



# WHO recommendation on **Uterine balloon tamponade** for the treatment of postpartum haemorrhage



World Health  
Organization

human  
reproduction  
programme **hrp.**  
research for impact  
UNDP · UNFPA · UNICEF · WHO · WORLD BANK



WHO recommendation on  
**Uterine balloon tamponade**  
**for the treatment of postpartum**  
**haemorrhage**

WHO recommendation on uterine balloon tamponade for the treatment of postpartum haemorrhage

ISBN 978-92-4-001384-1 (electronic version)

ISBN 978-92-4-001385-8 (print version)

© **World Health Organization 2021**

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition".

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization (<http://www.wipo.int/amc/en/mediation/rules/>).

**Suggested citation.** WHO recommendation on uterine balloon tamponade for the treatment of postpartum haemorrhage. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

**Cataloguing-in-Publication (CIP) data.** CIP data are available at <http://apps.who.int/iris>.

**Sales, rights and licensing.** To purchase WHO publications, see <http://apps.who.int/bookorders>. To submit requests for commercial use and queries on rights and licensing, see <http://www.who.int/about/licensing>.

**Third-party materials.** If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

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

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

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

# Contents

Acknowledgements	v
Acronyms and abbreviations	vi
Executive summary	vii
Introduction	vii
Target audience	vii
Guideline development methods	vii
Recommendation	vii
1. Introduction	1
1.1 Background	1
1.2 Rationale and objectives	1
1.3 Target audience	2
1.4 Scope of the recommendation	2
1.5 Persons affected by the recommendations	2
2. Methods	3
2.1 Executive Guideline Steering Group (GSG)	3
2.2 WHO Steering Group	3
2.3 Guideline Development Group (GDG)	3
2.4 Evidence Synthesis Group (ESG)	4
2.5 External partners and observers	4
2.6 External Review Group (ERG)	4
2.7 Identification of priority questions and outcomes	4
2.8 Evidence identification and retrieval	5
2.9 Certainty assessment and grading of the evidence	6
2.10 Formulation of the recommendation	7
2.11 Management of declarations of interests	8
2.12 Decision-making during the GDG meeting	9
2.13 Document preparation	9
2.14 Peer review	9
3. Recommendation and supporting evidence	10
4. Dissemination, adaptation and implementation of the recommendation	11
4.1 Recommendation dissemination	11
4.2 Adaptation	12
4.3 Implementation considerations	12
5. Research implications	13
6. Applicability issues	13
6.1 Anticipated impact on the organization of care and resources	13
6.2 Monitoring and evaluating guideline implementation	14
7. Updating the recommendations	14
8. References	15

Annex 1.	External experts and who staff involved in the preparation of the recommendations	17
Annex 2.	Priority outcomes used in decision-making	20
Annex 3.	Summary and management of declared interests from GDG members	21
Annex 4.	Evidence to Decision frameworks	23
4.1	Uterine balloon tamponade compared with no uterine tamponade	23
4.2	Uterine balloon tamponade compared with another uterine balloon tamponade	42
4.3	Uterine balloon tamponade compared with a different type of uterine tamponade	58

## Acknowledgements

The World Health Organization (WHO) Department of Sexual and Reproductive Health and Research and Department of Maternal, Newborn, Child and Adolescent Health and Ageing gratefully acknowledge the contributions of many individuals and organizations to the updating of this recommendation. Work on this update was coordinated by Fernando Althabe, Tina Lavin, Olufemi Oladapo, Joshua Vogel and Mariana Widmer of the Department of Sexual and Reproductive Health and Research.

WHO extends its sincere thanks to Oluwarotimi Ireti Akinola, Melania Amorim, Brendan Carvalho, Catherine Deneux-Tharaux, Tippawan Liabsuetrakul, Martin Meremikwu, Suellen Miller, Mari Nagai, Hayfaa Wahabi, Dilys Walker and Andrew Weeks who served as members of the Guideline Development Group (GDG), and to Ashraf Nabhan (Chair) for leading the meeting. We also thank Christine East, Gill Gyte, Justus Hofmeyr, Syeda Batool Mazhar, Enrique Oyarzun and Qian Xu, who were members of the External Review Group (ERG). WHO also gratefully acknowledges the contribution of the members of the Executive Guideline Steering Group (GSG).

Edgardo Abalos, Anna Cuthbert, Virginia Diaz, Kenneth Finlayson, Leanne Jones, Frances Kellie, Veronica Pingray and Myfanwy Williams reviewed the scientific evidence, prepared the Grading of Recommendations Assessment, Development and Evaluation (GRADE) tables and drafted the narrative summary of the evidence. Fernando Althabe, Olufemi Oladapo, Joshua Vogel and Mariana Widmer revised the narrative summaries, double-checked the corresponding GRADE tables and prepared the Evidence to Decision (EtD) frameworks. The ERG peer reviewed the final document prior to executive clearance by WHO and publication.

We acknowledge the various organizations that were represented by observers, including Deborah Armbruster (United States Agency for International Development [USAID]), Ingela Wiklund (International Confederation of Midwives [ICM]) and Carlos Fuchtnr (International Federation of Gynecology and Obstetrics [FIGO]). We also appreciate the contributions of staff at the WHO regional offices, including Nino Berdzuli, Bremen De Mucio, Hayfa Elamin, Chandani Anoma Jayathilaka, Ramez Khairi Mahaini, Howard Sobel and Claudio Sosa.

WHO acknowledges the financial support for this work received from USAID, the UNDP–UNFPA–UNICEF–WHO–World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP) and the Department of Sexual and Reproductive Health and Research. WHO emphasizes that donors do not participate in any decision related to the guideline development process, including the composition of research questions, membership of the guideline development groups, conducting and interpretation of systematic reviews, or formulation of the recommendations. The views of the funding bodies have not influenced the content of this recommendation.

## Acronyms and 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
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
IV	intravenous
PICO	population (P), intervention (I), comparator (C), outcome (O)
PPH	postpartum haemorrhage
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

Postpartum haemorrhage (PPH) is commonly defined as a blood loss of at least 500 mL within 24 hours after birth and affects about 5% of all women giving birth around the world. Globally, nearly one quarter of all maternal deaths are associated with PPH and, in most low-income countries, it is the main cause of maternal mortality. Improving care during childbirth to prevent PPH is a necessary step towards achievement of the health targets of the third Sustainable Development Goal (SDG 3), particularly target 3.1: reduce the global maternal mortality ratio to less than 70 per 100 000 live births by 2030. Efforts to prevent and reduce morbidity and mortality due to PPH can help to address the profound inequities in maternal and perinatal health globally. To achieve this, skilled health personnel, health managers, policy-makers and other stakeholders need up-to-date and evidence-informed recommendations to guide clinical policies and practices.

In 2019, the Executive Guideline Steering Group (GSG) for the World Health Organization (WHO) maternal and perinatal health recommendation prioritized updating of the existing WHO recommendations on uterine balloon tamponade for treating PPH, in response to the availability of new evidence. The recommendation in this document thus supersedes the previous WHO recommendations on this intervention as published in the 2012 guideline, *WHO recommendations for the prevention and treatment of postpartum haemorrhage*.

## Target audience

The primary audience for these recommendations includes health professionals who are responsible for developing national and local health-care guidelines and protocols (particularly those related to PPH prevention and treatment) and those involved in the provision of care to women and their newborns during labour and childbirth, including midwives, nurses, general medical practitioners and obstetricians, as well as managers of maternal and child health programmes, and relevant staff in ministries of health and training institutions, in all settings.

## Guideline development methods

The updating 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 initially developed and updated using this process, namely: (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 recommendation was synthesized using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach. An updated systematic review was used to prepare the evidence profiles for the prioritized question. WHO convened a meeting on 11–12 March 2020 where the Guideline Development Group (GDG) members reviewed, deliberated and achieved consensus on the strength and direction of the recommendation presented herein. Through a structured process, the GDG reviewed the balance between the desirable and undesirable effects and the overall certainty of supporting evidence, values and preferences of stakeholders, resource requirements and cost-effectiveness, acceptability, feasibility and equity.

## Recommendation

The GDG reviewed the balance between the desirable and undesirable effects and the overall certainty of supporting evidence, values and preferences of stakeholders, resource requirements and cost-effectiveness, acceptability, feasibility and equity. The GDG issued

the new recommendation on uterine balloon tamponade for treating PPH, with remarks and implementation considerations. To ensure that the recommendation is correctly understood and applied in practice, guideline users may want to refer to the remarks, as well as to the evidence summary, including the considerations on implementation.

### **WHO recommendation on uterine balloon tamponade for treating postpartum haemorrhage**

**Uterine balloon tamponade is recommended for the treatment of postpartum haemorrhage due to uterine atony after vaginal birth in women who do not respond to standard first-line treatment, provided the following conditions are met:**

- Immediate recourse to surgical intervention and access to blood products is possible if needed.
- A primary postpartum haemorrhage first-line treatment protocol (including the use of uterotonics, tranexamic acid, intravenous fluids) is available and routinely implemented.
- Other causes of postpartum haemorrhage (retained placental tissue, trauma) can be reasonably excluded.
- The procedure is performed by health personnel who are trained and skilled in the management of postpartum haemorrhage, including the use of uterine balloon tamponade.
- Maternal condition can be regularly and adequately monitored for prompt identification of any signs of deterioration.

*(Context-specific recommendation)*

#### **Justification**

- While there is insufficient evidence from randomized trials conducted in low-resource settings to assess the benefits and potential harms of uterine balloon tamponade when used for postpartum haemorrhage treatment, several observational studies suggest a substantial reduction in the risk of maternal morbidity following uterine balloon tamponade use. It is unclear whether this disparity in findings reflects study design, balloon type, or access to other essential components of postpartum haemorrhage care.
- The impact of uterine balloon tamponade for postpartum haemorrhage treatment on health equity and cost is likely to vary according to uterine balloon tamponade designs (low-cost improvised or purpose-designed devices versus expensive purpose-designed devices). In contexts where standard postpartum haemorrhage treatment protocols are available and implemented, uterine balloon tamponade use for postpartum haemorrhage treatment is probably feasible and acceptable to women and providers.

#### **Remarks**

- The Guideline Development Group acknowledged that the conditions listed above may not be operationalized in a standard and consistent manner across settings. It is uncertain which preconditions are the most important in order to obtain clinical benefits from uterine balloon tamponade, and this would benefit from further research. In setting these preconditions, the panel's emphasis was on minimizing harm to the woman, which could result from failure to or delay in implementing other temporizing and more invasive postpartum haemorrhage treatment, incorrect patient selection for application of uterine balloon tamponade, poor monitoring, or the redirection of resources away from other essential components of quality postpartum haemorrhage care.

- In settings where these conditions cannot be met, the Guideline Development Group agreed that additional rigorous research evidence is needed to determine if the clinical benefits outweigh the potential harms of uterine balloon tamponade in such settings.
- There is currently insufficient evidence to determine the comparative effectiveness and safety of improvised devices or purpose-designed devices. Evidence for the above recommendation came from trials which used improvised devices, for which there were reported concerns or problems in placement, including delays in inserting the device.
- This updated recommendation supersedes the previous recommendation on uterine balloon tamponade for postpartum haemorrhage treatment, which was issued in the 2012 *WHO recommendations for prevention and treatment of postpartum haemorrhage*.

# 1. Introduction

## 1.1 Background

An estimated 295 000 women and adolescent girls died as a result of pregnancy and childbirth-related complications in 2017, and around 99% of these deaths occurred in low-resource settings (1). Obstetric haemorrhage, especially postpartum haemorrhage (PPH), is responsible for more than a quarter of all maternal deaths worldwide (2). In most low-income countries, PPH is the leading cause of maternal deaths. Thus, improving access to safe and effective interventions to prevent PPH is critical to World Health Organization (WHO) strategic priorities (particularly universal health coverage) for achieving the targets of the third Sustainable Development Goal (SDG 3) (3).

International human rights law includes 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). WHO envisions a world where “every pregnant woman and newborn receives quality care throughout pregnancy, childbirth and the postnatal period” (5). To provide good-quality care, skilled health personnel at all levels of the health system need to have access to appropriate medications and training in relevant procedures (6). Health-care providers, health managers, health policy-makers and other stakeholders also need up-to-date, evidence-informed recommendations to guide clinical policies and practices to optimize quality of care and improve health-care outcomes.

PPH is commonly defined as a blood loss of at least 500 mL within 24 hours after birth and affects about 5% of all women giving birth around the world (7). Severe maternal complications, such as organ dysfunction or death, generally occur following substantial blood loss that compromises maternal haemodynamic stability. Uterine atony is the most common cause of PPH and a leading cause of PPH-related maternal mortality worldwide (8). Genital tract trauma (including vaginal or cervical lacerations and uterine rupture), retained placental tissue, or maternal bleeding disorders can cause PPH. Although the majority of women presenting with PPH have no identifiable risk factor, grand multiparity, prolonged labour, prior history of PPH and multiple gestation are obstetric conditions that are associated with an increased risk of bleeding after birth (9). In addition, anaemia is a common aggravating factor (10). The majority of women with PPH respond well to first-line interventions (uterotonics, uterine massage, tranexamic acid and intravenous [IV] fluid with isotonic crystalloids). However, between 10% and 20% of these women are unresponsive to these interventions (denoted as “refractory PPH”). These women (of whom 30–50% have uterine atony) account for a substantial proportion of PPH-related morbidity and mortality overall. Laparotomy for compressive sutures, uterine artery ligation or hysterectomy are frequently needed to prevent deaths among these women (11).

Effective nonsurgical interventions to manage refractory PPH are critical in low-resource settings where operating theatres are not always available. WHO recommends bimanual uterine compression, external aortic compression, the use of non-pneumatic anti-shock garment, uterine balloon tamponade and a second dose of tranexamic acid as nonsurgical interventions (12). However, since the publication of the 2012 WHO PPH recommendations, several studies that assessed the effectiveness of uterine balloon tamponade have been published.

## 1.2 Rationale and objectives

WHO has established a new process for prioritizing and updating maternal and perinatal health 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 (13,14). Recommendations are prioritized for updating on the basis of changes or important new uncertainties in the underlying evidence base on benefits, harms, values placed on outcomes, acceptability,

feasibility, equity, resource use, cost-effectiveness, or factors affecting implementation. The Executive GSG prioritized updating of the existing WHO recommendations on uterine balloon tamponade for treating PPH in anticipation of the publication of new and potentially important evidence on these interventions.

These updated recommendations were developed in accordance with the standards and procedures in *WHO handbook for guideline development*, including synthesis of available research evidence, use of the Grading of Recommendations Assessment, Development and Evaluation (GRADE)<sup>1</sup> and GRADE Confidence in the Evidence from Reviews of Qualitative Research (GRADE-CerQUAL)<sup>2</sup> methodologies, and formulation of recommendations by a Guideline Development Group (GDG) composed of international experts and stakeholders (15). The recommendation published in this document thus supersedes the previous recommendations on uterine balloon tamponade for treating PPH that were published in 2012 in the *WHO recommendations for the prevention and treatment of postpartum haemorrhage* (12). The primary aim of this recommendation is to improve the quality of care and outcomes for women giving birth, as they relate to PPH and its complications. This recommendation thus provides a foundation for sustainable implementation of uterine balloon tamponade in the immediate postpartum period only in those settings where standard PPH treatment protocols are available and implemented.

### 1.3 Target audience

The primary audience includes health professionals who are responsible for developing national and local health-care guidelines and protocols (particularly those related to PPH prevention and treatment) and those involved in the provision of care to women during labour and childbirth, including midwives, nurses, general medical practitioners and obstetricians, as well as managers of maternal and child health programmes, and relevant staff in ministries of health and training institutions, in all settings.

This recommendation will also be of interest to women giving birth in a range of resource settings (low to high), as well as members of professional societies involved in the care of pregnant women, staff of nongovernmental organizations concerned with promoting people-centred maternal care, and implementers of maternal and perinatal health programmes.

### 1.4 Scope of the recommendation

Framed using the Population (P), Intervention (I), Comparison (C), Outcome (O) (PICO) format, the questions for this recommendation were:

- For women with PPH who do not respond to treatment with uterotonics (P), does the use of uterine balloon tamponade (I) compared with no uterine balloon tamponade (C) improve maternal outcomes (O)?
- For women with PPH who do not respond to treatment with uterotonics (P), does the use of a particular uterine balloon tamponade (I) compared with another uterine balloon tamponade (C) improve maternal outcomes (O)?
- For women with PPH who do not respond to treatment with uterotonics (P), does the use of uterine balloon tamponade (I) compared with a different type of uterine tamponade intervention (C) improve maternal outcomes (O)?

### 1.5 Persons affected by the recommendations

The population affected by this recommendation includes women experiencing PPH in low-, middle- or high-income settings.

<sup>1</sup> Further information is available at: <http://www.gradeworkinggroup.org/>.

<sup>2</sup> Further information is available at: <https://www.cerqual.org/>.

## 2. Methods

The recommendation was developed using standardized operating procedures in accordance with the process described in *WHO handbook for guideline development* (15). 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 recommendation; and (v) planning for the dissemination, implementation, impact evaluation and updating of the recommendation.

In 2019, the use of uterine balloon tamponade for treating PPH was identified by the Executive GSG as a high priority for development of a recommendation, in response to new, potentially important evidence on this question. Six main groups were involved in this process, with their specific roles described in the following sections.

### 2.1 Executive Guideline Steering Group (GSG)

The Executive GSG is an independent panel of 14 external experts and relevant stakeholders from the six WHO regions: African Region, Region of the Americas, Eastern Mediterranean Region, European Region, South-East Asia Region and Western Pacific Region. The Executive GSG advises WHO on the prioritization of new and existing PICO questions in MPH for development or updating of recommendations (13,14).

### 2.2 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 (that is, 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 meeting, 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.

### 2.3 Guideline Development Group (GDG)

The WHO Steering Group identified a pool of approximately 50 experts and relevant 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 who are 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. Members of the MPH-GDG are identified in a way that ensures geographic representation and gender balance, and there were no perceived or real conflicts of interest. Members' expertise cuts across thematic areas within maternal and perinatal health.

From the MPH-GDG pool, 14 external experts and relevant stakeholders were invited to participate as members of the GDG for updating this recommendation. Those selected were a diverse group with expertise in research, guideline development methods, gender, equity and rights, clinical policy and programmes relating to PPH prevention and treatment.

The 14 GDG members for this recommendation were also selected in a way that ensured geographic representation and gender balance; there were no important conflicts of interest. These members appraised the evidence that was used to inform the recommendation, advised on the interpretation of this evidence, formulated the final recommendation based on the draft prepared by the Steering Group, and reviewed and reached unanimous consensus for the recommendation in the final document. The members of the GDG are listed in Annex 1.

## 2.4 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. A systematic review on this question was updated, supported by the Cochrane Pregnancy and Childbirth Group. The WHO Steering Group reviewed and provided input into the updated protocol and worked closely with the Cochrane Pregnancy and Childbirth Group to appraise the evidence using the GRADE methodology. Representatives of the Cochrane Pregnancy and Childbirth Group and a methodologist attended the GDG meeting to provide an overview of the available evidence and GRADE tables, and to respond to technical queries from the GDG.

Systematic reviews of qualitative and cost-effectiveness studies were commissioned to generate evidence for other domains of the GRADE EtD frameworks. Researchers from the University of Central Lancashire, United Kingdom, conducted a systematic review of qualitative studies related to the views and experiences of women and health-care providers on interventions for the prevention and treatment of PPH (16). A research consultant from Burnet Institute, Melbourne, Australia led the work of conducting a systematic review of cost-effectiveness studies on uterine balloon tamponade for PPH treatment. These reviews were conducted in collaboration with the WHO Steering Group, whose members worked closely with all members of the ESG to review the evidence and prepare the GRADE EtD frameworks. All members of the ESG attended the GDG meetings to provide an overview of the synthesized evidence and to respond to technical queries from the GDG. The members of the ESG are listed in Annex 1.

## 2.5 External partners and observers

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

## 2.6 External Review Group (ERG)

The ERG included six technical experts with interests and expertise in the provision of evidence-based care to prevent and treat PPH. The group was geographically diverse and gender balanced, and the members had no important conflicts of interest. The 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 that were formulated by the GDG. Members of the ERG are listed in Annex 1.

## 2.7 Identification of priority questions and outcomes

The priority outcomes were aligned with those from the 2012 *WHO recommendations for prevention and treatment of postpartum haemorrhage* (12). 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 2012 guideline. After due consideration of the recently published core outcome set for prevention and treatment of PPH (17), three additional outcomes – maternal death, maternal well-being and maternal satisfaction – were included for 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. Additionally, three process outcomes were removed – reduction of time from decision-making to implementation,



availability of drugs and treatment, and accuracy in blood loss assessment – as they were considered not relevant for this treatment intervention. 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.

## **2.8 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.

### **2.8.1 Evidence on the effects of uterine balloon tamponade for PPH treatment**

An existing systematic review was updated for the purpose of updating this recommendation (18). This systematic review was the primary source of evidence for this recommendation.

Randomized controlled trials relevant to the key question were screened by the review authors and data on relevant outcomes and comparisons were entered into the 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 recommendation 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 (19). Finally, evidence profiles (in the form of GRADE summary of findings tables) were prepared for comparisons of interest, including the assessment and judgements for each outcome and the estimated risks.

### **2.8.2 Evidence on values, resource use and cost-effectiveness, equity, acceptability and feasibility**

For questions relating to the other domains of the GRADE EtD frameworks (other than effects – that is, resources, equity, acceptability and feasibility), new systematic reviews were commissioned from external experts. The external experts were asked to prepare a standard protocol before embarking on the review, including: (i) a clear and focused question; (ii) criteria for identification of studies, including search strategies for different bibliographic databases; (iii) methods for assessing risk of bias; and (iv) a data analysis plan. Each protocol was reviewed and endorsed by the WHO Steering Group before the respective review teams embarked on the review process. The entire systematic review development process was iterative, with the review teams in constant communication with the WHO Steering Group to discuss challenges and agree on solutions.

A qualitative systematic review was conducted on the views and experiences of women and health-care providers on interventions for the prevention of PPH (16). For the purposes of this recommendation, this review was updated and expanded to identify qualitative evidence on the use of uterine balloon tamponade for the treatment of PPH. This updated review was the primary source of evidence on acceptability, feasibility and equity as they relate to the EtD frameworks for the treatment of refractory PPH with uterine balloon tamponades. Evidence for these domains was also supplemented by findings from a qualitative systematic review on women's views and experiences during intrapartum care (20).

Evidence on resource use and cost-effectiveness was based on a systematic review of the literature. The review aimed to evaluate all available evidence regarding which uterine balloon tamponade devices are cost-effective when used for treating PPH. Eligible studies were identified from the following databases from 1980 up to January 2020: MEDLINE, Embase, the Cochrane Central Register of Controlled Trials and the National Health Services Economic Evaluation Database. Reference lists of included studies were also reviewed to identify any additional eligible studies. Eligible studies included those evaluating costs and cost-effectiveness of any uterine balloon tamponade device in comparison with standard care or another uterine tamponade device for the treatment of PPH, in any setting. Unit costs were extracted, as well as measures of costs, incremental costs and incremental cost-effectiveness.



## 2.9 Certainty assessment and grading of the evidence

The certainty assessment of the body of evidence for each outcome was performed using the GRADE approach (19). Using this approach, the certainty of evidence for each outcome was rated as “high”, “moderate”, “low” or “very low” based on a set of established criteria. The final rating of certainty of evidence 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 outcome. For randomized trials, 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 the outcome.

**Inconsistency of the results:** The similarity in 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.

**Imprecision:** This assessed the degree of uncertainty around the estimate of 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.

**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.

The findings of the qualitative reviews were appraised for quality using the GRADE-CERQual tool (21). 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 in evidence from reviews of qualitative research. The systematic review team used the GRADE-CERQual tool to assign a level of confidence (“high”, “moderate”, “low” and “very low”) to each review finding according to four components: methodological limitations of the individual studies; adequacy of data; coherence; and relevance to the review question of the individual studies contributing to a review finding. Findings from individual cost-effectiveness studies were reported narratively for each comparison of interest.

## 2.10 Formulation of the recommendation

The WHO Steering Group supervised and finalized the preparation of summary of findings tables and narrative evidence summaries in collaboration with the ESG using the GRADE EtD framework. 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, judgements were 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:

- **Effects:** The evidence on the priority outcomes was summarized in this domain to answer the questions: “What are the desirable and undesirable effects of uterine balloon tamponade when used for treating PPH?” and “What is the certainty of the evidence on effects?” Where benefits clearly outweighed 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 (and their families) value the main outcomes associated with uterine balloon tamponade for PPH treatment?” When the intervention resulted in benefit for 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 use of uterine balloon tamponade for PPH treatment?” and “Is the intervention cost-effective?” The resources required to implement uterine tamponade devices for the treatment of PPH mainly include the costs of providing supplies, training, equipment and skilled human resources. A judgement in favour of or against the intervention was likely where the resource implications were clearly advantageous or disadvantageous, respectively.
- **Acceptability:** For this domain, the question was: “Is uterine balloon tamponade for PPH treatment acceptable to women and health-care providers?” Qualitative evidence from systematic reviews on the views and experiences of women and provider (16) informed the judgements for this domain. 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-care providers responsible for administering it. The question addressed was: “Is it feasible for the relevant stakeholders to implement uterine balloon tamponade for PPH treatment?” Qualitative evidence from the systematic reviews on women’s and providers’ views and experiences and from two trials was used to inform judgements for this domain (16,22,23). Where major barriers were identified, it was less likely that a judgement would be made in favour of the intervention.

- **Equity:** This domain encompasses evidence or considerations as to whether or not the intervention would reduce health inequities. Therefore, this domain addressed the question: “What is the anticipated impact of uterine balloon tamponade for PPH treatment on equity?” The findings of the systematic review on cost-effectiveness of uterine balloon tamponade for the treatment of PPH, as well as the experiences and opinions of the GDG members, were used to inform judgements for this domain. The intervention was likely to be recommended if its proven (or anticipated) effects reduce (or could reduce) health inequalities among different groups of women and their families.

For each of the above domains, additional evidence of potential harms or unintended consequences are described in the Additional considerations subsections. 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 frameworks – including evidence summaries, summary of findings tables and other documents related to each recommendation – 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 GDG meeting. During the GDG meeting (11–12 March 2020), which was conducted under the leadership of the GDG chairperson, the members collectively reviewed the EtD frameworks and any comments received through preliminary feedback, and formulated the recommendations. The purpose of the meeting was to reach consensus on each recommendation, including its direction and in some instances the specific context, based on explicit consideration of the range of evidence presented in each EtD framework and the judgement of the GDG members. The GDG was asked to select one of the following categories for the recommendation:

- **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.

## 2.11 Management of declarations of interests

WHO has a robust process to protect the integrity of its normative work as well as to protect the integrity of 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 prior to participation in WHO guideline development processes and meetings according to the guidelines for declaration of interest (DOI) for WHO experts (75). 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 processes. The WHO Steering Group reviewed all DOI before finalizing the experts’ invitations to participate. Where any conflict of interest was 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 Steering Group applied the criteria for assessing the severity of conflicts of interests as outlined in the WHO handbook for guideline development to all participating experts. All findings from the DOI statements received were managed in accordance with the WHO procedures to assure the work of WHO and the contributions of its experts is, actually and ostensibly, objective and independent. The names and biographies of individuals were published online four weeks prior to the meeting. Where a conflict of interest was not considered significant enough to pose any risk to the guideline development process or to reduce its credibility, the 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.

## **2.12 Decision-making during the GDG meeting**

During the meeting, the GDG reviewed and discussed the evidence summary and sought clarification. 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 recommendation. These criteria included stakeholders' values, resource implications, acceptability, feasibility and equity. Considerations were based on the experiences and opinions of the GDG members and supported by evidence from a literature search where available. EtD tables were used to describe and synthesize these considerations.

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

## **2.13 Document preparation**

Prior to the online meeting, the WHO Steering Group prepared a draft version of the GRADE evidence profiles, the evidence summary and other documents relevant to the GDG's deliberation. The draft documents were made available to the participants of the meeting two weeks before the meeting for their comments. During the 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.

## **2.14 Peer review**

Following review and approval by GDG members, the final document was sent to six external independent experts (comprising the ERG) who were not involved in the guideline panel for peer review. The WHO Steering Group evaluated the inputs of the peer reviewers for inclusion in this document. After the meeting and external peer review, the modifications made by the WHO Steering Group to the document consisted only of the correction of factual errors and improving language to address any lack of clarity.

### 3. Recommendation and supporting evidence

The following section outlines the recommendation and the corresponding narrative summary of evidence for the prioritized question. The EtD table 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, acceptability, feasibility and equity that were considered in determining the strength and direction of the recommendation. It is presented in the EtD framework (Annex 4).

The following recommendation was adopted by the GDG. Evidence on the effectiveness of this intervention was derived from the updated systematic review and summarized in GRADE tables (Annex 4). The certainty of the supporting evidence was rated as “moderate” for most of the critical outcomes.

To ensure that the recommendation is correctly understood and appropriately implemented in practice, additional remarks reflecting the summary of the discussion by the GDG are included under the recommendation below.

**Uterine balloon tamponade is recommended for the treatment of postpartum haemorrhage due to uterine atony after vaginal birth in women who do not respond to standard first-line treatment, provided the following conditions are met:**

- Immediate recourse to surgical intervention and access to blood products is possible if needed.
- A primary postpartum haemorrhage first-line treatment protocol (including the use of uterotonics, tranexamic acid, IV fluids) is available and routinely implemented.
- Other causes of postpartum haemorrhage (retained placental tissue, trauma) can be reasonably excluded.
- The procedure is performed by health personnel who are trained and skilled in the management of postpartum haemorrhage, including the use of uterine balloon tamponade.
- Maternal condition can be regularly and adequately monitored for prompt identification of any signs of deterioration.

*(Context-specific recommendation)*

#### Justification

- While there is insufficient evidence from randomized trials conducted in low-resource settings to assess the benefits and potential harms of uterine balloon tamponade when used for postpartum haemorrhage treatment, several observational studies suggest a substantial reduction in the risk of maternal morbidity following uterine balloon tamponade use. It is unclear whether this disparity in findings reflects study design, balloon type or access to other essential components of postpartum haemorrhage care.
- The impact of uterine balloon tamponade for postpartum haemorrhage treatment on health equity and cost is likely to vary according to uterine balloon tamponade designs (low-cost improvised or purpose-designed devices versus expensive purpose-designed devices). In contexts where standard postpartum haemorrhage treatment protocols are available and implemented, uterine balloon tamponade use for postpartum haemorrhage treatment is probably feasible and acceptable to women and providers.

### Remarks

- The Guideline Development Group acknowledged that the conditions listed above may not be operationalized in a standard and consistent manner across settings. It is uncertain which preconditions are the most important in order to obtain clinical benefits from uterine balloon tamponade, and this would benefit from further research. In setting these preconditions, the panel's emphasis was on minimizing harm to the woman, which could result from failure to or delay in implementing other temporizing and more invasive postpartum haemorrhage treatment, incorrect patient selection for application of uterine balloon tamponade, poor monitoring, or lack of other essential components for quality postpartum haemorrhage care.
- In settings where these conditions cannot be met, the Guideline Development Group agreed that additional rigorous research evidence is needed to determine if the clinical benefits outweigh the potential harms of uterine balloon tamponade in such settings.
- There is currently insufficient evidence to determine the comparative effectiveness and safety of improvised devices or purpose-designed devices. Evidence for the above recommendation came from trials which used improvised devices for which there were reported concerns or problems in placement, including delays in inserting the device.
- This updated recommendation supersedes the previous recommendation on uterine balloon tamponade for postpartum haemorrhage treatment, which was issued in the 2012 *WHO recommendations for prevention and treatment of postpartum haemorrhage*.

## 4. Dissemination, adaptation and implementation of the recommendation

The dissemination and implementation of this recommendation 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 and to 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 country and health-care facility levels, where appropriate.

### 4.1 Recommendation dissemination

The recommendation 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. This recommendation will also be available on the WHO website and the WHO Reproductive Health Library.<sup>1</sup> Updated recommendations are also routinely disseminated during meetings or scientific conferences attended by WHO maternal and perinatal health staff.

The recommendation 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 recommendation into any of these languages.

<sup>1</sup> Available at: [www.who.int/rhl](http://www.who.int/rhl).

## 4.2 Adaptation

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

Existing global models such as those for WHO antenatal and intrapartum care guidelines can be adapted to different countries, contexts, and individual needs and preferences of women. The conceptual basis of these models is to drive improvements in the quality of maternal health care, by aiming to achieve the best possible physical, emotional and psychological outcomes for the woman and her baby, irrespective of the influence of generic policies that may exist within and across health systems and countries. Both models address relevant health policy, organizational and user-level considerations. These models thus support implementation of WHO recommendations and are intended to be adapted by stakeholders and partners at regional, country and local levels into locally appropriate documents and tools.

The successful introduction of evidence-based policies (relating to 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 this recommendation, including changes in the behaviour of health-care practitioners to enable the use of evidence-based practices.

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

## 4.3 Implementation considerations

- The recommendation 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 recommendation, where necessary, should be justified in an explicit and transparent manner.
- An enabling environment should be created for the implementation of this recommendation, including education to support behaviour change among skilled health personnel to facilitate the use of evidence-based practices.
- In settings where uterine balloon tamponade is used, appropriate training for skilled health personnel is required. While the most effective approach to uterine balloon tamponade training is not yet known, this training should include competent use of uterine balloon tamponade and timely and effective PPH management more broadly. Competency-based training, onsite, with training models and PPH emergency drills/simulations is advised, with periodic refresher training.
- Wherever uterine balloon tamponade is used, effective maternal analgesia or anaesthesia should be available.
- Before uterine balloon tamponade is used, a direct visual examination of the vaginal upper third and uterine cervix should be conducted to exclude trauma as the cause of the bleeding. Similarly, a careful visual examination of the placenta should be done to exclude retained placental tissue as a cause.



## 5. Research implications

The GDG identified important knowledge gaps that need to be addressed through primary research, which may have an impact on this recommendation. The following questions were identified as those that demand urgent priority:

In settings where the uterine balloon tamponade treatment preconditions cannot be reasonably met:

- What is the effectiveness and safety of purpose-designed uterine balloon tamponade devices as treatment for atonic refractory PPH in the reduction of PPH-related severe maternal morbidity and mortality?
- What is the effectiveness and safety of uterine balloon tamponade when using it as a temporizing measure for treatment of atonic refractory PPH in preparation for referral to a higher level of care, in the reduction of PPH-related severe maternal morbidity and mortality?
- What are the essential preconditions that health services should meet in order for uterine balloon tamponade devices to be effective and safe in women with atonic refractory PPH?

In adequately resourced settings with good-quality PPH care:

- What is the comparative effectiveness of different types of uterine balloon tamponade devices (including improvised or low-cost purpose-designed devices) in the reduction of PPH-related maternal morbidity and mortality?
- What is the comparative effectiveness of uterine balloon tamponades compared to other tamponade interventions (such as suction devices) in the reduction of PPH-related maternal morbidity and mortality?
- What is the safety and comparative effectiveness of different tamponade devices for the treatment of refractory PPH at caesarean section in the reduction of PPH-related maternal morbidity and mortality?
- What is the most effective modality for training and assuring competency in the use of uterine balloon tamponade?

## 6. Applicability issues

### 6.1 Anticipated impact on the organization of care and resources

Implementing this evidence-based recommendation requires resources for sustainable procurement and storage of uterine balloon tamponade devices, in addition to the commodities needed for first-line PPH treatment. The GDG noted that updating training curricula and providing training on the recommendation would increase its impact and facilitate its implementation. Standardization of care, by including this recommendation in existing intrapartum and immediate postpartum care packages, can encourage behaviour change in health-care providers.

As part of efforts to implement this recommendation, 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 understanding of changes in recommended interventions among skilled care personnel and systems managers;
- resistance of skilled care personnel to changing from the use of non-evidence-based to evidence-based practices;



- lack of infrastructure to support interventions (such as recourse to surgical procedures);
- lack of essential equipment, supplies and medicines (such as needles, syringes, gloves, blood products, uterotonics and analgesics);
- lack of effective mechanisms to identify women who are experiencing PPH, in order to trigger PPH management pathways;
- lack of effective mechanisms to exclude other causes of PPH (such as retained placental tissue and trauma); and
- lack of health information management systems designed to document and monitor recommended practices (such as patient records and registers).

Various strategies for addressing these barriers and facilitating implementation are provided under implementation considerations in section 4.

## 6.2 Monitoring and evaluating guideline implementation

The implementation and impact of this recommendation 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* (24) 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 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, clinical audits or criterion-based audits could be used to obtain the relevant data on the use of interventions contained in this guideline.

With regard to PPH treatment, 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 (25).

## 7. Updating the recommendations

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

Following publication and dissemination of the updated recommendation, any concerns about the validity of the recommendation should be promptly communicated to the guideline implementers, in addition to any plans to update the recommendation.

WHO welcomes suggestions regarding additional questions for inclusion in the updated recommendation. Please email your suggestions to [srhmp@who.int](mailto:srhmp@who.int).

## 8. References

1. Trends in maternal mortality 2000 to 2017: estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division: executive summary. Geneva: WHO; 2019 (<https://apps.who.int/iris/handle/10665/327596>, accessed 9 July 2020).
2. Say L, Chou D, Gemmill A, Tuncalp O, Moller AB, Daniels J, et al. Global causes of maternal death: a WHO systematic analysis. *Lancet Glob Health*. 2014;2(6):e323–33. doi:10.1016/S2214-109X(14)70227-X.
3. Alkema L, Chou D, Hogan D, Zhang SQ, Moller AB, Gemmill A, et al. Global, regional, and national levels and trends in maternal mortality between 1990 and 2015, with scenario-based projections to 2030: a systematic analysis by the UN Maternal Mortality Estimation Inter-Agency Group. *Lancet*. 2016;387(10017):462–74. doi:10.1016/S0140-6736(15)00838-7.
4. Office of the United Nations High Commissioner for Human Rights. Technical guidance on the application of a human rights-based approach to the implementation of policies and programmes to reduce preventable maternal morbidity and mortality. Human Rights Council, twentieth session. New York (NY): United Nations General Assembly; 2012 (<https://www.who.int/gender-equity-rights/knowledge/reduce-maternal-mortality/en/>, accessed 9 July 2020).
5. Tuncalp Ö, Were WM, MacLennan C, Oladapo OT, Gulmezoglu AM, Bahl R, et al. Quality of care for pregnant women and newborns – the WHO vision. *BJOG*. 2015;122(8):1045–9. doi:10.1111/1471-0528.13451.
6. WHO, UNFPA, UNICEF, ICM, ICN, FIGO, IPA. Definition of skilled health personnel: the 2018 joint statement by WHO, UNFPA, UNICEF, ICM, ICN, FIGO and IPA. Geneva: World Health Organization; 2018 (<https://www.who.int/reproductivehealth/publications/statement-competent-mnh-professionals/en/>, accessed 9 July 2020).
7. Carroli G, Cuesta C, Abalos E, Gulmezoglu AM. Epidemiology of postpartum haemorrhage: a systematic review. *Best Pract Res Clin Obstet Gynaecol*. 2008;22(6):999–1012. doi:10.1016/j.bpobgyn.2008.08.004.
8. Souza JP, Gulmezoglu AM, Vogel J, Carroli G, Lumbiganon P, Qureshi Z, et al. Moving beyond essential interventions for reduction of maternal mortality (the WHO Multicountry Survey on Maternal and Newborn Health): a cross-sectional study. *Lancet*. 2013;381(9879):1747–55. doi:10.1016/S0140-6736(13)60686-8.
9. Oyelese Y, Ananth CV. Postpartum hemorrhage: epidemiology, risk factors, and causes. *Clin Obstet Gynecol*. 2010;53(1):147–56. doi:10.1097/GRF.0b013e3181cc406d.
10. Daru J, Zamora J, Fernandez-Felix BM, Vogel J, Oladapo OT, Morisaki N, et al. Risk of maternal mortality in women with severe anaemia during pregnancy and post partum: a multilevel analysis. *Lancet Glob Health*. 2018; 6(5):e548–54. doi:10.1016/S2214-109X(18)30078-0.
11. Widmer M, Piaggio G, Nguyen TMH, Osoti A, Owa OO, Misra S, et al. Heat-stable carbetocin versus oxytocin to prevent hemorrhage after vaginal birth. *N Engl J Med*. 2018;379(8):743–52. doi:10.1056/NEJMoa1805489.
12. WHO recommendations for the prevention and treatment of postpartum haemorrhage. Geneva: World Health Organization; 2012 ([https://www.who.int/reproductivehealth/publications/maternal\\_perinatal\\_health/9789241548502/en/](https://www.who.int/reproductivehealth/publications/maternal_perinatal_health/9789241548502/en/), accessed 9 July 2020).

13. Executive Guideline Steering Group for updating WHO maternal and perinatal health recommendations. Geneva: World Health Organization; 2019 (<https://www.who.int/reproductivehealth/publications/updating-mnh-recommendations/en/>, accessed 9 July 2020).
14. Vogel JP, Dowswell T, Lewin S, Bonet M, Hampson L, Kellie F, et al. Developing and applying a 'living guidelines' approach to WHO recommendations on maternal and perinatal health. *BMJ Glob Health*. 2019;4(4):e001683. doi:10.1136/bmjgh-2019-001683.
15. WHO handbook for guideline development, second edition. Geneva: World Health Organization; 2014 (<https://apps.who.int/iris/handle/10665/145714>, accessed 9 July 2020).
16. Finlayson K, Downe S, Vogel JP, Oladapo OT. What matters to women and healthcare providers in relation to interventions for the prevention of postpartum haemorrhage: a qualitative systematic review. *PLoS One*. 2019;14(5):e0215919. doi:10.1371/journal.pone.0215919.
17. Meher S, Cuthbert A, Kirkham JJ, Williamson P, Abalos E, Aflaifel N, et al. Core outcome sets for prevention and treatment of postpartum haemorrhage: an international Delphi consensus study. *BJOG*. 2019;126(1):83–93. doi:10.1111/1471-0528.15335.
18. Mousa HA, Blum J, Abou El Senoun G, Shakur H, Alfirevic Z. Treatment for primary postpartum haemorrhage. *Cochrane Database Syst Rev*. 2014(2):CD003249. doi:10.1002/14651858.CD003249.pub3.
19. Alonso-Coello P, Schunemann HJ, Moher J, Brignardello-Petersen R, Akl EA, Davoli M, et al. GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 1: Introduction. *BMJ*. 2016;353:i2016. doi:<https://doi.org/10.1136/bmj.i2016>.
20. Downe S, Finlayson K, Oladapo OT, Bonet M, Gulmezoglu AM. What matters to women during childbirth: A systematic qualitative review. *PLoS One*. 2018;13(4):e0194906. doi:10.1371/journal.pone.0194906.
21. Lewin S, Booth A, Glenton C, Munthe-Kaas H, Rashidian A, Wainwright M, et al. Applying GRADE-CERQual to qualitative evidence synthesis findings: introduction to the series. *Implement Sci*. 2018;13(Suppl 1):2. doi:10.1186/s13012-017-0688-3.
22. Dumont A, Bodin C, Hounkpatin B, Popowski T, Traore M, Perrin R, et al. Uterine balloon tamponade as an adjunct to misoprostol for the treatment of uncontrolled postpartum haemorrhage: a randomised controlled trial in Benin and Mali. *BMJ Open*. 2017;7(9):e016590. doi:10.1136/bmjopen-2017-016590.
23. Anger HA, Dabash R, Durocher J, Hassanein N, Ononge S, Frye LJ, et al. The effectiveness and safety of introducing condom-catheter uterine balloon tamponade for postpartum haemorrhage at secondary level hospitals in Uganda, Egypt and Senegal: a stepped wedge, cluster-randomised trial. *BJOG*. 2019;126(13):1612–21. doi:10.1111/1471-0528.15903.
24. Standards for improving quality of maternal and newborn care in health facilities. Geneva: World Health Organization; 2016 ([https://www.who.int/maternal\\_child\\_adolescent/documents/improving-maternal-newborn-care-quality/en/](https://www.who.int/maternal_child_adolescent/documents/improving-maternal-newborn-care-quality/en/), accessed 14 July 2020).
25. Evaluating the quality of care for severe pregnancy complications: the WHO near-miss approach for maternal health. Geneva: World Health Organization; 2011 (<https://apps.who.int/iris/handle/10665/44692>, accessed 14 July 2020).

# Annex 1. External experts and WHO staff involved in the preparation of the recommendations

## Participants at the WHO Guideline Development Group (GDG) Meeting (11–12 March 2020)

### GUIDELINE DEVELOPMENT GROUP (GDG)

#### **Oluwarotimi Ireti AKINOLA**

President  
Society of Gynaecology and Obstetrics in Nigeria (SOGON)  
Abuja, Nigeria

#### **Melania AMORIM**

Obstetrician & Gynaecologist  
Instituto Paraibano de Pesquisa Professor Joaquim Amorim Neto and Instituto de Medicina Integral Professor Fernando Figueira  
Paraiba, Brazil

#### **Brendan CARVALHO \***

Chief, Division of Obstetric Anaesthesia  
Department of Anaesthesiology, Perioperative and Pain Medicine  
Stanford University School of Medicine  
Stanford, United States of America (USA)

#### **Catherine DENEUX-THARAUX**

Obstetrical, Perinatal and Pediatric Epidemiology Research Team  
Centre of Research in Epidemiology and Statistics Sorbonne  
Paris, France

#### **Tippawan LIABSUETRAKUL \***

Professor of Epidemiology  
Faculty of Medicine  
Prince of Songkla University  
Songkla, Thailand

#### **Martin MEREMIKWU \***

Professor of Paediatrics & Clinical Epidemiology  
University of Calabar  
Calabar, Nigeria

#### **Suellen MILLER \***

Director, Safe Motherhood Program  
Department of Obstetrics, Gynecology and Reproductive Sciences  
University of California, San Francisco (UCSF)  
San Francisco, USA

#### **Ashraf NABHAN**

Professor  
Department of Obstetrics and Gynecology  
Ain Shams University  
Cairo, Egypt

#### **Mari NAGAI**

Deputy Director, Health System Team Lead  
Bureau of International Health Cooperation  
National Centre for Global Health and Medicine  
Tokyo, Japan

#### **Hayfaa WAHABI \***

Professor and Chair  
Evidence-based Healthcare and Knowledge Translation  
College of Medicine, King Saud University  
Riyadh, Saudi Arabia

#### **Dilys WALKER \***

Professor  
Department of Obstetrics, Gynecology & Reproductive Sciences  
UCSF  
San Francisco, USA

#### **Andrew WEEKS**

Professor of International Maternal Health  
University of Liverpool  
Liverpool, United Kingdom of Great Britain and Northern Ireland (United Kingdom)

*\* Participated by video conference*

### OBSERVERS

#### **Deborah ARMBRUSTER \***

Senior Maternal and Newborn Health Advisor  
United States Agency for International Development (USAID) Bureau for Global Health  
Jakarta, Indonesia

#### **Carlos FUCHTNER \***

President  
International Federation of Gynecology and Obstetrics (FIGO)  
Santa Cruz, Bolivia

**Ingela WIKLUND**

Representative  
International Confederation of Midwives  
(ICM)  
Stockholm, Sweden

*\* Participated by video conference.*

**EVIDENCE SYNTHESIS GROUP (ESG)****Edgardo ABALOS \***

Vice Director  
Centro Rosarino de Estudios Perinatales  
Rosario, Argentina

**Virginia DIAZ \*\***

Researcher  
Centro Rosarino de Estudios Perinatales  
Rosario, Argentina

**Kenneth FINLAYSON (Methodologist)**

Research Associate  
Research in Childbirth and Health Unit  
(ReaCH)  
University of Central Lancashire  
Preston, United Kingdom

**Leanne JONES (Methodologist)**

Research Associate  
Cochrane Pregnancy and Childbirth Group  
Editorial Office  
University of Liverpool  
Liverpool, United Kingdom

**Frances KELLIE \*\***

Managing Editor  
Cochrane Pregnancy and Childbirth Group  
Editorial Office  
University of Liverpool  
Liverpool, United Kingdom

**Veronica PINGRAY**

Staff Research Midwife  
Instituto de Efectividad Clínica y Sanitaria  
(IECS)  
Buenos Aires, Argentina

**Myfanwy WILLIAMS (Methodologist)**

Research Associate  
Cochrane Pregnancy and Childbirth Group  
Editorial Office  
University of Liverpool  
Liverpool, United Kingdom

*\* Participated by video conference*

*\*\* Unable to attend*

**EXTERNAL REVIEW GROUP (ERG)****Christine EAST**

Professor of Nursing and Midwifery,  
Nursing  
La Trobe University  
Melbourne, Australia

**Gill GYTE**

Research Associate  
Cochrane Pregnancy and Childbirth Group  
University of Liverpool  
Liverpool Women's Hospital NHS Trust  
Crown Street  
Liverpool, United Kingdom

**Justus HOFMEYR**

Director  
Effective Care Research Unit  
University of the Witwatersrand/University  
of Fort Hare/  
Eastern Cape Department of Health  
Eastern Cape, South Africa

**Syeda BATOOL MAZHAR**

Professor of Obstetrics and Gynaecology  
Mother and Child Health Centre (MCH)  
Pakistan Institute of Medical Sciences  
Islamabad, Pakistan

**Enrique OYARZUN**

Chairman  
Department Obstetrics and Gynaecology  
Facultad de Medicina Pontificia  
Universidad Católica de Chile  
Santiago, Chile

**Qian XU**

Professor  
Department of Maternal, Child and  
Adolescent Health  
School of Public Health, Fudan University  
Shanghai, China

## WHO COUNTRY AND REGIONAL OFFICERS

### **Nino BERDZULI\*\***

Sexual and Reproductive Health  
Noncommunicable Diseases and Life-course  
WHO Regional Office for Europe  
Copenhagen, Denmark

### **Bremen De MUCIO\*\***

Sexual and Reproductive Health  
WHO Regional Office for the Americas  
Montevideo, Uruguay

### **Hayfa ELAMIN**

Reproductive, Maternal Health and Ageing  
WHO Regional Office for Africa  
Harare, Zimbabwe

### **Chandani Anoma JAYATHILAKA\*\***

Family Health, Gender and Life Course  
WHO Regional Office for South-East Asia  
New Delhi, India

### **Ramez Khairi MAHAINI\*\***

Reproductive and Maternal Health  
WHO Regional Office for the Eastern  
Mediterranean  
Cairo, Egypt

### **Howard SOBEL\*\***

Reproductive, Maternal, Newborn, Child  
and Adolescent Health Division  
of NCD and Health through the Life-Course  
Regional Office for the Western Pacific  
Manila, Philippines

### **Claudio SOSA\*\***

Regional Advisor, AMRO/CLP  
Sexual and Reproductive Health  
WHO Regional Office for the Americas  
Montevideo, Uruguay

*\*\* Unable to attend*

## WHO STEERING GROUP

### Department of Sexual and Reproductive Health and Research

### **Fernando ALTHABE**

Medical Officer  
Maternal and Perinatal Health  
Sexual and Reproductive Health and  
Research

### **Tina LAVIN**

Technical Officer  
Maternal and Perinatal Health  
Sexual and Reproductive Health and  
Research

### **Olufemi T. OLADAPO**

Unit Head  
Maternal and Perinatal Health  
Sexual and Reproductive Health and  
Research

### **Joshua P. VOGEL**

Consultant  
Maternal and Perinatal Health  
Sexual and Reproductive Health and  
Research

### **Mariana WIDMER**

Technical Officer  
Maternal and Perinatal Health  
Sexual and Reproductive Health and  
Research

### Department of Maternal, Newborn, Child and Adolescent Health and Ageing

### **Maurice BUCAGU**

Medical Officer  
Maternal Health Unit  
Maternal, Newborn, Child and Adolescent  
Health and Ageing

## Annex 2. Priority outcomes used in decision-making

### Critical outcomes:

- Maternal death
- Additional blood loss  $\geq 500$  mL
- Additional blood loss  $\geq 1000$  mL
- Blood transfusion
- Additional uterotonics
- Other invasive nonsurgical interventions (including artery embolization)
- Surgical interventions (including hysterectomy)
- Maternal temperature  $\geq 40$  °C
- Procedure-related complications
- Infections
- Severe morbidity
- Maternal transfer

### Important outcomes:

- Mean blood loss
- Postpartum anaemia
- Additional nonsurgical interventions (such as external aortic compression and compression garments)
- Nausea, vomiting or shivering
- Maternal temperature  $\geq 38$  °C
- Delayed initiation of breastfeeding
- Prolonged hospitalization
- Maternal well-being
- Maternal satisfaction

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

Name	Expertise contributed to guideline development	Declared interest	Management of conflict of interest
<b>Oluwarotimi I Akinola</b>	Content expert and end user	None declared	Not applicable
<b>Melania Amorim</b>	Content expert and end user	None declared	Not applicable
<b>Brendan Carvalho</b>	Content expert and end user	Serves as technical consultant for Gauss Surgical (company that measures peripartum and operative blood loss).  Receives share options from Gauss Surgical.	The conflict was not considered serious enough to affect Guideline Development Group (GDG) membership or participation.
<b>Catherine Deneux-Tharaux</b>	Content expert and end user	None declared	Not applicable
<b>Tippawan Liabsuetrakul</b>	Content expert and end user	None declared	Not applicable.
<b>Martin Meremikwu</b>	Content expert and end user	None declared	Not applicable.
<b>Suellen Miller</b>	Content expert and end user	Serves as a technical advisor to the Blue Fuzion Group , which manufactures and distributes one brand of non-pneumatic anti-shock garment, the LifeWrap. UCSF receives a royalty for the trademark.	The conflict was not considered serious enough to affect GDG membership or participation.
<b>Ashraf Nabhan</b>	Content expert and implementer	None declared	Not applicable
<b>Mari Nagai</b>	Content expert and end user	None declared	Not applicable
<b>Hayfaa Wahabi</b>	Content expert and end user	None declared	Not applicable
<b>Dilys Walker</b>	Content expert and end user	Co-founder and President of the nongovernmental organization PRONTO International. PRONTO designs and implements simulation and team training for obstetric and neonatal emergencies, including PPH. Professor Walker has donated funds to the organization. PRONTO International has the rights to the low-tech birth simulator, PARTO Pants and the PRONTO Pack simulation training kit.	The conflict was not considered serious enough to affect GDG membership or participation.



<b>Andrew Weeks</b>	Content expert and end user	Chief investigator of the COPE trial, and co-inventor of the Butterfly device to treat PPH, as well as chief investigator of the development study. Both funded by National Institute for Health Research (United Kingdom) research grants to the University of Liverpool. The University is the device patent holder, but as co-inventor Professor Weeks would receive a share of the profits.	The conflict was not considered serious enough to affect GDG membership or participation.
---------------------	-----------------------------	---	---

## Annex 4. Evidence to Decision frameworks

### 4.1 Uterine balloon tamponade compared with no uterine tamponade

#### Question

The question of interest in PICO (population (P), intervention (I), comparator (C), outcome (O)) format:

- For women with PPH who do not respond to treatment with uterotonics (P), does the use of a uterine balloon tamponade (I) compared with no uterine tamponade (C) improve maternal outcomes (O)?

**Problem:** PPH due to uterine atony that is unresponsive to uterotonic treatment

**Perspective:** Clinical practice recommendation – population perspective

**Population (P):** Women with PPH who do not respond to standard uterotonic treatment

**Intervention (I):** Uterine balloon tamponade

**Comparators (C):** No uterine tamponade

**Setting:** Hospital or community setting

**Subgroups:** By mode of birth.

#### Priority outcomes (O):<sup>1</sup>

##### Critical outcomes:

- Maternal death
- Additional blood loss  $\geq 500$  mL
- Additional blood loss  $\geq 1\,000$  mL
- Blood transfusion
- Additional uterotonics
- Other invasive nonsurgical interventions (including artery embolization)
- Surgical interventions (including hysterectomy)
- Maternal temperature  $\geq 40$  °C
- Procedure-related complications
- Infections
- Severe morbidity
- Maternal transfer

<sup>1</sup> These outcomes reflect the prioritized outcomes used in the development of this recommendation, in *WHO recommendations for the prevention and treatment of postpartum haemorrhage* (2012). The outcomes “reduction of time from decision-making to implementation”, “availability of drugs and treatment” and “accuracy in blood loss assessment” were also included in 2012 for this question, when only evidence from observational studies was available. For this update, where evidence of effectiveness comes from randomized studies, these outcomes have been removed. The outcomes “maternal death”, “maternal well-being” and “maternal satisfaction” have been added as part of this update.

### Important outcomes:

- Mean blood loss
- Postpartum anaemia
- Additional nonsurgical interventions (such as external aortic compression and compression garments)
- Nausea, vomiting or shivering
- Maternal temperature  $\geq 38^{\circ}\text{C}$
- Delayed initiation of breastfeeding
- Prolonged hospitalization
- Maternal well-being
- Maternal satisfaction

## Assessment

### Effects of interventions

What is the effect of uterine balloon tamponade compared with no uterine balloon tamponade on the priority outcomes, when used for treating PPH?

### Research evidence

#### Summary of evidence

##### Source and characteristics of studies

Evidence on the effects of uterine balloon tamponade for treatment of PPH is from one Cochrane systematic review, which includes nine trials with 947 women (1). Four of these trials (634 women) provided evidence on the use of uterine balloon tamponade for treating primary PPH after vaginal birth. Two further trials (63 women) provided evidence on the use of uterine balloon tamponade for treating primary PPH intraoperatively after caesarean birth. The other three trials included in the Cochrane review addressed different questions (the use of either external compression or surgical methods to treat primary PPH) and were therefore not included in this evidence summary.

The trials were published between 2007 and 2018, with the earliest beginning enrolment in 2003.

Two trials compared the use of uterine balloon tamponade versus no uterine balloon tamponade. Both trials included only women who gave birth vaginally and had primary PPH due to suspected uterine atony. The data from the trials were not pooled in the Cochrane review, because the uterine balloon tamponade devices were inflated differently (with saline or with air) and uterine balloon tamponade was used at different stages of treatment in the intervention group in each trial (as second response or as first response):

*a. Condom-loaded Foley catheter intrauterine tamponade (saline filled) plus standard care (misoprostol) versus standard care (misoprostol)*

One of these trials (116 women) took place across three mid-level community health-care facilities and four hospitals in Benin and Mali (2). Women were randomized if they experienced PPH that was unresponsive to oxytocin within 20 minutes of initial treatment. Women in the intervention group were treated with a condom-loaded Foley catheter inflated with saline by increments of 250 mL every 5 minutes up to a maximum of 1000 mL, plus standard care (misoprostol, either 1000  $\mu\text{g}$  rectally or 600  $\mu\text{g}$  sublingually). Women in the control group received standard care only. If

bleeding had not stopped within 15 minutes, immediate surgery (laparotomy for uterine compression sutures, artery ligations, or hysterectomy) was recommended. Women in both groups received antibiotics (cefazolin or ampicillin; dose not described).

PPH was diagnosed according to visual estimation of blood loss and patient status (blood pressure, cardiac frequency). Women with uterine rupture or placenta accreta were excluded; however, women with retained placenta were not excluded from this trial.

*b. Latex balloon-loaded Nelson catheter intrauterine tamponade (air filled) plus stitch and standard care (uterine massage and uterotonics) versus standard care (uterine massage and uterotonics)*

The other trial (240 women) took place in one hospital in Egypt, where women were treated for PPH following birth at home or in the hospital (3). Women were randomized upon presentation with PPH to receive different treatments as first response. The intervention group received standard care (including oxytocin and/or ergometrine; regimen and dose unclear), plus latex balloon-loaded Nelson catheter inflated with air up to a pressure of 140 mmHg (El-Menia balloon). The women received transient aortic compression to reduce bleeding and allow insertion of the balloon, which was secured with cerclage. The control group received standard care only. Where treatment failed in the control group, women also received the balloon intervention as second response. Women receiving the intervention were given metronidazole 500 mg, gentamycin 80 mg and ampicillin 500 mg after insertion of the balloon every eight hours for three days.

PPH was not defined in this study and there was no information reported on the method of blood loss assessment. According to the trial paper, women with traumatic PPH and retained placental tissues were excluded pre-randomization.

**Effects of uterine balloon tamponade compared with no uterine balloon tamponade**

*a. Condom-loaded Foley catheter intrauterine tamponade (saline filled) plus standard care (misoprostol) versus standard care (misoprostol)*

The Cochrane review included one study reporting on this comparison (2). It reported the priority outcomes: **maternal death** (mortality due to bleeding; all-cause mortality; and mortality from causes other than bleeding reported); **additional blood loss  $\geq 1000$  mL** (proxy outcome **total blood loss  $\geq 1000$  mL** reported); **blood transfusion** (red cell or whole blood reported); **surgical interventions (hysterectomy to control bleeding; uterine compression sutures; and artery ligation)**; **maternal transfer; nausea, vomiting, or shivering (severe shivering, diarrhoea, vomiting reported)**; **maternal temperature  $\geq 38$  °C** and **maternal temperature  $\geq 40$  °C** (the trial reported **high temperatures** as a side-effect of treatment, but parameters were undefined). However, the effect estimates for all these priority outcomes were assessed to be of very low certainty; therefore, the true effects of this type of uterine balloon tamponade may differ substantially from the reported results.

The included study did not report on any other priority outcomes.

*b. Latex balloon-loaded Nelson catheter intrauterine tamponade (air filled) plus stitch and standard care (uterine massage and uterotonics) versus standard care (uterine massage and uterotonics)*

The Cochrane review included one trial for this comparison (3), which reported on the priority outcomes **maternal death (mortality due to bleeding; all-cause mortality; mortality from causes other than bleeding were reported)**; **maternal temperature  $\geq 38$  °C** and **maternal temperature  $\geq 40$  °C** (the trial reported the proxy outcome **pyrexia**, but parameters were undefined); **prolonged hospitalization (days in hospital reported)**. The effect estimates for all of these outcomes was assessed to be of very low certainty. Results were also reported for **surgical interventions (hysterectomy to**

**control bleeding; B-lynch suture and artery ligation**), where all women experiencing these events were in the control group, and had received uterine balloon tamponade as second response (a total of 19 of 120 women in the control group received it as second response). However, the results for both of these outcomes were also of very low certainty.

Three women in the included study experienced **procedure-related complications** due to over-inflation of the balloon (two women had cervical tears; one woman had tachycardia and hypotension due to an increase in uterine size above the umbilicus). In the control group, 19 of 120 women also received uterine balloon tamponade as second-line treatment for PPH. The trial did not report which group the women experiencing these complications belonged to and therefore these results were only presented narratively in the Cochrane review.

The included study did not report on any other priority outcomes.

### Additional considerations

The studies included in the Cochrane review assessing uterine balloon tamponade after vaginal birth used the uterine balloon tamponade as first response to PPH; as second response (for refractory PPH); and also in case of failure of both first and second responses. However, no included studies sought to directly assess the safety and efficacy of uterine balloon tamponade when used at these different stages of treatment. It is, however, of note that the study in Egypt (3) did use the uterine balloon tamponade as first response intervention and then as second response in the control group (the second response use was apparently in deviation from their methods).

#### *Other systematic reviews*

The 2012 WHO recommendation was based on observational evidence, as no randomized controlled trials (RCTs) were available at that time. Two systematic reviews (summarized below) have considered the updated observational evidence (4,5).

A 2019 systematic review included RCTs (n=7), nonrandomized studies (n=15) and case series (n=69), and reported on efficacy, effectiveness, and/or safety of uterine balloon tamponade device placement in women with PPH due to a variety of causes, after vaginal and/or caesarean birth (4). The main outcome was the successful arrest of bleeding without maternal death and additional surgical or radiological interventions in women in which the uterine balloon tamponade was placed.<sup>1</sup>

The results that are considered of interest to this Evidence to Decision (EtD) framework are summarized below:

- The overall pooled uterine balloon tamponade success rate as defined above was 85.9% (95% confidence interval [CI], 83.9–87.9) (90 studies).
- There were no important differences among the uterine balloon tamponade success rates for all causes of PPH estimated from RCTs (88.8%), nonrandomized studies (85.2%) and case series (85.7%).
- The pooled success rates of uterine balloon tamponade in PPH due to uterine atony was 88.1% (95% CI, 81.7–93.3) in vaginal deliveries (15 studies) and 75.2% (95% CI, 63.4–85.4) in caesarean deliveries (eight studies).
- However, the evidence on uterine balloon tamponade efficacy and effectiveness (compared to no use of uterine balloon tamponade) was conflicting. Two

<sup>1</sup> Note: By this definition, success rate cannot be measured in similar women who have not received uterine balloon tamponade, and it is therefore not a measure of comparative effect.

experimental studies (2,6) did not show beneficial effect; however, meta-analysis of observational studies indicated beneficial effects.

A second systematic review focused on uterine balloon tamponade studies conducted in women with refractory PPH presumed to be caused by uterine atony after vaginal birth (5). RCTs and nonrandomized studies were included but case series were excluded. It included five studies published between 2007 and 2019. There were two main outcomes: the need for surgical interventions or maternal death; and hysterectomy. The results that are considered of interest to this EtD framework are summarized below:

- Evidence from the RCTs assessing either the effect of uterine balloon tamponade devices on women with refractory PPH, or the effect of the introduction of uterine balloon tamponades in clinical settings, did not show a reduction in the use of invasive surgery or maternal deaths when compared with no uterine balloon tamponade use or introduction. Similar results were observed for hysterectomy.
- Conversely, the observational studies analysing the effect of the introduction of uterine balloon tamponades in clinical settings showed a substantial relative reduction on the same outcomes.
- However, the experimental studies evaluating improvised uterine balloon tamponades (condom catheter) were all conducted in low- and middle-income countries (LMICs). Conversely, the observational studies included in the review assessed purpose-designed uterine balloon tamponades and were conducted in high-income countries (HICs).
- It was not possible to disentangle the independent effects of the type of uterine balloon tamponade and the setting, and their role in the conflicting evidence coming from RCTs and nonrandomized studies.

### Desirable effects

How substantial are the desirable anticipated effects of uterine balloon tamponade versus no uterine balloon tamponade?

#### Judgement

✓ Don't know	— Varies	— Trivial	— Small	— Moderate	— Large
-----------------	-------------	--------------	------------	---------------	------------

### Undesirable effects

How substantial are the undesirable anticipated effects of uterine balloon tamponade versus no uterine balloon tamponade?

#### Judgement

✓ Don't know	— Varies	— Large	— Moderate	— Small	— Trivial
-----------------	-------------	------------	---------------	------------	--------------

### Certainty of the evidence

What is the overall certainty of the evidence on effects of uterine balloon tamponade versus no uterine balloon tamponade?

— No included studies	✓ Very low	— Low	— Moderate	— High
--------------------------	---------------	----------	---------------	-----------

## Values

Is there important uncertainty about, or variability in, how much women (and their families) value the main outcomes associated with uterine balloon tamponade for PPH treatment?

## Research evidence

In a review of qualitative studies evaluating “what women want” from intrapartum care, findings indicate that most women want a normal birth (with good outcomes for mother and baby) but acknowledge that medical intervention may sometimes be necessary (*high confidence*) (6). Most women, especially those giving birth for the first time, are apprehensive about labour and birth (*high confidence*) and wary of medical interventions, although, in certain contexts and/or situations, women welcome interventions to address recognized complications (*low confidence*). Where interventions are introduced, women would like to receive relevant information from technically competent health-care providers who are sensitive to their needs (*high confidence*).

Findings from an update of a qualitative systematic review exploring perceptions of PPH prevention and treatment among women and providers suggest that women do not recognize the clinical definitions of blood loss or what might be considered “normal” blood loss (*moderate confidence*) (7). Furthermore, in some LMICs, women place a greater value on the expulsion of so-called “dirty blood”, which they perceive as a normal cleansing process and something that should not be prevented (*moderate confidence*). The same review highlighted women’s need for information about PPH, ideally given during antenatal care (*moderate confidence*), and the importance of kind, clinically competent staff with a willingness to engage in shared decision-making around PPH management (*moderate/low confidence*). In addition, it was found that women are concerned about feelings of exhaustion and anxiety (at being separated from their babies) following PPH, as well as the long-term psychological effects of experiencing PPH and the negative impact this may have on their ability to breastfeed (*moderate/low confidence*).

## Additional considerations

None.

## Judgement

— Important uncertainty or variability	— Possibly important uncertainty or variability	✓ Probably no important uncertainty or variability	— No important uncertainty or variability
--	--	---	--

## Balance of effects

Does the balance between desirable and undesirable effects favour uterine balloon tamponade for PPH treatment versus no uterine balloon tamponade?

## Judgement

✓ Don't know	— Varies	— Favours no treatment	— Probably favours no treatment	— Does not favour either	— Probably favours UBT	— Favours UBT
-----------------	-------------	------------------------------	--	-----------------------------------	------------------------------	---------------------

## Resources

How large are the resource requirements (costs) of uterine balloon tamponade for PPH treatment?

## Research evidence

Cost or economic outcomes were not prespecified in the Cochrane review on effectiveness of uterine balloon tamponade (1). A systematic review of cost-effectiveness studies on uterine balloon tamponade for PPH treatment identified two cost-effectiveness studies (8,9). Both studies were of high quality according to the Consensus Health Economic Criteria (CHEC) checklist, and both used a model-based approach to estimate the incremental costs of introducing uterine balloon tamponade to treat PPH.

One was a cost-effectiveness analysis on the introduction of a low-cost uterine balloon tamponade model into routine PPH management at health centre and hospital levels for women giving birth in Kenya in 2015 (8). Cost data were obtained via interviews with staff at 30 purposively selected facilities in Kenya, and included medications, supplies, laboratory tests and time spent managing women with PPH. Costs for training health-care providers were also included. The analysis took a health systems perspective and was applied to an estimation of all PPH cases occurring in Kenya in a one-year period. The intervention (ESM-UBT) was not commercially available at the time; however, price assumptions of US\$ 5 and US\$ 15 were used. Estimates of the effects of uterine balloon tamponade were derived from a 2016 multicentre case series study conducted in Kenya, Nepal, Senegal and Sierra Leone (10). The analysis considered (a) the base case (current practice, where uterine balloon tamponade was not used), (b) availability of uterine packing at health centres for women with PPH prior to transfer to hospital and (c) same conditions as (a) and (b), as well as availability of ESM-UBT at health centres or hospitals after uterotonic drugs and mechanical interventions had failed to stop PPH. It was assumed that only women who continued to experience PPH were transferred to hospitals. The third scenario totalled an additional US\$ 64 341 beyond the base case. The analysis found US\$ 26 incremental cost per disability-adjusted life-year (DALY) averted (with a US\$ 5 price) and US\$ 40 incremental cost per DALY averted (with a US\$ 15 price). This was considered highly cost-effective, considering that Kenya's gross domestic product per capita was US\$ 1358 in 2014.

The second study was a global economic assessment of a number of PPH prevention and treatment interventions, including uterine balloon tamponade (9). It estimated the cost-effectiveness of these interventions, as well as sensitivity analyses for different protection rates, coverage rates and prices of drugs and products, which were derived from international sources and consultation with country experts in four countries. The protection rate of uterine balloon tamponade against PPH was assumed to be 75%, referencing two case series studies conducted in Bangladesh and the United Kingdom (11,12) and the authors noted that the evidence of uterine balloon tamponade effects was considerably weaker than for other interventions. No market price was available for uterine balloon tamponade; hence, an estimated price of US\$ 6 was used (sum of the price of a condom, catheter, 500 mL saline and other materials, including pre-packaging and sterilization). Costs were estimated for the years 2006, 2010 and 2015. The authors reported that uterine balloon tamponade was highly cost-effective, associated with a cost of US\$ 1.00 per DALY averted (the lowest amongst all considered interventions), with a cost-benefit ratio of US\$ 1644.21.



## Additional considerations

In an update of a qualitative systematic review exploring perceptions of PPH prevention and treatment among women and health-care providers (7), findings indicate that providers felt the use of a uterine balloon tamponade reduced referral rates to higher-level facilities and the need for more complicated (and expensive) surgical procedures such as hysterectomy (*moderate confidence*).

The Guideline Development Group (GDG) noted that both cost-effectiveness studies used published effect estimates from case series studies to inform calculations. We did not identify any cost-effectiveness studies based on meta-analyses or trials. In light of the lack of evidence of benefit from the Cochrane review, the GDG considered that the cost-effectiveness of this intervention is not known.

## Main resource requirements

Resource	Description
Staff	Staff trained in recognition and prompt treatment of refractory PPH. All models of uterine balloon tamponade require placement by trained maternity staff working in adequately equipped health facilities (including anaesthetic staff).
Training	Introduction of a uterine balloon tamponade would require additional training. Costs of training health-care providers in using uterine balloon tamponade were estimated by one study as US\$ 30.29 per provider (includes costs for transportation, venue and equipment rentals, meals, printing, and office supplies for a one-day training session) (8). Periodic refresher training is required.
Supplies	The review identified several studies that reported a unit price for different types of uterine balloon tamponade. Unit prices were: <ul style="list-style-type: none"> <li>■ Condom catheter (various designs): US\$ 0.63–5<sup>a</sup> (2,8-10,13,14)</li> <li>■ Uterine suction tube (using FG36 Levin stomach tube): &lt; US\$ 2 (15)</li> <li>■ Bakri balloon: US\$ 171–300 (13,16)</li> <li>■ Vacuum-induced tamponade device (InPress): &lt; US\$ 400 (17)</li> <li>■ Commercial devices: US\$ 7.50–350 (18,19).</li> </ul> Condom catheter typically requires: <ul style="list-style-type: none"> <li>■ Foley (urinary) catheter size 24</li> <li>■ Condoms</li> <li>■ Needleless suture or cotton for securing</li> <li>■ 1 L bag of normal saline</li> <li>■ 50 mL syringe</li> <li>■ Compresses</li> <li>■ Sterile gloves.</li> </ul>

<sup>a</sup> One study (Dumont et al., 2017) quoted a higher price of \$10 for a uterine balloon tamponade kit that included misoprostol tablets: "Tablets of 200 µg misoprostol and uterine balloon tamponade kits (including Foley catheter size 24, condom, 1 L bag of solute, needleless suture, 50 mL syringe, compresses, sterile gloves) were implemented in the participating centres (each kit costing US\$ 10 but free of charge for the patients)" (2).

Resource	Description
Equipment and infrastructure	<p>Placement of uterine balloon tamponade typically also requires:</p> <ul style="list-style-type: none"> <li>■ Intravenous fluids</li> <li>■ Instruments (speculum, forceps)</li> <li>■ Analgesia or anaesthesia</li> <li>■ Antibiotics.</li> </ul> <p>Should uterine balloon tamponade fail, transfer to a surgical theatre or to a health facility able to perform hysterectomy is required to treat unresponsive PPH.</p> <p>However, typically in HICs such as France, the United Kingdom and the United States, the uterine balloon tamponade is placed with the woman in the surgical theatre and after exploration of the uterine cavity to exclude trauma as the cause of the bleeding. Conversely, in LMICs the placement is commonly done in the delivery room, frequently without exploration of the uterine cavity.</p>
Time	The time from start of insertion to stop bleeding was reported as 9 minutes (standard deviation [SD], 6) with the Bakri Balloon and 12 minutes (SD, 7) (rounded figures) with the condom catheter balloon in a trial comparing both uterine balloon tamponade devices (13).
Supervision and monitoring	Supervision and monitoring to ensure appropriate use, stock availability and quality.

## Resources required

### Judgement

— Don't know	✓ Varies	— Large costs	— Moderate costs	— Negligible costs or savings	— Moderate savings	— Large savings
-----------------	-------------	------------------	---------------------	----------------------------------	-----------------------	--------------------

## Certainty of the evidence on required resources

What is the certainty of the evidence on costs?

### Judgement

— No included studies	— Very low	✓ Low	— Moderate	— High
--------------------------	---------------	----------	---------------	-----------

## Cost-effectiveness

### Judgement

— Don't know	✓ Varies	— Favours no uterine balloon tamponade treatment	— Probably favours no uterine balloon tamponade treatment	— Does not favour either	— Probably favours uterine balloon tamponade	— Favours uterine balloon tamponade
-----------------	-------------	---	--	-----------------------------	---	--

## Equity

What would be the impact of uterine balloon tamponade for PPH treatment on health equity?

### Research evidence

The cost of the commercially available uterine balloon tamponade devices ranges between US\$ 7.50 and US\$ 400, while that of the improvised devices such as the condom catheter is between US\$ 0.63 and US\$ 5. It is unclear whether potential benefits from the uterine balloon tamponade use can be associated with either type of device. If commercially available devices are found to be effective and safe, their costs may limit their use in low-resource settings, which may reduce equity. Conversely, if improvised devices are found to be effective and safe, they could increase equity, as these devices are cheaper. Additionally, in some settings the cost of these devices must be covered directly by the patients, which may decrease equity.

### Additional considerations

The 2015 World Health Organization (WHO) *State of inequality report* indicates that women who are poor, least educated, and who reside in rural areas have lower coverage of health interventions and worse health outcomes than more advantaged women (20). Therefore, reducing maternal morbidity due to PPH could have a positive impact on health equity and improve outcomes among disadvantaged women. Reducing the need for transfer and surgical interventions to treat refractory PPH would probably reduce inequities, especially in contexts where health services are covered through out-of-pocket means.

### Judgement

— Don't know	✓ Varies	— Reduced	— Probably reduced	— Probably no impact	— Probably increased	— Increased
-----------------	-------------	--------------	-----------------------	-------------------------	-------------------------	----------------

## Acceptability

Is uterine balloon tamponade for PPH treatment acceptable to key stakeholders?

### Research evidence

In an update of a qualitative systematic review exploring perceptions of PPH prevention and treatment among women and health-care providers (7), findings from providers indicate that the use of a simple uterine balloon tamponade device is effective as a second-response treatment in arresting blood loss associated with PPH (*moderate confidence*). Findings from providers also suggest that a uterine balloon tamponade is relatively easy to use and, with appropriate training, could be administered by a variety of cadres, including midwives and medical officers (*moderate confidence*). In addition, providers felt that the use of a uterine balloon tamponade reduced referral rates to higher-level facilities and the need for more complicated surgical procedures (hysterectomy) (*moderate confidence*). A few providers were also aware that some women might be reluctant to have a condom inserted on cultural or religious grounds and that the uterine balloon tamponade should be referred to as a “tamponade” rather than a condom for this reason (*low confidence*). There was very little direct evidence from women about their experiences of uterine balloon tamponade.

### Additional considerations

None.

### Judgement

— Don't know	— Varies	— No	— Probably No	✓ Probably Yes	— Yes
-----------------	-------------	---------	------------------	-------------------	----------

### Feasibility

Is uterine balloon tamponade for PPH treatment feasible to implement?

### Research evidence

Findings from an update of a qualitative systematic review on PPH prevention and treatment (7) suggest that a uterine balloon tamponade is a practical and affordable solution in many low-resource settings and could be improvised from readily available items (condoms, surgical gloves) (*low confidence*). In most of the studies contributing to this review finding, the uterine balloon tamponade consisted of a condom, urinary catheter, cotton string and a luer lock valve. Findings from the same review also suggest that there may be some confusion amongst providers about how long to leave a uterine balloon tamponade in place and they highlighted the need for regular “hands-on” training to maintain their skills (*moderate confidence*). There was very little direct evidence from women relating to the feasibility of using a uterine balloon tamponade.

### Additional considerations

It is commonly accepted that insertion of a uterine balloon tamponade is a relatively simple procedure and that the required level of competence can be achieved after a short training in simulated conditions. For example, trials of uterine balloon tamponade have used a half-day onsite training at participating hospitals (2,21). In these trials, the training sessions were conducted by trained obstetricians, who were trained by experienced obstetricians (using a “train-the-trainers” approach). These trials described either concerns with the use of the uterine balloon tamponade, or substantial delays in insertion of the uterine balloon tamponade (2). In the trial conducted in Benin and Mali and comparing uterine balloon tamponade versus no uterine balloon tamponade, the condom catheter was inserted 30 minutes or more after the diagnosis of PPH in 58% of the cases, despite efforts to improve the availability of the different components of the uterine balloon tamponade device (2). In the stepped-wedge cluster RCT conducted in Egypt, Senegal and Uganda assessing the effectiveness of the introduction of condom-catheter uterine balloon tamponade as an option for treatment of refractory PPH after vaginal birth, providers reported a problem with the uterine balloon tamponade in 52% of the cases (21). Whether those factors were related to the training, the type of device, or the previous expertise of the providers is unknown.

If commercially available devices were those proven to be more effective, accessing them in low-resource settings may be a challenge due to their higher cost.

### Judgement

— Don't know	— Varies	— No	— Probably No	✓ Probably Yes	— Yes
-----------------	-------------	---------	------------------	-------------------	----------

## Summary of judgements table

Desirable effects	✓ Don't know	— Varies		— Trivial	— Small	— Moderate	— Large
Undesirable effects	✓ Don't know	— Varies		— Large	— Moderate	— Small	— Trivial
Certainty of the evidence	— No included studies			✓ Very low	— Low	— Moderate	— High
Values				— Important uncertainty or variability	— Possibly important uncertainty or variability	✓ Probably no important uncertainty or variability	— No important uncertainty or variability
Balance of effects	✓ Don't know	— Varies	— Favours no uterine balloon tamponade treatment	— Probably favours no uterine balloon tamponade treatment	— Does not favour either	— Probably favours uterine balloon tamponade	— Favours uterine balloon tamponade
Resources required	— Don't know	✓ Varies	— Large costs	— Moderate costs	— Negligible costs or savings	— Moderate savings	— Large savings
Certainty of the evidence on required resources	— No included studies			— Very low	✓ Low	— Moderate	— High
Cost-effectiveness	— Don't know	✓ Varies	— Favours no uterine balloon tamponade treatment	— Probably favours no uterine balloon tamponade treatment	— Does not favour either	— Probably favours uterine balloon tamponade	— Favours uterine balloon tamponade
Equity	— Don't know	✓ Varies	— Reduced	— Probably reduced	— Probably no impact	— Probably increased	— Increased
Acceptability	— Don't know	— Varies		— No	— Probably No	✓ Probably Yes	— Yes
Feasibility	— Don't know	— Varies		— No	— Probably No	✓ Probably Yes	— Yes

## Summary of findings tables

**Question:** Condom-loaded Foley catheter intrauterine tamponade (saline filled) plus standard care (misoprostol) compared with standard care (misoprostol) for treating primary postpartum haemorrhage

**Setting:** Hospitals and community health-care facilities (Benin and Mali)

**Reference:** Kellie FJ, Wandabwa JN, Mousa HA, Weeks AD. Mechanical and surgical interventions for treating primary postpartum haemorrhage. Cochrane Database Syst Rev. 2020;7:CD013663.

Certainty assessment												
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other consid- erations	No. of patients		Effect		Certainty	Importance
							Condom-loaded Foley catheter intrauterine tamponade (saline filled) plus standard care (misoprostol)	Standard care (misoprostol)	Relative (95% CI)	Absolute (95% CI)		
MORTALITY DUE TO BLEEDING												
1	randomized trials	very serious <sup>a</sup>	not serious	not serious	very serious <sup>b,c</sup>	none	6/57 (10.5%)	1/59 (1.7%)	<b>RR 6.21</b> (0.77 to 49.98)	<b>88 more per 1000</b> (from 4 fewer to 830 more)	⊕⊖⊖⊖ VERY LOW	CRITICAL
ALL-CAUSE MORTALITY												
1	randomized trials	very serious <sup>a</sup>	not serious	not serious	very serious <sup>b,c</sup>	none	6/57 (10.5%)	1/59 (1.7%)	<b>RR 6.21</b> (0.77 to 49.98)	<b>88 more per 1000</b> (from 4 fewer to 830 more)	⊕⊖⊖⊖ VERY LOW	CRITICAL
MORTALITY FROM CAUSES OTHER THAN BLEEDING												
1	randomized trials	very serious <sup>a</sup>	not serious	not serious	very serious <sup>d</sup>	none	0/57 (0.0%)	0/59 (0.0%)	not estimable		⊕⊖⊖⊖ VERY LOW	CRITICAL
TOTAL POSTNATAL BLOOD LOSS ≥ 1000 ML												
1	randomized trials	very serious <sup>a</sup>	not serious	not serious	serious	none	43/54 (79.6%)	31/59 (52.5%)	<b>RR 1.52</b> (1.15 to 2.00)	<b>273 more per 1000</b> (from 79 more to 525 more)	⊕⊖⊖⊖ VERY LOW	CRITICAL

Certainty assessment							No. of patients		Effect		Certainty	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other consid- erations	Condom-loaded Foley catheter intrauterine tamponade (saline filled) plus standard care (misoprostol)	Standard care (misoprostol)	Relative (95% CI)	Absolute (95% CI)		
BLOOD TRANSFUSION (RED CELL OR WHOLE BLOOD)												
1	randomized trials	very serious <sup>a</sup>	not serious	not serious	very serious <sup>b,e</sup>	none	23/57 (40.4%)	16/59 (27.1%)	<b>RR 1.49</b> (0.88 to 2.51)	<b>133 more per 1000</b> (from 33 fewer to 409 more)	⊕⊖⊖⊖ VERY LOW	CRITICAL
SURGICAL INTERVENTIONS - HYSTERECTOMY TO CONTROL BLEEDING												
1	randomized trials	very serious <sup>a</sup>	not serious	not serious	very serious <sup>c,f</sup>	none	4/57 (7.0%)	1/59 (1.7%)	<b>RR 4.14</b> (0.48 to 35.93)	<b>53 more per 1000</b> (from 9 fewer to 592 more)	⊕⊖⊖⊖ VERY LOW	CRITICAL
SURGICAL INTERVENTIONS - UTERINE COMPRESSION SUTURES												
1	randomized trials	very serious <sup>a</sup>	not serious	not serious	very serious <sup>c,f</sup>	none	2/57 (3.5%)	0/59 (0.0%)	RR 5.17 (0.25 to 105.44)	<b>0 fewer per 1000</b> (from 0 fewer to 0 fewer)	⊕⊖⊖⊖ VERY LOW	CRITICAL
SURGICAL INTERVENTIONS - ARTERY LIGATION												
1	randomized trials	very serious <sup>a</sup>	not serious	not serious	very serious <sup>c,f</sup>	none	4/57 (7.0%)	3/59 (5.1%)	<b>RR 1.38</b> (0.32 to 5.90)	<b>19 more per 1000</b> (from 35 fewer to 249 more)	⊕⊖⊖⊖ VERY LOW	CRITICAL
MATERNAL TRANSFER (TO INTENSIVE CARE UNIT)												
1	randomized trials	very serious <sup>a</sup>	not serious	not serious	very serious <sup>c,f</sup>	none	10/57 (17.5%)	8/59 (13.6%)	<b>RR 1.29</b> (0.55 to 3.04)	<b>39 more per 1000</b> (from 61 fewer to 277 more)	⊕⊖⊖⊖ VERY LOW	CRITICAL
DIARRHOEA												
1	randomized trials	very serious <sup>a</sup>	not serious	not serious	very serious <sup>d</sup>	none	0/57 (0.0%)	0/59 (0.0%)	not estimable		⊕⊖⊖⊖ VERY LOW	IMPORTANT

No. of studies		Certainty assessment						No. of patients		Effect		Certainty	Importance
		Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other consid- erations	Condom-loaded Foley catheter intrauterine tamponade (saline filled) plus standard care (misoprostol)	Standard care (misoprostol)	Relative (95% CI)	Absolute (95% CI)		
SEVERE SHIVERING													
1	randomized trials	very serious <sup>a</sup>	not serious	not serious	not serious	very serious <sup>d</sup>	none	0/57 (0.0%)	0/59 (0.0%)	not estimable		⊕⊖⊖⊖ VERY LOW	IMPORTANT
VOMITING													
1	randomized trials	very serious <sup>a</sup>	not serious	not serious	not serious	very serious <sup>d</sup>	none	0/57 (0.0%)	0/59 (0.0%)	not estimable		⊕⊖⊖⊖ VERY LOW	IMPORTANT
HIGH TEMPERATURE (NOT DEFINED)													
1	randomized trials	very serious <sup>a</sup>	not serious	not serious	not serious	very serious <sup>d</sup>	none	0/57 (0.0%)	0/59 (0.0%)	not estimable		⊕⊖⊖⊖ VERY LOW	IMPORTANT

CI: confidence interval; RR: risk ratio

- <sup>a</sup> All of pooled effect provided by study at high risk of bias.
- <sup>b</sup> Wide CI including both no difference in effect and appreciable harm.
- <sup>c</sup> Few events, small sample size.
- <sup>d</sup> Small sample size. No events, not estimable.
- <sup>e</sup> Small sample size.
- <sup>f</sup> Wide CI including both appreciable benefit and appreciable harm.



**Question:** Latex balloon–loaded Nelson catheter intrauterine tamponade (air filled) plus stitch and standard care (uterine massage and uterotonics) compared to standard care (uterine massage and uterotonics) for treating primary postpartum haemorrhage

**Setting:** Hospital (Egypt)

**Reference:** Kellie FJ, Wandabwa JN, Mousa HA, Weeks AD. Mechanical and surgical interventions for treating primary postpartum haemorrhage. Cochrane Database Syst Review. 2020;7:CD013663.

Certainty assessment						No. of patients		Effect		Certainty	Importance	
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Latex balloon-loaded Nelson catheter intrauterine tamponade (air filled) plus stitch care and standard care (uterine massage and uterotonics)	Standard care (uterine massage and uterotonics)	Relative (95% CI)			Absolute (95% CI)
MORTALITY DUE TO BLEEDING												
1	randomized trials	serious <sup>a</sup>	not serious	serious <sup>b</sup>	very serious <sup>c</sup>	none	0/120 (0.0%)	0/120 (0.0%)	not estimable	⊕⊖⊖⊖⊖ VERY LOW	CRITICAL	
ALL-CAUSE MORTALITY												
1	randomized trials	serious <sup>a</sup>	not serious	serious <sup>b</sup>	very serious <sup>c</sup>	none	0/120 (0.0%)	0/120 (0.0%)	not estimable	⊕⊖⊖⊖⊖ VERY LOW	CRITICAL	
MORTALITY FROM CAUSES OTHER THAN BLEEDING												
1	randomized trials	serious <sup>a</sup>	not serious	serious <sup>b</sup>	very serious <sup>c</sup>	none	0/120 (0.0%)	0/120 (0.0%)	not estimable	⊕⊖⊖⊖⊖ VERY LOW	CRITICAL	
SURGICAL INTERVENTIONS - HYSTERECTOMY TO CONTROL BLEEDING												
1	randomized trials	serious <sup>a</sup>	not serious	serious <sup>b</sup>	very serious <sup>d,e</sup>	none	0/120 (0.0%)	3/120 (2.5%)	RR 0.14 (0.01 to 2.74)	22 fewer per 1000 (from 25 fewer to 44 more)	⊕⊖⊖⊖⊖ VERY LOW	CRITICAL
SURGICAL INTERVENTIONS - B-LYNCH SUTURE AND ARTERY LIGATION (ALL WOMEN RECEIVED BOTH)												
1	randomized trials	serious <sup>a</sup>	not serious	serious <sup>b</sup>	very serious <sup>d,e</sup>	none	0/120 (0.0%)	2/120 (1.7%)	RR 0.20 (0.01 to 4.12)	13 fewer per 1000 (from 17 fewer to 52 more)	⊕⊖⊖⊖⊖ VERY LOW	CRITICAL

Certainty assessment							No. of patients		Effect		Certainty	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Latex balloon-loaded Nelson catheter intrauterine tamponade (air filled) plus stitch and standard care (uterine massage and uterotonics)	Standard care (uterine massage and uterotonics)	Relative (95% CI)	Absolute (95% CI)		
PROCEDURE-RELATED COMPLICATIONS – ALLERGIC REACTION												
1	randomized trials	serious <sup>a</sup>	not serious	serious <sup>b</sup>	very serious <sup>c</sup>	none	0/120 (0.0%)	0/120 (0.0%)	not estimable		⊕⊖⊖⊖ VERY LOW	CRITICAL
PYREXIA (NOT DEFINED)												
1	randomized trials	serious <sup>a</sup>	not serious	serious <sup>b</sup>	very serious <sup>c</sup>	none	0/120 (0.0%)	0/120 (0.0%)	not estimable		⊕⊖⊖⊖ VERY LOW	IMPORTANT
DAYS IN HOSPITAL												
1	randomized trials	serious <sup>a</sup>	not serious	serious <sup>b</sup>	serious <sup>f</sup>	none	120	120	-	<b>MD 1.2 lower</b> (1.33 lower to 1.07 lower)	⊕⊖⊖⊖ VERY LOW	IMPORTANT

**CI:** confidence interval; **MD:** mean difference; **RR:** risk ratio

<sup>a</sup> All of pooled result provided by study at moderate risk of bias.

<sup>b</sup> Study population included all women with postpartum haemorrhage (uterine balloon tamponade was used as first-line treatment), rather than only those who had not responded to treatment with uterotonics.

<sup>c</sup> Small sample size. No events, not estimable.

<sup>d</sup> Small sample size, few events.

<sup>e</sup> Wide CI including appreciable benefit and appreciable harm.

<sup>f</sup> Small sample size (continuous outcome).

## References

1. Kellie F, Wandabwa J, Mousa H, Weeks A. Mechanical and surgical interventions for treating primary postpartum haemorrhage. *Cochrane Database Syst Rev*. 2020;7:CD013663. doi:10.1002/14651858.CD013663.
2. Dumont A, Bodin C, Hounkpatin B, Popowski T, Traore M, Perrin R, et al. Uterine balloon tamponade as an adjunct to misoprostol for the treatment of uncontrolled postpartum haemorrhage: a randomised controlled trial in Benin and Mali. *BMJ Open*. 2017;7(9):e016590. doi:10.1136/bmjopen-2017-016590.
3. Soltan MH, Mohamed A, Ibrahim E, Gohar A, Ragab H. El-menia air inflated balloon in controlling atonic post partum hemorrhage. *Int J Health Sci (Qassim)*. 2007;1(1):53–9.
4. Suarez S, Conde-Agudelo A, Borovac-Pinheiro A, Suarez-Rebling D, Eckardt M, Theron G, et al. Uterine balloon tamponade for the treatment of postpartum hemorrhage: a systematic review and meta-analysis. *Am J Obstet Gynecol*. 2020;222(4):293.e1–e52. doi:10.1016/j.ajog.2019.11.1287.
5. Pingray V, Widmer M, Ciapponi A, Cormick G, Bloemenkamp K, Deneux-Tharaux C, et al. Effectiveness of uterine tamponade devices for refractory postpartum hemorrhage after vaginal delivery: a systematic review and meta-analysis. *Authorea*. 2020. doi:10.22541/au.159225308.86644919.
6. Downe S, Finlayson K, Oladapo OT, Bonet M, Gulmezoglu AM. What matters to women during childbirth: a systematic qualitative review. *PLoS One*. 2018;13(4):e0194906. doi:10.1371/journal.pone.0194906.
7. Finlayson K, Downe S, Vogel JP, Oladapo OT. What matters to women and healthcare providers in relation to interventions for the prevention of postpartum haemorrhage: a qualitative systematic review. *PLoS One*. 2019;14(5):e0215919. doi:10.1371/journal.pone.0215919.
8. Mvundura M, Kokonya D, Abu-Haydar E, Okoth E, Herrick T, Mukabi J, et al. Cost-effectiveness of condom uterine balloon tamponade to control severe postpartum hemorrhage in Kenya. *Int J Gynaecol Obstet*. 2017;137(2):185–91. doi:10.1002/ijgo.12125.
9. Seligman B, Xingzhu L. Economic assessment of interventions for reducing postpartum hemorrhage in developing countries. Bethesda (MD): Abt Associates Inc.; 2006 (<https://www.abtassociates.com/insights/publications/report/economic-assessment-of-interventions-for-reducing-postpartum>, accessed 21 July 2020).
10. Burke TF, Ahn R, Nelson BD, Hines R, Kamara J, Oguttu M, et al. A postpartum haemorrhage package with condom uterine balloon tamponade: a prospective multi-centre case series in Kenya, Sierra Leone, Senegal, and Nepal. *BJOG*. 2016;123(9):1532–40. doi:10.1111/1471-0528.13550.
11. Akhter S, Begum MR, Kabir Z, Rashid M, Laila TR, Zabeen F. Use of a condom to control massive postpartum hemorrhage. *MedGenMed*. 2003;5(3):38.
12. Doumouchtsis SK, Papageorgiou AT, Vernier C, Arulkumaran S. Management of postpartum hemorrhage by uterine balloon tamponade: prospective evaluation of effectiveness. *Acta Obstet Gynecol Scand*. 2008;87(8):849–55. doi:10.1080/00016340802179822.
13. Darwish AM, Abdallah MM, Shaaban OM, Ali MK, Khalaf M, Sabra AMA. Bakri balloon versus condom-loaded Foley's catheter for treatment of atonic postpartum hemorrhage secondary to vaginal delivery: a randomized controlled trial. *J Matern Fetal Neonatal Med*. 2018;31(6):747–53. doi:10.1080/14767058.2017.1297407.

14. Mishra N, Gulabani K, Agrawal S, Shrivastava C. Efficacy and feasibility of Chhattisgarh balloon and conventional condom balloon tamponade: a 2-year prospective study. *J Obstet Gynaecol India*. 2019;69(Suppl 2):133–41. doi:10.1007/s13224-018-1185-6.
15. Hofmeyr GJ, Middleton K, Singata-Madliki M. Randomized feasibility study of suction-tube uterine tamponade for postpartum hemorrhage. *Int J Gynaecol Obstet*. 2019;146(3):339–43. doi:10.1002/ijgo.12889.
16. Kaya B, Guralp O, Tuten A, Unal O, Celik MO, Dogan A. Which uterine sparing technique should be used for uterine atony during cesarean section? The Bakri balloon or the B-Lynch suture? *Arch Gynecol Obstet*. 2016;294(3):511–7. doi:10.1007/s00404-016-4015-z.
17. Purwosunu Y, Sarkoen W, Arulkumaran S, Segnitz J. Control of postpartum hemorrhage using vacuum-induced uterine tamponade. *Obstet Gynecol*. 2016;128(1):33–6. doi:10.1097/AOG.0000000000001473.
18. Herrick T, Mvundura M, Burke TF, Abu-Haydar E. A low-cost uterine balloon tamponade for management of postpartum hemorrhage: modeling the potential impact on maternal mortality and morbidity in sub-Saharan Africa. *BMC Pregnancy Childbirth*. 2017;17(1):374. doi:10.1186/s12884-017-1564-5.
19. Ellavi [website]. Sinapi Biomedical; 2018 (<https://ellavi.com/>; accessed 7 August 2020).
20. State of inequality: reproductive, maternal, newborn and child health. Geneva: World Health Organization; 2015 ([https://www.who.int/gho/health\\_equity/report\\_2015](https://www.who.int/gho/health_equity/report_2015), accessed 10 July 2020).
21. Anger HA, Dabash R, Durocher J, Hassanein N, Ononge S, Frye LJ, et al. The effectiveness and safety of introducing condom-catheter uterine balloon tamponade for postpartum haemorrhage at secondary level hospitals in Uganda, Egypt and Senegal: a stepped wedge, cluster-randomised trial. *BJOG*. 2019;126(13):1612–21. doi:10.1111/1471-0528.15903.

## 4.2 Uterine balloon tamponade compared with another uterine balloon tamponade

### Question

The question of interest in PICO (population (P), intervention (I), comparator (C), outcome (O)) format:

- For women with PPH who do not respond to treatment with uterotonics (P), does the use of a particular uterine balloon tamponade (I) compared with another uterine balloon tamponade (C) improve maternal outcomes (O)?

**Problem:** PPH due to uterine atony that is unresponsive to uterotonic treatment

**Perspective:** Clinical practice recommendation – population perspective

**Population (P):** Women with PPH who do not respond to standard uterotonic treatment

**Intervention (I):** Uterine balloon tamponade device

**Comparators (C):** Other uterine balloon tamponade devices

**Setting:** Hospital or community setting

**Subgroups:** By mode of birth.

### Priority outcomes (O):<sup>1</sup>

#### Critical outcomes:

- Maternal death
- Additional blood loss  $\geq 500$  mL
- Additional blood loss  $\geq 1000$  mL
- Blood transfusion
- Additional uterotonics
- Invasive nonsurgical interventions (including artery embolization)
- Surgical interventions (including hysterectomy)
- Maternal temperature  $\geq 40$  °C
- Procedure-related complications
- Infections
- Severe morbidity
- Maternal transfer

#### Important outcomes:

- Mean blood loss
- Postpartum anaemia
- Additional nonsurgical interventions (e.g. external aortic compression and compression garments)

<sup>1</sup> These outcomes reflect the prioritized outcomes used in the development of this recommendation, in *WHO recommendations for the prevention and treatment of postpartum haemorrhage* (2012). The outcomes “reduction of time from decision-making to implementation”, “availability of drugs and treatment” and “accuracy in blood loss assessment” were also included in 2012 for this question, when only evidence from observational studies was available. For this update, where evidence of effectiveness comes from randomized studies, these outcomes have been removed. The outcomes “maternal death”, “maternal well-being” and “maternal satisfaction” have been added as part of this update.

- Nausea, vomiting or shivering
- Maternal temperature  $\geq 38^{\circ}\text{C}$
- Delayed initiation of breastfeeding
- Prolonged hospitalization
- Maternal well-being
- Maternal satisfaction

## Assessment

### Effects of interventions

What is the effect of different uterine balloon tamponade devices on the priority outcomes, when used for treating PPH?

### Research evidence

#### Summary of evidence

##### Source and characteristics of studies

Evidence on the effects of uterine balloon tamponade for treatment of PPH is from one Cochrane systematic review that includes nine trials with 947 women (1). Four of these trials (634 women) provided evidence on the use of uterine balloon tamponade for treating primary PPH after vaginal birth. Two further trials (63 women) provided evidence on the use of uterine balloon tamponade for treating primary PPH intraoperatively after caesarean birth. The other three trials included in the Cochrane review addressed different questions (the use of either external compression or surgical methods to treat primary PPH) and were therefore not included in this evidence summary.

The trials were published between 2007 and 2018, with the earliest beginning enrolment in 2003.

One trial compared the use of uterine balloon tamponade versus another uterine balloon tamponade after vaginal birth:

##### *Bakri balloon intrauterine tamponade (saline filled) versus condom-loaded Foley catheter intrauterine tamponade (saline filled)*

The trial (66 women) took place at a single district hospital in Egypt (2). All women had PPH due to uterine atony and had given birth vaginally. Women were randomized to receive either Bakri balloon intrauterine tamponade or condom-loaded Foley catheter, if PPH was intractable after both first and second response had failed (first response was uterine massage plus 40 IU oxytocin; second response was 1000  $\mu\text{g}$  rectal misoprostol). The Bakri balloon and condom-loaded Foley catheter were inflated according to the same protocol (150 mL saline, up to 400–500 mL), with either device recorded as failed if bleeding had not stopped within 15 minutes. In both groups, vaginal packing with 20 cm gauze was used to prevent expulsion of the balloon. All women received intravenous (IV) cephradine 1 g every 12 hours after balloon insertion.

PPH was not defined, and an accurate method of blood loss assessment was not used. Women with traumatic PPH, placental abruption, placenta praevia, pregnancy complications (such as pre-eclampsia, diabetes, anaemia, rheumatic heart disease) or women known to have coagulation problems were excluded from this study. Traumatic lesions and placental remnants were excluded under general anaesthesia before recruitment.

One trial in the Cochrane review included only women who had primary PPH during caesarean section, where women in both groups were treated with an intrauterine balloon tamponade:

***Bakri balloon intrauterine tamponade (saline filled) plus traction stitch versus Bakri balloon intrauterine tamponade (saline filled)***

The trial (50 women) took place at a military hospital in Saudi Arabia (3). All women were at  $\geq 28$  weeks' gestation and had uncontrolled primary atonic PPH during caesarean section that was not responsive to standard treatment (not described). The Bakri balloon was placed inside the uterine cavity intraoperatively, then inflated with saline after suturing of the uterine incision "until it conformed to the contour of the uterus". No further vaginal packing was used in either group. Women in the intervention group also received a traction stitch to secure the tamponade. Both groups of women received IV broad-spectrum antibiotics (drug and dose not described) for the first 48 hours postoperatively, and oxytocin infusion for the first eight hours.

The method of assessing blood loss and the definition of PPH were not described. Women with bleeding due to trauma or placenta praevia were excluded from this study, and coagulopathy was also excluded as a possible cause of PPH. The study was stopped after 50 cases because of the high rate of balloon displacement in the control group.

**Effects of one uterine balloon tamponade device compared with another uterine balloon tamponade device (vaginal birth)*****Bakri balloon intrauterine tamponade (saline filled) versus condom-loaded Foley catheter intrauterine tamponade (saline filled)***

One trial included in the Cochrane review reported on this comparison (2). There may be little or no difference between Bakri balloon and condom-loaded Foley catheter in reducing the risk of **blood transfusion (red cell or whole blood)**. The trial also reported on the priority outcomes **surgical interventions (hysterectomy to control bleeding; B-lynch suture); procedure-related complications (uterine perforation); infections (endometritis); severe morbidity (disseminated intravascular coagulation); maternal transfer (to intensive care unit); and maternal temperature  $\geq 38^\circ\text{C}$**  (recorded in this trial any time in the first 24 hours postpartum); however, the results for all of these outcomes were of very low certainty and therefore inconclusive.

The included study did not report on any other priority outcomes.

**Effects of uterine balloon tamponade device compared with another uterine balloon tamponade device or procedure (during caesarean section)*****Bakri balloon intrauterine tamponade (saline filled) plus traction stitch versus Bakri balloon intrauterine tamponade (saline filled)***

One study reported on this comparison, but only provided data relevant to three priority outcomes. Although **additional blood loss  $\geq 1000\text{ mL}$**  was not reported in this trial, low-certainty evidence suggests that the addition of traction stitch may make little or no difference to the proxy outcome **total blood loss  $\geq 1000\text{ mL}$**  (25/25 versus 25/25; risk ratio [RR] 1.00, 95% confidence interval [CI] 0.93 to 1.08). The evidence on the surgical interventions **hysterectomy to control bleeding and uterine artery and internal iliac artery ligation, or arterial embolization** was of very low certainty.

This study did not report any other WHO priority outcomes.

**Additional considerations*****Other systematic reviews***

The 2012 WHO recommendation was based on observational evidence, as no randomized controlled trials (RCTs) were available at that time. Two systematic reviews (summarized below) have considered the updated observational evidence (4,5).

A 2019 systematic review included RCTs (n=7), nonrandomized studies (n=15) and case series (n=69), and reported on efficacy, effectiveness, and/or safety of uterine balloon tamponade device placement in women with PPH due to a variety of causes, after vaginal and/or caesarean birth (4). The main outcome was the success of uterine balloon tamponade application, defined as bleeding arrested without maternal death and additional surgical or radiological interventions in women in which the uterine balloon tamponade was placed.<sup>1</sup>

A second systematic review focused on uterine balloon tamponade studies conducted in women with refractory PPH presumed to be caused by uterine atony after vaginal birth (5). RCTs and nonrandomized studies were included; however, case series were excluded. It included five studies published between 2007 and 2019. There were two main outcomes: the need for surgical interventions or maternal death; and hysterectomy.

Both reviews included one RCT that compared the Bakri balloon with the condom uterine balloon tamponade (2), already included in the Cochrane review and described above. No further comments from either review were considered of interest to this Evidence to Decision framework.

***Additional considerations on the comparison of improvised uterine balloon tamponades versus purpose-designed uterine balloon tamponades***

Improvised devices might show a lower effectiveness than purpose-designed devices because their improvised nature may increase difficulties with assembly and/or insertion of the device.

The trial comparing the condom-loaded catheter uterine balloon tamponade versus the Bakri balloon included in the Cochrane review and described above showed that the time from start of insertion to stop bleeding was reported as 9 minutes (standard deviation [SD], 6) with the Bakri Balloon and 12 minutes (SD, 7) with the condom catheter balloon (rounded figures) (2).

### Desirable effects

How substantial are the desirable anticipated effects of different uterine balloon tamponade devices versus other uterine balloon tamponade devices?

#### Judgement

✓ Don't know	— Varies	— Trivial	— Small	— Moderate	— Large
-----------------	-------------	--------------	------------	---------------	------------

### Undesirable effects

How substantial are the undesirable anticipated effects of different uterine balloon tamponade devices versus other uterine balloon tamponade devices?

#### Judgement

✓ Don't know	— Varies	— Large	— Moderate	— Small	— Trivial
-----------------	-------------	------------	---------------	------------	--------------

### Certainty of the evidence

What is the overall certainty of the evidence on effects of different uterine balloon tamponade devices versus other uterine balloon tamponade devices?

<sup>1</sup> Note: By this definition, success rate cannot be measured in similar women who have not received uterine balloon tamponade, and it is therefore not a measure of comparative effect.



### Judgement

— No included studies	✓ Very low	— Low	— Moderate	— High
-----------------------------	---------------	----------	---------------	-----------

### Values

Is there important uncertainty about, or variability in, how much women (and their families) value the main outcomes associated with uterine balloon tamponade for PPH treatment?

### Research evidence

In a review of qualitative studies looking at “what women want” from intrapartum care, findings indicate that most women want a normal birth (with good outcomes for mother and baby), but acknowledge that medical intervention may sometimes be necessary (*high confidence*) (6). Most women, especially those giving birth for the first time, are apprehensive about labour and birth (*high confidence*) and wary of medical interventions, although, in certain contexts and/or situations, women welcome interventions to address recognized complications (*low confidence*). Where interventions are introduced, women would like to receive relevant information from technically competent health-care providers who are sensitive to their needs (*high confidence*). Findings from an update of a qualitative systematic review exploring perceptions of PPH prevention and treatment among women and providers suggest that women do not recognize the clinical definitions of blood loss or what might be considered “normal” blood loss (*moderate confidence*) (7). Furthermore, in some low- and middle-income countries (LMICs), women place a greater value on the expulsion of so-called “dirty blood”, which they perceive as a normal cleansing process and something that should not be prevented (*moderate confidence*). The same review highlighted women’s need for information about PPH, ideally given during antenatal care (*moderate confidence*), and the importance of kind, clinically competent staff with a willingness to engage in shared decision-making around PPH management (*moderate/low confidence*). In addition, it was found that women are concerned about feelings of exhaustion and anxiety (at being separated from their babies) following PPH, as well as the long-term psychological effects of experiencing PPH and the negative impact this may have on their ability to breastfeed (*moderate/low confidence*).

### Additional considerations

None.

### Judgement

— Important uncertainty or variability	— Possibly important uncertainty or variability	✓ Probably no important uncertainty or variability	— No important uncertainty or variability
--	--	---	--

Balance of effects

Does the balance between desirable and undesirable effects favour any particular uterine balloon tamponade device?

Judgement

— Don't know	— Varies	— Favours control intervention	— Probably favours control intervention	✓ Does not favour either	— Probably favours experimental uterine balloon tamponade	— Favours experimental uterine balloon tamponade
-----------------	-------------	-----------------------------------	--	-----------------------------	--	---

Resources

How large are the resource requirements (costs) of different uterine balloon tamponade devices for PPH treatment?

Research evidence

Cost or economic outcomes were not prespecified in the Cochrane review on effectiveness of uterine balloon tamponade (1). A systematic review of cost-effectiveness studies on uterine balloon tamponade for PPH treatment identified two cost-effectiveness studies (8,9). Both studies were of high quality according to the Consensus Health Economic Criteria (CHEC) checklist, and both used a model-based approach to estimate the incremental costs of introducing uterine balloon tamponade to treat PPH. Neither study compared cost-effectiveness for different uterine balloon tamponade devices.

Additional considerations

Both cost-effectiveness studies used published effect estimates from case series studies to inform calculations. No cost-effectiveness studies based on effect estimates using meta-analyses or trials were identified.

## Main resource requirements

Resource	Description
Staff	Staff trained in recognition and prompt treatment of refractory PPH. All models of uterine balloon tamponade require placement by trained maternity staff working in adequately equipped health facilities (including anaesthetic staff).
Training	Introduction of a uterine balloon tamponade device would require additional training. Costs of training health-care providers in using uterine balloon tamponade were estimated by one study as USD\$ 30.29 per provider (includes costs for transportation, venue and equipment rentals, meals, printing, and office supplies for a 1-day training session) (8). Periodic refresher training is required.
Supplies	The review identified several studies that reported a unit price for different types of uterine balloon tamponade. Unit prices were: <ul style="list-style-type: none"> <li>■ Condom catheter (various designs): US \$ 0.63–5<sup>a</sup> (2,8–12)</li> <li>■ Uterine suction tube (using FG36 Levin stomach tube): &lt; US\$ 2 (13)</li> <li>■ Bakri balloon: US\$ 171–300 (2,14)</li> <li>■ Vacuum-induced tamponade device (Inpress): &lt; US\$ 400 (15)</li> <li>■ Commercial devices: US\$ 7.50–350 (16,17).</li> </ul> Condom catheter typically requires: <ul style="list-style-type: none"> <li>■ Foley (urinary) catheter size 24</li> <li>■ Condoms</li> <li>■ Needleless suture or cotton for securing</li> <li>■ 1 L bag of normal saline</li> <li>■ 50 mL syringe</li> <li>■ Compresses</li> <li>■ Sterile gloves.</li> </ul>
Equipment and infrastructure	Placement of uterine balloon tamponade typically also requires: <ul style="list-style-type: none"> <li>■ IV fluids</li> <li>■ Instruments (speculum, forceps)</li> <li>■ Analgesia or anaesthesia</li> <li>■ Antibiotics.</li> </ul> Should uterine balloon tamponade fail, transfer to a surgical theatre or to a health facility able to perform hysterectomy is required to treat unresponsive PPH. However, typically in high-income countries such as France, the United Kingdom and the United States, the uterine balloon tamponade is placed with the woman in the surgical theatre, and after exploration of the uterine cavity to exclude trauma as the cause of the bleeding. Conversely, in LMICs, the placement is commonly done in the delivery room, frequently without exploration of the uterine cavity.
Time	The time from start of insertion to stop bleeding was reported as 9 minutes (SD, 6) with the Bakri Balloon and 12 minutes (SD, 7) with the condom catheter balloon (rounded figures) in a trial comparing both uterine balloon tamponade devices (2).
Supervision and monitoring	Supervision and monitoring to ensure appropriate use, stock availability and quality.

<sup>a</sup> One study (Dumont et al., 2017) quoted a higher price of \$10 for a uterine balloon tamponade kit that included misoprostol tablets: “Tablets of 200 µg misoprostol and uterine balloon tamponade kits (including Foley catheter size 24, condom, 1-litre bag of solute, needleless suture, 50 mL syringe, compresses, sterile gloves) were implemented in the participating centres (each kit costing US\$ 10 but free of charge for the patients)” (11).

## Resources required

### Judgement

— Don't know	✓ Varies	— Large costs	— Moderate costs	— Negligible costs or savings	— Moderate savings	— Large savings
-----------------	-------------	------------------	---------------------	----------------------------------	-----------------------	--------------------

## Certainty of the evidence on required resources

What is the certainty of the evidence on costs?

### Judgement

— No included studies	— Very low	✓ Low	— Moderate	— High
--------------------------	---------------	----------	---------------	-----------

## Cost-effectiveness

### Judgement

✓ Don't know	— Varies	— Favours control intervention	— Probably favours control intervention	— Does not favour either	— Probably favours experimental uterine balloon tamponade	— Favours experimental uterine balloon tamponade
-----------------	-------------	-----------------------------------	--	-----------------------------	--	---

## Equity

What would be the impact of different uterine balloon tamponade devices for PPH treatment on health equity?

## Research evidence

The cost of the commercially available uterine balloon tamponade devices ranges between US\$ 7.50 and US\$ 400, while those of the improvised devices like the condom catheter are between US\$ 0.63 and US\$ 5. It is unclear whether potential benefits from the uterine balloon tamponade use can be associated with either type of device. If commercially available devices are found to be effective and safe, their costs may limit their use in low-resource settings, which may reduce equity. Conversely, if improvised devices are found to be effective and safe, they could increase equity, as these devices are cheaper. Additionally, in some settings the cost of these devices must be covered directly by the patients, which may decrease equity.

## Additional considerations

None.

### Judgement

✓ Don't know	— Varies	— Reduced	— Probably reduced	— Probably no impact	— Probably increased	— Increased
-----------------	-------------	--------------	-----------------------	-------------------------	-------------------------	----------------

## Acceptability

Are different uterine balloon tamponade devices acceptable to key stakeholders?

### Research evidence

In an update of a qualitative systematic review exploring perceptions of PPH prevention and treatment among women and health-care providers (7), findings from providers indicate that the use of a simple uterine balloon tamponade device is effective as a second-line treatment in arresting blood loss associated with PPH (*moderate confidence*). Findings from providers also suggest that a uterine balloon tamponade is relatively easy to use and, with appropriate training, could be administered by a variety of cadres, including midwives and medical officers (*moderate confidence*). In addition, providers felt that the use of a uterine balloon tamponade reduced referral rates to secondary facilities and the need for more complicated surgical procedures (hysterectomy) (*moderate confidence*). A few providers were also aware that some women might be reluctant to have a condom inserted on cultural or religious grounds and that the uterine balloon tamponade should be referred to as a “tamponade” rather than a condom for this reason (*low confidence*).

The same review also found that neither women nor providers expressed a preference for a particular type of uterine balloon tamponade; providers in most of the studies utilized a simple “device” consisting of a condom, urinary catheter, cotton string and luer lock valve.

There was very little direct evidence from women about their experiences of uterine balloon tamponade.

### Additional considerations

None.

### Judgement

—	—	—	—	✓	—
Don't know	Varies	No	Probably No	Probably Yes	Yes

## Feasibility

Are different uterine balloon tamponade devices feasible to implement?

### Research evidence

Findings from an update of a qualitative systematic review on PPH prevention and treatment (7) suggest that a uterine balloon tamponade is a practical and affordable solution in many low-resource settings and could be improvised from readily available items (condoms, surgical gloves) (*low confidence*). In most of the studies contributing to this review finding, the uterine balloon tamponade consisted of a condom, urinary catheter, cotton string and a luer lock valve. Findings from the same review also suggest that there may be some confusion amongst providers about how long to leave a uterine balloon tamponade in place and they highlighted the need for regular “hands-on” training to maintain their skills (*moderate confidence*). There was very little direct evidence from women relating to the feasibility of using a uterine balloon tamponade.

Additional considerations

It is commonly accepted that insertion of a uterine balloon tamponade is a relatively simple procedure and that the required level of competence can be achieved after a short training in simulated conditions. For example, trials of uterine balloon tamponade have used a half-day onsite training at participating hospitals (11,18). In these trials, the training sessions were conducted by trained obstetricians, who were trained by experienced obstetricians (using a “train-the-trainers” approach). These trials described either concerns with the use of the uterine balloon tamponade, or substantial delays in insertion of the uterine balloon tamponade (11). In the trial conducted in Benin and Mali and comparing uterine balloon tamponade versus no uterine balloon tamponade, the condom catheter was inserted 30 minutes or more after the diagnosis of PPH in 58% of the cases, despite efforts to improve the availability of the different components of the uterine balloon tamponade device (11). In the stepped-wedge cluster RCT conducted in Egypt, Senegal and Uganda assessing the effectiveness of the introduction of condom-catheter uterine balloon tamponade as an option for treatment of refractory PPH after vaginal birth, providers reported a problem with the uterine balloon tamponade in 52% of the cases (18). Whether those factors were related to the training, the type of device, or the previous expertise of the providers is unknown.

If commercially available devices were proven to be more effective than the improvised devices, accessing them in low-resource settings may be a challenge due to their higher cost.

Judgement

— Don't know	— Varies	— No	— Probably No	✓ Probably Yes	— Yes
-----------------	-------------	---------	------------------	-------------------	----------

## Summary of judgements table

Desirable effects	✓ Don't know	— Varies		— Trivial	— Small	— Moderate	— Large
Undesirable effects	✓ Don't know	— Varies		— Large	— Moderate	— Small	— Trivial
Certainty of the evidence	— No included studies			✓ Very low	— Low	— Moderate	— High
Values				— Important uncertainty or variability	— Possibly important uncertainty or variability	✓ Probably no important uncertainty or variability	— No important uncertainty or variability
Balance of effects	— Don't know	— Varies	— Favours control intervention	— Probably favours control intervention	✓ Does not favour either	— Probably favours experimental uterine balloon tamponade	— Favours oxytocin experimental uterine balloon tamponade
Resources required	— Don't know	✓ Varies	— Large costs	— Moderate costs	— Negligible costs or savings	— Moderate savings	— Large savings
Certainty of the evidence on required resources	— No included studies			— Very low	— Low	✓ Moderate	— High
Cost-effectiveness	✓ Don't know	— Varies	— Favours control intervention	— Probably favours control intervention	— Does not favour either	— Probably favours experimental uterine balloon tamponade	— Favours experimental uterine balloon tamponade
Equity	✓ Don't know	— Varies	— Reduced	— Probably reduced	— Probably no impact	— Probably increased	— Increased
Acceptability	— Don't know	— Varies		— No	— Probably No	✓ Probably Yes	— Yes
Feasibility	— Don't know	— Varies		— No	— Probably No	✓ Probably Yes	— Yes

## Summary of findings table

**Question:** Bakri balloon intrauterine tamponade (saline filled) compared to condom-loaded Foley catheter intrauterine tamponade (saline filled) for treating primary postpartum haemorrhage

**Setting:** Hospital (Egypt)

**Reference:** Kellie FJ, Wandabwa JN, Mousa HA, Weeks AD. Mechanical and surgical interventions for treating primary postpartum haemorrhage. Cochrane Database Syst Rev. 2020;7:CD013663.

Certainty assessment											Effect		Certainty	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other consid- erations	No. of patients		Relative (95% CI)	Absolute (95% CI)				
BLOOD TRANSFUSION (RED CELL OR WHOLE BLOOD)														
1	randomized trials	serious <sup>a</sup>	not serious	not serious	serious <sup>b</sup>	none	29/30 (96.7%)	28/28 (100.0%)	<b>RR 0.97</b> (0.88 to 1.06)	<b>30 fewer per 1000</b> (from 120 fewer to 60 more)	⊕⊕⊕⊕ LOW	CRITICAL		
SURGICAL INTERVENTIONS - HYSTERECTOMY TO CONTROL BLEEDING														
1	randomized trials	serious <sup>a</sup>	not serious	not serious	very serious <sup>c,d</sup>	none	1/33 (3.0%)	2/33 (6.1%)	<b>RR 0.50</b> (0.05 to 5.25)	<b>30 fewer per 1000</b> (from 58 fewer to 258 more)	⊕⊕⊕⊕ VERY LOW	CRITICAL		
SURGICAL INTERVENTIONS: B-LYNCH SUTURE														
1	randomized trials	serious <sup>a</sup>	not serious	not serious	very serious <sup>c,d</sup>	none	2/33 (6.1%)	3/33 (9.1%)	<b>RR 0.67</b> (0.12 to 3.73)	<b>30 fewer per 1000</b> (from 80 fewer to 248 more)	⊕⊕⊕⊕ VERY LOW	CRITICAL		
PROCEDURE-RELATED COMPLICATIONS: UTERINE PERFORATION														
1	randomized trials	serious <sup>a</sup>	not serious	not serious	very serious <sup>e</sup>	none	0/33 (0.0%)	0/33 (0.0%)	not estimable		⊕⊕⊕⊕ VERY LOW	CRITICAL		



Certainty assessment							No. of patients		Effect		Certainty	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Bakri balloon intrauterine tamponade (saline filled)	Condom-loaded Foley catheter intrauterine tamponade (saline filled)	Relative (95% CI)	Absolute (95% CI)		
<b>INFECTIONS: ENDOMETRITIS</b>												
1	randomized trials	serious <sup>a</sup>	not serious	not serious	very serious <sup>e</sup>	none	0/33 (0.0%)	0/33 (0.0%)	not estimable		⊕⊖⊖⊖ VERY LOW	CRITICAL
<b>SEVERE MORBIDITY: DISSEMINATED INTRAVASCULAR COAGULATION</b>												
1	randomized trials	serious <sup>a</sup>	not serious	not serious	very serious <sup>c,d</sup>	none	1/30 (3.3%)	2/28 (7.1%)	<b>RR 0.47</b> (0.04 to 4.87)	<b>38 fewer per 1000</b> (from 69 fewer to 276 more)	⊕⊖⊖⊖ VERY LOW	CRITICAL
<b>ADMISSION TO HIGHER LEVEL OF CARE</b>												
1	randomized trials	serious <sup>a</sup>	not serious	not serious	very serious <sup>c,d</sup>	none	2/30 (6.7%)	4/28 (14.3%)	<b>RR 0.47</b> (0.09 to 2.35)	<b>76 fewer per 1000</b> (from 130 fewer to 193 more)	⊕⊖⊖⊖ VERY LOW	CRITICAL
<b>FEVER ≥ 38°C IN FIRST 24 HOURS POSTPARTUM</b>												
1	randomized trials	serious <sup>a</sup>	not serious	not serious	very serious <sup>c,d</sup>	none	2/30 (6.7%)	1/28 (3.6%)	<b>RR 1.87</b> (0.18 to 19.47)	<b>31 more per 1000</b> (from 29 fewer to 660 more)	⊕⊖⊖⊖ VERY LOW	IMPORTANT

CI: confidence interval; RR: risk ratio

- <sup>a</sup> All of pooled effect provided by study at moderate risk of bias.
- <sup>b</sup> Small sample size.
- <sup>c</sup> Small sample size, few events.
- <sup>d</sup> Wide CI including appreciable benefit and appreciable harm.
- <sup>e</sup> Small sample size. No events, not estimable.

**Question:** Bakri balloon intrauterine tamponade (saline filled) plus traction stitch compared to Bakri balloon intrauterine tamponade (saline filled) without stitch for treating primary postpartum haemorrhage during caesarean section

**Setting:** Hospital (Saudi Arabia)

**Reference:** Kellie FJ, Wandabwa JN, Mousa HA, Weeks AD. Mechanical and surgical interventions for treating primary postpartum haemorrhage. Cochrane Database Syst Rev. 2020;7:CD013663.

Certainty assessment							No. of patients		Effect		Certainty	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other consid- erations	Bakri balloon intrauterine tamponade (saline filled) plus traction stitch	Bakri balloon intrauterine tamponade (saline filled) without stitch	Relative (95% CI)	Absolute (95% CI)		
TOTAL BLOOD LOSS ≥ 1000 ML (BEFORE AND AFTER RANDOMIZATION)												
1	randomized trials	serious <sup>a</sup>	not serious	not serious	serious <sup>b</sup>	none	25/25 (100.0%)	25/25 (100.0%)	RR 1.00 (0.93 to 1.08)	0 fewer per 1000 (from 70 fewer to 80 more)	⊕⊕⊖⊖ LOW	CRITICAL
SURGICAL INTERVENTION – HYSTERECTOMY TO CONTROL BLEEDING												
1	randomized trials	serious <sup>a</sup>	not serious	not serious	very serious <sup>c,d</sup>	none	0/25 (0.0%)	2/25 (8.0%)	RR 0.20 (0.01 to 3.97)	64 fewer per 1000 (from 79 fewer to 238 more)	⊕⊖⊖⊖ VERY LOW	CRITICAL
SURGICAL INTERVENTIONS – UTERINE ARTERY AND INTERNAL ILIAC ARTERY LIGATION, OR ARTERIAL EMBOLIZATION												
1	randomized trials	serious <sup>a</sup>	not serious	not serious	very serious <sup>c,d</sup>	none	1/25 (4.0%)	3/25 (12.0%)	RR 0.33 (0.04 to 2.99)	80 fewer per 1000 (from 115 fewer to 239 more)	⊕⊖⊖⊖ VERY LOW	CRITICAL

**CI:** confidence interval; **RR:** risk ratio

- <sup>a</sup> All of pooled effect provided by single study at moderate risk of bias.
- <sup>b</sup> Small sample size.
- <sup>c</sup> Small sample size, few events.
- <sup>d</sup> Wide CI including appreciable benefit and appreciable harm.

## References

1. Kellie F, Wandabwa J, Mousa H, Weeks A. Mechanical and surgical interventions for treating primary postpartum haemorrhage. *Cochrane Database Syst Rev*. 2020;7:CD013663. doi:10.1002/14651858.CD013663.
2. Darwish AM, Abdallah MM, Shaaban OM, Ali MK, Khalaf M, Sabra AMA. Bakri balloon versus condom-loaded Foley's catheter for treatment of atonic postpartum hemorrhage secondary to vaginal delivery: a randomized controlled trial. *J Matern Fetal Neonatal Med*. 2018;31(6):747-53. doi:10.1080/14767058.2017.1297407.
3. Khalil MI, Al-Dohami H, Aldahish MM. A method to improve the effectiveness of the Bakri balloon for management of postpartum hemorrhage at cesarean. *Int J Gynaecol Obstet*. 2011;115(2):198-200. doi:10.1016/j.ijgo.2011.04.018.
4. Suarez S, Conde-Agudelo A, Borovac-Pinheiro A, Suarez-Rebling D, Eckardt M, Theron G, et al. Uterine balloon tamponade for the treatment of postpartum hemorrhage: a systematic review and meta-analysis. *Am J Obstet Gynecol*. 2020;222(4):293.e1-e52. doi:10.1016/j.ajog.2019.11.1287.
5. Pingray V, Widmer M, Ciapponi A, Cormick G, Bloemenkamp K, Deneux-Tharaux C, et al. Effectiveness of uterine tamponade devices for refractory postpartum hemorrhage after vaginal delivery: a systematic review and meta-analysis. *Authorea*. 2020. doi:10.22541/au.159225308.86644919.
6. Downe S, Finlayson K, Oladapo OT, Bonet M, Gulmezoglu AM. What matters to women during childbirth: a systematic qualitative review. *PLoS One*. 2018;13(4):e0194906. doi:10.1371/journal.pone.0194906.
7. Finlayson K, Downe S, Vogel JP, Oladapo OT. What matters to women and healthcare providers in relation to interventions for the prevention of postpartum haemorrhage: a qualitative systematic review. *PLoS One*. 2019;14(5):e0215919. doi:10.1371/journal.pone.0215919.
8. Mvundura M, Kokonya D, Abu-Haydar E, Okoth E, Herrick T, Mukabi J, et al. Cost-effectiveness of condom uterine balloon tamponade to control severe postpartum hemorrhage in Kenya. *Int J Gynaecol Obstet*. 2017;137(2):185-91. doi:10.1002/ijgo.12125.
9. Seligman B, Xingzhu L. Economic assessment of interventions for reducing postpartum hemorrhage in developing countries. Bethesda (MD): Abt Associates Inc.; 2006 (<https://www.abtassociates.com/insights/publications/report/economic-assessment-of-interventions-for-reducing-postpartum>, accessed 21 July 2020).
10. Burke TF, Ahn R, Nelson BD, Hines R, Kamara J, Oguttu M, et al. A postpartum haemorrhage package with condom uterine balloon tamponade: a prospective multi-centre case series in Kenya, Sierra Leone, Senegal, and Nepal. *BJOG*. 2016;123(9):1532-40. doi:10.1111/1471-0528.13550.
11. Dumont A, Bodin C, Hounkpatin B, Popowski T, Traore M, Perrin R, et al. Uterine balloon tamponade as an adjunct to misoprostol for the treatment of uncontrolled postpartum haemorrhage: a randomised controlled trial in Benin and Mali. *BMJ Open*. 2017;7(9):e016590. doi:10.1136/bmjopen-2017-016590.
12. Mishra N, Gulabani K, Agrawal S, Shrivastava C. Efficacy and feasibility of Chhattisgarh balloon and conventional condom balloon tamponade: a 2-year prospective study. *J Obstet Gynaecol India*. 2019;69(Suppl 2):133-41. doi:10.1007/s13224-018-1185-6.
13. Hofmeyr GJ, Middleton K, Singata-Madliki M. Randomized feasibility study of suction-tube uterine tamponade for postpartum hemorrhage. *Int J Gynaecol Obstet*. 2019;146(3):339-43. doi:10.1002/ijgo.12889.

14. Kaya B, Guralp O, Tuten A, Unal O, Celik MO, Dogan A. Which uterine sparing technique should be used for uterine atony during cesarean section? The Bakri balloon or the B-Lynch suture? *Arch Gynecol Obstet.* 2016;294(3):511-7. doi:10.1007/s00404-016-4015-z.
15. Purwosunu Y, Sarkoen W, Arulkumaran S, Segnitz J. Control of postpartum hemorrhage using vacuum-induced uterine tamponade. *Obstet Gynecol.* 2016;128(1):33-6. doi:10.1097/AOG.0000000000001473.
16. Herrick T, Mvundura M, Burke TF, Abu-Haydar E. A low-cost uterine balloon tamponade for management of postpartum hemorrhage: modeling the potential impact on maternal mortality and morbidity in sub-Saharan Africa. *BMC Pregnancy Childbirth.* 2017;17(1):374. doi:10.1186/s12884-017-1564-5.
17. Ellavi [website]. Sinapi Biomedical; 2018 (<https://ellavi.com/>, accessed 7 August 2020).
18. Anger HA, Dabash R, Durocher J, Hassanein N, Ononge S, Frye LJ, et al. The effectiveness and safety of introducing condom-catheter uterine balloon tamponade for postpartum haemorrhage at secondary level hospitals in Uganda, Egypt and Senegal: a stepped wedge, cluster-randomised trial. *BJOG.* 2019;126(13):1612-21. doi:10.1111/1471-0528.15903.

## 4.3 Uterine balloon tamponade compared with a different type of uterine tamponade

### Question

The question of interest in PICO (population (P), intervention (I), comparator (C), outcome (O)) format:

- For women with PPH who do not respond to treatment with uterotonics (P), does the use of a uterine balloon tamponade (I) compared with a different type of uterine tamponade intervention (C) improve maternal outcomes (O)?

**Problem:** PPH due to uterine atony that is unresponsive to uterotonic treatment.

**Perspective:** Clinical practice recommendation – population perspective

**Population (P):** Women with PPH who do not respond to standard uterotonic treatment

**Intervention (I):** Uterine balloon tamponade

**Comparators (C):** Other types of tamponade interventions, or surgical procedures

**Setting:** Hospital or community setting

**Subgroups:** By mode of birth.

### Priority outcomes (O):<sup>1</sup>

#### Critical outcomes:

- Maternal death
- Additional blood loss  $\geq 500$  mL
- Additional blood loss  $\geq 1\,000$  mL
- Blood transfusion
- Additional uterotonics
- Invasive nonsurgical interventions
- Surgical interventions (including hysterectomy)
- Maternal temperature  $\geq 40$  °C
- Procedure-related complications
- Infections
- Severe morbidity
- Maternal transfer

<sup>1</sup> These outcomes reflect the prioritized outcomes used in the development of this recommendation, in *WHO recommendations for the prevention and treatment of postpartum haemorrhage* (2012). The outcomes “reduction of time from decision-making to implementation”, “availability of drugs and treatment” and “accuracy in blood loss assessment” were also included in 2012 for this question, when only evidence from observational studies was available. For this update, where evidence of effectiveness comes from randomized studies, these outcomes have been removed. The outcomes “maternal death”, “maternal well-being” and “maternal satisfaction” have been added as part of this update.

### Important outcomes:

- Mean blood loss
- Postpartum anaemia
- Additional nonsurgical interventions (e.g. external aortic compression and compression garments)
- Nausea, vomiting or shivering
- Maternal temperature  $\geq 38^{\circ}\text{C}$
- Delayed initiation of breastfeeding
- Prolonged hospitalization
- Maternal well-being
- Maternal satisfaction

## Assessment

### Effects of interventions

What is the effect of uterine balloon tamponade compared to other types of tamponade interventions on the priority outcomes, when used for treating PPH?

### Research evidence

#### Summary of evidence

##### Source and characteristics of studies

Evidence on the effects of uterine balloon tamponade for treatment of PPH is from one Cochrane systematic review, which includes nine trials with 947 women (1). Four of these trials (634 women) provided evidence on the use of uterine balloon tamponade for treating primary PPH after vaginal birth. Two further trials (63 women) provided evidence on the use of uterine balloon tamponade for treating primary PPH intraoperatively after caesarean birth. The other three trials included in the Cochrane review addressed different questions (the use of either external compression or surgical methods to treat primary PPH) and were therefore not included in this evidence summary.

The trials were published between 2007 and 2018, with the earliest beginning enrolment in 2003.

One trial in the Cochrane review compared the use of uterine balloon tamponade with another type of tamponade after vaginal birth:

##### *Condom-loaded catheter intrauterine tamponade versus uterovaginal packing*

The trial (212 women) took place at a single hospital in Pakistan (2). Women were aged 20 to 40 years, at  $> 37$  weeks' gestation, and had primary PPH following vaginal birth. PPH was unresponsive to first-response medical treatment (not described). Women in the intervention group received condom-loaded catheter intrauterine tamponade. Women in the control group received intrauterine packing with roll gauze and vaginal packing with an epipad. All women received antibiotic prophylaxis (drug and dose not described).

PPH was defined as excessive blood loss from the genital tract, but the method of blood loss estimation was not described. Women were excluded if they had PPH due to perineal, cervical or vaginal tear or episiotomy; PPH due to retained placenta; vaginal birth following previous caesarean section; coagulation disorder.

One trial included only women who had primary PPH during caesarean section, where women in one group were treated with uterine balloon tamponade:

***Bakri balloon intrauterine tamponade (saline filled) versus endouterine square suture***

The trial (13 women) took place at a university hospital in Turkey (3). All women had intractable PPH due to complete placenta praevia during elective caesarean section. The PPH was unresponsive to treatment (IV oxytocin and IV methylergonovine). Women in the intervention group received bimanual compression while the uterine balloon tamponade was prepared (5 minutes), then Bakri balloon tamponade inserted intraoperatively through the uterine incision (then inflated with 100–200 mL saline, according to uterine size). The control group received endouterine haemostatic square suture to the lower segment of the uterus. All women received broad-spectrum antibiotic prophylaxis (drug and dose not described).

PPH was not defined. Blood loss during the operation was calculated by the anaesthetist (evaluation of blood collected via suction plus weighing of absorbent pads). Postoperative blood loss was measured by weighing pads worn by patients. Women were excluded if they had: serious medical, haematological, or surgical diseases; placental implantation anomalies such as placenta accreta/increta/percreta; history of thromboembolism; emergency caesarean section; macrosomia; polyhydramnios; pre-eclampsia; gestational diabetes; intrauterine growth retardation; or multiple gestations.

**Effects of one uterine balloon tamponade compared with another type of tamponade (vaginal birth)**

***Condom-loaded catheter intrauterine tamponade versus uterovaginal packing***

The single study reporting on this comparison provided data relevant to two priority outcomes, **maternal temperature  $\geq 40^{\circ}\text{C}$**  and **maternal temperature  $\geq 38^{\circ}\text{C}$**  (the authors reported **fever**; parameters not defined); however, the evidence was of very low certainty.

The included study did not report on any other priority outcomes.

**Effects of uterine balloon tamponade compared with surgical procedure (during caesarean section)**

***Bakri balloon intrauterine tamponade (saline filled) versus endouterine square suture***

The single small study making this comparison reported on the priority outcomes: **maternal death (mortality due to bleeding; all-cause mortality; mortality from causes other than bleeding); blood transfusion (red cell or whole blood); surgical interventions (hysterectomy to control bleeding; arterial ligation, compressive, uterine sutures, arterial embolization, or laparotomy to control bleeding); procedure-related complications; severe morbidity (renal or respiratory failure, cardiac arrest or multiple organ failure); and mean blood loss**. The results for all outcomes were of very low certainty.

This study did not report any other priority outcomes.

**Additional considerations**

***Other systematic reviews***

The 2012 WHO recommendation was based on observational evidence, as no RCTs were available at that time. Two systematic reviews (summarized below) have considered the updated observational evidence (4,5).

A 2019 systematic review included RCTs (n=7), nonrandomized studies (n=15) and case series (n=69), and reported on efficacy, effectiveness, and/or safety of uterine

balloon tamponade device placement in women with PPH due to a variety of causes, after vaginal and/or caesarean birth (4). The main outcome was the success of uterine balloon tamponade application, defined as bleeding arrested without maternal death and additional surgical or radiological interventions in women in which the uterine balloon tamponade was placed.<sup>1</sup>

A second systematic review focused on uterine balloon tamponade studies conducted in women with refractory PPH presumed to be caused by uterine atony after vaginal birth (5). RCTs and nonrandomized studies were included; however, case series were excluded. It included five studies published between 2007 and 2019. There were two main outcomes: the need for surgical interventions or maternal death; and hysterectomy.

While the former review included the two RCTs already included in the Cochrane review and described above, the latter did not consider them eligible. No further comments from either review were considered of interest to this Evidence to Decision (EtD) framework.

**Desirable effects**

How substantial are the desirable anticipated effects of uterine balloon tamponade versus other tamponade interventions?

**Judgement**

✓ Don't know	— Varies	— Trivial	— Small	— Moderate	— Large
-----------------	-------------	--------------	------------	---------------	------------

**Undesirable effects**

How substantial are the undesirable anticipated effects of uterine balloon tamponade versus other tamponade interventions?

**Judgement**

✓ Don't know	— Varies	— Large	— Moderate	— Small	— Trivial
-----------------	-------------	------------	---------------	------------	--------------

**Certainty of the evidence**

What is the overall certainty of the evidence on effects of uterine balloon tamponade versus other tamponade interventions?

— No included studies	✓ Very low	— Low	— Moderate	— High
--------------------------	---------------	----------	---------------	-----------

**Additional considerations**

None.

<sup>1</sup> Note: By this definition, success rate cannot be measured in similar women who have not received uterine balloon tamponade, and it is therefore not a measure of comparative effect.



## Values

Is there important uncertainty about, or variability in, how much women (and their families) value the main outcomes associated with uterine balloon tamponade for PPH treatment?

## Research evidence

In a review of qualitative studies looking at “what women want” from intrapartum care, findings indicate that most women want a normal birth (with good outcomes for mother and baby), but acknowledge that medical intervention may sometimes be necessary (*high confidence*) (6). Most women, especially those giving birth for the first time, are apprehensive about labour and birth (*high confidence*) and wary of medical interventions, although, in certain contexts and/or situations, women welcome interventions to address recognized complications (*low confidence*). Where interventions are introduced, women would like to receive relevant information from technically competent health-care providers who are sensitive to their needs (*high confidence*).

Findings from an update of a qualitative systematic review exploring perceptions of PPH prevention and treatment among women and providers suggest that women do not recognize the clinical definitions of blood loss or what might be considered “normal” blood loss (*moderate confidence*) (7). Furthermore, in some low- and middle-income countries (LMICs), women place a greater value on the expulsion of so-called “dirty blood”, which they perceive as a normal cleansing process and something that should not be prevented (*moderate confidence*). The same review highlighted women’s need for information about PPH, ideally given during antenatal care (*moderate confidence*), and the importance of kind, clinically competent staff with a willingness to engage in shared decision-making around PPH management (*moderate/low confidence*). In addition, it was found that women are concerned about feelings of exhaustion and anxiety (at being separated from their babies) following PPH, as well as the long-term psychological effects of experiencing PPH and the negative impact this may have on their ability to breastfeed (*moderate/low confidence*).

## Additional considerations

None.

## Judgement

— Important uncertainty or variability	— Possibly important uncertainty or variability	✓ Probably no important uncertainty or variability	— No important uncertainty or variability
--	--	---	--

## Balance of effects

Does the balance between desirable and undesirable effects favour uterine balloon tamponade or other tamponade interventions?

Judgement

✓ Don't know	— Varies	— Favours other tamponade interven- tions	— Probably favours other tamponade interven- tions	— Does not favour either	— Probably favours uterine balloon tamponade	— Favours uterine balloon tamponade
-----------------	-------------	--	--	-----------------------------------	---	---

Resources

How large are the resource requirements (costs) of uterine balloon tamponade and other tamponade interventions for PPH treatment?

Research evidence

Cost or economic outcomes were not prespecified in the Cochrane review on effectiveness of uterine balloon tamponade (1). A systematic review of cost-effectiveness studies on uterine balloon tamponade for PPH treatment identified two cost-effectiveness studies (8,9). Both studies were of high quality according to the Consensus Health Economic Criteria (CHEC) checklist, and both used a model-based approach to estimate the incremental costs of introducing uterine balloon tamponade to treat PPH. Neither study compared cost-effectiveness for uterine balloon tamponade versus other tamponade interventions.

Additional considerations

Both cost-effectiveness studies used published effect estimates from case series studies to inform calculations. No cost-effectiveness studies based on effect estimates using meta-analyses or trials were identified.

## Main resource requirements

Resource	Description
Staff	<p>Staff trained in recognition and prompt treatment of refractory PPH.</p> <p>All models of UB uterine balloon tamponade require placement by trained maternity staff working in adequately equipped health facilities (including anaesthetic staff).</p> <p>Similar staff is needed for other tamponade interventions.</p>
Training	<p>Introduction of a uterine balloon tamponade device would require additional training.</p> <p>Costs of training health-care providers in using uterine balloon tamponade were estimated by one study as US\$ 30.29 per provider (includes costs for transportation, venue and equipment rentals, meals, printing, and office supplies for a one-day training session) (8).</p> <p>Periodic refresher training is required.</p> <p>Similar training would be needed for other tamponade interventions in PPH after vaginal births.</p>
Supplies	<p>The review identified several studies that reported a unit price for different types of uterine balloon tamponade. Unit prices were:</p> <ul style="list-style-type: none"> <li>■ Condom catheter (various designs): US\$ 0.63–5<sup>a</sup> (2,8–12).</li> <li>■ Uterine suction tube (using FG36 Levin stomach tube): &lt; US\$ 2 (13)</li> <li>■ Bakri balloon: US\$ 171–300 (2,14)</li> <li>■ Vacuum-induced tamponade device (Inpress): &lt; US\$ 400 (15)</li> <li>■ Commercial devices: US\$ 7.50–350 (16,17).</li> </ul> <p>Condom catheter typically requires:</p> <ul style="list-style-type: none"> <li>■ Foley (urinary) catheter size 24</li> <li>■ Condoms</li> <li>■ Needleless suture or cotton for securing</li> <li>■ 1 L bag of normal saline</li> <li>■ 50 mL syringe</li> <li>■ Compresses</li> <li>■ Sterile gloves.</li> </ul>
Equipment and infrastructure	<p>Placement of uterine balloon tamponade typically also requires:</p> <p>IV fluids</p> <p>Instruments (speculum, forceps)</p> <p>Analgesia or anaesthesia</p> <p>Antibiotics.</p> <p>Should uterine balloon tamponade fail, transfer to a surgical theatre or to a health facility able to perform hysterectomy is required to treat unresponsive PPH.</p> <p>However, typically in high-income countries such as France, the United Kingdom and United States, the uterine balloon tamponade is placed with the woman in the surgical theatre, and after exploration of the uterine cavity to exclude trauma as the cause of the bleeding. Conversely, in LMICs the placement is commonly done in the delivery room, frequently without exploration of the uterine cavity.</p>
Time	–
Supervision and monitoring	Supervision and monitoring to ensure appropriate use, stock availability and quality.

<sup>a</sup> One study (Dumont et al., 2017) quoted a higher price of \$10 for a uterine balloon tamponade kit that included misoprostol tablets: “Tablets of 200 µg misoprostol and uterine balloon tamponade kits (including Foley catheter size 24, condom, 1-litre bag of solute, needleless suture, 50 mL syringe, compresses, sterile gloves) were implemented in the participating centres (each kit costing US\$ 10 but free of charge for the patients)” (11).

## Resources required

### Judgement

— Don't know	✓ Varies	— Large costs	— Moderate costs	— Negligible costs or savings	— Moderate savings	— Large savings
-----------------	-------------	------------------	---------------------	----------------------------------	-----------------------	--------------------

## Certainty of the evidence on required resources

What is the certainty of the evidence on costs?

### Judgement

— No included studies	— Very low	✓ Low	— Moderate	— High
--------------------------	---------------	----------	---------------	-----------

## Cost-effectiveness

### Judgement

✓ Don't know	— Varies	— Favours other tamponade interventions	— Probably favours other tamponade interventions	— Does not favour either	— Probably favours uterine balloon tamponade	— Favours uterine balloon tamponade
-----------------	-------------	--	---	-----------------------------	---	--

## Equity

What would be the impact of uterine balloon tamponade compared to other tamponade interventions for PPH treatment on health equity?

## Research evidence

The cost of the commercially available uterine balloon tamponade devices ranges between US\$ 7.50 and US\$ 400, while those of the improvised devices like the condom catheter are between US\$ 0.63 and US\$ 5. It is unclear whether potential benefits from the uterine balloon tamponade use can be associated with either type of device. If commercially available devices are found to be effective and safe, their costs may limit their use in low-resource settings, which may reduce equity. Conversely, if improvised devices are found to be effective and safe, they could increase equity, as these devices are cheaper. Additionally, in some settings the cost of these devices must be covered directly by the patients, which may decrease equity.

## Additional considerations

None.

### Judgement

✓ Don't know	— Varies	— Reduced	— Probably reduced	— Probably no impact	— Probably increased	— Increased
-----------------	-------------	--------------	-----------------------	-------------------------	-------------------------	----------------

## Acceptability

Is uterine balloon tamponade for PPH treatment acceptable to key stakeholders?

### Research evidence

In an update of a qualitative systematic review exploring perceptions of PPH prevention and treatment among women and health-care providers (7), findings from providers indicate that the use of a simple uterine balloon tamponade device is effective as second-line treatment in arresting blood loss associated with PPH (*moderate confidence*). Findings from providers also suggest that a uterine balloon tamponade is relatively easy to use and, with appropriate training, could be administered by a variety of cadres, including midwives and medical officers (*moderate confidence*). In addition, providers felt that the use of a uterine balloon tamponade reduced referral rates to secondary facilities and the need for more complicated surgical procedures (hysterectomy) (*moderate confidence*). A few providers were also aware that some women might be reluctant to have a condom inserted on cultural or religious grounds and that the uterine balloon tamponade should be referred to as a “tamponade” rather than a condom for this reason (*low confidence*).

The same review also found that neither women nor providers expressed a preference for a particular type of uterine balloon tamponade; providers in most of the studies utilized a simple “device” consisting of a condom, urinary catheter, cotton string and luer lock valve.

There was very little direct evidence from women about their experiences of uterine balloon tamponade.

### Additional considerations

None.

### Judgement

—	—	—	—	✓	—
Don't know	Varies	No	Probably No	Probably Yes	Yes

## Feasibility

Is uterine balloon tamponade for PPH treatment feasible to implement?

### Research evidence

Findings from an update of a qualitative systematic review on PPH prevention and treatment (7) suggest that a uterine balloon tamponade is a practical and affordable solution in many low-resource settings and could be improvised from readily available items (condoms, surgical gloves) (*low confidence*). In most of the studies contributing to this review finding, the uterine balloon tamponade consisted of a condom, urinary catheter, cotton string and a luer lock valve. Findings from the same review also suggest that there may be some confusion amongst providers about how long to leave a uterine balloon tamponade in place and they highlighted the need for regular “hands-on” training to maintain their skills (*moderate confidence*).

There was very little direct evidence from women relating to the feasibility of using a uterine balloon tamponade.

Additional considerations

It is commonly accepted that insertion of a uterine balloon tamponade is a relatively simple procedure and that the required level of competence can be achieved after a short training in simulated conditions. For example, trials of uterine balloon tamponade have used a half-day onsite training at participating hospitals (11,18). In these trials, the training sessions were conducted by trained obstetricians, who were trained by experienced obstetricians (using a “train-the-trainers” approach). These trials described either concerns with the use of the uterine balloon tamponade, or substantial delays in insertion of the uterine balloon tamponade (11). Whether those factors were related to the training, the type of device, or the previous expertise of the providers is unknown. However, it must be acknowledged that these trials did not include other tamponade interventions as comparisons. Problems with other tamponade interventions might be plausible as well.

If commercially available devices were those proven to be more effective, accessing them in low-resource settings may be a challenge based on their more expensive cost.

Judgement

— Don't know	— Varies	— No	— Probably No	✓ Probably Yes	— Yes
-----------------	-------------	---------	------------------	-------------------	----------

## Summary of judgements table

Desirable effects	✓ Don't know	— Varies		— Trivial	— Small	— Moderate	— Large
Undesirable effects	✓ Don't know	— Varies		— Large	— Moderate	— Small	— Trivial
Certainty of the evidence	— No included studies			✓ Very low	— Low	— Moderate	— High
Values				— Important uncertainty or variability	— Possibly important uncertainty or variability	✓ Probably no important uncertainty or variability	— No important uncertainty or variability
Balance of effects	✓ Don't know	— Varies	— Favours other tamponade interventions	— Probably favours other tamponade interventions	— Does not favour either	— Probably favours uterine balloon tamponade	— Favours uterine balloon tamponade
Resources required	— Don't know	✓ Varies	— Large costs	— Moderate costs	— Negligible costs or savings	— Moderate savings	— Large savings
Certainty of the evidence on required resources	— No included studies			— Very low	— Low	✓ Moderate	— High
Cost-effectiveness	✓ Don't know	— Varies	— Favours placebo/no treatment	— Probably favours placebo/no treatment	— Does not favour either	— Probably favours oxytocin	— Favours oxytocin
Equity	✓ Don't know	— Varies	— Reduced	— Probably reduced	— Probably no impact	— Probably increased	— Increased
Acceptability	— Don't know	— Varies		— No	— Probably No	✓ Probably Yes	— Yes
Feasibility	— Don't know	— Varies		— No	— Probably No	✓ Probably Yes	— Yes

## Summary of findings table

**Question:** Condom-loaded catheter intrauterine balloon tamponade compared to uterovaginal packing for treating primary postpartum haemorrhage

**Setting:** Hospital (Pakistan)

**Reference:** Kellie FJ, Wandabwa JN, Mousa HA, Weeks AD. Mechanical and surgical interventions for treating primary postpartum haemorrhage. Cochrane Database Syst Rev. 2020;7:CD013663.

Certainty assessment							No. of patients		Effect		Certainty	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other con- siderations	Condom- loaded catheter intrauterine balloon tamponade	Uterovaginal packing	Relative (95% CI)	Absolute (95% CI)		
MATERNAL TEMPERATURE $\geq$ 38°C (FEVER, PARAMETERS NOT DEFINED)												
1	randomized trials	very serious <sup>a</sup>	not serious	not serious	serious <sup>b</sup>	none	46/106 (43.4%)	98/106 (92.5%)	RR 0.47 (0.38 to 0.59)	490 fewer per 1000 (from 573 fewer to 379 fewer)	$\oplus\ominus\ominus\ominus$ VERY LOW	IMPORTANT

**CI:** confidence interval; **RR:** risk ratio

<sup>a</sup> All of pooled effect provided by study at high risk of bias.



<sup>b</sup> Small sample size.

**Question:** Bakri balloon intrauterine tamponade compared to haemostatic square suturing to the lower segment of the uterus for treating primary postpartum haemorrhage during caesarean section

**Setting:** Hospital (Turkey)

**Reference:** Kellie FJ, Wandabwa JN, Mousa HA, Weeks AD. Mechanical and surgical interventions for treating primary postpartum haemorrhage. Cochrane Database Syst Rev. 2020;7:CD013663.

No. of studies		Certainty assessment					No. of patients		Effect		Certainty	Importance
	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Bakri balloon intrauterine tamponade	Haemostatic square suturing to the lower segment of the uterus	Relative (95% CI)	Absolute (95% CI)		
MORTALITY DUE TO BLEEDING												
1	randomized trials	very serious <sup>a</sup>	not serious	not serious	very serious <sup>b</sup>	none	0/7 (0.0%)	0/6 (0.0%)	not estimable		⊕⊖⊖⊖ VERY LOW	CRITICAL
ALL-CAUSE MORTALITY												
1	randomized trials	very serious <sup>a</sup>	not serious	not serious	very serious <sup>b</sup>	none	0/7 (0.0%)	0/6 (0.0%)	not estimable		⊕⊖⊖⊖ VERY LOW	CRITICAL
MORTALITY FROM CAUSES OTHER THAN BLEEDING												
1	randomized trials	very serious <sup>a</sup>	not serious	not serious	very serious <sup>b</sup>	none	0/7 (0.0%)	0/6 (0.0%)	not estimable		⊕⊖⊖⊖ VERY LOW	CRITICAL
BLOOD TRANSFUSION (RED CELL OR WHOLE BLOOD)												
1	randomized trials	very serious <sup>a</sup>	not serious	not serious	very serious <sup>c,d</sup>	none	2/7 (28.6%)	3/6 (50.0%)	RR 0.57 (0.14 to 2.36)	215 fewer per 1000 (from 430 fewer to 680 more)	⊕⊖⊖⊖ VERY LOW	CRITICAL
SURGICAL INTERVENTIONS - HYSTERECTOMY TO CONTROL BLEEDING												
1	randomised trials	very serious <sup>a</sup>	not serious	not serious	very serious <sup>b</sup>	none	0/7 (0.0%)	0/6 (0.0%)	not estimable		⊕⊖⊖⊖ VERY LOW	CRITICAL
SURGICAL INTERVENTIONS - ARTERIAL LIGATION, COMPRESSIVE, UTERINE SUTURES, ARTERIAL EMBOLIZATION OR LAPAROTOMY TO CONTROL BLEEDING												
1	randomized trials	very serious <sup>a</sup>	not serious	not serious	very serious <sup>b</sup>	none	0/7 (0.0%)	0/6 (0.0%)	not estimable		⊕⊖⊖⊖ VERY LOW	CRITICAL

Certainty assessment							No. of patients		Effect		Certainty	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Bakri balloon intrauterine tamponade	Haemostatic square suturing to the lower segment of the uterus	Relative (95% CI)	Absolute (95% CI)		
PROCEDURE-RELATED COMPLICATIONS – ADVERSE EFFECTS REQUIRING FURTHER SURGICAL INTERVENTION												
1	randomized trials	very serious <sup>a</sup>	not serious	not serious	very serious <sup>b</sup>	none	0/7 (0.0%)	0/6 (0.0%)	not estimable		⊕⊖⊖⊖⊖ VERY LOW	CRITICAL
SEVERE MORBIDITY – RENAL OR RESPIRATORY FAILURE, CARDIAC ARREST OR MULTIPLE ORGAN FAILURE												
1	randomized trials	very serious <sup>a</sup>	not serious	not serious	very serious <sup>b</sup>	none	0/7 (0.0%)	0/6 (0.0%)	not estimable		⊕⊖⊖⊖⊖⊖ VERY LOW	CRITICAL
MEAN BLOOD LOSS (ML)												
1	randomized trials	very serious <sup>a</sup>	not serious	not serious	serious <sup>e</sup>	none	7	6	-	<b>MD 426 lower</b> (631.28 lower to 220.72 lower)	⊕⊖⊖⊖⊖⊖ VERY LOW	IMPORTANT

## References

1. Kellie F, Wandabwa J, Mousa H, Weeks A. Mechanical and surgical interventions for treating primary postpartum haemorrhage. *Cochrane Database Syst Rev*. 2020;7:CD013663. doi:10.1002/14651858.CD013663.
2. Ashraf N, Ashraf A, Khursheed K. Efficacy and safety of intrauterine balloon tamponade versus ueterovaginal roll gauze packing in patient presenting with primary postpartum haemorrhage after normal vaginal delivery. *Annals of King Edward Medical University* 2018;24(S):889–92. doi:10.21649/akemu.v24iS.2581
3. Kavak SB, Atilgan R, Demirel I, Celik E, Ilhan R, Sapmaz E. Endouterine hemostatic square suture vs. Bakri balloon tamponade for intractable hemorrhage due to complete placenta previa. *J Perinat Med*. 2013;41(6):705–9. doi:10.1515/jpm-2013-0002.
4. Suarez S, Conde-Agudelo A, Borovac-Pinheiro A, Suarez-Rebling D, Eckardt M, Theron G, et al. Uterine balloon tamponade for the treatment of postpartum hemorrhage: a systematic review and meta-analysis. *Am J Obstet Gynecol*. 2020;222(4):293.e1–e52. doi:10.1016/j.ajog.2019.11.1287.
5. Pingray V, Widmer M, Ciapponi A, Cormick G, Bloemenkamp K, Deneux-Tharaux C, et al. Effectiveness of uterine tamponade devices for refractory postpartum hemorrhage after vaginal delivery: a systematic review and meta-analysis. *Authorea*. 2020. doi:10.22541/au.159225308.86644919.
6. Downe S, Finlayson K, Oladapo OT, Bonet M, Gulmezoglu AM. What matters to women during childbirth: a systematic qualitative review. *PLoS One*. 2018;13(4):e0194906. doi:10.1371/journal.pone.0194906.
7. Finlayson K, Downe S, Vogel JP, Oladapo OT. What matters to women and healthcare providers in relation to interventions for the prevention of postpartum haemorrhage: A qualitative systematic review. *PLoS One*. 2019;14(5):e0215919. doi:10.1371/journal.pone.0215919.
8. Mvundura M, Kokonya D, Abu-Haydar E, Okoth E, Herrick T, Mukabi J, et al. Cost-effectiveness of condom uterine balloon tamponade to control severe postpartum hemorrhage in Kenya. *Int J Gynaecol Obstet*. 2017;137(2):185–91. doi:10.1002/ijgo.12125.
9. Seligman B, Xingzhu L. Economic assessment of interventions for reducing postpartum hemorrhage in developing countries. Bethesda (MD): Abt Associates Inc.; 2006 (<https://www.abtassociates.com/insights/publications/report/economic-assessment-of-interventions-for-reducing-postpartum>, accessed 21 July 2020).
10. Burke TF, Ahn R, Nelson BD, Hines R, Kamara J, Oguttu M, et al. A postpartum haemorrhage package with condom uterine balloon tamponade: a prospective multi-centre case series in Kenya, Sierra Leone, Senegal, and Nepal. *BJOG*. 2016;123(9):1532–40. doi:10.1111/1471-0528.13550.
11. Dumont A, Bodin C, Hounkpatin B, Popowski T, Traoré M, Perrin R, et al. Uterine balloon tamponade as an adjunct to misoprostol for the treatment of uncontrolled postpartum haemorrhage: a randomised controlled trial in Benin and Mali. *BMJ Open*. 2017;7(9):e016590. doi:10.1136/bmjopen-2017-016590.
12. Mishra N, Gulabani K, Agrawal S, Shrivastava C. Efficacy and feasibility of Chhattisgarh balloon and conventional condom balloon tamponade: a 2-year prospective study. *J Obstet Gynaecol India*. 2019;69(Suppl 2):133–41. doi:10.1007/s13224-018-1185-6.
13. Hofmeyr GJ, Middleton K, Singata-Madliki M. Randomized feasibility study of suction-tube uterine tamponade for postpartum hemorrhage. *Int J Gynaecol Obstet*. 2019;146(3):339–43. doi:10.1002/ijgo.12889.

14. Kaya B, Guralp O, Tuten A, Unal O, Celik MO, Dogan A. Which uterine sparing technique should be used for uterine atony during cesarean section? The Bakri balloon or the B-Lynch suture? *Arch Gynecol Obstet.* 2016;294(3):511-7. doi:10.1007/s00404-016-4015-z.
15. Purwosunu Y, Sarkoen W, Arulkumaran S, Segnitz J. Control of postpartum hemorrhage using vacuum-induced uterine tamponade. *Obstet Gynecol.* 2016;128(1):33-6. doi:10.1097/AOG.0000000000001473.
16. Herrick T, Mvundura M, Burke TF, Abu-Haydar E. A low-cost uterine balloon tamponade for management of postpartum hemorrhage: modeling the potential impact on maternal mortality and morbidity in sub-Saharan Africa. *BMC Pregnancy Childbirth.* 2017;17(1):374. doi:10.1186/s12884-017-1564-5.
17. Ellavi. [website]. Sinapi Biomedical; 2018 (<https://ellavi.com/>, accessed 7 August 2020).
18. Anger HA, Dabash R, Durocher J, Hassanein N, Ononge S, Frye LJ, et al. The effectiveness and safety of introducing condom-catheter uterine balloon tamponade for postpartum haemorrhage at secondary level hospitals in Uganda, Egypt and Senegal: a stepped wedge, cluster-randomised trial. *BJOG.* 2019;126(13):1612-21. doi:10.1111/1471-0528.15903.

**For more information, please contact:**

World Health Organization  
Avenue Appia 20, CH-1211 Geneva 27, Switzerland

Maternal and Perinatal Health Unit, Department of Sexual  
and Reproductive Health and Research  
E-mail: [srhmph@who.int](mailto:srhmph@who.int).

**Website:** [www.who.int/reproductivehealth](http://www.who.int/reproductivehealth)

Department of Maternal, Newborn, Child, Adolescent Health,  
and Ageing  
Email: [mncah@who.int](mailto:mncah@who.int)

**Website:** [www.who.int/maternal\\_child\\_adolescent](http://www.who.int/maternal_child_adolescent)

