPH treatment, into national health programmes and health-care services depends on well-planned, participatory and consensus-driven processes of adaptation and implementation. These processes may include the development or revision of national guidelines or protocols based on these recommendations, and engagement with all relevant stakeholder groups, including skilled health personnel. Modifications to the recommendations, if necessary, should be made with justification and documented in an explicit and transparent manner. The SRH and MCA Departments at WHO will support national and subnational groups to adapt and implement the recommendations based on existing strategies.
- Implementation of these two joint recommendations needs to be coordinated and
 conducted in a manner appropriate to local needs, intended users and recipients, and the
 overall health system. It must be considered within the broader context of ensuring that all
 women have access to respectful, women-centred care in the intrapartum and postpartum
 periods. They should also be nested within existing programmes and policies relating more
 broadly to the prevention, detection and treatment of PPH.
- National health systems must support an enabling environment for the implementation
 of these two recommendations, including education to support behaviour change among
 skilled health personnel teams to facilitate the use of evidence-based practices. Clear and
 up-to-date clinical protocols should be available to skilled health-care personnel regarding
 the quantification of blood loss after birth, early detection of PPH, prompt initiation of PPH
 treatment and escalation of care as appropriate.
- Local professional societies and training institutions can have an important role in implementation; an all-inclusive and participatory process should be encouraged.
- National health systems must ensure that supplies of medicines and equipment (e.g. calibrated drapes, good-quality uterotonics, intravenous fluids and tranexamic acid) are available in health-care facilities where childbirth services are provided. These resources must be safe, legitimate and manufactured according to good manufacturing practices. Thus, to ensure that the resources are of high quality, robust and sustainable regulatory, procurement and logistics processes must be established, which can ensure that good-quality products are obtained, transported and stored correctly. Health systems must also invest in the safe disposal of non-reusable equipment (e.g. drapes) and the supplies necessary to clean and disinfect reusable equipment (e.g. blood collection tools).
- Procurement agencies at all levels of supply chains should procure only quality-certified uterotonic medicines and tranexamic acid. For example, those responsible for the

procurement of oxytocin should procure only quality-certified oxytocin, labelled for storage at 2–8 °C, in single-use ampoules or vials of 10 international units. While some manufacturer labelling may seem to indicate that oxytocin is stable at room temperature, stability may not have been tested in the much warmer conditions that may be prevalent in some countries, and different formulations have different stability characteristics. Careful consideration must be taken to store medications in suitable environments that can safeguard quality and prevent degradation.

- Special attention needs to be given to the correct dosage and safe use of uterotonics; efforts are needed to ensure that uterotonics are not misused for other indications. Similarly, for tranexamic acid, efforts are needed to minimize the risk of intrathecal use and avoid mixing with oxytocin before administration because there is a risk of interaction with some tranexamic acid products (27).
- Programmes that are going to implement these two recommendations must also ensure
 that women are adequately informed in advance about PPH prevention and management,
 including possible side-effects, and their rights to choose what care they receive. Women
 and their families or labour companions benefit from clear and effective communication
 about blood loss, PPH prevention and management, including the potential need for
 transport to a higher level of care and any long-term consequences of PPH. Such efforts
 to engage with local women and their families is key to fostering participatory and shared
 decision-making.
- Skilled health-care personnel working in settings where women give birth will require training and supportive supervision on how to perform these two recommendations appropriately and safely, and how to inform and counsel women. In settings where a new practice is introduced (or where recommended practices are changed), additional training and monitoring may be required. Especially in contexts with high rates of personnel turnover, regular opportunities for training and competency assessment is important.
- The beneficial effects of a standardized and timely approach to PPH detection and treatment (including the use of a care bundle for PPH treatment) were shown in a multicountry trial conducted in secondary-level hospitals where comprehensive emergency obstetric care services were routinely available. These hospitals also had on-site access to surgical interventions, if required. The intervention was supported by an active implementation strategy that included:
 - audit and feedback: newsletters with monthly rates of PPH detection, bundle use and rates of selected health outcomes, with feedback at monthly departmental meetings;
 - facility-level champions: midwife and doctor at each health-care facility to oversee change, were trained and supported to troubleshoot and give feedback;
 - PPH trolley or carry case that was regularly checked and restocked with medicines and devices for PPH treatment;
 - training: on-site, simulation-based and peer-assisted training for health workers. This was supported by guides, flip charts and job aids displayed in labour wards.
- Sufficient staffing is needed to ensure that women can be reliably and regularly monitored
 for postpartum blood loss (including clinical signs and symptoms), particularly in the
 first few hours after birth. Adequate staffing also ensures that all PPH treatment bundle
 interventions are implemented in a coordinated and timely manner. Ensuring sufficient
 staff, high-quality commodities and appropriate training maximizes the opportunity to
 replicate the findings of the trial.

- There may be a need for consideration of which health personnel have prescription and administration authority for drugs to treat PPH, and whether this is reflected in their scope of practice.
- Robust, easily navigable and reliable data management systems can drive the optimization
 of implementation activities. These systems can record and monitor information about
 blood loss, treatments for PPH and health outcomes.

4.3 Anticipated impact on the organization of care and resources

Effective implementation of the recommendations in this guideline may require reorganization of care and redistribution of health-care resources, particularly in LMICs. The GDG noted that updating training curricula and providing training on the recommendations would increase their impact and facilitate their implementation. Standardization of care, by including these recommendations into existing intrapartum and immediate postpartum care packages, can encourage behaviour change in health workers.

As part of efforts to implement these recommendations, health system stakeholders may wish to consider the following potential barriers to their application:

- lack of human resources with the necessary expertise and skills to implement, supervise and support recommended practices;
- lack of infrastructure to support interventions;
- lack of resources for active implementation strategies;
- lack of essential equipment, supplies and medicines;
- lack of health information management systems designed to document and monitor recommended practices (e.g. patient records, registers);
- lack of consistent staffing from high health worker turnover impacting the sustainability and scalability of the bundle.

4.4 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 (28)* 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 SRH and MCA Departments, data on country- and regional-level implementation of the recommendations will be collected and evaluated in the short- to medium-term to assess their impact on national policies of individual WHO Member States. Interrupted time series could be used to obtain the relevant data on the use of interventions contained in this guideline.

With regard to PPH, WHO recommends that the coverage of prophylactic uterotonics be used as a process indicator for the monitoring and prevention of PPH (14). The suggested "prophylactic uterotonic coverage indicator" is calculated as the number of women receiving

prophylactic uterotonics during the third stage of labour divided by all women giving birth. This indicator provides an overall assessment of adherence to the recommendation included in this guideline. The use of other locally agreed and more specific indicators may be necessary to obtain a more complete assessment of the quality of care related to the prevention and treatment of PPH.

WHO has developed specific guidance for evaluating the quality of care for severe maternal complications (including PPH) based on the near-miss and criterion-based clinical audit concepts (29). Monitoring the quality of uterotonic drugs available in low-resource settings may help guide skilled health-care personnel in selecting the most effective uterotonic option for PPH prevention in the context in which they are working.

5 Research implications

The GDG identified important knowledge gaps directly related to the PICO question, or which may have a direct impact on the implementation of this recommendation. The following questions were identified as high priority:

- What are the most accurate method(s) of objectively quantifying blood loss after childbirth, including for women experiencing a caesarean section?
- Which methods of objective postpartum blood loss quantification are most acceptable for women and health workers, and feasible to use?
- What is the most accurate approach for postpartum blood loss quantification for women giving birth at home or in community settings?
- What are the main outcomes that women (and their families) value in relation to interventions to detect and treat PPH?
- For women who experience PPH after a caesarean section, what care bundle is recommended?
- What are the strategies necessary to sustain the use of PPH treatment bundles over time, outside of a research context?

6 Updating the recommendations

The Maternal Perinatal Health Guideline Technical Advisory Group convenes regularly to review WHO's current portfolio of MPH recommendations and to help WHO prioritize new and existing questions for recommendation development and updating. These recommendations will be included in those reviews. In the event that new evidence that could potentially impact the current evidence base is identified, these recommendations may be updated. If no new reports or information is identified, the recommendations may be revalidated.

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

7 References

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Annex 2. Priority outcomes used in decisionmaking

Priority outcomes for the assessment of postpartum blood loss

The critical maternal outcomes considered were:

- accuracy in blood loss measurement, defined as the detection of postpartum haemorrhage (PPH) or severe PPH (≥ 500 ml and ≥ 1000 ml, respectively);
- postpartum anaemia (defined as a haemoglobin (Hb) lower than 9 mg/dl);
- severe morbidity (including coagulopathy, organ failure, intensive care unit admission, or as defined by the authors).

Important maternal outcomes considered were:

- blood loss greater than 500 ml;
- blood transfusion;
- use of plasma expanders;
- use of therapeutic uterotonics;
- changes in vital parameters, such as heart rate, blood pressure and urine output;
- further surgical procedures (e.g. curettage, laparotomy, laparoscopy, surgical exploration, manual removal of the placenta);
- hysterectomy due to PPH;
- maternal infection;
- maternal change in Hb concentration before and after delivery;
- maternal death;
- any side-effects related to the method used (e.g. phlebitis at the site of puncture for blood extraction);
- maternal satisfaction with the intervention (as defined by the authors);
- health worker's satisfaction with the intervention (as defined by the authors).

Priority outcomes for care bundles for the treatment of PPH

The critical maternal outcomes considered were:

- maternal death;
- severe PPH (blood loss ≥ 1000 ml);
- severe morbidity (intensive care admission or intubation, signs or symptoms of end-organ dysfunction or failure and maternal transfer);
- blood transfusion;

- additional blood loss (≥ 500 ml or ≥ 1000 ml);
- invasive non-surgical interventions, including artery embolization and manual removal of the placenta;
- surgical interventions (including hysterectomy);
- procedure-related complications (e.g. anaesthetic complications);
- sepsis.

Important maternal outcomes considered were:

- PPH ≥ 500 ml;
- mean blood loss (ml);
- · postpartum anaemia;
- any side-effects of the intervention or side-effects requiring treatment, including nausea, vomiting, diarrhoea, headache, abdominal pain, hypotension, shivering and maternal temperature ≥ 38 °C;
- additional non-surgical interventions (e.g. external aortic compression, use of compression garments);
- any additional treatments;
- artery embolization;
- delayed initiation of breastfeeding;
- prolonged hospitalization;
- maternal well-being;
- maternal satisfaction.

Important infant outcomes considered were:

- neonatal death (or perinatal death);
- neonatal intensive care unit admission;
- anaemia in infancy.

The health system outcomes considered were:

- acceptability of care bundle (to the target population of a care bundle);
- measures of health worker's adherence to a care bundle (e.g. number of components of the care bundle that were implemented);
- accuracy in blood loss assessment;
- reduction of time from decision-making to implementation;
- availability of drugs and treatment;
- costs of care.

Annex 3. Summary and management of declared interests

Name and title	Expertise contributed to guideline development	Declared interest	Management of declared interest
Guideline Development G	iroup		
Oluwarotimi Ireti Akinola	Content expert and end user (obstetrics)	None declared	Not applicable
Melania Amorim	Content expert and end user (obstetrics)	None declared	Not applicable
Brendan Carvalho	Content expert and end user (obstetric anaesthesia)	He has been a coauthor on one study included within the evidence synthesis. He was a paid consultant for Gauss Surgical, which developed artificial intelligence informed gravimetric products to measure blood loss. His last involvement with this work was in 2021.	This declared conflict of interest was not considered significant enough to pose any risk to the guideline development process or to reduce its credibility.
Catherine Deneux- Tharaux	Content expert and end user (obstetrics epidemiology)	She has been a coauthor on two studies recovered within the evidence synthesis.	This declared conflict of interest was not considered significant enough to pose any risk to the guideline development process or to reduce its credibility.
Caroline Homer	Content expert and end user (midwifery)	She has been a coauthor on one study recovered within the evidence synthesis.	This declared conflict of interest was not considered significant enough to pose any risk to the guideline development process or to reduce its credibility.
Rajat Khosla	Content expert (human rights)	None declared	Not applicable

Name and title	Expertise contributed to guideline development	Declared interest	Management of declared interest
Tippawan Liabsuetrakul	Content expert and end user (obstetrics)	None declared	Not applicable
Elliott Kingwill Main	Content expert and end user (obstetrics)	He consulted on the development of perinatal quality improvement collaboratives to implement national safety bundles in the United States of America. His contract with this work ended on 31 August 2023.	This declared conflict of interest was not considered significant enough to pose any risk to the guideline development process or to reduce its credibility.
		He has been a coauthor on one study recovered within the evidence synthesis.	
Hadil Ali-Masri	Content expert and end user (obstetrics)	None declared	Not applicable
Martin Meremikwu	Content expert and end user (neonatology)	None declared	Not applicable
Kui Muraya	Content expert (gender and social determinants, equity)	None declared	Not applicable
Mari Nagai	Content expert (health systems)	None declared	Not applicable
Angela Ndunge Nguku	Community and stakeholder perspective	None declared	Not applicable
Aris Papageorghiou (GDG Chair)	Content expert and end user (obstetrics)	He is a current clinician using the medications and interventions included in the guideline in his clinical practice.	This declared conflict of interest was not considered significant enough to pose any risk to the guideline development process or to reduce its credibility.

Name and title	Expertise contributed to guideline development	Declared interest	Management of declared interest
Dilys Walker	Content expert and end user (obstetrics)	She received a Saving Lives at Birth grant; through this she acts as a virtual mentor for a chatbot on PPH management. She is the co-founder of	This declared conflict of interest was not considered significant enough to pose any risk to the guideline development process or to reduce its credibility.
		PRONTO.	
		She has a patent on PartoPants, a simulation training tool.	
		She has provided a lecture on heat-stable carbetocin at a FIGO conference side event sponsored by Ferring Pharmaceuticals.	
		She was funded by the Gates Foundation to perform a scoping on sponge and suction tools for PPH.	
Evidence Synthesis Group)		
Virginia Diaz	Evidence synthesis	None declared	Not applicable
Joshua Ginnane	Evidence synthesis	None declared	Not applicable
Annie McDougall	Content expert, evidence synthesis	None declared	Not applicable
Phoebe Nguyen	Evidence synthesis	None declared	Not applicable
Jen Ramson	Content expert, evidence synthesis, guideline methodology	None declared	Not applicable
Joshua Vogel	Content expert, evidence synthesis, guideline methodology	None declared	Not applicable

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