National Women & Infants Health Programme

National Clinical Practice Guideline

Prevention and Management of Primary Postpartum Haemorrhage

INSTITUTE OF OBSTETRICIANS & GYNAECOLOGISTS

ROYAL COLLEGE OF PHYSICIANS OF IRELAND

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The National Women and Infants Health Programme (NWIHP) and the Institute of Obstetricians and Gynaecologists (IOG) Clinical Advisory Group (CAG) 2022

Version Number: Version 1.0

Publication Date: December 2022

Date for Revision: December 2025

Electronic Location:

https://www.hse.ie/eng/about/who/acute-hospitals-division/woman-infants/clinical-guidelines/

https://www.rcpi.ie/faculties/obstetricians-and-gynaecologists/national-clinical-guidelines-in-obstetrics-and-gynaecology/

Version control

Version	Date Approved	Section numbers changed	Author

Cite this document as:

Byrne B, Spring A, Barrett N, Power J, McKernan J, Brophy, D, Houston C, Faryal R, McMahon E, Manning C, Murphy P, Ni Ainle F. National Clinical Practice Guideline: Prevention and Management of Primary Postpartum Haemorrhage. National Women and Infants Health Programme and The Institute of Obstetricians and Gynaecologists, December 2022.

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Algorithms

Staged approach to prevention and management of PPH

All women Antenatal/ Intrapartum

Check that an antenatal risk assessment for PPH was completed

Complete and document risk assessment

ACT
- Consent obtained
- Blood: group and ab screen xmatched
- Ensure IV access

TREAT
Active 3rd stage management is considered

>500ml ongoing blood loss. SVD & Instrumental deliveries

GET HELP
Notify Senior Staff

ACT
- Record observations BP and HR and interventions
- Start blood loss Assessment
- IV access - large bore
- Bloods can be taken
- Inspect genital tract, check placenta and membranes
- Assign scribe (if available)

TREAT
- Uterine massage
- Give uterotonics
- Empty bladder

What is the cause of the bleeding?

>1000mL blood loss OR clinical concern

GET HELP
Senior Staff

ACT
- Continue to measure and record cumulative blood loss
- 2ndIV access
- Give IV fluids
- Take bloods including FBC, coagulation studies with fibrinogen level, point of care blood gas
- Inform transfusion lab and check availability of compatible red cell components/take sample as required

TREAT
- Review uterotonics
- Transfuse as appropriate
- Give tranexamic acid
- Foley catheter inserted
- Inspect genital tract
- Repair genital tract

What is the cause of the bleeding?

>1500mL blood loss OR clinical concern

Communicate current measured blood loss to team

ACT
Activate MOH/life threatening obstetric haemorrhage protocol

What is the cause of the bleeding?

Post event checks

Complete post event checks

Discuss event with woman and partner

Complete documentation Including management plan.

Discuss event with other staff

ALERT : Consider the possibility of underestimated or concealed blood loss

Please note that the nature of PPH is such that depending on the clinical circumstances, staffing, etc these stages are not prescriptive and some interventions (e.g. blood testing or establishing adequate IV access) may occur at an earlier stage. This algorithm is designed to aid recognition, guide management with the aim of reducing the incidence of progression to LTH/MOH.

Prevention and Management of Postpartum Haemorrhage Checklist*

MRN:

Most recent

Hb

Plt

Date:

STAGE 0: PPH Risk Assessment Complete for all women on admission (including LSCS Labour)	
Check Antenatal Risk Assessment TIME:	**ACT**
Retained products of conception/Placenta	Woman group & ab screen Yes | No
Induction of labour/Augmentation of labour	Woman xmatched Yes | No
Placenta Previa/Accreta/Abruption	IV access required? Yes | No
Chorioamnionitis	Consent obtained Yes | No
Labour Delivery (Please make an on going assessment of the following risk factors throughout labour and delivery)	**TREAT**
Sepsis/Pyrexia in labour	Planned active 3rd stage management? Yes | No
Prolonged 1st of labour > 12 hours active	**PLAN TO MEASURE AND RECORD ALL BLOOD LOSS**
Prolonged 2nd stage of labour >4hours	Please make an on going assessment of risk factors throughout labour and delivery
> 12 hours of Syntocinon	
Operative Vaginal Delivery	
Emergency Caesarean Section	
Baby >4.5kg	

STAGE 1: >500ml ongoing blood loss. SVD & Instrumental deliveries	
GET HELP TIME:	**ACT** TIME:
Notify Midwife/Obstetrician	Check placenta and membranes
ACT	Inspect genital tract
Assign scribe (if available)	**TREAT**
Measure Blood Loss (cumulative measurement)	Uterine Massage
Record observations HR + BP)	Empty bladder
IV access – large bore	Give uterotonics
Blood can be taken	Bimanual uterine compression
What is the cause of the bleeding? Tone | Trauma | Tissue | Thrombin. (please circle cause/s)	

ALERT : Consider the possibility of underestimated or concealed blood loss

Communicate current measured blood loss to team

STAGE 2: >1000mL blood loss OR clinical concern

e.g. abruption or concealed bleeding OR abnormal vital signs RR>30, HR ≥ 120, BP ≤ 90/40mmHg, SpO2<95%. Progress here from stage 1 if SVD/Instrumental delivery. Restart here after stage 0 if LSCS.

GET HELP	**TIME:**	Hb
MW in charge		Coag
Obstetrician		PT
Anaesthetist		APTT
Other staff		Fibrinogen
ACT	**TIME:**	**TREAT** **TIME:**
Measure and record cumulative blood loss		Review uterotonics
Record observations (HR + BP)		Give tranexamic (1g IV, if no CI's)
2nd IV access and fluids		Transfuse as appropriate
Take bloods		Uterine Compression
Lab tests FBC, Coag, Xmatch, U&E, FIB		Foley catheter inserted
Inform transfusion lab and check availability of compatible RCC take sample as required		Inspect genital tract
		Repair genital tract
		Check placenta and membranes

What is the cause of the bleeding? Tone | Trauma | Tissue | Thrombin. (please circle cause/s)

ALERT : Consider the possibility of underestimated or concealed blood loss

Communicate current measured blood loss to team

STAGE 3: >1500ml blood loss OR clinical concern
IF BLEEDING ONGOING TRANSFER PATIENT TO THEATRE

STATE I am activating the Life Threatening Haemorrhage Protocol, CODE RED OBSTETRICS

ACT	**TIME:**	**TREAT** **TIME:**
Activate the MOH/ life threatening haemorrhage protocol		Review uterotonics
Identify Emergency Coordinator Identify Communication Lead		Consider repeat tranexamic acid
Inform consultant obstetrician and anaesthetist		Consider advanced surgical techniques
Resuscitate		**ONCE BLEEDING STOPPED ENSURE PPH CHECKLIST IS COMPLETED AND MANAGEMENT PLAN WRITTEN IN NOTES**
Order blood components as per the MOH poster		

What is the cause of the bleeding? Tone | Trauma | Tissue | Thrombin. (please circle cause/s)

Adapted with permission from California Maternal Quality Care Collaborative and OBS Cymru

Names of Staff Present

MEASURED CUMULATIVE BLOOD LOSS		
Time	Blood Loss (ml)	Running total

Total Measured Blood Loss: _____ml

BLOOD & BLOOD PRODUCTS TRANSFUSED	TIME

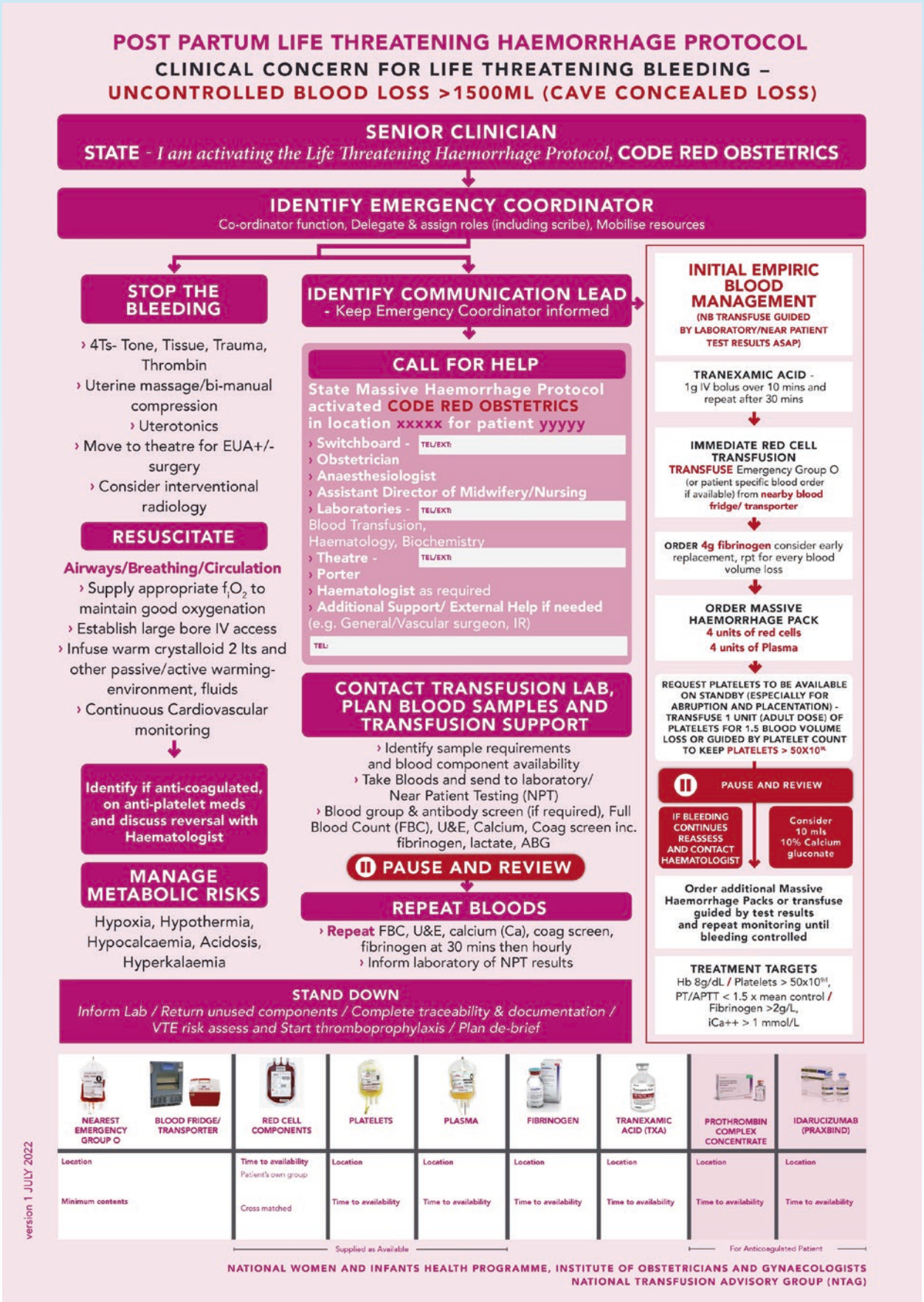
Remember to discuss the event with the woman and her partner

RECORD OF UTEROTONICS USED – TO PREVENT BLEEDING		
Drug	Dose	Time

RECORD OF UTEROTONICS USED – TO TREAT BLEEDING

Notes

Post Partum Life-Threatening Haemorrhage Protocol



Key Recommendations

A summary list of the Guideline recommendations is presented below together with the quality of evidence and strength of each recommendation.

		Quality of evidence	Strength	Grade
	PREPAREDNESS			
1	Women who are at higher Post Partum Haemorrhage (PPH) risk should be identified and actively managed at each care opportunity. This should include screening for and management of antenatal anaemia and recognised PPH risk factors.	Low	Strong	Best practice
2	Each maternity unit should have a policy in place for identification and management of women with red cell antibodies (where specific additional blood transfusion matching is required).	Low	Strong	Best practice
3	Women who do not wish to receive blood products should be identified at their booking visit. There should be a detailed discussion and documentation of acceptable and unacceptable treatments. Advance Decision to Refuse Specified Medical Treatment should be completed and kept in the maternity chart and updated during pregnancy.	Low	Strong	Best practice
4	Women with inherited bleeding disorders should be identified at booking and referred for planning of pregnancy, intrapartum and postpartum care by experienced fetomaternal specialists, haematologists and anaesthetists.	Low	Strong	Best practice
5	Women should have a FBC at booking and at 28 weeks gestation to screen for anaemia with the aim of treating and optimising haemoglobin before birth. Keeping in line with UK recommendations repeat blood group at 28 weeks to further screen for red cell alloantibodies should be considered.	Low	Strong	Best practice
6	Placental site should be determined at routine fetal anomaly scanning, particularly if there is a previous Caesarean Section.	Low	Strong	Best practice
7	If placenta accreta spectrum has been diagnosed, planned delivery before term in a unit with an experienced skilled multidisciplinary team of specialists and resources, is recommended.	Low	Strong	Best practice

		Quality of evidence	Strength	Grade
8	Risk factor assessment for PPH should continue intrapartum and should be clearly communicated during handover of clinical care.	Low	Strong	Best practice
9	Women with retained placenta, or who require intrapartum Caesarean Section (especially in the second stage of labour) require close surveillance for PPH.	Low	Strong	Best practice
10	It is important to remain vigilant for excessive blood loss at all births because many women who suffer a PPH do so without identifiable risk factors.	Low	Strong	Best practice
11	All obstetric units should maintain a supply of O Rh D negative, Kell negative blood for emergency use.	Low	Strong	Best practice
12	Each maternity unit should develop local policies and protocols to include standards of documentation, defined roles and responsibilities, blood component and pharmaceutical location/availability, reporting and review processes.	Low	Strong	Best practice
13	Each maternity unit should identify and document the turn around times (TAT) for laboratory tests relevant to management of MOH. Near patient testing (blood gas analysis and coagulation testing), if used, should be compliant with national guidelines/standards.	Low	Strong	Best practice
14	Local hospital blood group serology testing and blood order schedules for delivery method should be developed and periodically reviewed for appropriateness. Sample acceptance and component release policies should be agreed.	Low	Strong	Best practice
15	Local simulated multidisciplinary team (including laboratory staff) drills should be used to promote learning. Each maternity unit should undertake training of all staff engaged in the management/support of PPH/MOH in compliance with their policies and local procedures. Training should include the use of multidisciplinary 'drills' on a specified periodic basis and eLearning if available.	Low	Strong	Best practice
16	Appropriately trained colleagues should provide simulation training for life threatening MOH to anaesthesiologists, obstetricians, midwives, laboratory and portering staff.	Low	Strong	Best practice
17	We recommend that a national MOH poster be adopted and personalised by each unit delivering maternity care. This poster should be prominently displayed in each labour ward/ theatre.	Low	Strong	Best practice

		Quality of evidence	Strength	Grade
	PREVENTION			
18	Delayed cord clamping is recommended for neonatal benefit. The cord should be clamped immediately if there is active maternal bleeding or a need for neonatal resuscitation.	Mod	Strong	Best practice
19	Prophylactic uterotonics should be administered to all women immediately following birth to prevent PPH.	Mod	Strong	Grade 1B
20	Administration of oxytocin at a dose of 10 IU IM or 5 IU by slow IV, is recommended following a vaginal birth.	Mod	Strong	Grade 1B
21	While oxytocin can be administered at lower doses at elective CS and followed by low dose infusion, higher initial doses and infusions may be required for intrapartum CS especially when an oxytocin infusion has been used in labour.	Low	Weak	Grade 1C
22	Prophylactic oxytocin (5IU) in combination with ergometrine (500µg) [Syntometrine] IM may reduce blood loss more than oxytocin alone and may be considered as a first line prophylactic uterotonic in women at high PPH risk. We do not recommend it as a first line uterotonic in women at low risk because of a five-fold higher risk of nausea, vomiting and hypertension compared to use of oxytocin alone.	Mod	Weak	Grade 2B
23	Carbetocin is non-inferior to oxytocin in preventing PPH following vaginal birth and elective CS. We do not recommend it as an alternative first line uterotonic because of unproven cost benefit.	Mod	Weak	Grade 2B
24	Women requesting physiological management of the third stage of labour should be informed of the risk and benefits, especially if they have PPH risk factors. They should be supported in their choice, once fully informed, but advised that a uterotonic should be administered if excessive bleeding occurs or if the placenta has not separated after 30 minutes.	Low	Strong	Best practice
25	Preparations should be made to transfer the woman to theatre for manual removal of placenta (MROP) 30 to 60 minutes after birth and sooner if there is active bleeding.	Low	Strong	Best practice
26	We suggest that prophylactic tranexamic acid administration may be considered in women who are at high PPH risk (including combinations of risk factors).	Mod	Weak	Grade 2B

		Quality of evidence	Strength	Grade
	RECOGNITION			
27	Gravimetric or calibrated methods of blood loss measurement are recommended at CS, operative vaginal birth and after spontaneous vaginal birth if visual estimation of blood loss is >500 ml.	Low	Strong	Best practice
28	Cumulative measured blood loss during PPH should be recorded and communicated to the team.	Low	Strong	Best practice
29	Care providers should be vigilant for symptoms and signs of hypovolemia as these may not always correlate with blood loss and should consider the possibility of underestimated or concealed blood loss.	Low	Strong	Best practice
	MANAGEMENT: STOP THE BLEEDING			
30	A staged approach to PPH response is recommended with escalation of care depending on blood loss and clinical concerns.	Low	Strong	Best practice
31	We recommend that each Maternity unit implement the NPEC/NWIHP-documented pathway checklist for PPH management with local agreed modifications.	Low	Strong	Best practice
32	Standard components of initial uterine atony management should include uterine massage, insertion of an indwelling catheter and a check of the completeness of the placenta and membranes.	Low	Strong	Best practice
33	Oxytocin is recommended as the first-line PPH treatment, either as a slow IV bolus or infusion. It is preferable to administer oxytocin using a controlled infusion device.	Mod	Strong	Grade 1B
34	We suggest that ergometrine is administered as the second line uterotonic for PPH treatment (in the absence of contra-indications) followed by either misoprostol or carboprost depending on the clinical circumstances Table 6.	Low	Weak	Grade 2C
35	Each obstetric unit should have a clear local policy on uterotonic use in PPH treatment, providing suggested drug sequences and dosing recommendations that may be individualised.	Low	Strong	Best practice
36	Tranexamic acid administration is recommended early during PPH treatment.	High	Strong	Grade 1A

		Quality of evidence	Strength	Grade
37	The most appropriate surgical intervention should be determined by the cause of PPH, the haemodynamic stability of the woman, the available surgical expertise and access to supportive services (such as imaging and interventional radiology).	Low	Strong	Best practice
38	Hysterectomy should be considered when interventions to arrest bleeding and/or resuscitation measures to compensate for bleeding are not effective. Efforts should be made to obtain a second opinion before proceeding to hysterectomy if feasible in a timely manner.	Low	Strong	Best practice
	MANAGEMENT: RESUSCITATE			
39	Restrictive crystalloid administration < 3.5L is suggested during severe ongoing haemorrhage.	Low	Weak	Grade 2C
40	The use of blood components should be guided by the clinical situation and should not be delayed while awaiting laboratory results. Access emergency/patient specific red cell support immediately and refer to the national MOH poster.	Low	Strong	Best practice
41	Platelet components should be ordered at a platelet count of 100 x 10^9/l. Platelet transfusion should be given when the platelet count falls <75 x 10^9/l, in order to maintain a count >50 x 10^9/l. Early platelet transfusion should be considered for abruption and abnormal placentation.	Low	Strong	Best practice
42	A plasma fibrinogen level of > 2 g/l should be maintained by administration of fibrinogen concentrate.	Low	Strong	Grade 1C
43	Empiric early fibrinogen replacement may be considered if the fibrinogen result (or Viscoelastic haemostatic assay (VHA) equivalent) is not rapidly available, especially in the setting of placental abruption/praevia or amniotic fluid embolism.	Low	Moderate	Best practice
44	VHA may be considered in the management of PPH if local resources and governance structures permit.	Low	Weak	Grade 2C
45	Cell salvage may have a role in the management of PPH in selected cases, if local resources and governance structures permit.	Low	Weak	Grade 2C
46	There is no evidence favouring either general or regional anaesthesia in postpartum haemorrhage management in the operating room.	Low	Weak	Best practice

		Quality of evidence	Strength	Grade
	MANAGEMENT: COMMUNICATE – CODE RED OBSTETRICS			
47	The major obstetric haemorrhage (MOH) protocol (articulated as **CODE RED OBSTETRICS**) should be activated for uncontrolled bleeding >1500ml blood loss or if a clinical concern warrants it.	Low	Strong	Best practice
48	Each maternity unit should adopt the nationally agreed term **'life threatening haemorrhage: code red – obstetrics'.**	Low	Strong	Best practice
49	Clear communication pathways are recommended to alert all relevant team members and a designated person should coordinate further management. The team should use the ISBAR (Identify – Situation-Background-Assessment-Recommendation) technique as a simple way to plan and structure communication.	Low	Strong	Best practice
50	The woman and her partner should be informed and supported by appropriate staff throughout the event.	Low	Strong	Best practice
51	A scribe should be assigned to document staff present and timing of interventions.	Low	Strong	Best practice
52	The emergency should be stood down when bleeding is controlled or as appropriate with clear communication to all team members including laboratory staff.	Low	Strong	Best practice
	MANAGEMENT: POST EVENT CARE			
53	A restrictive transfusion policy (Hb < 7 g/dl) may be considered in stable women without severe symptoms following a postpartum haemorrhage.	Low	Weak	Grade 2C
54	All women should undergo a formal VTE and bleeding risk assessment after haemostasis has been secured (and repeated when the clinical situation changes). Pharmacological and/or mechanical thromboprophylaxis should be considered as appropriate. Multidisciplinary discussion may be required to determine the optimal timing of initiation of pharmacological thromboprophylaxis. Women should be informed of the signs and symptoms of a VTE, and that such an event may occur post-discharge. Women should be provided with a HSE VTE alert card before leaving hospital.	Low	Strong	Best practice

		Quality of evidence	Strength	Grade
55	There should be debriefing of the staff, the woman, and her partner as soon as possible after the event. A further debrief should be offered to the woman and her partner following hospital discharge, usually around six weeks following birth.	Low	Strong	Best practice
56	Documentation of events, and completion of component traceability should be carried out if not completed contemporaneously.	Low	Strong	Best practice
57	MOH should be reported through the hospital clinical incident reporting system.	Low	Strong	Best practice
58	Serious adverse events and serious adverse reactions (SAE/SAR) associated with transfusion/life threatening haemorrhage should be reported to the National Haemovigilance Office (NHO).	Low	Strong	Best practice
	AUDIT, EVALUATE, ASSIMILATE			
59	Each maternity unit should have processes in place for auditing clinical practice and agreed data set, providing feedback to team members.	Low	Strong	Best practice
60	Cases of MOH should be reviewed at local serious incident management team (SIMT) meetings (or similar risk management team meetings), hospital transfusion committee (HTC) and overarching transfusion committees (OTCs) to evaluate the effectiveness of care, treatment and services provided. Systems learning should be identified, and change effected through communication and education.	Low	Strong	Best practice

Chapter 1: **Initiation**

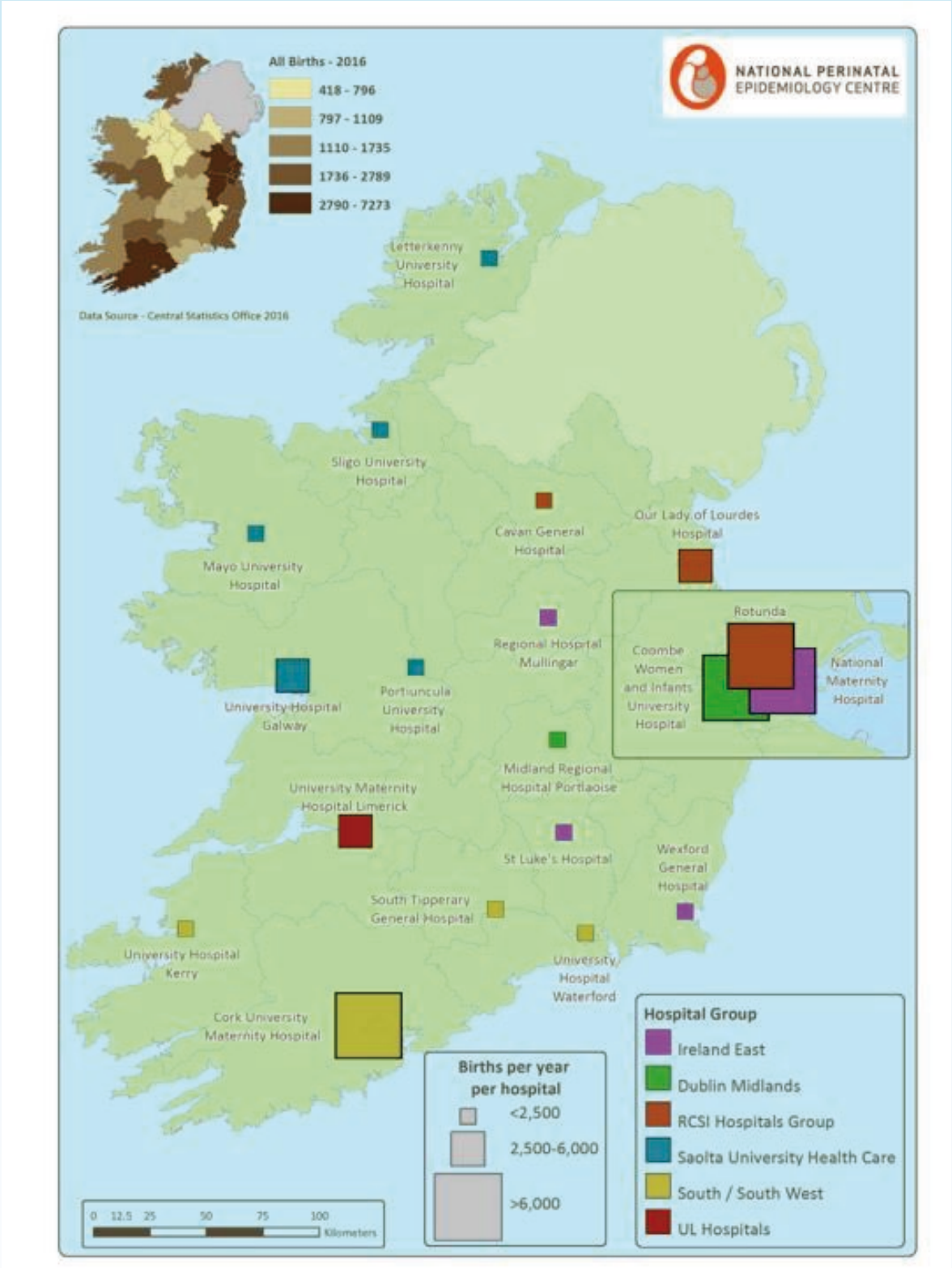
The National Clinical Effectiveness Committee (NCEC) and Health Information and Quality Authority (HIQA) define clinical guidelines as systematically developed statements, based on a thorough evaluation of the evidence, to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances, across the entire clinical spectrum.[1]

1.1 Purpose

The purpose of this publication is to provide a comprehensive and evidence-based Guideline for the prevention and management of primary postpartum haemorrhage (PPH). This Guideline replaces the HSE Guideline published in 2014. [1] A joint venture between the National Women and Infants Health Programme (NWIHP) and the National Perinatal Epidemiology Centre (NPEC) has led to the establishment of a working group with representatives from the State Claims Agency, Midwifery, Institute of Obstetricians and Gynaecologists, Haematology, National Transfusion Advisory Group, and HSE QI to address the increasing incidence of PPH and MOH in our maternity hospitals/units. This Guideline has been developed to inform and complement this quality improvement project. A NCEC Guideline has recently been developed for unexpected intra-operative life-threatening haemorrhage (2022), and recommendations from this have also informed this Guideline.[2]

1 National Clinical Effectiveness Committee (NCEC) and Health Information and Quality Authority (HIQA) (2015) National quality assurance criteria for clinical guidelines. Version 2. Dublin: NCEC and HIQA. https://www.hiqa.ie/sites/default/files/2017-01/National-Quality-Assurance-Criteria.pdf

Figure 1: Map of maternity units and hospital groups in the Republic of Ireland[3]



1.2 Scope

Target Users

This Guideline is intended for use by healthcare professionals providing care for women in the antenatal, intrapartum and postpartum periods. This includes, healthcare staff and students, doctors, midwives, nurses, laboratory medical scientists, health and social care professionals.

Target Population

Women at risk of and experiencing a PPH.

1.3 Objective

To provide evidence-based recommendations for the care of women at risk of/during/after a PPH and promote a standardised approach nationally across all maternity units.

1.4 Guideline development process

The Guideline Developers agreed to undertake this work under the direction of the Guideline Programme Team (GPT). An Expert Advisory Group (EAG) was commissioned by the GPT. Their role was to critically review the Guideline prior to submission to the NWIHP for final approval.

See Appendix 1 for Guideline Programme Process and Appendix 2 for EAG group membership.

The following were involved in developing this Guideline:

1. Dr Bridgette Byrne (Consultant Obstetrician and Gynaecologist)
2. Dr Nicholas Barrett (Consultant in Anaesthesia and Intensive care medicine)
3. Dr Aidan Spring (Consultant in Anaesthesia and Intensive care medicine)
4. Professor Fionnuala Ni Ainle (Consultant Haematologist)
5. Dr Joan Power (Consultant Haematologist)
6. Joye McKernan PhD Project Manager Post-Partum Haemorrhage Quality Improvement initiative (PPHQII)
7. Dr David Brophy (Consultant Interventional Radiologist)
8. Dr Conal Houstoun (Specialist Registrar Haematology)
9. Dr Rehman Faryal (Registrar, Haematology)
10. Dr Ellen Mc Mahon (Specialist Registrar Obstetrics and Gynaecology)
11. Ms Catherine Manning (Clinical Midwife Specialist – Maternal Medicine)
12. Mr Paul Murphy (Information specialist).

Guideline Methodology

Step 1: Formulate the key questions.

The scope of the Guideline was discussed at early meetings of the GDG and the following broad areas of focus for the literature review were identified.

- Preparedness
- Identification of risk factors for PPH/antenatally and intrapartum
- Prevention
- Strategies that reduce the risk of PPH
- Recognition
- Management of PPH: Communication and teamwork/Medical and surgical management of PPH/ Resuscitation/Transfusion/MOH/After event care
- Audit
- Evaluate
- Assimilate

Step 2: Search methodology

Step 3: Screen and appraise evidence

Step 4: Develop and grade the recommendations

1.5 Stakeholder involvement

Stakeholders are people who have a common interest in improving health services. This includes persons responsible for delivering and those receiving services related to the Guideline.

This Guideline was reviewed by Dr Thomas Drew Consultant Anaesthesiologist, The Rotunda and Beaumont Hospitals, Dublin. Honorary Clinical Senior Lecturer, RCSI University of Medicine and Health Sciences.

This Guideline was reviewed by Mr Morgan McMonagle, Consultant General, Vascular/Endovascular & Trauma Surgeon, HSE lead for Mass Casualty Planning.

The following additional stakeholders were consulted in regard to this Guideline.

- This Guideline was reviewed by the local champions of the post-partum haemorrhage quality improvement initiative (PPHQII) and their steering group. Members of this group are from clinical practice across all 19 maternity units. A member of the Patient Advocacy Service is also a member of the steering committee of the PPHQII and they too reviewed the document.
- Haematology and blood transfusion national transfusion advisory group (NTAG), Irish Haematology Society transfusion special interest group (SIG), Academy of Clinical Science and Laboratory Medicine (ACSLM), National haemovigilance SIG, Irish Blood Transfusion Service (IBTS) (Appendix 3)

1.6 Disclosure of interests

Guideline developers and reviewers bring a range of experiences and perspectives to the work of the national Guideline Programme. It is likely that both Guideline developers and stakeholders/reviewers will have a variety of interests, arising from different contexts and activities done in a professional or personal capacity. These can include employment and other sources of income, speaking engagements, publications and research, and membership of professional or voluntary organisations. The involvement of individuals with relevant content expertise is essential for enhancing the value of Guideline recommendations, but these individuals may also have interests that can lead to conflicts of interest, as may peer reviewers, patient representatives and researchers.

All interests should be declared if, in the view of a reasonable person, they are relevant, or could be perceived to be relevant, to the work of the clinical practice Guideline in question.[2] Declaring an interest does not mean there is a conflict of interest.

It is important that interests are openly declared so they can be appropriately managed. Conflicts of interest can bias recommendations and ultimately be harmful to patients and the health system. Disclosures of interests and appropriate management of conflicts of interest, when identified, are therefore essential to producing high-quality, credible health guidelines.[3]

2 NICE (2019) Policy on declaring and managing interests for NICE advisory committees. https://www.nice.org.uk/Media/Default/About/Who-we-are/Policies-and-procedures/declaration-of-interests-policy.pdf

3 Traversy G, Barnieh L, Akl EA, Allan GM, Brouwers M, Ganache I, Grundy Q, Guyatt GH, Kelsall D, Leng G, Moore A, Persaud N, Schünemann HJ, Straus S, Thombs BD, Rodin R, Tonelli M. CMAJ. 2021, 193(2):E49-E54. DOI: 10.1503/cmaj.200651 https://www.cmaj.ca/content/193/2/E49

The Guidelines International Network (GIN), a global network of Guideline developers that aims to promote best practices in the development of high-quality guidelines, developed a set of 9 principles to provide guidance on how financial and non-financial conflicts of interest should be both disclosed and managed. It is recommended that Guideline developers follow the GIN principles.[4]

For this National Clinical Practice Guideline, all Guideline developers are asked to complete a conflict of interest declaration form. The response to declared interests will be managed by the Guideline programme team, in accordance with GIN principles. Conflicts of interest may be reported in the published Guideline and declarations of interest can be made available.

1.7 Disclaimer

These guidelines have been prepared to promote and facilitate standardisation and consistency of good clinical practice using a multidisciplinary approach. Information in this Guideline is current at the time of publication.

The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the Clinician in light of clinical data presented by the patient and the diagnostic and treatment options available.

Clinical material offered in this Guideline does not replace or remove clinical judgment or the professional care and duty necessary for each specific woman.

Clinical care carried out in accordance with this Guideline should be provided within the context of locally available resources and expertise.

This Guideline does not address all elements of standard practice and assumes that individual clinicians are responsible for:

- Discussing care with women in an environment that is appropriate, and which enables respectful confidential discussion. This includes the use of interpreter services where necessary
- Advising women about their choices and ensuring informed consent is obtained
- Provide care with professional scope of practice, meeting all legislative requirements and maintaining standards of professional conduct
- Applying standard precautions and additional precautions, as necessary, when delivering care
- Documenting all care in accordance with local and mandatory requirements

4 Holger J. Schünemann, Lubna A. Al-Ansary, Frode Forland, *et al.*; for the Board of Trustees of the Guidelines International Network. Guidelines International Network: Principles for disclosure of interests and management of conflicts in guidelines. Ann Intern Med. 2015;163:548-553. doi:10.7326/M14-1885 https://www.acpjournals.org/doi/10.7326/m14-1885

1.8 Use of language

Within this guidance we use the terms 'woman' and 'women's health'. However, it is important to acknowledge that people who do not identify as cis-gender women are excluded from this descriptor, including people who identify as transgender, gender diverse and gender non-binary[5]. We also appreciate that there are risks to desexing language when describing female reproduction[6 7]. Services and delivery of care must be appropriate, inclusive and sensitive to the needs of people whose gender identity does not align with the sex they were assigned at birth. This includes training and education regarding diverse pathways to pregnancy and the use of practices which affirm the sexual and gender identities of all people using Obstetrics and Gynaecology services.

Language use is key to effectively communicate options, recommendations, and respectfully accept a woman's fully informed decision[8]. With this in mind, the use of birth is preferable to the term delivery in all circumstances and is used consistently where possible throughout the guidelines. It is acknowledged that in some circumstances (e.g., in the case of a medically indicated intervention or surgery) and in some contexts, substituting with the term delivery is considered appropriate and this term may be used instead.

5 Moseson H, Zazanis N, Goldberg E, *et al.* The Imperative for Transgender and Gender Nonbinary Inclusion. Obstet Gynecol. 2020;135(5):1059-1068. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7170432/

6 Brotto LA, Galea LAM. Gender inclusivity in women's health research. BJOG: An International Journal of Obstetrics & Gynaecology. https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/1471-0528.17231

7 Gribble KD, Bewley S, Bartick MC, *et al.* Effective Communication About Pregnancy, Birth, Lactation, Breastfeeding and Newborn Care: The Importance of Sexed Language. *Frontiers in Global Women's Health*. 2022;3. Accessed June 9, 2022. https://www.frontiersin.org/article/10.3389/fgwh.2022.818856

8 https://blogs.bmj.com/bmj/2018/02/08/humanising-birth-does-the-language-we-use-matter/

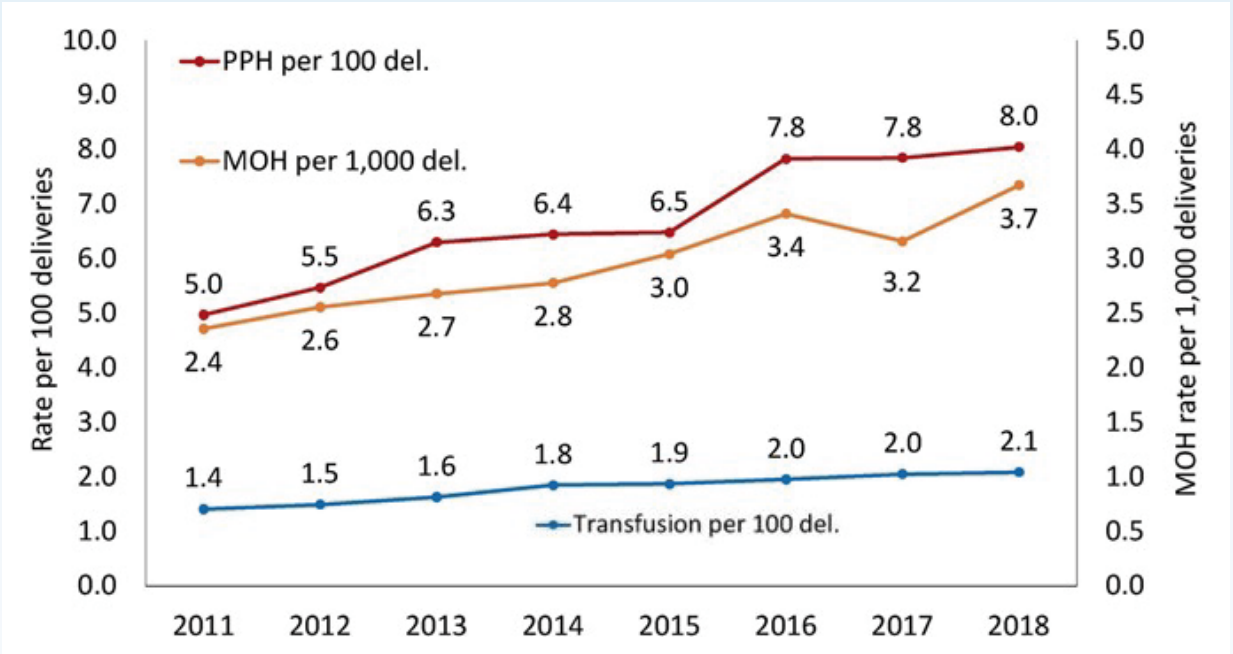
Chapter 2:
Clinical Practice Guideline

Background

Incidence and trends of Postpartum Haemorrhage

PPH accounts for almost one quarter of all maternal deaths worldwide [4] and is the second leading cause of direct maternal mortality in the UK and Ireland.[5] PPH is also a significant contributor to severe maternal morbidity (SMM) and long-term disability. In an Irish context, Major Obstetric Haemorrhage (MOH) remains the most frequently reported SMM event, accounting for over half (51.2%) of reported cases. [6] Alarmingly, the incidence of PPH is increasing both nationally [7,8] and internationally [9–11], for reasons that are not fully characterised. There was a 60% increase in PPH, a 50% increase in blood transfusion, and a 54% increase in MOH, nationally from 2011 to 2018.[8]

Figure 2: Time trend in postpartum haemorrhage (PPH), blood transfusion (one or more units) and major obstetric haemorrhage (MOH) in Ireland, 2011–2018. Del = deliveries [8] *



* The definitions used for PPH, include greater than or equal to 500 ml, cases of PPH were identified by the presence of both diagnosis codes Z37 and O72. Cases of blood transfusion were identified using the diagnosis code Z37 and administration of at least one of the following: autologous blood (code 9,206,000), whole blood (1,370,601), packed cells (1,370,602), platelets (1,370,603), other serum (9,206,200). The annual incidence is reported per 100 deliveries. The definition of MOH used in this national clinical audit was: blood loss of at least 2500 ml or transfusion of five or more units of blood or documented treatment for coagulopathy.

PPH accounted for 21% of (n = 177 of 826) major haemorrhage protocol activations reported in the UK National Comparative Audit of Blood Transfusion (NHSBT) in 2018.[12] This figure is similar to the 25% reported in Irish Model 3 hospitals with a maternity unit in 2018.

A detailed MOH audit which was conducted by the NPEC between 2011-2013, suggested good overall practice in all 19 Irish maternity units but reported variation between units in PPH identification and management.[13,8] The introduction of a standardised PPH 'care bundle' may improve clinical outcomes, as demonstrated by a recent Welsh PPH quality improvement project (Obstetric Bleeding Strategy Cymru).[14] In this initiative, conducted between 2017 and 2018 in Wales, which has similar number of maternity units as the Republic of Ireland, the introduction of a PPH 'care bundle' and staff training showed that massive PPH (defined in this study as ≥ 2500 ml blood loss), decreased by 1.10 (95% CI 0.28 to 1.92, p=0.011) per 1000 maternities per year. Similarly, number of units of red cell transfused decreased by 7.4 (95% CI 1.6-13.2, p=0.015) per 1000 maternities per year.

Definitions

PPH has been traditionally defined as blood loss of ≥ 500 ml from the genital tract following birth. Primary PPH occurs within 24 hours after birth, and secondary PPH from 24 hours to six weeks after birth. Subsequent modifications of this definition have raised the threshold following Caesarean Section (CS) birth to ≥ 1000 ml.[15] However, in recognition of the importance of the clinical response to haemorrhage, a more recent definition includes a blood loss associated with signs and symptoms of hypovolemia, regardless of the volume of blood lost or the mode of delivery indicated on the national poster (pink poster) and the PPHQII algorithm.[15,16] PPH may also be classified into minor and major categories, defined as blood loss of ≥ 500 ml and > 1000 ml, respectively.[17] Previous versions of this Guideline used this definition. MOH may be defined by a combination of events, including estimated blood loss of ≥ 2.5 L and/or transfusion of ≥5 units of Red Cell Concentrate (RCC) and/or a requirement for treatment of coagulopathy. [3,18] Of note, PPH is often defined or categorised after the event, and not contemporaneously. It is important to note that triggers for escalation of care during PPH are not necessarily consistent with the categories outlined.

Aetiology

The four main drivers of PPH have traditionally been described as the "the four Ts": **Tone** (failure of the uterus to contract), **Tissue** (retained placenta/membranes), **Trauma** (lacerations/uterine rupture) and **Thrombin** (abnormal coagulation). The most common cause of primary PPH is uterine atony, [17,19,20] whereas secondary PPH is more commonly associated with retained tissue with/or without infection.[21]

PPH Risk Factors

PPH risk factors can be identified prior to labour (antepartum) and during labour (intrapartum). Table 2 outlines risk factors reported to be associated with PPH by expert consensus in international guidelines [15–17,22] and observational studies[23–25] Several PPH risk prediction algorithms have been developed for clinical use but have not yet been validated. The positive predictive values for PPH in both medium and high-risk patients appear to be low (<10%).[26] Moreover, 40% of women who experience PPH are defined as "low PPH-risk". It is therefore important to remain vigilant for excess bleeding in all births, even in women with no identified PPH risk factors.

Table 2: Variables associated with an increased PPH risk

Antenatal Risk Factors	Intrapartum Risk Factors
Previous PPH [17]	Prolonged Labour [15–17]
Obesity [23–25]	Precipitous Labour [15,16,22]
Ethnicity (Asian/Hispanic)[27]	Instrumental birth [15,16]
Pre-eclampsia [15–17]	Uterine rupture [16]
Overdistention of uterus	
(multiple pregnancy, polyhydramnios, macrosomia) [15–17]	Augmented Labour [15,16]
Anaemia[15,17,22]	Episiotomy [15–17,22]
Inherited bleeding disorders[15–17,22]	Volatile anaesthetic agents [15–17]
High parity[15,16]	PROM [16]
Fetal death[15]	Infection/Chorioamnionitis [15,16,22]
Uterine anomalies (fibroid uterus, previous uterine surgery) [15,16]	Uterine inversion [15,16,22]
Induction of labour[15]	Placental abruption [15]
Placenta previa [16]	Retained Placenta [15–17,22]
Abnormal placentation (accreta spectrum)[15–17,22]	

Recommendations relevant to this Guideline can also be found in the:

- National Clinical Practice Guideline: Diagnosis and Management of Placenta Accreta Spectrum[9]
- National Clinical Practice Guideline for the Induction of Labour (due 2023)

9 Bartels H.C, Walsh J.M, Ní Mhuircheartaigh R, Brophy D, Moriarty J, Geoghegan T, O'Leary M, Donnelly J. C, Colleran, G.C, Thompson, C, Cooney, N, Byrne, B, Downey, P, Greene, R, Higgins, S, Brennan, D.J. National Clinical Practice Guideline: Diagnosis and Management of Placenta Accreta Spectrum. National Women and Infants Health Programme and The Institute of Obstetricians and Gynaecologists. December 2022

Section 1: Preparedness

Introduction

The following section will discuss the identification of risk factors and interventions that may allow the woman and her caregivers to prepare for and reduce the risk of PPH.

Clinical Question 2.1: Antenatal risk management
Can identification of antenatal PPH risk factors prevent or improve outcome?

Evidence Statement

PPH risk factors can be identified from a detailed history and from the results of routine bloods taken when the woman books for antenatal care. Other risk factors may become evident as the pregnancy progresses. The evidence that identification of these risk factors can assist preparedness for PPH in varying circumstances is discussed below.

Blood group and antibody testing

Screening for antibodies to red blood cell antigens, as well as blood group testing, should be performed at the booking visit (10-14 weeks). All women should have a further blood sample taken at 28 weeks gestation, in order to further screen for red cell alloantibodies.[26,28]

If clinically significant antibodies are detected, they should be discussed with the hospital transfusion laboratory and the Irish Blood Transfusion Service (IBTS), and appropriate serial testing undertaken. For women with multiple antibodies, communication between obstetric, neonatology, haematology and transfusion laboratory staff and the IBTS is imperative, in order to plan blood availability for the birth. Do not delay blood transfusion in a life-threatening haemorrhage.[29] Provision of compatible blood, where unexpected antibodies are detected, may take several hours. For such patients, consult haematology/ transfusion laboratory re most appropriate emergency red cell transfusion which may be Group O, Rh D negative and, if immediately available, Kell negative blood.

Anaemia

Anaemia in pregnancy is defined by WHO as haemoglobin (Hb) < 11.0 g/dl.[30] If anaemia is identified, the underlying cause should be investigated and treated. Moderate anaemia at the start of pregnancy (Hb < 9 g/dl) was reported to be significantly associated with severe PPH, with an aOR of 4.27 (95% CI 2.79-6.54).[31] It is hypothesised that anaemic women are at a higher risk of uterine atony due to impaired oxygen transport to the uterus.[32] Iron deficiency is the most common cause of maternal anaemia. Iron requirements increase dramatically in pregnancy due to the expanding blood volume of the mother and high iron requirements for fetal RBC production and fetoplacental growth. A ferritin level of < 30 µg/l is diagnostic of iron deficiency.[33] The first-line treatment of iron deficiency in pregnancy is oral iron. Intravenous iron is considered if there is poor response or tolerance of oral iron.[34] In accordance with recent NICE guidelines, all women should have an FBC at booking and at 28 weeks to screen for anaemia.[35]

Refusal of blood products

It should be established at booking whether or not a woman will accept blood products if required. Where a refusal is established at booking, women should be managed as high risk, through the appropriate local pathways. Referral to a consultant haematologist for detailed discussion and documentation of acceptable and unacceptable treatments is advised. An Advance Decision to Refuse Specified Medical Treatment should be completed, and a certified copy placed in the chart. Acceptance of cell salvage should be explored in these circumstances. Acceptance or refusal of blood products should be discussed at each subsequent visit. In the event of significant PPH or life-threatening haemorrhage, a confidential discussion should be held outlining the current risk to explore the woman's decision with respect to acceptance/refusal at that time.

Maternal blood disorders

Women with congenital or acquired bleeding disorders are at increased risk of obstetric haemorrhage. It is important to identify these women at booking and refer for the planning of antenatal, intrapartum and postpartum care by experienced fetomaternal specialists, haematologists and anaesthetists. [36]

Previous CS

The risk of Placenta Accreta Spectrum" (PAS) is highest in women with previous CS and placenta praevia and increases with the number of previous caesarean deliveries.[37] The placental site should be identified at the time of fetal anomaly scanning in all women with a previous CS. If PAS is suspected, a referral should be made to a fetal medicine expert for a detailed assessment of the uteroplacental interface. Prenatal diagnosis of PAS facilitates multidisciplinary planning to minimise the mortality and morbidity that can be associated with this condition. [38]

Elective CS

Prior to an elective CS, an FBC should be checked, and a serum sample should be taken for group and antibody screen (within three days of the procedure) so that it is available in the laboratory in the event of excess bleeding to allow crossmatching for red cell components. Specific indications for red cell component requirements should be identified in the hospital blood order schedule. When the risk of PPH is deemed to be very high, there should be a higher level of 'preparedness' influencing site and timing of birth, and the availability of staffing with expertise and blood components. This is particularly important when PAS is suspected.

Placenta praevia and PAS

CS for placenta praevia is associated with increased blood loss, and it is advisable that the CS should be performed by an experienced obstetrician. PAS is associated with high maternal mortality and morbidity. However, this risk can be reduced if cases are anticipated and managed in a unit in which access to an experienced multidisciplinary team and resources for the management of severe haemorrhage are available and in which additional expertise can be obtained, if required. [38,39]

Clinical Practice

Identification of risk factors for PPH at booking and during pregnancy provides opportunity to optimise maternal iron stores, identify level of risk, and plan the availability of specific blood products (if required). In very high risk cases, the most appropriate location for birth can be planned on the basis of equipment, blood availability and staff expertise.

Clinical Question 2.2: Intrapartum risk management
Can identification of intrapartum risk factors prevent PPH or improve outcome?

Clinical Practice

It is imperative that those facilitating a birth are aware of intrapartum PPH risk factors (see table 2) and anticipate the potential for PPH in the presence of risk factors. Risk factors should be clearly communicated during handover of clinical care. Actions to prepare for PPH include securing intravenous access, taking a blood sample for group and save or cross match, planned active management of the third stage of labour (please see clinical question 2.4) and recording of blood loss immediately following birth (please see clinical question 2.7).

Clinical Question 2.3: Systems risk management
What are the important components of a maternity unit preparedness for PPH?

Clinical Practice

Maternity units must be adequately resourced in terms of staffing, infrastructure and laboratory support. There should be immediate access to medications and theatre if required. The capability to respond to MOH requires a skilled team of midwives, obstetricians, nurses, anaesthetists, medical scientists, porters, and there should be the capability to mobilise the additional expertise of advanced surgery, interventional radiology and haematology if required. In some cases, transport to another facility is warranted to access more specialised care.

Each maternity unit should have regular training of all staff engaged in the management of PPH/MOH in compliance with local policies and procedures. This training should include local multidisciplinary team drills enhanced by eLearning, if available.

In anticipation of possible haemorrhage, maternity units should maintain a supply of Group O, Rh D negative and Kell negative blood for emergency use. Local hospital blood group serology testing and blood order schedules for mode of delivery/clinical risk should be developed and reviewed periodically. There should be agreed sample acceptance and component release policies. Each maternity unit should identify and document the turnaround time (TAT) for laboratory tests relevant to the management of MOH. Units should develop local policies and protocols including documentation, defined roles and responsibilities, location and availability of blood components and pharmaceuticals, reporting and review processes. The transfusion laboratory should be advised of planned care/delivery for women at high risk for PPH and kept advised where risk emerges unexpectedly.

Recommendations – Preparedness

1. Women who are at higher Post Partum Haemorrhage (PPH) risk should be identified and actively managed at each care opportunity. This should include screening for and management of antenatal anaemia and recognised PPH risk factors.
2. Each maternity unit should have a policy in place for identification and management of women with red cell antibodies (where specific additional blood transfusion matching is required).
3. Women who do not wish to receive blood products should be identified at their booking visit. There should be a detailed discussion and documentation of acceptable and unacceptable treatments. Advance Decision to Refuse Specified Medical Treatment should be completed and kept in the maternity chart and updated during pregnancy.
4. Women with inherited bleeding disorders should be identified at booking and referred for planning of pregnancy, intrapartum and postpartum care by experienced fetomaternal specialists, haematologists and anaesthetists.
5. Women should have a FBC at booking and at 28 weeks gestation to screen for anaemia with the aim of treating and optimising haemoglobin before birth. Keeping in line with UK recommendations repeat blood group at 28 weeks to further screen for red cell alloantibodies should be considered.
6. Placental site should be determined at routine fetal anomaly scanning, particularly if there is a previous Caesarean Section.
7. If placenta accreta spectrum has been diagnosed, planned delivery before term in a unit with an experienced skilled multidisciplinary team of specialists and resources, is recommended.
8. Risk factor assessment for PPH should continue intrapartum and should be clearly communicated during handover of clinical care.
9. Women with retained placenta, or who require intrapartum Caesarean Section (especially in the second stage of labour) require close surveillance for PPH.
10. It is important to remain vigilant for excessive blood loss at all births because many women who suffer a PPH do so without identifiable risk factors.
11. All obstetric units should maintain a supply of O Rh D negative, Kell negative blood for emergency use.
12. Each maternity unit should develop local policies and protocols to include standards of documentation, defined roles and responsibilities, blood component and pharmaceutical location/availability, reporting and review processes.
13. Each maternity unit should identify and document the turn around times (TAT) for laboratory tests relevant to management of MOH. Near patient testing (blood gas analysis and coagulation testing), if used, should be compliant with national guidelines/ standards.
14. Local hospital blood group serology testing and blood order schedules for delivery should be developed and periodically reviewed for appropriateness. Sample acceptance and component release policies should be agreed.

15. Local simulated multidisciplinary team (including laboratory staff) drills should be used to promote learning. Each maternity unit should undertake training of all staff engaged in the management/support of PPH/MOH in compliance with their policies and local procedures. Training should include the use of multidisciplinary 'drills' on a specified periodic basis and eLearning if available.
16. Appropriately trained colleagues should provide simulation training for life threatening MOH to anaesthesiologists, obstetricians, midwives, laboratory and portering staff.
17. We recommend that a national MOH poster be adopted and personalised by each unit delivering maternity care. This poster should be prominently displayed in each labour ward/theatre.

Section 2: Prevention

Introduction

This section will discuss management of the third stage of labour, considering interventions that may reduce PPH risk**.**

Clinical Question 2.4: Third stage management
What interventions in the third stage of labour reduce the risk of PPH?

Evidence Statement

The third stage of labour can be actively or physiologically managed. The components of active management of the third stage of labour (AMTL) are prophylactic uterotonic administration, early cord clamping, controlled cord traction (CCT) to deliver the placenta and uterine massage.[40] One or all of these components may be implemented. Conversely, physiological management encompasses waiting for the placenta to deliver spontaneously, delayed cord clamping and non-administration of uterotonics.[40]

AMTL

AMTL may be associated with less blood loss, maternal anaemia and blood transfusion compared to physiological management.[41] Oxytocin is an effective first line agent for AMTL. The addition of ergometrine IM for women without contraindications may be beneficial (although without strong supporting data) but is associated with more adverse events, including vomiting and hypertension.[42]

Delayed cord clamping (DCC)

DCC involves delaying cord clamping for at least one minute after birth (and up to the time of cord pulsation cessation), rather than clamping the cord immediately following the birth.[43] DCC has been shown to decrease in-hospital mortality in preterm infants [44] and the risk of iron deficiency anaemia in term infants, which may be associated with potential neurodevelopmental benefits.[45] With respect to maternal outcome, the 2013 meta-analysis reported no significant reduction in median postpartum blood loss when DCC was compared with early cord clamping (400 v 350 ml; p=0.3).[43] However, the cord should be clamped immediately in the setting of active maternal bleeding or if neonatal resuscitation is required.

Uterine Massage

Although uterine massage to stimulate contraction after birth is a standard midwifery practice and may be beneficial in settings without access to uterotonics, no high-quality data support its association with a lower PPH risk.[46]

Controlled cord traction (CTT)

A 2015 Cochrane review concluded that placental delivery by CCT did not significantly reduce blood loss of ≥ 1000 ml but was associated with a reduced need for MROP when compared to spontaneous placental separation. However, the observed benefit was driven by a reduction in women who had received ergometrine in combination with oxytocin and was not evident in women that received oxytocin alone.[47]

Breastfeeding or nipple stimulation

Breastfeeding and/or nipple stimulation increases endogenous oxytocin production and may be of theoretical benefit in preventing PPH in low resource settings, although high-quality data are lacking.[48]

Clinical Practice

AMTL is associated with less blood loss postpartum but the contribution of the individual components of AMTL such as cord clamping, uterine massage and controlled cord traction is unclear. Delayed cord clamping is now recommended because of neonatal benefit. The most important component of AMTL appears to be uterotonic administration (See CQ 2.5).

Clinical Question 2.5:
What uterotonics are effective in preventing PPH after vaginal birth and after CS?

Evidence Statement

Prophylactic **uterotonics** are recommended following both vaginal and CS birth because they reduce the PPH risk.[49] Table 5 lists uterotonic medications that are used to prevent PPH in Ireland. It is advisable to administer uterotonics for PPH prevention immediately following birth, ideally within one minute. [57]

Oxytocin

Oxytocin is a peptide hormone released from the posterior pituitary that binds to oxytocin receptors in the uterus to stimulate uterine contractions. It can be administered IV or IM with a more rapid onset of action IV and a clinical response lasting 30 to 60 minutes. When administered after birth, oxytocin reduces the risk of blood loss and the need for additional uterotonics compared to no uterotonics or placebo.[50]

Following vaginal birth, the intravenous administration route is associated with less blood loss and lower blood transfusion requirements but a similar risk of rescue uterotonic requirement compared to the IM route.[51] A large meta-analysis reported no difference in the risk of hypotension between IV and IM routes of oxytocin administration.[52] However, while the IM dose of oxytocin (10 IU) was standard in these studies, there was considerable variation in how oxytocin was administered IV, and whether a bolus dose or infusion was given. Authors also recognise concerns that an oxytocin IV bolus may sometimes cause serious side effects, such as a sudden drop in blood pressure, especially when given rapidly in a small amount of solution undiluted and very rare cases of maternal deaths have been reported.[51,53]It is preferable to administer oxytocin infusions using a controlled infusion device. Rapid IV boluses are not recommended.

Following CS the optimum dose of oxytocin administered IV is unclear and reflected in the variation in recommendations of international guidelines.[54–57] The adverse effects of oxytocin include hypotension, tachycardia, cardiac arrhythmia and ischaemia.[58] Nausea, vomiting, chest pain, headache, and flushing are less serious but unpleasant side effects. These all appear to be dependent upon dose and route of administration.

There are, however, some observational studies that report good efficacy with fewer side effects when lower initial doses of oxytocin are used, with a 90% effective dose (ED 90) estimate of 0.35-1 unit bolus for a non-labouring parturient [59,60], and the use of small bolus followed by infusion administration should be considered.[54,55,61] It is important to recognise that a higher initial bolus and infusion rate may be required when an oxytocin infusion has been used to treat prolonged labour.[62,63] Balki *et al.* demonstrated that the ED 90 for a bolus in this context was 2.99 units[63] and Lavoie *et al.* suggested that, when administering an infusion only, the ED 90 should be close to 44 units/hour [62] for the first 4 minutes (resulting in a total dose of 2.93 units) but that this dose rate can subsequently be reduced if tone is adequate.

Administration of an initial oxytocin bolus dose of > 5 IU appears to confer little additional benefit in most scenarios and may increase the risk of adverse effects.[55,59,61] Some authors have advocated for a "rule of threes" algorithm.[64] Briefly, this algorithm suggests an initial prophylactic IV oxytocin dose of 3 IU administered over 30 seconds, followed by assessment of uterine tone at 3-minute intervals and re-administration of oxytocin (3 IU) until a total of three doses (if needed) have been administered before considering administration of second-line uterotonics.

Oxytocin infusion after vaginal or caesarean birth.

Fewer high-quality data support optimal administration strategies for prophylactic oxytocin infusion. In clinical practice, infusion doses of between 5-40 IU are widely considered in order to maintain uterine contractility for several hours after the birth. In a recent consensus statement, a two-hour maintenance infusion following the birth was suggested, at infusion rates of between 3-16 units/hour after low risk CS. Higher infusion rates may be suggested following intra partum Caesarean section.[54]

Carbetocin

Carbetocin is a synthetic oxytocin analogue with a longer half-life, and therefore, a single dose may obviate the need for oxytocin infusion. It is manufactured to be heat stable, whereas oxytocin must be stored and transported at 2-8°C. The CHAMPION trial (a multicentre double-blinded randomised controlled trial that included 29,645 women) compared carbetocin 100 µg IM with oxytocin 10 IU IM, administered immediately after vaginal birth. Blood loss was measured using gravimetric methods. The risk of a blood loss volume of ≥ 500 ml was 14.5% in the carbetocin group compared to 14.4% in the oxytocin group (Relative Risk (RR) 1.01, 95% Confidence Interval (CI) 0.95-1.06). Loss of ≥ 1000 ml blood volume was 1.51% vs 1.45% (RR 1.04, 95% CI 0.87-1.25) respectively, but the event rate for this outcome was low. There was no difference between the groups in the use of additional uterotonic agents, requirement for interventions to stop bleeding or side effects.[65]

A subsequent network meta-analysis reported that carbetocin was associated with a lower risk of PPH ≥ 500 ml (RR 0.72, 95% CI 0.56-0.93) and less use of additional uterotonics compared to oxytocin, but rates of PPH ≥ 1000 ml, blood transfusion and side effects were no different. [66] These effects were demonstrable in both vaginal and Caesarean section and resulted in the WHO recommendation that carbetocin 100 µg IM/IV be used for the prevention of PPH for all births where its cost is comparable to other effective uterotonics.[67]

A recent double-blind randomised controlled trial (IMox)[68] compared IM carbetocin, IM oxytocin and IM syntometrine (the latter consisting of oxytocin 5 IU and ergometrine 500 µg) for primary PPH prevention after vaginal birth. There was no significant difference in the need for further uterotonics between groups who received carbetocin and oxytocin. However, syntometrine was associated with significantly less requirement for further uterotonic use than the carbetocin and oxytocin groups. The risk of PPH was not different between groups.

When used following elective CS for primary PPH prevention, carbetocin has been reported to be non-inferior to oxytocin, it may be associated with less requirement for supplemental uterotonic use and therefore may obliviate the need for an infusion. [69] Current guidelines suggest a dose of 100 µg IV slowly at the birth, however a dose of 20 µg may be sufficient for non-obese parturients at elective CS. [54,70] Dose requirements for obese parturients may be 4 times higher in the elective setting but should not exceed 100 µg.[71] However, a dose-finding study in the setting of intrapartum CS reported that the ED 90 for adequate uterine tone was between 120-140 µg.[72] At these higher doses in particular, the risk of tachycardia and arrhythmias was increased. These findings may limit both the usefulness and cost-effectiveness of carbetocin in non-elective CS.

Carbetocin (Pabal 100 µg/ml) is available in Ireland but is more costly than oxytocin at the time of the review. The potential benefit of simpler preparation and administration (compared to an oxytocin infusion) may allow for better staff time utilisation and fewer drug administration errors. Cost-benefit studies have reported variable results[73] and further studies are required to identify the clinical scenario and health care setting for optimal cost-effectiveness. Unlike oxytocin, the heat stable formulation of carbetocin does not require refrigeration for storage or cold chain transport and may be of great benefit in low-income countries. This drug is available at a sustainable access price for use in public sector health care facilities in low and low-middle income countries e.g. India, South Sudan, Sierra Leone and Tanzania.[74]

Syntometrine

The combination of oxytocin 5 IU and ergometrine 500 µg (syntometrine) IM has been in clinical use for many years. Ergometrine is an ergot alkaloid that produces more sustained uterine contraction when compared to oxytocin. It can be administered IV or IM with an onset of action in 1 to 3 minutes, and a duration of effect ranging from 45 mins to 3 hours. Side effects include nausea, vomiting and hypertension and it is contra-indicated in hypertension, pre-eclampsia, cardiac disease and severe renal or hepatic impairment (See table 5). A 2004 meta-analysis conducted by McDonald [75] *et al.* (updated in 2007) demonstrated a reduced risk of blood loss ≥ 500 ml (odds ratio (OR) 0.82, 95% CI 0.71-0.95) but not ≥1000 ml when syntometrine was compared to oxytocin alone. This was at the cost of a five-fold increase in the side effects of nausea, vomiting and hypertension (OR 4.9,95% CI 4.03-6), which has shaped previous Guideline recommendations favouring oxytocin alone. [40] There have been concerns that the incidence of PPH volumes of > 1000 ml have increased since the introduction of these recommendations, and a survey of maternity units in the UK published in 2012 revealed that, despite NICE recommendations, 67% of units still use syntometrine as a first choice prophylactic uterotonic (while cognisant of PPH risk and listed contraindications, which include hypertension and preeclampsia).[76]

Misoprostol

Misoprostol is a PGE1 analogue and has been shown to be an effective uterotonic that decreases the risk of blood loss ≥ 500 ml when compared to placebo or no treatment. [66] It has an alternative mode of action and does not require IM or IV administration (see table 5). It can be administered orally, sublingual, vaginally or rectally with the first two routes having a more rapid onset of action. Side effects include shivering, vomiting, diarrhoea and pyrexia. Compared to oxytocin alone, the combination of misoprostol and low-dose oxytocin was reported in a network meta-analysis to reduce the risk of a PPH volume of ≥ 500 ml (RR 0.70, 95% CI 0.58-0.86), but not that of a PPH volume of ≥ 1000 ml (RR 0.88, 95% CI 0.7-1.11). The authors noted that the evidence was of low certainty. Misoprostol and oxytocin in combination reduced the requirement for additional uterotonics (RR 0.56, 95% CI 0.42-0.73) and the risk of blood transfusion (RR 0.51, 95% CI 0.37-0.70) when compared with oxytocin alone, but an increased risk of vomiting and fever was reported with the use of this combination.[66]

Clinical Practice

The uterotonics recommended for the prevention of PPH are outlined in Table 5. Oxytocin is recommended as the first line uterotonic because of proven clinical efficacy and side effect profile. Uncertainty remains about optimum dosing, particularly IV and at intrapartum CS but guidance is provided by expert consensus (See Table 4). The remaining uterotonics have proven efficacy but have more side effects, or, are more costly than oxytocin. Women who request physiological management of the third stage of labour should be informed of the risk and benefits of this choice, especially if they have risk factors for PPH. They should be supported in their choice, once fully informed, but advised that a uterotonic will likely be required if they are bleeding excessively or if the placenta has not separated after 30 minutes.

Table 4: Oxytocin prophylaxis for elective and emergency CS

First-line drugs [54]	
Elective CS; no PPH risk factors	**Intrapartum CS or any CS with PPH risk factors**
Bolus oxytocin 1 IU; start oxytocin infusion at 2.5–7.5 IU/hr.	3 IU oxytocin over ≥ 30 s; start oxytocin infusion at 7.5–15 IU/hr
Consider a further dose of 3 IU over ≥ 30 seconds, if required upon assessment after 2 minutes.	If required upon assessment after 2 min, give a further dose of 3 IU over ≥ 30 s
Consider a second-line uterotonic agent early in the event of failure of this regimen to produce sustained uterine tone.	
Review the patient's clinical condition before discontinuing the infusion; this assessment will usually be required between 2 h and 4 h after commencement of uterotonic.	

Table 5: Uterotonics for PPH Prophylaxis

Medication	Mode of action	Dosing	Adverse Effects
Oxytocin	Stimulates oxytocin receptors in the uterus *O/S Immediate IV/3-7 mins IM* *Duration 30 – 60 mins **	**Vaginal birth** Bolus: 10 IU IM or 5 IU slowly IV **CS birth** Bolus: 1-3 IU slowly IV Infusion: 7.5-15 IU/hr (over 4 hours)	Rapid administration may cause hypotension, tachycardia and arrhythmia. Caution with SIADH and hypotension.
Ergometrine (Administered as syntometrine in combination with oxytocin)	Ergot alkaloid causes sustained uterine contractions *O/S IV 1 min; IM 2-3 mins* *Duration 45 mins to 3 hours **	Oxytocin (5IU)/ Ergometrine (500 µg) IM	Nausea and vomiting, elevated blood pressure. Cautious use with other vasoconstrictors ***Contraindications: Severe hypertension/ pre-eclampsia/ cardiac disease/ severe renal or hepatic impairment.***
Misoprostol	PGE1 analogue *O/S 9-15 mins* *More rapid O/S PO and SL* *Longer duration PR and PV*	400 to 600 µg PO Can be administered SL/PV/PR	Associated with shivering, diarrhoea and pyrexia
Carbetocin	Synthetic oxytocin analogue stimulates oxytocin receptors in the uterus *O/S IV 2 mins* *Duration IV 60 mins; IM 3 hours**	100 micrograms IM or slowly IV	Rapid admin may cause hypotension, tachycardia and arrhythmia. Caution with SIADH and hypotension

* Approximate duration of action

Clinical Question 2.6:
Does tranexamic acid have a role in the prevention of PPH?

Evidence Statement

Tranexamic acid

Tranexamic acid (TXA) is a synthetic lysine analogue that prevents plasmin-mediated fibrin degradation (fibrinolysis). TXA has been shown to reduce blood loss in some types of surgery [77–79] and to reduce death following traumatic brain injury.[80] The WOMAN RCT demonstrated a significant reduction in bleeding-related mortality in women with PPH who were randomised to receive TXA.[81]

Several large studies have recently examined the routine prophylactic use of TXA in obstetrics. A multicentre RCT from the TRAAP (TRAnexamic Acid for Preventing PPH after vaginal delivery) investigators reported no significant difference in the incidence of PPH > 500 ml amongst women who were randomised to prophylactic TXA versus placebo following vaginal birth.[82] These investigators also completed another large (n=4551) multicentre RCT (TRAAP2) in which women undergoing CS were randomised to TXA or placebo.[82] The primary outcome (PPH, defined as blood loss of > 1000 ml or requirement for a red-cell transfusion within 2 days after birth) occurred in 26.7% and 31.6% of patients randomised to TXA and placebo, respectively (adjusted relative risk (aRR) 0.84, 95% CI 0.75-0.94). Nausea and vomiting were significantly more common in patients receiving TXA. However, the authors questioned the clinical relevance of the approximately 100 ml observed mean between-group blood loss difference, particularly as there was no significant change in secondary clinical outcomes (including provider-assessed clinically significant haemorrhage and the use of additional uterotonics). Neither the WOMAN[81] nor the TRAAP[82] trials observed excess of thromboembolic events in the TXA group. Similarly, a large recently published meta-analysis including obstetric patients did not find an excess of thromboembolic events in the women treated with TXA.[83] However, no trial has been powered to specifically evaluate the thromboembolic risk associated with TXA, and most studies actively exclude patients who have an increased risk of thrombosis.[84] Other potential risks reported in association with TXA use include the possibility of an increase seizure risk associated with high doses of TXA in the setting of cardiac surgeries.[78,85]

Clinical Practice

Currently, the routine prophylactic use of TXA in obstetrics is not recommended. [15,82] However, the prophylactic use of TXA may still be considered in obstetric patients who are at higher risk of bleeding or bleeding-related complications. Trials investigating some of these questions are actively recruiting at present.

Recommendations – Prevention

18. Delayed cord clamping is recommended for neonatal benefit. The cord should be clamped immediately if there is active maternal bleeding or a need for neonatal resuscitation.
19. Prophylactic uterotonics should be administered to all mothers immediately following the birth to prevent PPH.
20. Administration of oxytocin at a dose of 10 IU IM or 5 IU by slow IV, is recommended following a vaginal birth.
21. While oxytocin can be administered at lower doses at elective CS and followed by low dose infusion, higher initial doses and infusions may be required for intrapartum CS especially when an oxytocin infusion has been used in labour.
22. Prophylactic oxytocin (5IU) in combination with ergometrine (500µg) [Syntometrine] IM may reduce blood loss more than oxytocin alone and may be considered as a first line prophylactic uterotonic in women at high PPH risk. We do not recommend it as a first line uterotonic in women at low risk because of a five-fold higher risk of nausea, vomiting and hypertension compared to use of oxytocin alone.
23. Carbetocin is non-inferior to oxytocin in preventing PPH following vaginal birth and elective CS. We do not recommend it as an alternative first line uterotonic because of unproven cost benefit.
24. Women requesting physiological management of the third stage of labour should be informed of the risk and benefits, especially if they have PPH risk factors. They should be supported in their choice, once fully informed, but advised that a uterotonic should be administered if excessive bleeding occurs or if the placenta has not separated after 30 minutes.
25. Preparations should be made to transfer the woman to theatre for manual removal of placenta (MROP) 30 to 60 minutes after the birth and sooner if there is active bleeding.
26. We suggest that prophylactic tranexamic acid administration may be considered in women who are at high PPH risk (including combinations of risk factors).

Section 3: Recognition

The early recognition of excessive blood loss is paramount to the optimal management of PPH. This section will explore how PPH can be identified.

Clinical Question 2.7:
How can PPH be recognised?

Evidence Statement:

Estimation of Blood Loss

The key to the management of PPH is early recognition of excessive blood loss that may be 'revealed' or 'concealed'. The volume of 'revealed' blood loss has traditionally been estimated visually and is known to underestimate the exact volume.[86] Blood loss can also be measured using gravimetric and calibrated methods. In the former, blood volume is determined by weighing swabs, pads, incontinence sheets and drapes. The differences in weight between blood-soaked and dry unused materials can increase the accuracy of measuring blood loss. A difference of 1 gram is considered to be equivalent to 1 ml of blood. Alternatively, blood that has been collected in a disposable funnelled collection bag is weighed. In the calibrated method, blood is collected in a bag that is calibrated to allow direct measurement of volume.

When visual estimation of blood loss was compared with the calibration method following vaginal birth in a hospital setting, no difference in the resultant use of therapeutic uterotonics, plasma expanders, blood transfusion and SMM was observed.[87] In another RCT, calibrated methods were superior to gravimetric methods in the detecting blood loss > 500 ml, but there was no difference in the resultant use of therapeutic uterotonics, plasma expanders or blood transfusion. [88]

When PPH occurs, however, it is important to accurately measure ongoing blood loss, and recording of cumulative measured loss is recognised to be one of the most important factors when providing safe quality care.[89]

Clinical signs of hypovolaemia

The clinical signs of hypovolaemia may not manifest in pregnancy until blood loss is greater than 1000 ml. [90] However, it is important to be aware that the amount of blood loss required to cause haemodynamic instability can depend on the pre-existing condition of the woman. In addition, blood loss may be concealed. Haemodynamic compromise may occur following lower amounts of blood loss in conditions such as anaemia or volume-contracted states (for example, dehydration). Care providers should be vigilant for the signs of hypovolaemia (tachycardia, hypotension, altered consciousness or tachypnoea) in those with ongoing bleeding.

Laboratory studies

Laboratory studies can aid in estimating blood loss, and relevant blood samples should be procured and sent to the lab promptly. These include a full blood count, coagulation studies, including prothrombin time (PT), activated partial thromboplastin time (APTT) and fibrinogen levels. Importantly, these data may not assist in the immediate estimation of blood loss.

The turn-around time (TAT) for PPH-relevant laboratory tests should be identified in each institution.

Woman's blood group should be confirmed and where required obtain sample to confirm this. Red cell transfusion should be managed as per section 4: Management – below, guided by the urgency for transfusion resuscitation

Clinical Practice

The diagnosis of PPH is dependent on the recognition and accurate estimation of excessive blood loss and/or the recognition of the clinical signs of hypovolemia. When the clinical signs of hypovolemia are greater than expected, always consider the possibility of underestimated or concealed blood loss.

Recommendations – Recognition

27. Gravimetric or calibrated methods of blood loss measurement are recommended at CS, operative vaginal birth and after spontaneous vaginal birth if visual estimation of blood loss is >500 ml.
28. Cumulative measured blood loss during PPH should be recorded and communicated to the team.
29. Care providers should be vigilant for symptoms and signs of hypovolemia as these may not always correlate with blood loss and should consider the possibility of underestimated or concealed blood loss.

Section 4: Management

Clinical Question 2.8:
What is the optimal initial response to PPH?

Evidence Statement

The initial response to PPH is outlined in algorithm Postpartum Haemorrhage outlined at the beginning of the document. Co-ordinated teamwork is required to **"Stop the bleeding**, **Resuscitate and Communicate"** simultaneously. The steps involved in achieving this are outlined in textbooks and obstetric emergency manuals (PROMPT [91]/MOET [92]). More recently, a stepwise approach to the management of PPH based on volume of blood loss and clinical concern has been developed to trigger escalation of intervention when required (CMQCC [93]/OBS Cymru[94]) with reported benefit in clinical outcomes.

STAGE 1

When blood loss is > 500 ml but < 1 L, following vaginal birth

Get Help

The midwife in charge and the first-line obstetric and anaesthetic staff should be alerted when women present with PPH without clinical shock

Act

Measure pulse, blood pressure and respiratory rate every 15 minutes.

Establish IV access

Take blood samples for FBC, "group and and antibody screen" and coagulation testing (including PT, APTT, fibrinogen)

Measure and record cumulative blood loss

Treat

Massage the uterus and expel clots

Give uterotonics

Empty the bladder

Inspect the genital tract and confirm that the placenta and membranes are complete

Commence warmed crystalloid infusion

STAGE 2

When blood loss is > 1 L or when there is clinical concern

Get Help

A multidisciplinary team involving senior members of staff should be summoned to attend to women when PPH is associated with ongoing bleeding or clinical shock.

Alert Blood Transfusion laboratory to evolving situation

Act

Measure vital signs

Take blood samples for FBC, group and cross match, coagulation testing (including PT, APTT, fibrinogen), renal profile (including creatinine)

Advise transfusion laboratory of PPH, confirm availability of compatible red blood cell components or take sample as required for cross-matching

Continue to measure and record cumulative blood loss

Treat

Massage the uterus/Bimanual compression

Review and consider further uterotonics

Insert a urinary catheter (if not already done)

Inspect genital tract

Repair genital tract

Give tranexamic acid (see below).

Transfuse with red cell components, as appropriate

Management: Stop The Bleeding

Clinical Question 2.9: Stop the Bleeding
What is the most effective medical management of uterine atony?

Evidence Statement: Uterotonics

The choice of uterotonic agents for treating PPH is outlined in Table 6. There is considerable variation in the choice and sequence in which they are used and some variation in Guideline recommendations.[15,16,17] This is because the evidence for most agents used as first-line treatment for PPH is limited.

A recently published meta-analysis identified 7 trials (including 3738 women) that examined the effectiveness of uterotonics in treating PPH.[95] The deliveries were mainly vaginal and occurred in hospital settings. When misoprostol was compared to oxytocin as a first-line treatment for PPH (in which women received AMTL in one study that included 809 women and no prophylactic uterotonics in another study that included 978 women), blood transfusion (RR 1.47, 95% CI 1.02-2.14), and additional blood loss of ≥ 1000 ml (RR 2.57, 95% CI 1.00-6.64) was greater in the misoprostol group, with a greater risk of side

effects that included vomiting (RR 2.47, 95% CI 1.37-4.47) and fever (RR 3.43, 95% CI 0.65-18.18). Oxytocin remains the first line suggested treatment for PPH due to its better efficacy and fewer side effects.

There is limited evidence supporting the efficacy of ergometrine or injectable prostaglandins in treating PPH, but they remain widely used in managing this condition. All have proven efficacy in preventing PPH [49] and have different mechanisms of action. The sequence of uterotonics used to treat PPH after oxytocin may be determined by individual patient characteristics, staff familiarity with the medications and ease of administration. Most international guidelines recommend Ergometrine (or an equivalent ergot alkaloid) as a second line uterotonic in the absence of contraindications.[15,16,96] It induces sustained uterine contractions with rapid onset whether administered IM or IV and duration of action is approximately 45 mins to 3 hours. The RCOG recommend ergometrine as the next uterotonic to consider after oxytocin to treat PPH (in the absence of contraindications), a strategy that is endorsed in obstetric emergency training programmes. [91,92]

The two remaining uterotonics are the prostaglandin analogues misoprostol and carboprost. Carboprost tromethanine is a 15-methyl analogue of prostaglandin F2alpha (250ug/ml) that induces myometrial contraction when administered IM, by increasing the permeability of the cell membrane and intracellular calcium. It can be administered intramyometrially but it is not licensed for such use and if inadvertent intravascular administration occurs there can be adverse side effects such as severe hypertension and tonic clonic seizure. [97]

Misoprostol is a synthetic prostaglandin E1 analogue that induces uterine contractions (onset and duration of action) when administered orally (8 mins – 2 hours), sublingually (11 mins – 3hours), vaginally (20 mins – 4 hours) or rectally (100 mins – 4 hours). These are simpler routes of administration but have a slower onset of action compared to carboprost.[98]

In the metananalysis of uterotonics to treat PPH mentioned above (95), four trials (1881 women) were identified that addressed whether a combination treatment of misoprostol and oxytocin as first-line treatment of PPH is superior to oxytocin alone. The analysis could not rule out the benefit of using misoprostol plus oxytocin over oxytocin alone for additional blood loss of ≥500 ml (RR 0.84, 95% CI 0.66-1.06), additional blood loss ≥ 1000 ml (RR 0.76, 95% CI 0.43-1.34) and maternal mortality or morbidity (RR 1.09, 95% CI 0.35-3.39). However, the meta-analysis generated high-certainty evidence that misoprostol plus oxytocin made no difference to the use of additional uterotonics (RR 0.99, 95% CI 0.94-1.05) or to blood transfusion (RR 0.95, 95% CI 0.77-1.17) compared with oxytocin. Moreover, fever and vomiting were reported more commonly in the group receiving this combination therapy. There is, therefore, no evidence to support the use of a combination of misoprostol and oxytocin over oxytocin alone in the initial treatment of PPH.[95]

Clinical Practice

Standard components of the initial management of uterine atony include uterine massage to encourage uterine contraction and to expel clots, insertion of an indwelling catheter and check that the placenta and membranes appear to be complete. The uterotonic agents used to treat PPH are outlined in Table 6. Oxytocin is the first line agent because of proven efficacy and side effect profile. The remaining agents have differing modes, onset and duration of action. The sequence of administration suggested below can be influenced by uterotonics already used for prophylaxis, patient profile, side effects, staff expertise and whether the PPH follows a vaginal or caesarean birth.

Table 6: Uterotonic agents for treating PPH

Medication	Mode of action	Dosing	Adverse Effects
Oxytocin	Stimulates oxytocin receptors in the uterus *O/S Immediate IV/3-7 mins IM* *Duration 30 – 60 mins **	Bolus: 5-10 IU (IM or slowly IV) Infusion: 7.5-15 IU/hr (over 4 hours)	Rapid admin may cause hypotension, tachycardia and arrhythmia. ***Caution with SIADH and hypotension.***
Ergometrine	Ergot alkaloid causes sustained uterine contractions *O/S IV 1 min; IM 2-3 mins* *Duration 45 mins to 3 hours **	Bolus: 250 – 500 µg (IM or slowly IV) Can be repeated after 5 mins	Nausea and vomiting, elevated blood pressure. Cautious use with other vasoconstrictors ***Contraindications: Severe hypertension/ pre-eclampsia/ cardiac disease/ severe renal or hepatic impairment.***
Carboprost	PGF2α agonist in uterine myometrium Half life 8 mins	250 ug IM or intramyometrial (*not licensed for intramyometrial use*) Can be repeated every 15 mins (maximum dose 2 mg, which is equivalent to 8 doses)	Nausea, vomiting, diarrhoea ***Caution in Asthma, cardiovascular disease, hepatic disease, renal disease.***
Misoprostol	PGE1 analogue *O/S 9-15 mins* *More rapid O/S PO and SL* *Longer duration PR and PV*	800 to 1000 µg PO/SL Slower onset of action if administered PR or PV	Associated with shivering, diarrhoea and pyrexia

* Approximate duration of action

Clinical Question 2.10: Stop the Bleeding
What is the optimal surgical management of uterine atony?

If bleeding continues, an examination under anaesthesia (EUA) should be performed. This facilitates assessment of the four "T"s. The uterine cavity should be explored to ensure the absence of residual placental tissue or membranes or uterine rupture and to assess whether the uterus remains atonic or not. Trauma of the lower genital tract should be repaired. The surgical management is determined by the underlying cause.

Evidence Statement

The efficacy of surgical interventions are mainly determined from observational studies.

Uterine Balloon Tamponade (UBT)

UBT may be useful, although with very limited high-quality data. Expert opinion suggests that the intervention may be associated with benefit in particular in the setting of uterine atony or placenta praevia and less in the setting of PAS or when there are retained products of conception.[99] Importantly, complications reported with UBT are low (< 6.5%). While UBT appears to be effective in achieving haemostasis in observational studies, results from two randomised control trials comparing UBT to standard care are conflicting. In one study, use of a condom-loaded catheter appears to increase blood loss ≥ 1000ml, blood transfusion, hysterectomy and maternal mortality[100]. However, the study was underpowered and the primary outcome (composite outcome) analysis showed that the proportion of women with invasive surgery or who died before hospital discharge did not differ significantly between the intervention group and control group (RR 2.23, 95% CI 0.76-7.14, p=0.238). In another study, a latex balloon catheter was associated with a non-significant trend to reduced requirement for additional uterotonics and hysterectomy[101]. Both studies were underpowered for their respective primary outcomes and were challenged by other methodological limitations. Consequently, the potential magnitude of the effect of UBT is of low or very low certainty.

Clinical Practice

If the uterus is empty and atony persists, tamponade of the uterine cavity and placental bed can be achieved by placement of an intrauterine balloon that can be distended with air or saline. The balloon can be placed into the uterine cavity via the uterine incision at the time of CS or can be placed vaginally after vaginal birth or CS (if the abdomen has been closed). It is preferable that the woman is placed in lithotomy and that the balloon is inserted and inflated with ultrasound guidance if possible. Careful examination should be carried out (preferably with good anaesthesia) to ensure the absence of retained tissue or trauma before balloon placement.

Table 7: Uterine Balloon Tamponade – Key clinical points

Balloon tamponade	Ensure that the uterus is empty and intact
	Insert preferably under anaesthetic and ultrasound control
	Bleeding should be controlled during balloon distention (*Tamponade test*)
	Monitor external loss (*drainage port*)
	Monitor internal loss (*fundal height/ultrasound/haemodynamics*)
	Continue oxytocin infusion
	Consider broad-spectrum antibiotic cover

Evidence Statement

Uterine compression sutures

Uterine compression sutures include the use of the "B-Lynch" suture (figure 4).[102] The uterus is initially compressed manually to control bleeding and sutures are applied as outlined in figure 4 [102], in order to maintain compression. The method appears to be effective in controlling bleeding in approximately 70% of patients. [103] Subsequent reproductive outcome appears to be good and there does not appear to be an increase in the risk of abnormal placentation. Variations of the technique have been described. [104,105]

Ligation

Ligation of the uterine and utero-ovarian arteries can decrease bleeding and are simple procedures. Ligation of the internal iliac arteries requires good exposure of the pelvic sidewall and a skilled surgeon. Additionally, the presence of collateral pelvic vessels can limit the efficacy of these procedures, but overall success is reported to range from 36-96%.[103]

Clinical Practice

Uterine compression sutures have a role in surgically treating uterine atony that is refractory to oxytocics. Ligation of vessels supplying the uterus can reduce blood loss but ligation of the internal iliac arteries requires the presence of a skilled surgeon.

Clinical Question 2.11: Stop the Bleeding
What is the optimal management of retained tissue?

Evidence Statement

The management of retained tissues is outlined in obstetric textbooks.[106]

Clinical Practice

Table 8: Key points in the clinical management of PPH associated with retained tissue

Clots in the uterine cavity

1. Presence of clots in the uterine cavity may be detected by a uterine fundus that is high in the abdomen, sometimes with uterine atony
2. Express clots by compression of the fundus
3. Measure volume, perform uterine massage; administer uterotonics
4. Examination of the placenta following delivery is important to ensure that it is complete.

Retained tissue

Following vaginal birth – If there is a suspicion of retained tissue or if uterine atony is not responding to initial interventions, EUA should be conducted with careful examination of the uterine cavity and entire genital tract**.**

Manual Removal of Placenta

Gently remove the placenta by shearing it off from the placental bed using the dominant hand in the uterine cavity, while the non-dominant hand controls the uterine fundus. If there is an area of adherence, remove the tissue piecemeal. Consider using ultrasound to direct removal of placental remnants and to reassure that the uterus is empty. (Be aware of the limitations of postpartum ultrasound). In the rare event that MROP is unsuccessful, and bleeding continues, laparotomy and hysterectomy may be considered.

PAS[38] (See Guideline)

Placental tissue removed should be sent for pathological examination

Clinical Question 2.12: Stop the Bleeding
What is the optimal management of genital tract trauma?

Evidence Statement

There is no other evidence available other than what management of genital tract trauma is outlined in obstetric textbooks.[106]

Clinical Practice

Table 9: Key points in the clinical management of PPH associated with genital tract trauma

Trauma following vaginal birth

Adequate anaesthesia, exposure and surgical assistance are required. Clamp or compress actively bleeding vessels prior to repair.

Cervical tear

Apply two sponge forceps 2-3 cms apart, removing and re-applying them individually while moving in a clockwise fashion around the full circumference of the cervix in order to identify the tear. Inspect for a tear between the forceps after each repositioning.

Uterine inversion

May occur in the setting of an adherent placenta, during cord traction. A bluish-grey mass may be observed at the uterine introitus. May present with sudden maternal collapse +/- PPH. The fundus may be either non-palpable or "dimpled".

Leave the placenta attached if it is not separating (it can be removed later in the theatre). Stop oxytocin if it is being administered. Consider giving a tocolytic, such as Glyceryl Trinitrate (GTN) 400 µg spray SL; or Terbutaline 250 µg SC or IV; or Magnesium Sulphate 4 g IV infusion over 5 minutes.

Manoeuvres to replace the uterus (these must be conducted promptly)

Manual reduction: Grasp the protruding fundus with the palm of hand and lift the uterus up through the cervix into the abdomen and towards the umbilicus by directing fingers towards the posterior fornix.

Hydrostatic reduction: Lie the woman flat and consider also applying a head-down position. Commence reduction manually until the fundus is in the vagina. Ask an assistant to approximate the labia to create a vaginal seal. Introduce the tubing of an IV set into the vagina along fingers and infuse warm saline to create increased intravaginal pressure. The uterus should return gradually into the abdomen over 10 to 15 minutes. Up to 2 L of warm saline may be required.

Surgical reduction: Consider this approach if there is a dense constriction ring and the manoeuvres above are ineffective or if haemodynamic instability occurs. Administer anaesthetic and a tocolytic agent (as explained above). Proceed to laparotomy to allow for vaginal and abdominal manipulation of the fundus. Use a deep traction suture to manipulate the fundus and maintain in position once replaced

In all of the above manoeuvres, once the uterus has been restored to normal, apply bimanual compression and commence oxytocin to maintain contractility

Trauma following Caesarean birth

Extension of lower uterine segment (LUS) incision
Broad ligament haematoma

Uterine rupture

Maternal signs:

PV bleed, haematuria, scar pain, shoulder tip pain, abdominal distension, tachycardia and shock, fetal parts easier to palpate abdominally, high presenting part on vaginal examination.

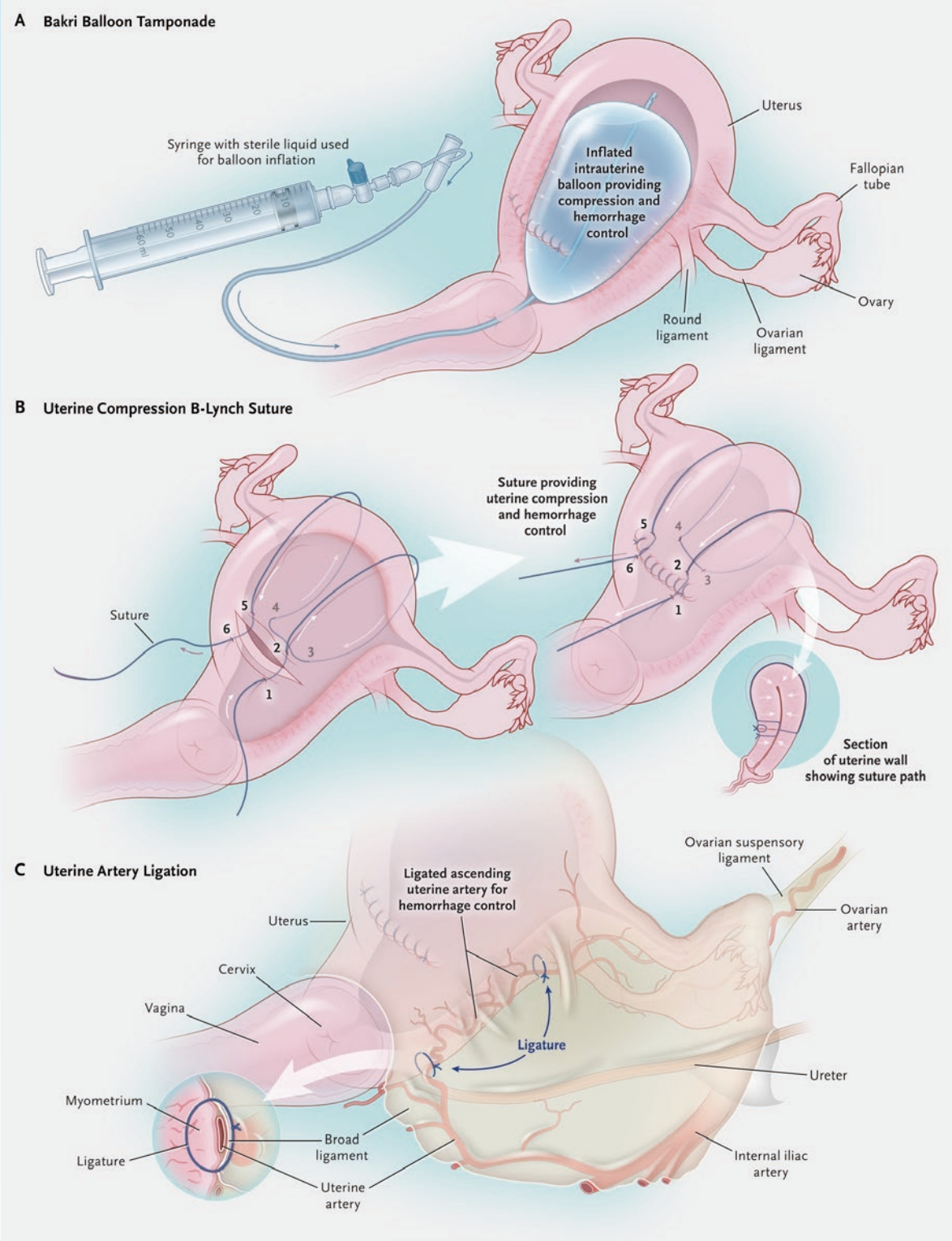
Fetal signs:

Abnormal CTG, profound fetal bradycardia, IUD.

Actions:

Laparotomy, repair of uterus**.** Consider hysterectomy if the defect is large or difficult to repair and bleeding uncontrolled.

Figure 4: A – Bakri Balloon Tamponade, B – Uterine Compression B-Lynch Suture, C-Uterine Artery Ligation [102]



Used with permission from Bienstock JL, Eke AC, Hueppchen NA. Postpartum Hemorrhage. New England Journal of Medicine. 2021 Apr 29;384(17):1635–45.

Clinical Question 2.13: Stop the Bleeding
When should hysterectomy be performed?

Evidence Statement

Hysterectomy

Hysterectomy can be a life-saving procedure when interventions to arrest bleeding and/or resuscitation measures to compensate for bleeding are not effective. A recent population-based study of peripartum hysterectomy in nine countries conducted by the International Network of Obstetric Surveillance Systems (INOSS) demonstrated the wide variation in medical and surgical managements utilised before peripartum hysterectomy.[107] The main complications reported during this procedure were haematological (8%), respiratory (7%), genitourinary (4%) and cardiovascular (4%). 60% of the women were admitted to ICU and the mortality rate was 1%.

In the rare circumstances where hysterectomy has been performed and arterial bleeding has been controlled, but there is continuing blood loss from the pelvic sidewall from venous ooze and/or coagulopathy, pelvic packing can be effective in stabilising the women, allowing for correction of DIC. This method has been described in cases where the uterus has been conserved also. [204]

Clinical Practice

In the absence of clear guidelines, timing of the hysterectomy presents a critical challenge for the obstetrician. If performed too early, the uterus may have been unnecessarily removed and if too late, morbidity and possibly mortality may occur. It is good practice to obtain a second opinion from another consultant obstetrician before proceeding to hysterectomy, but in the event of life-threatening haemorrhage, this may not always be possible. Likewise, the woman and her partner's preferences, in terms of retaining fertility, should be considered in the decision making if possible, and both should be informed and supported by appropriate staff during the event. The uterus should be sent for detailed pathological examination with clear communication of the clinical details. The pathologic examination of the uterus in cases of PAS in outlined in the PAS Guideline.

Clinical Question 2.14: Stop the Bleeding
What is the role of interventional radiology in PPH?

Evidence Statement:

The following statement pertains to the role of interventional radiology in the emergency PPH setting. The role of interventional radiology in preventing PPH in the setting of PAS is discussed in detail in the PAS Guideline.[38]

Pelvic artery embolisation

Pelvic artery embolisation (PAE) for PPH, first described in 1979, performed by interventional radiology (IR) specialists, is an evolving alternative to surgical treatment when PPH, of most aetiologies, is not responding to conservative and minimally invasive management. In general, embolisation is limited to haemodynamically stable patients who desire future fertility with ongoing blood loss/transfusion requirement. Clearly this is institution dependent as IR facilities and expertise are not available in all institutions. In experienced centres with a rapid response team, more aggressive utilisation of embolotherapy may be considered even in unstable patients with DIC.

A recent systematic review and meta-analysis including retrospective studies and 1274 PPH cases between 1979 and 2020 reported a success rate of 90.5% with this procedure.[108] The commonest indications for PAE were uterine atony, placental abnormalities and uterine trauma. A variety of occlusive materials were utilised and a variety of vessels were targeted. Procedure failure was more common when associated with DIC, haemodynamic instability, haemorrhage from a vessel other than the one occluded, genital tract trauma and uterine atony. Most women who experienced procedure failures responded to hysterectomy or repeat PAE and the overall mortality rate for PPH treated with PAE was 0.9%.

Complication rates of PAE are low and most commonly related to rebleeding and failure to control haemorrhage (5-10% depending on PPH aetiology). With evolving techniques tissue infarction and specifically, uterine infarction is a very rare but serious complication necessitating hysterectomy. There have been reports of ovarian failure, but recovery of menses is reported in 91 to 100% of women and the subsequent pregnancy rate may be slightly lower compared to the general population.[109] Of interest, the PPH risk in a subsequent pregnancy was 23%, necessitating hysterectomy in 16.7% of cases because of placenta accreta.[110]

One small study (23 women) compared radiological uterine artery embolisation with surgical devascularisation of the uterus combined with the use of a B-Lynch suture. There was no difference between the studies in the risk of hysterectomy or other side effects; however, major methodological limitations precluded firm conclusions. [111,112]

Balloon occlusion of the aorta (BOA)

Balloon occlusion of the aorta has been successfully used in the management of exsanguinating haemorrhage due to trauma.[113] BOA involves the placement of an inflatable balloon within the aorta to gain proximal control of haemorrhage. Correct placement is confirmed either by fluoroscopy or ultrasound. Alternating cycles of inflation and deflation reduce blood loss, while preventing organ ischaemia. BOA can be a lifesaving intervention, however major complications, including limb ischaemia and vessel dissection, have been reported. Case series have described the prophylactic use of BOA in the management of deliveries in women with PAS disorder.[114] Emergent use in PPH has also been described.[115] It allows time for other definitive measures to be effective. However, BOA is a resource-intensive intervention requiring significant skilled expertise, thus limiting use to major centres. At present, BOA cannot be recommended for routine use in the treatment of PPH.

Clinical Practice

PAE can be an effective treatment for PPH but depends on timely access to the appropriate resources and expertise.

Recommendations – Management: Stop the bleeding

30. A staged approach to PPH response is recommended with escalation of care depending on blood loss and clinical concerns.
31. We recommend that each Maternity unit implement the NPEC/NWIHP-documented pathway checklist for PPH management with local agreed modifications.
32. Standard components of initial uterine atony management should include uterine massage, insertion of an indwelling catheter and a check of the completeness of the placenta and membranes.
33. Oxytocin is recommended as the first-line PPH treatment, either as a slow IV bolus or infusion. It is preferable to administer oxytocin using a controlled infusion device.
34. We suggest that ergometrine is administered as the second line uterotonic for PPH treatment (in the absence of contra-indications) followed by either misoprostol or carboprost depending on the clinical circumstances Table 6.
35. Each obstetric unit should have a clear local policy on uterotonic use in PPH treatment, providing suggested drug sequences and dosing recommendations that may be individualised.
36. Tranexamic acid is recommended early during PPH treatment.
37. The most appropriate surgical intervention should be determined by the cause of PPH, the haemodynamic stability of the woman, the available surgical expertise and access to supportive services (such as imaging and interventional radiology).
38. Hysterectomy should be considered when interventions to arrest bleeding and/or resuscitation measures to compensate for bleeding are not effective. Efforts should be made to obtain a second opinion before proceeding to hysterectomy if feasible in a timely manner.

Management: Resuscitation

Clinical Question 2.15: Resuscitation
What are the key guiding principles in the resuscitation of a woman with PPH?

Evidence Statement

This section will discuss optimal resuscitation and management of the woman with postpartum bleeding. The evidence to support the various components of care will be explored.

Management of PPH consists of obstetric and haemostatic interventions to stop bleeding and fluid resuscitation to prevent and treat hypovolaemic shock. There is a paucity of high-quality data (randomised trials) evaluating resuscitative and transfusion strategies in PPH. In some cases, planned RCTs have been suspended because of recruitment failures (including the PERFECT PPH USA trial [116],which intended to evaluate the early administration of 3g of fibrinogen). Protocol adherence has been challenging in others (ACROBAT UK) [117] and studies have been underpowered. Instead, protocols have been developed by consensus among obstetricians, anaesthetists and haematologists.[118]

Clinical Practice

There are some key principles to guide clinical practice

RESUSCITATION: Key guiding principles	
1	Prompt and aggressive treatment of PPH leads to improved outcomes.
2	Recognition and communication that a PPH is ongoing is crucial.
3	A composite of signs and symptoms should be evaluated. Severe blood loss can be abrupt and is often underestimated at delivery. Increased circulating maternal blood volume may also initially mask the physiological signs of significant blood loss. Do not await laboratory results prior to transfusing in the face of significant blood loss.
4	Institutions should have emergency blood release and MOH protocols in place. In life-threatening emergencies, when crossmatched blood is not available use un-crossmatched O RhD negative blood.[119](or as guided by haematology/transfusion where antibodies are detected). Were time permits group specific/crossmatched blood should be transfused.
5	The decision to transfuse is guided by multiple factors. This includes an estimate of blood loss, patient stability, likelihood of further bleeding and haematological parameters (laboratory and near patient testing).
6	Ensure patent large bore IV access during resuscitation. Resuscitative fluids should be warmed, as should the patient's environment to maintain normothermia. The coagulopathy associated with major haemorrhage may be exacerbated by hypothermia and acidosis.
7	During massive transfusion, frequent monitoring of arterial blood gases, electrolytes, haematological and coagulation indices should be performed. Intravenous calcium replacement will often be necessary in massive blood transfusion.

Clinical Question 2.16: Resuscitation
What is the optimal use of crystalloid and colloid during resuscitation for PPH?

Evidence Statement

Crystalloid and colloid administration

Crystalloid administration is used to restore circulating blood volume either as a sole therapy or pending administration of blood products. Guidelines suggest administration of up to 2L of warmed isotonic fluid, with careful consideration of a further 1500 ml (while awaiting blood products). [17,120] However, excessive use of "clear fluids" may be deleterious. Excessive "clear fluid" administration (> 4L) was associated with adverse maternal outcomes and dilutional coagulopathy in a large retrospective Dutch study of women who suffered a severe PPH. [121,122] Restrictive crystalloid administration, therefore, should be considered in severe ongoing PPH. [123]

Use of pressors and hypotensive resuscitation

Use of pressors (ephedrine, phenylephrine and noradrenaline) to manage hypotension while concurrent resuscitation is ongoing to correct hypovolaemia is a frequently practised clinical strategy. Benefits include maintaining cerebral perfusion to prevent syncope and preventing nausea and vomiting. An opposing strategy is the use of hypotensive resuscitation to limit bleeding until haemostasis has been achieved. [124] This is typically poorly tolerated by conscious patients. Neither strategy has been rigorously evaluated in PPH. [124]

Clinical Question 2.17: Resuscitation
What is the optimal use of blood products in PPH?

Evidence Statement

Empirical Blood Transfusion

Empiric blood transfusion protocols have been established to assist timely access to blood components in major haemorrhage[125]. Delayed blood transfusion is the second most frequent cause of transfusion associated death.[126] However, it is recommended that transfusion resuscitation is guided by laboratory blood science or near patient testing results as soon as possible. Point-of-care technologies can provide early feedback about coagulation changes during PPH and may be more advantageous than protocol-directed transfusion, which has been implicated in over-transfusion. Collins *et al.* achieved restrictive FFP administration for PPH when guided by viscoelastic tests, and this was not associated with poorer outcomes. [127] In the trauma setting, transfusion of fixed ratios of plasma to red blood cells has been associated with decreased mortality due to exsanguination.[128] It remains unknown whether these approaches can be extrapolated to PPH management due to a lack of high-quality data. The availability of blood components and the suggested timing of their administration are highlighted on the National MOH poster (page 7) which should be customised and implemented at each individual maternity hospital site.

Blood Components

Early and continuous haemostatic resuscitation is recommended. Early empiric management has been advocated in the setting of life-threatening haemorrhage (arising from experience in trauma) and in the presence of placental pathology. Such protocols have been associated with a reduction in the usage of red cell and platelet components but conversely, with an increase in plasma usage. [129] With appropriate storage, the current plasma post-thaw shelf life of 5 days should enable minimisation and management of plasma wastage.

Targeted therapy guided by laboratory/NPT results should be introduced as soon as possible as the pattern of haematological changes and coagulopathy varies dramatically, depending on the aetiology of bleeding. For example, uterine atony may not be associated with coagulopathy, while rapid and profound fibrinogen consumption may characterise bleeding due to placental abruption. Obstetric haemorrhage may therefore present very differently to trauma-associated bleeding, and extrapolation of management principles may therefore not be appropriate. It is crucial to consider local laboratory test turn-around times (TAT), as longer TATs challenge management and may warrant consideration of empiric use of blood components (including plasma and fibrinogen) if coagulation test results are delayed and if severe prolonged bleeding is ongoing. Conversely, units providing very short TATs will be able to deliver care directed by laboratory results from a very early stage in the PPH journey, and empiric use of major haemorrhage pack may be unwarranted. In some scenarios, coagulation tests may not become abnormal even during very large bleeds.[130] Awareness of ethnic diversity is crucial: for example, an increased risk of PPH has been reported with Asian ethnicity [17] amongst whom blood group B is more common than in the general Irish population.

The “Post Partum Life Threatening Haemorrhage Protocol Poster” (page 4) indicates the availability and timeline to access specific components at each individual maternity site.

A recent Welsh study reported that 80% of patients required a red cell transfusion, while almost 30% received at least one other blood product at MOH of ≥ 2500 ml (OBS Cymru review).[131] In women who required ≥ 8 red cell unit transfusions after MOH, more than 99% were transfused with plasma and 77% with platelet components (UKOSS review).[132] The aetiology of MOH differed between these studies: in the former, genital tract trauma was the predominant cause, while in the latter it was uterine atony.

A national standardised ‘Massive haemorrhage pack (MHP)’ of 4 red cell components and 4 adult therapeutic doses of plasma has been introduced for unexpected intra-operative LTH. Depending on clinical presentation, local pathways, resources, laboratory test TATs and availability of NPT, these packs may be required in some units or circumstances for obstetric LTH. It is acknowledged that such empiric transfusion may not be required in all cases or obstetric units.

Red Blood Cells Components

It is reasonable to aim for a target haemoglobin of > 8 g/dl. [125] In a 2021 study, of the 80% of patients with MOH ≥ 2500 ml who required transfusion with red cell components, almost 32% required ≥ 4 units of red cells, 16% ≥ 5 units, 11% ≥ 6 units and 4.6% required ≥ 8 units.[131] Placenta accreta, in particular, was associated with the requirement for > 20 units.[20] All but one obstetric unit in Ireland has a transfusion laboratory on site. However, this unit has access to an on-site haemo-bank.

All obstetric units should maintain a supply of Group O, Rh D negative and Kell negative blood for emergency use.[17] This should be immediately accessible to the labour ward or theatre within 10 minutes. Where blood has been crossmatched in advance, to manage an anticipated risk for an individual patient, those units should be accessed. For other patients, red cell transfusions should be switched from emergency to group-specific when available, then to crossmatched blood when laboratory testing is completed. The timeline to availability will depend on whether there is a valid sample in the laboratory or whether a fresh sample is required.

Each institution should identify the timeline to availability of emergency red cell components, group-specific red cell components and crossmatched red cell components both for elective and 'out of hours' work. The timeline to access O Rh D negative emergency blood is within 5 minutes for most maternity units in Ireland, between 10 to 30 minutes for group specific blood; and between 40 to 50 minutes for crossmatched blood (personal communication; Dr J Power). The timeline to delivery of the first red blood cell component was shorter in a recent UKOSS review for weekday elective CS (provided at a median of 15 minutes) compared to weekday non-elective CS (median 43 minutes) and out of hours CS (median 56 minutes). [132]

Where red cell antibodies are detected the timeline may be several hours and haematology/transfusion advice should be sought on the most appropriate emergency/interim red cell components.

Fibrinogen

Fibrinogen should be maintained at >2 g/l. A therapeutic dose of 4g increases plasma fibrinogen concentration by approximately 1 g/l in the steady state. Fibrinogen levels in pregnant women at term are typically higher than non-pregnant patients, at ~4-6 g/l, compared with levels of 2-4 g/l in non-pregnant patients.[133]

Fibrinogen plays a key role in the final stage of blood clot formation. Hypofibrinogenemia is the most frequently observed coagulation deficit during PPH. Crucially, fibrinogen levels drop earlier than other coagulation factors during obstetric haemorrhage.[134] Hypofibrinogenemia may be particularly profound and life threatening in the setting of placental abruption, amniotic fluid embolism and uterine inversion. A plasma fibrinogen level of ≤2 g/l is associated with progression of bleeding, increased RBC and blood component requirement and an increased need for invasive procedures.[135,136]

During MOH/life threatening obstetric haemorrhage, hypofibrinogenemia is strongly associated with larger bleeds. The French "FIDEL" RCT reported fibrinogen levels of > 3 g/l in 90% of patients with PPH volumes ≥ 500 ml and conversely, fibrinogen levels of < 2g/l in only 1% during 2-hourly monitoring.[19] These observations were consistent with Cortet's report of the PM11A-GOREG study of >700 women in French maternity units experiencing >500 ml PPH volumes after vaginal birth, excluding those requiring surgical intervention and those with abnormal placentation. In this study, the mean (SD) fibrinogen level was 4.2 (1.2) g/l. When PPH became severe, the mean (SD) fibrinogen level reduced to 3.4 (0.9) g/l. Moreover, the fibrinogen level was associated with the severity of PPH, independently of other factors (adjusted odds ratio (aOR) 1.9, 95% CI 1.16-3.09 for a fibrinogen level between 2-3 g/l and aOR 11.9; 95% CI 2.56-56.06 for fibrinogen level of < 2 g/l). [137] McNamara *et al.* reported a reduced fibrinogen level in 23% of women with a PPH volume of ≥ 1500 ml [138] and Lascia *et al.* reported a reduced fibrinogen level in 52% of patients who required a transfusion of ≥ 8 red cell components (along with a platelet count of <50 x10 ^{9}/l in 16% of women and a PT ratio >1.5 in 18% of women).[139] Bell *et al.* reported on patients who had experienced a similar volume of blood loss (≥2,500ml and/or a ≥ 5 unit red cell transfusion) in a prospective Welsh cohort study and noted that a fibrinogen level of < 2 g/l was found in 17.1% of patients, rising to 80.8% of the 16 women who received ≥ 8 units of red cells. [131] Similarly, Green *et al.* on behalf of UKOSS, reported that the median fibrinogen level fell to < 2 g/l in all women who required a transfusion of ≥ 8 units of red cell components for bleeding. Patients experiencing placental abruption and placenta accreta were reported to have median fibrinogen levels of 0.7 g/l and 1.5 g/l, respectively.[132]

Zaidi *et al.* undertook a systematic review to assess whether early fibrinogen replacement (within 90 minutes of a bleed commencing) improves outcomes in severe PPH (defined in this study as an estimated blood loss of ≥ 500 ml). They identified 5 RCTs (2 completed, 2 in progress and one suspended) and concluded that there was insufficient evidence that early administration of fibrinogen in PPH reduces the need for allogeneic blood transfusion at 24 hrs or improves other outcomes.[140] Of these, the completed studies were underpowered (FIB-PPH by Wikkelso *et al.* and OBS2 by Collins *et al.,* which reported

on fibrinogen doses of 2g and 1g, respectively).[141] The FIDEL study, although underpowered, did not demonstrate a significant difference in the risk of a ≥ 4 g/l drop in haemoglobin or the risk of requiring a transfusion of at least 2 units of red cell components in 48 hours following early administration of 3g of fibrinogen.[19]

Fibrinogen is available as a pooled concentrate in Ireland. There are two products currently available, termed 'Riastap' and 'Fibryga'. Fibrinogen concentrate has several advantages over cryoprecipitate for the treatment of hypofibrinogenemia, namely rapid reconstitution and superior dose (component to component, batch to batch) predictability.[142] While cryoprecipitate contains coagulation factors in addition to fibrinogen, this component requires thawing and a median 180 minutes delivery time has been reported.[143] Moreover, cryoprecipitate is not available in obstetric units in Ireland.

Plasma

During management of MOH, the prothrombin time (PT) and activated partial thromboplastin time (APTT) should be maintained at < 1.5 times the upper limit of the normal range. The PT and APTT may be shortened in the pregnant and postpartum woman compared with the non-pregnant patient.[144] A prolonged PT or APTT has been identified in as few as 3.4% of patients experiencing MOH, rising to 36% in situations where ≥8 units of red cell transfusion are required.[131]

In Ireland, Plasma is a 200 ml frozen pooled fractionated solvent detergent (SD) treated product (SDP – Octaplas LG), currently sourced from Austrian donors. This must be thawed for clinical use with a 20-40 minutes thaw time, which varies by technology. The current post-thaw shelf life is 5 days. It is unclear whether plasma administration improves outcomes in PPH. [145] However, plasma administration may be considered after transfusion of four red cell components, in situations where a woman is experiencing prolonged bleeding, where coagulation tests are not yet known or delayed or in conditions associated with the development of a coagulopathy (placental abruption, amniotic fluid embolism).[17] Another consideration is that the use of plasma may cause a paradoxical dilutional hypofibrinogenaemia in obstetrics.

Platelets

We recommend that care providers aim to keep the platelet count >50 x10 ^{9}/L. Platelet components should be ordered when the platelet count falls below 100 x10 ^{9}/L and transfused when the count falls below 75 x10 ^{9}/L, in order to maintain this target platelet count. Suggested indications for empiric platelet transfusion are rare but may include cases with pre-existing thrombocytopenia, haemorrhage with consumptive coagulopathy and blood loss greater than 5000ml (if the availability of FBC results are delayed). [17] The incidence of thrombocytopaenia in women experiencing PPH is low[146] and is a later feature. In one retrospective study, platelet transfusion was more likely in women who had evidence of pre-delivery thrombocytopaenia or consumptive coagulopathy (which is commonly associated with placental abruption and amniotic fluid embolism).[146] A recent study reported thrombocytopenia (with a median platelet count of 75 x10 ^{9}/L) in all PPH scenarios (other than trauma) in which ≥ 8 red cell components were transfused within 24 hours of delivery.[132] In Wales, 5% of patients experiencing a ≥2500 ml MOH were found to have a platelet count of < 75 x10 ^{9}/L, rising to 36% in women who required a blood transfusion of at least 8 units. [131] In another study from the Australian and New Zealand registry, 16% of patients with MOH requiring ≥ 8 units of red cells had a platelet count of < 50 x10 ^{9}/L. [139]

Of particular note, platelet components are not available at all maternity sites and the additional time required to bring on-site has to be considered where they are not immediately available and where additional platelet components may be required – see local hospital version of national poster (page 4). Platelet components from the IBTS have a shelf life of 7 days. IBTS is developing a programme to make available Whole Blood which has evidence of platelet function for immediate haemorrhage control for up to 3 weeks of refrigerated storage. This component will be considered for distribution to maternity hospitals.

Table 10: Target results (use pregnant reference ranges for plasma targets)

Test	Target	Intervention
Hb	**> 8 g/dl**	**Blood transfusion**
Plt	**> 50 x 10^9/l**	**Platelet transfusion (triggered if <75 x 10^9/l)**
Fibrinogen	**> 2 g/l**	**Fibrinogen 4 g**
PT	**< 1.5 x mean normal**	**FFP 12-15 ml/kg**
APTT	**< 1.5 x mean normal**	**FFP 12-15 ml/kg**

Recombinant factor VIIa

Recombinant factor VIIa is licensed for the treatment of bleeding in patients with specific inherited bleeding disorders. There are limited data to support its use off-label in LTH, and its use is associated with an increased risk of thrombosis. [147] The off-label use of recombinant factor VIIa should be minimised and used only in collaboration with a haematologist, or in the setting of a clinical trial. [148]

Acid-base balance, electrolytes and body temperature

During massive transfusion, arterial blood gas and electrolytes have to be monitored carefully and corrected. Body temperature should be maintained by warming of infusions. Hypocalcaemia is a frequently observed electrolyte disturbance in massive transfusion. Transfused red blood cells and plasma contains citrate that chelates serum calcium. Calcium is necessary for optimal coagulation and cardiac function and may optimise uterotonic action. In a series of women undergoing caesarean hysterectomy for PAS, blood loss >1500 ml and transfusion of ≥4 units of packed red cells was associated with severe hypocalcaemia. [149] Ionised calcium levels can be readily measured by blood gas analysers to guide calcium replacement with the aim of maintaining the level above 1 mmol/L.

Clinical Question 2.18: Resuscitation
What is the role of cell salvage in PPH?

Evidence Statement – Cell Salvage

Cell salvage is a process whereby blood is collected from the surgical field, filtered and transfused back to the woman. It has been proposed to reduce the demand on the national blood supply.[150] Concerns about its use in obstetrics include the possibility of amniotic fluid embolism and maternal alloimmunisation. Modern cell savers that incorporate a leucocyte depletion process appear to minimise the risk of amniotic fluid embolism (but at the potential cost of prolonging operational time. [151,152] Maternal alloimmunisation can potentially occur because the cell saver cannot differentiate between maternal and fetal red cells.

However, the fetal cell transference rate in salvaged blood is of the same magnitude as during a feto-maternal haemorrhage.[153] This can be treated by appropriate administration of anti-D immunoglobulin.

A large 2018 UK RCT reported that it would cost an additional £8110 to avoid a donor blood transfusion through cell salvage compared with standard care. [152] At that time, cell salvage was used in 15% of MOH cases requiring ≥8 units of red cell components, mainly associated with elective CS, and provided a median of 835ml (IQR 400-1560ml), while in Wales, some 11% of women with MOH ≥2500 ml had salvaged blood transfused with a lower median volume of 300 ml (range 200-489.5).[131] In the latter cohort, 81% also received a red cell transfusion and 45% coagulation components.

Clinical Practice

Cell salvage is available in 3 of the 4 Irish maternity units with >6000 deliveries per annum. In the fourth, it is used in the co-located hospital theatre, however, not for obstetrics. It is available for obstetric use in a further Irish maternity unit with >4000 deliveries per annum. These are managed by speciality theatre staff and as a consequence, are limited by staff availability. Use of cell salvage may be considered, under appropriate governance, in elective cases where high-risk patients have noted their refusal to receive a blood transfusion (however may also refuse non-continuous cell salvage), and for patients with red cell antibodies where the provision of compatible antigen negative donor blood is particularly difficult. Its use in emergency situations would require 24-hour availability of trained staff. There is not enough evidence to mandate the financial and staffing resources that this would demand.

Clinical Question 2.19: Resuscitation
What is the role of TXA in the management of PPH?

Evidence Statement – Tranexamic acid

As discussed in section 2 prevention, the WOMAN multicentre multinational RCT enrolled 20,060 women with a clinical diagnosis of PPH after a vaginal birth or CS in 21 countries and demonstrated a reduction in a pre-specified secondary endpoint, death due to bleeding, in women randomised to TXA compared with placebo (1.5% and 1.9% respectively; (RR 0.81, 95% CI 0.65-1.00), particularly when TXA was given within 3 hours of birth (RR 0.69, 95% CI 0.52-0.91).[81] The primary endpoint (all-cause death or hysterectomy within 42 days of birth) was similar in both TXA and placebo groups. In this trial, TXA was administered as an infusion of 1g over 10 minutes. A further 1g could be administered if bleeding persisted after 30 mins or recurred within 24 hours. Although the generalisability of the WOMAN trial to well-resourced settings is unclear, consideration of TXA use in the treatment of PPH is recommended by international guidelines.[15,17] Higher TXA doses have been associated with seizures when given during cardiac surgery.[154] Higher doses are also associated with seizures and increased venous thromboembolic risk when given to patients with upper GI bleeds.[155] Accidental intrathecal administration causing seizures and death due to drug substitution errors have also been reported.[156] Dose-optimisation studies in PPH are currently ongoing.

Clinical Practice

The WHO recommends early treatment (within 3 hours of birth) with a fixed TXA dose of 1g intravenously in women with PPH following vaginal or Caesarean section.[157] A second dose may be given if bleeding continues after 30 mins or if bleeding restarts within 24 hrs of completing the first dose.

Clinical Question 2.20: Resuscitation
What is the role of Point Of Care coagulation testing in PPH?

Evidence Statement

Point of care coagulation testing

Viscoelastic haemostatic assays (VHA) are increasingly used in the management of intraoperative and trauma-related bleeding. Commonly used commercial systems include TEG® and ROTEM®. Potential advantages, compared with conventional coagulation testing, include whole blood analysis, additional characterisation of coagulation parameters, and quicker turnaround times. Trials in cardiac surgery have suggested reduced transfusion rates and major bleeding events with the use of VHA.[158] However, definitive evidence of clinical benefit is lacking. A recently published multicentre trial found no evidence of benefit when major transfusion protocols in trauma patients were managed according to VHA-based algorithms.[159]

VHA has also been used in the management of PPH.[160] It has the potential to quickly identify hypofibrinogenaemia[161] and hyperfibrinolysis [162] that may be implicated in PPH.[162] This can enable targeted treatment and avoid unnecessary blood product administration. Introduction of a PPH care bundle incorporating VHA demonstrated improved clinical outcomes in Wales.[163] However, consistent evidence of the benefit of VHA-based treatment in PPH is lacking.[164] Issues with VHA include the requirement for pregnancy-specific reference values and the need for evidence-based transfusion algorithms guided by these results.[162] Other limitations include the expense of acquiring and maintaining these machines and the need for expertise and experience in using them.

Clinical Practice

Some guidelines give a qualified endorsement of VHA use in PPH. [17,165] However, consistent evidence of the benefit of VHA-based treatment in PPH is lacking.[164] Further studies are required before widespread adoption of VHA into obstetric bleeding algorithms.[166] Compliance with national guidelines should be in place where these are applied. It is reasonable, however, that units that have successfully integrated VHA use into their PPH pathways continue to do so.

Clinical Question 2.21: Resuscitation
What is the optimal anaesthesia to administer in the management of PPH?

Considerations for Anaesthesia

Evidence Statement:

PPH is commonly encountered and managed in the operating room. This may occur in the context of a Caesarean section or an ongoing haemorrhage requiring surgical intervention. The decision whether to proceed under general or regional anaesthesia is often not straightforward. A reasonable initial strategy is to proceed under regional anaesthesia if already established and effective. Anaesthetic induction and positive pressure ventilation can present a significant physiologic challenge to the parturient with haemorrhagic shock. This is without considering the well-recognised difficulties of the maternal airway.[167] However, massive blood loss is unlikely to be tolerated in the conscious patient due to agitation and loss of consciousness. Most cases of PPH in the operating room will be managed using regional anaesthesia

alone. [168] The ultimate responsibility for this decision rests with the most senior anaesthetist following clinical assessment and consultation with the most senior obstetrician. Total intravenous anaesthesia compared to the volatile anaesthetic agents may be associated with reduced uterine atony.[168] How this impacts PPH outcomes is uncertain.

Recommendations – Management: Resuscitate

39. Restrictive crystalloid administration < 3.5L is suggested during severe ongoing haemorrhage.
40. The use of blood components should be guided by the clinical situation and should not be delayed while awaiting laboratory results. Access emergency/patient specific red cell support immediately and refer to the national MOH/LTH poster.
41. Platelet components should be ordered at a platelet count of 100 x 109/l. Platelet transfusion should be given when the platelet count falls <75 x 109/l, in order to maintain a count >50 x 109/l. Early platelet transfusion should be considered for abruption and abnormal placentation. Order early from IBTS where not available onsite.
42. A plasma fibrinogen level of > 2 g/l should be maintained by administration of fibrinogen concentrate.
43. Empiric early fibrinogen replacement may be considered if the fibrinogen result (or Viscoelastic haemostatic assay (VHA) equivalent) is not rapidly available, especially in the setting of placental abruption/praevia or amniotic fluid embolism.
44. VHA may be considered in the management of PPH if local resources and governance structures permit.
45. Cell salvage may have a role in the management of PPH in selected cases, if local resources and governance structures permit.
46. There is no evidence favouring either general or regional anaesthesia in postpartum haemorrhage management in the operating room.

PART 4: MANAGEMENT; COMMUNICATION

Clinical Question 2.22:
What is the role of communication in PPH?

Each maternity unit should develop and have their documented policy and associated protocols, documentation, defined roles and responsibilities, blood component and pharmaceuticals location/availability, reporting and review processes readily available locally, incorporating these guidelines and the national life-threatening PPH poster (massive obstetric haemorrhage, code red – obstetrics) customised to their hospital circumstances. This poster should be prominently displayed in each labour ward/theatre.

Teamwork and communication are essential for quality healthcare and patient safety. The successful management of a woman with PPH requires multiple sources of expertise and healthcare providers from different professional backgrounds working together as a team to manage a potentially life-threatening situation.[169] Effective teamwork has been shown to reduce medical errors, increase patient safety and improve patient mortality rates. It also leads to better staff outcomes, including reduced stress and improved job satisfaction.[170] The role of the team Emergency co-ordinator during an obstetric emergency is multi-dimensional, requiring strong communication, decision making and management skills. Composed and clear in their direction, they bring logic to the emergency situation with a confident presence noticeable to colleagues and patients. With this situational awareness, they simultaneously assess the patient, escalate care and provide treatment or delegate tasks while communicating with the woman and her support person.[171] Closed-loop communication should be used to ensure communication is understood.

A communication lead is designated by the Emergency co-ordinator who is responsible for communication with support services outside the labour ward/theatre. They should identify themselves and provide their contact number and use closed loop communication throughout.

The team should include midwife in charge, senior obstetric registrar, anaesthetic registrar, senior midwifery staff, obstetric consultant on call, anaesthetic consultant on call, midwife/nurse in charge of OT, blood transfusion laboratory, porters and alert Haematology consultation on call if necessary.

All maternity units should have an effective communication system and an emergency call system in place to prevent a delay between activating a call for a review/help and the arrival of a medical doctor/ multidisciplinary team. The team should use the ISBAR (Identify – Situation-Background-Assessment-Recommendation) technique as a simple way to plan and structure communication. It allows staff an easy and focused way to set expectations for what will be communicated and to ensure they get a timely and appropriate response.[172]

This Guideline highlights the importance of communication with language that is clearly understood by the multidisciplinary team supporting/Life Threatening Obstetric Haemorrhage/code red obstetrics and use of closed loop communication. This recognises that a clearly understood common language/ terminology is required for health care staff rotating between maternity hospitals across the country.

Teamwork and communication can be enhanced with training and drills. Hospital communication pathways and clarity/meaning of terminology should be identified in hospital documentation and national posters. Multidisciplinary drills should include all laboratories supporting PPH.

Communication with the woman

Communication with the woman and her birthing partner is important, and clear information of what is happening should be given from the outset. PPH often occurs unexpectedly and can be very stressful for the woman and her partner or birth attendants; it is crucial that, where feasible, they are kept informed and reassured, if appropriate, of the clinical development and proposed management.

Who should be informed when the woman presents with PPH?

Relevant staff with an appropriate level of expertise should be alerted of PPH. The midwife in charge and the first-line obstetric and anaesthetic staff should be alerted when women present with PPH without clinical shock (**Stage 1**).

A multidisciplinary team involving senior members of staff should be summoned to attend to women when PPH is associated with ongoing bleeding or clinical shock (**Stage 2**). Early involvement of appropriate senior staff (including the anaesthetic team and laboratory specialists) is fundamental to the management of PPH.

A team member should be allocated the job of scribe by the team emergency co-ordinator, if resources permit. The team member recording the events (the scribe) is valuable during the management of PPH and the team leader should communicate with the scribe during the PPH to ensure that no steps have been omitted. It is important to record the names and roles of staff in attendance, the time at which they arrived and the sequence of events.

In the setting of uncontrolled >1500 ml blood loss or where clinical concern exists (**Stage 3**), the consultant obstetrician and consultant anaesthetist should be alerted if bleeding is ongoing, asked to attend, and the blood transfusion laboratory should be informed. One member of the team should be assigned the task of recording events, fluids, drugs, blood and components transfused, and vital signs.

Communication with the laboratories to support management – The timeline to availability of specific blood components is defined for each maternity hospital site on the MOH/LTH poster and should inform the specific request for transfusion and pharmacological support in any individual clinical circumstance. Where PPH escalates to uncontrolled bleeding >1500 ml or there is clinical concern (bearing in mind blood loss may be concealed) the appropriate terminology is *'life threatening haemorrhage/code red obstetrics'*. This informs the pre-agreed local hospital communication process (as captured on the national poster) in unambiguous language and empowers the laboratory in optimising appropriate support.

Clinical Question 2.23: Major Obstetric Haemorrhage
What are the important components of a system's immediate response to MOH?

Clinical Practice

Stage 3 PPH is identified when there is ongoing bleeding associated with > 1500 ml of blood loss or where there is clinical concern bearing in mind blood loss may be concealed.

At this point, a MOH is declared, and there should be rapid communication and mobilisation of the necessary staff and resources. Resuscitation, interventions to stop the bleeding and evaluation of response to treatment are all continuing simultaneously. See algorithm – MOH/LTH poster.

The timeline to availability of specific blood components is defined for each maternity hospital site on the MOH/LTH poster and should inform the specific request for transfusion and pharmacological support in any individual clinical circumstance. Where PPH escalates to uncontrolled bleeding >1500 ml or there is clinical concern (bearing in mind blood loss may be concealed) the appropriate terminology is *'life threatening haemorrhage/code red obstetrics'*. This informs the pre-agreed local hospital communication process (as captured on the national poster) in unambiguous language and empowers the laboratory in optimising appropriate support.

Each maternity unit should develop and have their documented policy and associated protocols, documentation, defined roles and responsibilities, blood component and pharmaceuticals location/availability, reporting and review processes readily available locally, incorporating these guidelines and the national life-threatening PPH poster (massive obstetric haemorrhage, code red – obstetrics) customised to their hospital circumstances. This poster should be prominently displayed in each labour ward/theatre.

STAGE 3

If > 1500 ml uncontrolled blood loss or where there is clinical concern

Noting bleed may be concealed

Act

Activate the MOH/LTH protocol. See MOH/LTH poster

Inform and request attendance of consultant obstetrician and anaesthetist

Communicate current measured blood loss to team

Treat

Review uterotonics

Consider advanced surgical techniques to stop bleeding

Consider repeat tranexamic acid

Review possible causes of bleeding (Four T's)

Recommendations – Management Communication Code Red Obstetrics

47. The major obstetric haemorrhage (MOH) protocol (articulated as CODE RED OBSTETRICS) should be activated for uncontrolled bleeding >1500ml blood loss or if a clinical concern warrants it.
48. Each maternity unit should adopt the nationally agreed term 'life threatening haemorrhage: code red – obstetrics'.
49. Clear communication pathways are recommended to alert all relevant team members and a designated person should coordinate further management. The team should use the ISBAR (Identify – Situation-Background-Assessment-Recommendation) technique as a simple way to plan and structure communication.
50. The woman and her partner should be informed and supported throughout the event.
51. Assignation of a scribe should be considered to document staff present and timing of interventions.
52. The emergency should be stood down when bleeding is controlled or as appropriate with clear communication to all team members including laboratory staff.

PART 4: MANAGEMENT; AFTER THE EVENT.

Clinical Question 2.24: Postnatal care after PPH
What monitoring is required after major PPH?

Evidence Statement:

Monitoring

Following a PPH, when haemostasis has been achieved and initial resuscitation completed, the most suitable location for ongoing care needs to be decided. This decision is ideally a collaborative decision by senior decision makers including obstetricians, anaesthetists and midwives. This location will be determined by ongoing care requirements such as concerns about further bleeding, the need for further intervention, and the requirement for organ support such as ventilation or renal replacement therapy. The resources and comfort of local maternity units caring for the critically unwell mother are also a consideration. [173,174] Larger maternity units and standalone units will have considerable expertise in caring for the stable mother following a PPH locally.[175] This will typically be in a maternity HDU (High Dependency Unit) or on the birthing suite. This area should be capable of managing invasive monitoring and running low-dose vasoactive medication. Clinical care is ideally provided jointly by obstetricians and obstetric anaesthetists. A stable woman following a significant PPH in a smaller unit co-located with a Model 3 hospital may be best cared for in a critical care unit.[176] However, this should be determined by local policy. Women who have suffered a massive PPH requiring large volume resuscitation, who require further intervention for control of bleeding or who require organ support need ICU (Intensive Care Unit) care. Access to this care should be expedited by early direct discussion with a consultant intensivist. They should be admitted under the care of a named obstetric consultant. It is recommended practice that obstetric anaesthetists remain involved in the care of these women while they are in ICU. Fortunately, most women can be cared for locally. This has undoubted clinical and psychological advantages for the mother. This includes ready access to obstetric care and proximity to the baby/babies. In the event of ICU transfer, every effort should be made to foster the mother-newborn bond. Similarly, every reasonable effort (in line with local policies and legal requirements) should be made to ensure the family is kept updated regarding woman's condition.

Clinical Question 2.25: Postnatal anaemia
What is the optimal management of postnatal anaemia?

Evidence Statement

Postpartum anaemia is associated with lethargy, physical weakness, decreased mental alertness and a predisposition to postnatal depression. Transfusion triggers in the stable woman following PPH (without severe symptoms due to anaemia) are unclear. In the non-obstetric setting, restrictive transfusion practices are recommended, i.e. transfusing when the haemoglobin concentration is less than 7 g/dl.[177] A multicentre Dutch study randomised women with postpartum anaemia (Hb ≤ 7.9 g/dl at 12-24 hours after delivery) following a PPH to either receive a blood transfusion or not. [178] This was a non-inferiority trial and the primary outcome was physical fatigue on day 3. Although non-inferiority of the restrictive strategy was not demonstrated, the clinical relevance of this was deemed negligible by the authors. Other outcomes such as breastfeeding rates, infective complications and hospital length of stay were not significantly different between the groups. On this basis, the authors concluded that a restrictive

transfusion policy following a PPH could be justified in stable women without severe symptoms. This is endorsed by international guidelines.[90] A complementary (or alternative) strategy is the use of intravenous iron to treat postpartum anaemia. A large multicentre RCT is currently underway comparing intravenous iron with red cell transfusion in stable anaemic women following PPH.[179]

Clinical Practice

Haemoglobin less than 7 g/dl following a PPH is a trigger for consideration of blood transfusion. Blood transfusion may, however, be indicated at a higher level if there are significant symptoms of anaemia, such as dizziness, dyspnoea and palpitations. Oral iron supplementation is advised for at least six weeks.[33]

Clinical Question 2.26: Thromboprophylaxis
What is the role of thromboprophylaxis and what thromboprophylaxis should be considered after PPH?

Evidence Statement

Venous thromboembolism (VTE) remains a leading cause of death in pregnancy and in the postpartum period.[180] During 2014-2016, VTE was reported to be the top cause of direct maternal death in the UK and Ireland, occurring in 1.39 (95% CI 0.95-1.96) per 100,000 pregnancies.[181] VTE risk is increased in pregnancy through several mechanisms.[180,181] This baseline pregnancy-associated elevated VTE risk is increased in the presence of additional VTE risk factors, including PPH, thus highlighting the crucial importance of repeating a VTE and bleeding risk assessment postpartum.

Several studies with heterogeneous designs and study populations have suggested an increase in pregnancy-associated VTE risk following obstetric haemorrhage and blood transfusion.[182–186] A population-based US case-control study included women who had experienced a documented first lifetime VTE during pregnancy or the postpartum period (defined as birth of a newborn within 3 months before the VTE event).[182] In this study, PPH was associated with a 9-fold increased VTE risk upon univariate analysis, compared with no PPH (OR 9.00, 95% CI 1.14-71.04). The OR for VTE following blood transfusion was non-significantly increased (OR 5.00, 95% CI 0.58-42.80). A subsequent retrospective population-based study utilising data from a large US database reported an association between PPH and VTE (OR 1.3, 95% CI 1.1-1.6) and also between blood transfusion and VTE (OR 7.6, 95% CI 6.2-9.4).[183] In a large hospital-based case-control study, the aOR for postpartum bleeding ≥1000 ml not requiring surgical intervention was 4.1 (95% CI 2.3-7.3) compared with bleeding <1000 ml and no surgery. Moreover, an interaction between PPH and surgery was reported: the aOR for postpartum bleeding ≥1000 ml in women who underwent postpartum surgery compared with those with bleeding <1000 ml and no surgery was 12 (95% CI 3.9-36.9).[184] A retrospective cohort study using data from a large UK longitudinal database (the English Clinical Practice Research Datalink (CPRD), linked to Hospital Episode Statistics) reported a significant association between PPH and risk of (confirmed) VTE events, with an incident rate ratio of 2.00 (95% CI 1.35-2.96).[185] Of note, this risk was significant only during the period up to 3 weeks postpartum.

Other international guidelines suggest that all women should have a VTE and bleeding risk assessment repeated in the postpartum period. These guidelines suggest the inclusion of PPH in this risk assessment as a VTE risk factor and, if indicated, that pharmacological thromboprophylaxis (with low molecular weight heparin)[187] should be commenced when haemostasis has been secured and when the overall balance of risks permits commencement.

High-quality data supporting the optimal risk threshold at which thromboprophylaxis should be instituted, along with the optimal duration of anticoagulation, are lacking. International Guideline recommendations are mainly based on expert opinion rather than high-quality evidence. [188–193]

Clinical Practice

PPH is an identifiable risk factor for VTE and the balance of risk of thrombosis and haemorrhage should be carefully assessed, with implementation of the most appropriate thromboprophylaxis as soon as is feasible after delivery.

Table 11: Recommendations: VTE prevention

Recommendations: VTE prevention (summarised in main recommendations)	
1	All women should undergo a formal VTE and bleeding risk assessment in the postpartum period.
2	Refer to the National Guideline on VTE prevention during pregnancy. This Guideline is due for update in 2023.
3	We suggest that pharmacological or mechanical measures to prevent VTE be considered if the woman's VTE and bleeding risk assessment favours this, according to the institutional protocol.
4	If pharmacological thromboprophylaxis is being considered, it should be instituted when ongoing bleeding has been controlled, when haemostasis is secured and when the balance of VTE and bleeding risks is favourable. If pharmacological TPX is indicated but bleeding risk unfavourable mechanical thromboprophylaxis should be considered as an interim measure.
5	The pharmacological thromboprophylactic agent of choice should be low molecular weight heparin, dosed according to product SmPC.
6	We suggest that women be encouraged to mobilise if feasible and to avoid dehydration.
7	Women should be informed of the signs and symptoms of a VTE, and that such an event may occur post-discharge. Women should be provided with a HSE VTE alert card before leaving the hospital. Information on preventing VTE/blood clots: information for patients and families.

Recommendations – Post Event Care

53. A restrictive transfusion policy (Hb < 7 g/dl) may be considered in stable women without severe symptoms following a postpartum haemorrhage.

54. All women should undergo a formal VTE and bleeding risk assessment after haemostasis has been secured (and repeated when the clinical situation changes). Pharmacological and/or mechanical thromboprophylaxis should be considered as appropriate. Multidisciplinary discussion may be required to determine the optimal timing of initiation of pharmacological thromboprophylaxis. Women should be informed of the signs and symptoms of a VTE, and that such an event may occur post-discharge. Women should be provided with a HSE VTE alert card before leaving hospital. Information on preventing VTE/blood clots: information for patients and families.

Clinical Question 2.27:
What other support is important for the woman who experiences PPH?

Evidence Statement

Debrief woman/birthing partner

PPH can be a traumatic event for women and their families. A study of the long-term effect of severe PPH showed that 70% of women experienced unpleasant memories of the birth, and this persisted in 41% of cases with 10% reporting that the impact contributed to relationship difficulties subsequently. [194] An opportunity to discuss the events surrounding the obstetric haemorrhage should be offered to the woman (possibly with her birthing partner) at a mutually convenient time and the earliest opportunity by a senior member of the team who was involved. Follow-up appointments with team consultants should be given to the woman and support partner in major PPH to ensure the woman has the opportunity to discuss events at a later stage and have all questions answered and investigations arranged if necessary. Support from the perinatal mental health service should be offered if needed.[195]

Lactation support: There may be greater difficulty initiating breastfeeding because of anaemia and exhaustion, and a review by a lactation consultant would be of benefit.

Recommendations – Management: Post Event Care

55. There should be debriefing of the staff, the woman, and birthing partner as soon as possible after the event. A further debrief should be offered to the woman and her partner following hospital discharge, usually around six weeks following birth.
56. Documentation of events, and completion of component traceability should be carried out if not completed contemporaneously.
57. MOH should be reported through the hospital clinical incident reporting system.
58. Serious adverse events and serious adverse reactions (SAE/SAR) associated with transfusion/life threatening haemorrhage should be reported to the National Haemovigilance Office (NHO).

PART 5: EVALUATE, ASSIMILATE, AUDIT

Clinical Question 2.28:
What are the important components of a system's response to MOH after the event?

Evidence Statement:

Staff debriefing

Staff debriefing is crucial after a major PPH. It provides a safe forum for the group to discuss and process the experience. Timely debriefing enhances the team members' ability to deal with the events, as well as to challenge what happened, especially if there has been an incident involving serious injury or death. Debriefing can reduce the possibility of emotional harm by talking about what has happened; facts can be reviewed, and misunderstandings corrected. Optimally all team members should be included in debriefing, including staff outside of the theatre or labour ward/laboratory staff. [196]

Documentation

Documentation is important for further clinical management, the provision of safe, quality healthcare and teamwork. The importance of allocating the role of a scribe during the event has been discussed above but, in some cases, there is such a rapid sequence of events or staff shortage that details of the care are not recorded contemporaneously. It is important that this documentation occurs as soon as possible after the event for greater accuracy. The emergency co-ordinator is responsible to assign this role. Documentation of traceability of blood components is a mandatory requirement.[17]

Incident reporting

Uncontrolled PPH > 1500 ml should be notified through the clinical incident reporting system communication with Hospital Transfusion Committee (HTC). Incident reporting after PPH should be notified through the clinical instant reporting system. [197]This should be included in the LTH cases reported to the HTC. Serious adverse reactions and serious adverse events (SAE/R) associated should be reported to haemovigilance system and under a staff debriefing. Staff debriefing can be assisted by technology to include non-theatre staff. Incident review should occur for life-threatening events, including a timeline to provision of transfusion support, communication etc.

Audit

All maternity hospitals should have processes in place for auditing clinical practice and outcomes. [198]There should be a process to provide feedback to team members. Any systems learning should be identified and change effected through communication, education, simulation and engagement with HTC. Hospitals should participate in future national audit.

Staff training (multidisciplinary)

All staff involved in maternity care should receive training in the management of obstetric emergencies, including the management of PPH.[199] Training for PPH should be multidisciplinary and include whole hospital support e.g. laboratory (medical scientists), portering staff etc. iMOET videos. [200]

Local simulation-based education should include drills that train teams to respond to triggers and facilitate a staged based response to PPH. Effective team debriefing should be incorporated into this process. Training of this nature has been shown to improve response times to PPH in the simulated setting [201] and to increase the comfort levels of the team members in managing PPH [202] in observational studies. In the latter study, a reduction in the rate of PPH was noted following the implementation of training. [202]

Recommendations – Audit, Evaluate, Assimilate

59. **Each maternity unit should have processes in place for auditing clinical practice and agreed data set, providing feedback to team members.**

60. **Cases of MOH should be reviewed at local serious incident management team (SIMT) meetings (or similar risk management team meetings), hospital transfusion committee (HTC) and overarching transfusion committees (OTCs) to evaluate the effectiveness of care, treatment and services provided. Systems learning should be identified, and change effected through communication and education.**

Chapter 3: Development of Clinical Practice Guideline

3.1 Literature search strategy

A comprehensive literature review was undertaken, which included national and international publications. The following databases were used to search for literature – Ovid Medline (all) from 2015, EMBASE and Cochrane Database of Systematic Reviews. See Appendix 5 for search terms. This Guideline also comprehensively reviewed and referenced international guidelines on the management of PPH.

3.2 Appraisal of evidence

Following a comprehensive literature review the quality, validity and relevance of the evidence gathered were critically appraised by the Guideline developers under the following headings:

- Study design
- Relevance of primary and secondary outcomes
- Consistency of results across studies
- Magnitude of benefit versus magnitude of harm
- Applicability to practice context

A number of evidence-based recommendations for management of PPH were agreed upon. They have been adapted to reflect care in the Irish healthcare setting.

3.3 AGREE II process

While being developed, the Guideline was assessed using the AGREE II checklist (Appendix 4) as recommended by the Department of Health in the 'How to Develop a National Clinical Guideline: a manual for guideline developers'.[10]

The purpose of AGREE II is to provide a framework to:

1. Assess the quality of guidelines;
2. Provide a methodological strategy for the development of guidelines; and
3. Inform what information and how the information ought to be reported in the guidelines

10 Department of Health (2019). How to develop a National Clinical Guideline: a manual for guideline developers. Available at: https://www.gov.ie/en/collection/cd41ac-clinical-effectiveness-resources-and-learning/

3.4 Literature review

Details of supportive evidence-based literature for the Guideline are reported in chapter two.

The literature was reviewed by members of the Guideline committee depending on their speciality. The following steps were taken to ensure a comprehensive review of the literature with continuous input and discussion between committee members:

- The Guideline committee met to consider the clinical questions to be addressed.
- Committee members were divided into groups and performed literature reviews based on their area of expertise to address the questions for each area;
    - Obstetrics and Gynaecology: B. Byrne, E. Mc Mahon
    - Anaesthetics: N. Barrett, A. Spring.
    - Haematology: F. Ní Ainle, J. Power, C. Houstoun, R. Faryal
    - Radiology: D Brophy
    - Midwifery: C. Manning
    - Literature search: P. Murphy
- The Guideline committee met regularly to discuss the recommendations for each area
- Where there was no evidence to support certain recommendations, these were made based on group consensus and committee expertise
- The final draft of the Guideline was reviewed by all committee members.

3.5 Grades of recommendation

GRADE offers a transparent and structured process for developing and presenting evidence summaries and carrying out the steps involved in developing recommendations.[203] While we acknowledge that for this particular work an extensive GRADE approach is not possible, we have used the suggested language set out in the GRADE table when making recommendations.[11] (Appendix 6)

3.6 Future research

Resourcing and conduct of large, adequately powered RCTs in women's health must be prioritised by funding agencies and policymakers, as the current availability of mainly poor-quality data to support most aspects of PPH care represents a clinical risk. An important outcome of the Guideline development process is highlighting gaps in the evidence base. There is more evidence in the prevention of, rather than treatment of PPH and, even in this area, results are difficult to interpret because of background variations in clinical practice. An example is the research in the AMTL, where uncertainty persists about the value of uterine massage and controlled cord traction, both standard midwifery practices for decades. Debate continues about the impact of using oxytocin instead of syntometrine as prophylaxis for PPH, and the dosing of oxytocin for elective and emergency CS. Evidence-based research in the treatment of PPH is limited. The optimum sequence of uterotonic administration, the role viscoelastic haemostatic assays (VHA) to guide transfusion and the role of interventional radiology remains unclear.

11 SMFM adopts GRADE (Grading of Recommendations Assessment, Development, and Evaluation) for clinical guidelines. Society for Maternal-Fetal Medicine (SMFM), Chauhan SP, Blackwell SC. Am J Obstet Gynecol. 2013 Sep;209(3):163-5. doi: 10.1016/j.ajog.2013.07.012. PMID: 23978245 https://pubmed.ncbi.nlm.nih.gov/23978245/

During the preparation of this document, we identified current research that may have clinical applications.

1. The role of TXA in the prevention of PPH
2. The optimal clinical application and cost-effectiveness of carbetocin
3. Whole blood for transfusion in an emergency situation.
4. VHA role in PPH algorithms

Chapter 4: Governance and Approval

4.1 Formal governance arrangements

This Guideline was written by the Guideline Developers under the direction of the Guideline Programme Team. An Expert Advisory Group was formed to review the Guideline prior to submission for final approval with the NWIHP. The roles and responsibilities of the members of each group and their processes were clearly outlined and agreed.

4.2 Guideline development standards

This Guideline was developed by the Guideline Developer Group (GDG) within the template of the HSE National Framework[12] for developing Policies, Procedures, Protocols and guidelines (2016) (Appendix 7) and under supervision of the Guideline Programme Team (GPT).

A review was conducted by a group of experts, specialists and advocates (the EAG) prior to approval by the Clinical Advisory Group (CAG) of the National Women and Infants Health Programme (NWIHP) with final sign off for publication by CAG Co-Chairs, the Clinical Director of NWIHP and the Chair of the IOG. See appendix 8 for list of CAG members.

4.3 Copyright/Permission sought (if applicable)

This Guideline sought permission to replicate the images of how to insert a Bakri balloon and how to perform an Internal Iliac Artery ligation from the New England Journal of Medicine. from the following publication;

Bienstock JL, Eke AC, Hueppchen NA. Postpartum Hemorrhage. New England Journal of Medicine. 2021 Apr 29;384(17):1635–45.

12 Health Service Executive (2016). National Framework for developing Policies, Procedures, Protocols and Guidelines (PPPGs). Available from: https://www.hse.ie/eng/about/who/qid/nationalframeworkdevelopingpolicies/

Chapter 5: Communication and Dissemination

A communication and dissemination plan for this Guideline has been developed by the GPT and endorsed by NWIHP.

Effective ongoing clear communication is essential in explaining why the Guideline is necessary and securing continued buy-in. It provides an opportunity to instil motivation within the staff, helps overcome resistance to change and gives an opportunity for feedback.[13]

The Clinical Guideline will be circulated and disseminated through the GPT as well as through the professional networks that participated in developing and reviewing the document.

Senior management within the maternity units is responsible for the appropriately disseminating new and updated guidelines. Local hospital groups, including Guideline committees, hospital transfusion committee are also instrumental in circulating new and updated guidelines and promoting their use in the relevant clinical settings.

The HSE will make this Guideline available to all employees through standards networks as well as store it in the online PPPG repository. Electronic versions available on the NWIHP and RCPI websites and other communication means can be used to maximise distribution. The NWIHP website will also provide a training webinar introducing each Guideline, and where relevant, a downloadable version of the recommended algorithm will be available.

13 Department of Health (2018). NCEC Implementation Guide and Toolkit. Available at: https://health.gov.ie/national-patient-safety-office/ncec/

Chapter 6: **Implementation**

6.1 Implementation plan

Implementation was considered at the beginning and throughout the Guideline development process. The local multidisciplinary clinical team, senior executive and clinical management in each maternity and gynaecology unit are ultimately responsible for the appropriate structured adoption and implementation of the guidelines within their area of responsibility. They must ensure that all relevant personnel under their supervision have read and understood the Guideline and monitor both its effectiveness and adoption.

Within each site, local multidisciplinary teams are responsible for the clinical implementation of Guideline recommendations, and ensuring that their local clinical practices and processes reflect and are aligned with the Guideline recommendations

The lead haematologist for transfusion working with the PPHQII local champions/local team should ensure the completion of the poster customised to the local hospital information.

The following have been put in place to help facilitate the implementation of this Guideline.

- Quick Summary Document (QSD) for clinical staff (includes key recommendations, auditable standards, algorithms and important links)
- Clinical Guideline mobile application
- Plain language summary
- 'What this means for you' summary for the woman available on the PPHQII website that can be downloaded as a leaflet for staff to provide to staff.

The PPHQII is working towards providing a national focus to standardise the provision of care across the maternity services regarding post-partum haemorrhage. This national initiative allows for the PPHQII steering committee (Appendix 9), representatives from the 19 maternity units (local champions) and the PPH Guideline group to come together to provide support and engagement for the implementation of this Guideline.

6.2 Education plans required to implement the Guideline

It is acknowledged that this Guideline should be complemented by ongoing education, training and assessment where required. We acknowledge that simulation-based management of PPH is of value in reducing the morbidity from PPH. Through the PPHQII, training will be provided for the introduction of elements of the Guideline inhouse and online. This will complement the development of videos for the introduction of the Unexpected Intraoperative Life-Threatening Haemorrhage.

6.3 Barriers and facilitators

To ensure the successful implementation of guidelines, it is first necessary to look at potential barriers and facilitators. Taking these into account when developing the implementation plan should improve levels of support from relevant users. (DOH 2018, 2019; section 6.4) There are some barriers that may delay the progress of this Guideline.

Barriers may be categorised as internal (specific to the Guideline itself) or external (specific to the clinical environment). The Guideline Development Group has aimed to address any internal barriers during the development of this Guideline.

These include:

- Protected time for staff training
- Protected time to carry out drills
- Protected time for staff to learn and engage with the Guideline
- Cost implications for the implementation for units and senior management
- Requirement for the increase in documentation requirements.

The PPHQII developed a network of local champions that will allow for the creation of a forum for shared learning to facilitate the implementation of this Guideline. This network along with the steering committee and the Guideline development group provides an opportunity for continued interaction to ensure that staff feel supported for the implementation phase.

In the case of this Guideline it will be necessary to examine possible barriers and consider implementation strategies to address them. By example, this may include discussion with relevant management groups with regards budgetary impact or providing training to the relevant staff.

6.4 Resources necessary to implement recommendations

The implementation of this Guideline should be undertaken as part of the quality improvement process of each hospital. Hospitals should review existing service provisions against this Guideline, identifying necessary resources required to implement the recommendations in this Guideline.

The National Women and Infant's Health Programme have provided support for the PPHQII and are committed to continue to support the PPHQII regarding training materials, meetings, communication material and website development.

Other resources required include:

- The development of a mobile application that can be accessed easily with the relevant algorithms and recommendations would be useful.
- A programme to evaluate multidisciplinary training programmes and drills may ensure the standardised adaption of the Guideline.
- Resources are required to develop and monitor the auditable standards and for any data set that may be developed to monitor PPH.
- Resources are required to allow for the provision of practical solutions for the management of PPH including the availability of weighing scales.
- Resources are required to investigate other methods for the management of MOH for example surgical interventions.

Chapter 7: Audit and Evaluation

7.1 Introduction to audit

It is important that both implementation of the Guideline and its influence on outcomes are audited to ensure that this Guideline positively impacts patient care. Institutions and health professionals are encouraged to develop and undertake regular audits of Guideline implementation. Personnel tasked with conducting the audit should be identified on receipt of the most recent version of the Guideline.

Obstetric life-threatening haemorrhage should be included in the annual audit cycle for the hospital transfusion service and reported, together with the auditable standards below, to the HTC and OTC. Obstetric LTH should be included in the proposal for national life-threatening haemorrhage audit across all clinical presentations.

7.2 Auditable standards

An audit using the key recommendations as indicators should be undertaken to identify where improvements are required and to enable changes as necessary. The Audit should also be undertaken to provide evidence of continuous quality improvement initiatives. The Guideline development group have devised this Guideline with a view that there are several auditable elements of the Guideline e.g. Post Partum Life Threatening Haemorrhage Protocol poster displayed and local information displayed. The checklist outlined at the beginning of this document or the locally adapted checklist is a tool that can be used as an audit tool. Other suggested auditable items are listed below.

1. Proportion of women having an antenatal Hb at 28 weeks and appropriate response to antenatal anaemia
2. Proportion of women who have had red cell antibody screen at 28 weeks.
3. Proportion of women with previous CS having location of placenta documented
4. Proportion of women having consent to blood transfusion documented
5. Proportion of MOH events compliant with best practice
6. Proportion of women who have had antenatal PPH risk assessment documented
7. Proportion of women who received AMTL
8. Proportion of women receiving VTE risk assessment
9. Proportion of staff training for checklist/algorithm, drills completed
10. Drills completed and staff attending the drill

7.3 Evaluation

Evaluation is defined as a formal process to determine the extent to which the planned or desired outcomes of an intervention are achieved.[14] Implementation of this Guideline will be audited periodically at the national level, with standards for this set by the NWIHP. Evaluation of the auditable standards should also be undertaken locally by senior hospital management to support implementation.

14 Health Information Quality Authority (2012). National Standards for Safer Better Healthcare [Internet]. Available from: https://www.hiqa.ie/reports-and-publications/standard/national-standards-safer-better-healthcare

Chapter 8: Revision Plan

8.1 Procedure for the update of the Guideline

It may be a requirement to amend, update or revise this Guideline as new evidence emerges. This Guideline will be reviewed at national level every three years, or earlier if circumstances require it, and updated accordingly.[15]

The Guideline Development Group will be asked to review the literature and recent evidence to determine if changes are to be made to the existing Guideline. If the Guideline Development Group are unavailable, the GPT along with the NWIHP senior management team will select a suitable expert to replace them.

If there are no amendments required to the Guideline following the revision date, the detail on the revision tracking box must still be updated which will be a new version number and date.

The recommendations set out in this Guideline remain valid until a review has been completed.

8.2 Method for amending the Guideline

As new evidence becomes available, guideline recommendations will inevitably fall behind current evidence based clinical practice. It is essential that clinical guidelines are reviewed and updated with new evidence as it becomes available.

In order to request a review of this Guideline, one of the following criteria must be met:

a. 3 years since the Guideline was published

b. 3 years since the last review was conducted

c. Update required as a result of new evidence

Correspondence requesting a review of the Guideline should be submitted to the National Women and Infants Health Programme. Any such requests should be dealt with in a timely manner.

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Supporting Evidence

GRADE: http://www.gradeworkinggroup.org/

AGREE: http://www.agreetrust.org/agree-ii/

HSE: https://www.hse.ie/eng/about/who/qid/use-of-improvement-methods/nationalframeworkdevelopingpolicies/

Glossary
(for the Purpose of this Guideline)

AGREE Appraisal of Guidelines for Research and Evaluation

AMTL Active management of the third stage of labour

BOA Balloon occlusion of the aorta

CAG Clinical Advisory Group

CCT Controlled Cord Traction

CS Caesarean Section

DCC Delayed Cord Clamping

EAG Expert Advisory Group

FBC Full Blood Count

GPT Guideline Programme Team

GRADE Grading of Recommendations, Assessments, Developments and Evaluations

Hb Haemoglobin

HIQA Health Information and Quality Authority

HSE Health Service Executive

HSE Health Service Executive

HDU High Dependency Unit

HTC Hospital Transfusion Committee

IOG Institute of Obstetricians and Gynaecologists

LTH Life Threatening Haemorrhage

LUS Lower Uterine Segment

MOH Major Obstetric Haemorrhage

MROP Manual removal of Placenta

NICE The National Institute for Health and Care Excellence

NCEC National Clinical Effectiveness Committee

NPEC National Perinatal Epidemiology Centre

NWIHP National Women and Infants Health Programme

OTC Overarching transfusion Committee

PAE Pelvic Artery Embolisation

PAS Placenta Accreta Spectrum

PPH Postpartum Haemorrhage

PPPG Policy, Procedures, Protocols and Guidelines

Rh Rhesus blood group

RCC Red Cell Concentrate

RCOG Royal College of Obstetricians and Gynaecologists

RCPI Royal College of Physicians of Ireland

SDP solvent detergent plasma

SIADH Syndrome of Inappropriate Anti-Diuretic Hormone

SMM Severe Maternal Morbidity

TAT Turnaround Times

TXA Tranexamic Acid

UBT Uterine Balloon Tamponade

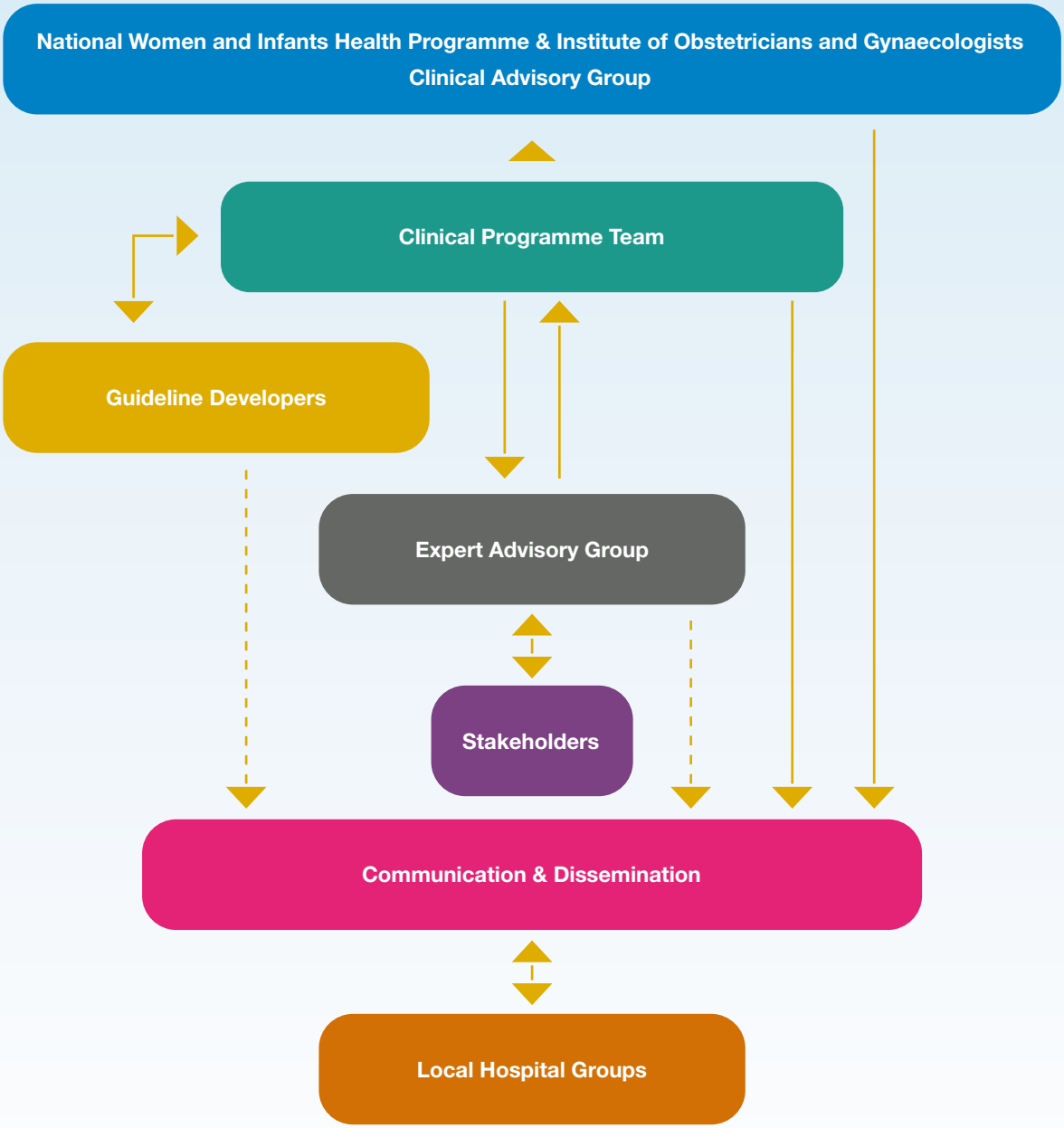
VHA Viscoelastic haemostatic assays

VTE Venous Thrombo-embolism

WHO World Health Organisation

Appendix 1:
Guideline Programme Process

Guideline Programme Process



Appendix 2:
Expert Advisory Group Members 2021-

Name	Profession	Location (2021)
Dr Fergus McCarthy	Consultant Obstetrician, Gynaecologist, Senior Lecturer and Maternal-Fetal Medicine Sub-specialist	Cork University Maternity Hospital, University College Cork
Dr Mairead Butler	Consultant Obstetrician and Gynaecologist	University Hospital Waterford
Prof Declan Keane	Professor of Obstetrics and Gynaecology	National Maternity Hospital Dublin, Royal College of Surgeons in Ireland
Dr Katherine Astbury	Consultant Obstetrician and Gynaecologist Gynaecology Oncology Sub-specialist	University Hospital Galway
Dr Sarah Petch	Specialist Registrar, Obstetrics and Gynaecology	National Maternity Hospital Dublin
Dr Orla Donohoe	Specialist Registrar, Obstetrics and Gynaecology	Sligo University Hospital
Prof John Murphy	Consultant Neonatologist and Clinical Lead for the National Clinical Programme for Paediatrics and Neonatology	National Women and Infants Health Programme
Ms Siobhan Canny	Group Director of Midwifery	Saolta University Health Care Group
Ms Fiona Hanrahan	Director of Midwifery and Nursing	Rotunda Hospital Dublin
Ms Margaret Quigley	National Lead for Midwifery	Office of Nursing and Midwifery Services Director
Prof Valerie Smith	Professor of Midwifery	School of Nursing and Midwifery, Trinity College Dublin
Ms Triona Cowman	Director of the Centre for Midwifery Education	Centre for Midwifery Education, Coombe Women & Infants University Hospital
Ms Janet Murphy	Advanced Midwifery Practitioner	University Hospital Waterford

Attendee	Profession	Location (2021)
Dr Ciara McCarthy	General Practitioner and ICGP Women's Health Lead	Irish College of General Practitioners
Mr Fergal O' Shaughnessy *And* Dr Brian Cleary *(Shared nomination)*	Senior Pharmacist, Honorary Lecturer *And* Chief Pharmacist, Honorary Clinical Associate Professor and Medications Lead, Maternal & Newborn Clinical Management System	Rotunda Hospital Dublin Royal College of Surgeons in Ireland
Ms Marie Finn	Medical Social Work Counsellor	Saolta University Health Care Group
Ms Marie Culliton	Lab Manager/Chief Medical Scientist	National Maternity Hospital Dublin
Ms Marita Hennessy	Post-Doctoral Researcher	Pregnancy Loss Research Group, INFANT Centre, University College Cork
Ms Niamh Connolly-Coyne *And* Ms Mandy Daly *(Shared nomination)*	Board of Directors	Irish Neonatal Health Alliance
Ms Caroline Joyce	Principal Clinical Biochemist PhD Candidate	Cork University Hospital University College Cork
Dr Richard Duffy	Consultant Perinatal Psychiatrist	Rotunda Hospital Dublin
Ms Clare Farrell	Physiotherapy Manager	Coombe Women & Infants University Hospital
Ms Fiona Dunlevy *And* Ms Sinéad Curran *(Shared nomination)*	Dietician Manager	Coombe Women & Infants University Hospital National Maternity Hospital
Dr Nicholas Barrett	Lead for Obstetric Anaesthesiology services	Limerick University Hospital
Dr Brendan Fitzgerald	Consultant Perinatal Pathologist	Cork University Hospital
Dr Niamh Conlon	Consultant Histopathologist	Cork University Hospital
Ms Georgina Cruise	Service Manager	Patient Advocacy Ireland

Appendix 3: **PPHQII Local Champions review of the PPHGL***

Cavan General Hospital
Michelle Rose

Coombe Women and Infants University Hospital
Fiona Noonan

Cork University Maternity Hospital
Karen Mulhern
Mary Prince
Fiona Kirby

Letterkenny University Hospital
Mary Lynch

Mayo University Hospital
Louise O'Malley
Mary Devers

Midland Regional Hospital Portlaoise
Emma Mullins

National Maternity Hospital
Dr Ingrid Browne

Our Lady of Lourdes Hospital
Adrienne Brady

Portiuncula University Hospital
Elaine Godfrey

Regional Hospital Mullingar
Karen Wilson

Rotunda Hospital
Fiona Walsh

St. Luke's Hospital
Susan Sherwood

Sligo University Hospital

Leanne Smith

Tipperary University Hospital

Maggie Dowling

Mary O'Donnell

University Hospital Kerry

Mary Stack Courtney

University Hospital Galway

Helen Heather

Louise Fitzpatrick

University Hospital Waterford

Janet Murphy

University Maternity Hospital Limerick

Bernadette Toolan

Wexford General Hospital

Helen McLoughlin

*Please note that the local champion represents the main lead on the project and that others in the units were involved in reviewing the document.

Appendix 4: AGREE II checklist[16]

AGREE Reporting Checklist 2016

This checklist is intended to guide the reporting of Clinical Practice Guidelines.

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
DOMAIN 1: SCOPE AND PURPOSE		
1. OBJECTIVES *Report the overall objective(s) of the guideline. The expected health benefits from the guideline are to be specific to the clinical problem or health topic.*	☐ Health intent(s) (i.e., prevention, screening, diagnosis, treatment, etc.) ☐ Expected benefit(s) or outcome(s) ☐ Target(s) (e.g., patient population, society)	
2. QUESTIONS *Report the health question(s) covered by the guideline, particularly for the key recommendations.*	☐ Target population ☐ Intervention(s) or exposure(s) ☐ Comparisons (if appropriate) ☐ Outcome(s) ☐ Health care setting or context	
3. POPULATION *Describe the population (i.e., patients, public, etc.) to whom the guideline is meant to apply.*	☐ Target population, sex and age ☐ Clinical condition (if relevant) ☐ Severity/stage of disease (if relevant) ☐ Comorbidities (if relevant) ☐ Excluded populations (if relevant)	
DOMAIN 2: STAKEHOLDER INVOLVEMENT		
4. GROUP MEMBERSHIP *Report all individuals who were involved in the development process. This may include members of the steering group, the research team involved in selecting and reviewing/ rating the evidence and individuals involved in formulating the final recommendations.*	☐ Name of participant ☐ Discipline/content expertise (e.g., neurosurgeon, methodologist) ☐ Institution (e.g., St. Peter's hospital) ☐ Geographical location (e.g., Seattle, WA) ☐ A description of the member's role in the guideline development group	

16 AGREE Reporting Checklist is available on the AGREE Enterprise website, a free and open access resource to support the practice guideline field (www. agreetrust.org).

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
5. TARGET POPULATION PREFERENCES AND VIEWS *Report how the views and preferences of the target population were sought/considered and what the resulting outcomes were.*	☐ Statement of type of strategy used to capture patients'/publics' views and preferences (e.g., participation in the guideline development group, literature review of values and preferences) ☐ Methods by which preferences and views were sought (e.g., evidence from literature, surveys, focus groups) ☐ Outcomes/information gathered on patient/public information ☐ How the information gathered was used to inform the guideline development process and/or formation of the recommendations	
6. TARGET USERS *Report the target (or intended) users of the guideline.*	☐ The intended guideline audience (e.g. specialists, family physicians, patients, clinical or institutional leaders/administrators) ☐ How the guideline may be used by its target audience (e.g., to inform clinical decisions, to inform policy, to inform standards of care)	
DOMAIN 3: RIGOUR OF DEVELOPMENT		
7. SEARCH METHODS *Report details of the strategy used to search for evidence.*	☐ Named electronic database(s) or evidence source(s) where the search was performed (e.g., MEDLINE, EMBASE, PsychINFO, CINAHL) ☐ Time periods searched (e.g., January 1, 2004 to March 31, 2008) ☐ Search terms used (e.g., text words, indexing terms, subheadings) ☐ Full search strategy included (e.g., possibly located in appendix)	
8. EVIDENCE SELECTION CRITERIA *Report the criteria used to select (i.e., include and exclude) the evidence. Provide rationale, where appropriate.*	☐ Target population (patient, public, etc.) characteristics ☐ Study design ☐ Comparisons (if relevant) ☐ Outcomes ☐ Language (if relevant) ☐ Context (if relevant)	

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
9. STRENGTHS & LIMITATIONS OF THE EVIDENCE *Describe the strengths and limitations of the evidence. Consider from the perspective of the individual studies and the body of evidence aggregated across all the studies. Tools exist that can facilitate the reporting of this concept.*	☐ Study design(s) included in body of evidence ☐ Study methodology limitations (sampling, blinding, allocation concealment, analytical methods) ☐ Appropriateness/relevance of primary and secondary outcomes considered ☐ Consistency of results across studies ☐ Direction of results across studies ☐ Magnitude of benefit versus magnitude of harm ☐ Applicability to practice context	
10. FORMULATION OF RECOMMENDATIONS *Describe the methods used to formulate the recommendations and how final decisions were reached. Specify any areas of disagreement and the methods used to resolve them.*	☐ Recommendation development process (e.g., steps used in modified Delphi technique, voting procedures that were considered) ☐ Outcomes of the recommendation development process (e.g., extent to which consensus was reached using modified Delphi technique, outcome of voting procedures) ☐ How the process influenced the recommendations (e.g., results of Delphi technique influence final recommendation, alignment with recommendations and the final vote)	
11. CONSIDERATION OF BENEFITS AND HARMS *Report the health benefits, side effects, and risks that were considered when formulating the recommendations.*	☐ Supporting data and report of benefits ☐ Supporting data and report of harms/side effects/risks ☐ Reporting of the balance/trade-off between benefits and harms/side effects/risks ☐ Recommendations reflect considerations of both benefits and harms/side effects/ risks	
12. LINK BETWEEN RECOMMENDATIONS AND EVIDENCE *Describe the explicit link between the recommendations and the evidence on which they are based.*	☐ How the guideline development group linked and used the evidence to inform recommendations ☐ Link between each recommendation and key evidence (text description and/or reference list) ☐ Link between recommendations and evidence summaries and/or evidence tables in the results section of the guideline	

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
13. EXTERNAL REVIEW *Report the methodology used to conduct the external review.*	☐ Purpose and intent of the external review (e.g., to improve quality, gather feedback on draft recommendations, assess applicability and feasibility, disseminate evidence) ☐ Methods taken to undertake the external review (e.g., rating scale, open-ended questions) ☐ Description of the external reviewers (e.g., number, type of reviewers, affiliations) ☐ Outcomes/information gathered from the external review (e.g., summary of key findings) ☐ How the information gathered was used to inform the guideline development process and/or formation of the recommendations (e.g., guideline panel considered results of review in forming final recommendations)	
14. UPDATING PROCEDURE *Describe the procedure for updating the guideline.*	☐ A statement that the guideline will be updated ☐ Explicit time interval or explicit criteria to guide decisions about when an update will occur ☐ Methodology for the updating procedure	
DOMAIN 4: CLARITY OF PRESENTATION		
15. SPECIFIC AND UNAMBIGUOUS RECOMMENDATIONS *Describe which options are appropriate in which situations and in which population groups, as informed by the body of evidence.*	☐ A statement of the recommended action ☐ Intent or purpose of the recommended action (e.g., to improve quality of life, to decrease side effects) ☐ Relevant population (e.g., patients, public) ☐ Caveats or qualifying statements, if relevant (e.g., patients or conditions for whom the recommendations would not apply) ☐ If there is uncertainty about the best care option(s), the uncertainty should be stated in the guideline	
16. MANAGEMENT OPTIONS *Describe the different options for managing the condition or health issue.*	☐ Description of management options ☐ Population or clinical situation most appropriate to each option	

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
17. IDENTIFIABLE KEY RECOMMENDATIONS *Present the key recommendations so that they are easy to identify.*	☐ Recommendations in a summarized box, typed in bold, underlined, or presented as flow charts or algorithms ☐ Specific recommendations grouped together in one section	
DOMAIN 5: APPLICABILITY		
18. FACILITATORS AND BARRIERS TO APPLICATION *Describe the facilitators and barriers to the guideline's application.*	☐ Types of facilitators and barriers that were considered ☐ Methods by which information regarding the facilitators and barriers to implementing recommendations were sought (e.g., feedback from key stakeholders, pilot testing of guidelines before widespread implementation) ☐ Information/description of the types of facilitators and barriers that emerged from the inquiry (e.g., practitioners have the skills to deliver the recommended care, sufficient equipment is not available to ensure all eligible members of the population receive mammography) ☐ How the information influenced the guideline development process and/or formation of the recommendations	
19. IMPLEMENTATION ADVICE/TOOLS *Provide advice and/or tools on how the recommendations can be applied in practice.*	☐ Additional materials to support the implementation of the guideline in practice. For example: • Guideline summary documents • Links to check lists, algorithms • Links to how-to manuals • Solutions linked to barrier analysis (see Item 18) • Tools to capitalize on guideline facilitators (see Item 18) • Outcome of pilot test and lessons learned	

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
20. RESOURCE IMPLICATIONS *Describe any potential resource implications of applying the recommendations.*	☐ Types of cost information that were considered (e.g., economic evaluations, drug acquisition costs) ☐ Methods by which the cost information was sought (e.g., a health economist was part of the guideline development panel, use of health technology assessments for specific drugs, etc.) ☐ Information/description of the cost information that emerged from the inquiry (e.g., specific drug acquisition costs per treatment course) ☐ How the information gathered was used to inform the guideline development process and/or formation of the recommendations	
21. MONITORING/ AUDITING CRITERIA *Provide monitoring and/or auditing criteria to measure the application of guideline recommendations.*	☐ Criteria to assess guideline implementation or adherence to recommendations ☐ Criteria for assessing impact of implementing the recommendations ☐ Advice on the frequency and interval of measurement ☐ Operational definitions of how the criteria should be measured	
DOMAIN 6: EDITORIAL INDEPENDENCE		
22. FUNDING BODY *Report the funding body's influence on the content of the guideline.*	☐ The name of the funding body or source of funding (or explicit statement of no funding) ☐ A statement that the funding body did not influence the content of the guideline	
23. COMPETING INTERESTS *Provide an explicit statement that all group members have declared whether they have any competing interests.*	☐ Types of competing interests considered ☐ Methods by which potential competing interests were sought ☐ A description of the competing interests ☐ How the competing interests influenced the guideline process and development of recommendations	

From: Brouwers MC, Kerkvliet K, Spithoff K, on behalf of the AGREE Next Steps Consortium. The AGREE Reporting Checklist: a tool to improve reporting of clinical practice guidelines. BMJ 2016;352:i1152. doi: 10.1136/bmj.i1152.

For more information about the AGREE Reporting Checklist, please visit the AGREE Enterprise website at http://www.agreetrust.org.

Appendix 5: Literature review supplementary information

(a) International guidelines reviewed

- FIGO International Federation of Gynecology and Obstetics Consensus guidelines on placenta accreta spectrum disorders (2018)
- International Postpartum Hemorrhage Collaborative Group Trends in postpartum hemorrhage in high resource countries: a review and recommendations from the International Postpartum Hemorrhage Collaborative Group BMC Pregnancy Childbirth 2009 Nov 27;9:55
- International Society on Thrombosis and Haemostasis (ISTH) Management of coagulopathy associated with postpartum hemorrhage: guidance from the SSC of the ISTH J Thromb Haemost 2016 Jan;14(1):205
- International Society of Ultrasound in Obstetrics and Gynecology (ISUOG) Hypogastric artery ligation in the management of postpartum hemorrhage (2019)
- Muñoz M, Stensballe J, Ducloy-Bouthors AS, Bonnet MP, De Robertis E, Fornet I, Goffinet F, Hofer S, Holzgreve W, Manrique S, Nizard J, Christory F, Samama CM, Hardy JF. Patient blood management in obstetrics: prevention and treatment of postpartum haemorrhage. A NATA consensus statement. Blood Transfus. 2019 Mar;17(2):112-136. doi: 10.2450/2019.0245-18. Epub 2019 Feb 6. PMID: 30865585; PMCID: PMC6476742.
- World Health Organization (WHO): Recommendations on uterotonics for the prevention of postpartum haemorrhage. update (2018)
- World Health Organization (WHO): Updated recommendation on tranexamic acid for the treatment of postpartum haemorrhage (2017)

Canada

- Society of Obstetricians and Gynaecologists of Canada (SOGC): Clinical practice guideline for active management of the third stage of labour – Prevention and treatment of postpartum hemorrhage (2009, reaffirmed 2018) Leduc D, Senikas V, Lalonde AB; CLINICAL PRACTICE OBSTETRICS COMMITTEE. Active management of the third stage of labour: prevention and treatment of postpartum hemorrhage. J Obstet Gynaecol Can. 2009 Oct;31(10):980-993. doi: 10.1016/S1701-2163(16)34329-8. PMID: 19941729.

United States

- American College of Radiology (ACR): Expert Panel on GYN and OB Imaging, Uyeda JW, George E, Reinhold C, Akin EA, Ascher SM, Brook OR, Henrichsen TL, Henwood PC, Learman LA, Maturen KE, Patlas MN, Robbins JB, Sadowski EA, Saphier C, Wall DJ, Glanc P. ACR Appropriateness Criteria® Postpartum Hemorrhage. J Am Coll Radiol. 2020 Nov;17(11S):S459-S471. doi: 10.1016/j.jacr.2020.09.011. PMID: 33153557

- American College of Radiology (ACR): Expert Panel on GYN and OB Imaging, Shipp TD, Poder L, Feldstein VA, Oliver ER, Promes SB, Strachowski LM, Sussman BL, Wang EY, Weber TM, Winter T, Glanc P. ACR Appropriateness Criteria® Second and Third Trimester Vaginal Bleeding. J Am Coll Radiol. 2020 Nov;17(11S):S497-S504. doi: 10.1016/j.jacr.2020.09.004. PMID: 33153560.
- American College of Obstetricians and Gynecologists (ACOG): Quantitative Blood Loss in Obstetric Hemorrhage: ACOG COMMITTEE OPINION SUMMARY, Number 794. Obstet Gynecol. 2019 Dec;134(6):1368-1369. doi: 10.1097/AOG.0000000000003565. PMID: 31764756.
- American College of Obstetricians and Gynecologists; Society for Maternal-Fetal Medicine. Obstetric Care Consensus No. 7: Placenta Accreta Spectrum. Obstet Gynecol. 2018 Dec;132(6):e259-e275. doi: 10.1097/AOG.0000000000002983. PMID: 30461695.
- American College of Obstetricians and Gynecologists: Committee on Practice Bulletins-Obstetrics. Practice Bulletin No. 183: Postpartum Hemorrhage. Obstet Gynecol. 2017 Oct;130(4):e168-e186. doi: 10.1097/AOG.0000000000002351. PMID: 28937571.
- American Society of Anesthesiologists (ASA) and Society for Obstetric Anesthesia and Perinatology (SOAP): Practice Guidelines for Obstetric Anesthesia: An Updated Report by the American Society of Anesthesiologists Task Force on Obstetric Anesthesia and the Society for Obstetric Anesthesia and Perinatology. Anesthesiology. 2016 Feb;124(2):270-300. doi: 10.1097/ALN.0000000000000935. PMID: 26580836.
- American Society of Anesthesiologists Task Force on Perioperative Blood Management. Practice guidelines for perioperative blood management: an updated report by the American Society of Anesthesiologists Task Force on Perioperative Blood Management*. Anesthesiology. 2015 Feb;122(2):241-75. doi: 10.1097/ALN.0000000000000463. PMID: 25545654.
- National Partnership for Maternal Safety: Recommendations for reducing obstetric hemorrhage (2015)
- National Partnership for Maternal Safety: Main EK, Goffman D, Scavone BM, Low LK, Bingham D, Fontaine PL, Gorlin JB, Lagrew DC, Levy BS. National Partnership for Maternal Safety: consensus bundle on obstetric hemorrhage. Anesth Analg. 2015 Jul;121(1):142-148. doi: 10.1097/AOG.0000000000000869. Erratum in: Anesth Analg. 2019 Dec;129(6):e206. PMID: 26091046.
- Society for Maternal-Fetal Medicine (SMFM) Consult Series #44: Management of bleeding in the late preterm period. Am J Obstet Gynecol. 2018 Jan;218(1):B2-B8. doi: 10.1016/j.ajog.2017.10.019. Epub 2017 Oct 25. PMID: 29079144.

Europe

- Network for the Advancement of Patient Blood Management, Haemostasis and Thrombosis (NATA), International Federation of Gynaecology and Obstetrics (FIGO), the European Board and College of Obstetrics and Gynaecology (EBCOG), and the European Society of Anaesthesiology (ESA): Muñoz M, Stensballe J, Ducloy-Bouthors AS, Bonnet MP, De Robertis E, Fornet I, Goffinet F, Hofer S, Holzgreve W, Manrique S, Nizard J, Christory F, Samama CM, Hardy JF. Patient blood management in obstetrics: prevention and treatment of postpartum haemorrhage. A NATA consensus statement. Blood Transfus. 2019 Mar;17(2):112-136. doi: 10.2450/2019.0245-18. pub 2019 Feb 6. PMID: 30865585; PMCID: PMC6476742.

United Kingdom

- British Committee for Standards in Haematology (BCSH) Guidelines on the management of massive blood loss Br J Haematol 2006 Dec;135(5):634
- Curry NS, Davenport R, Pavord S, Mallett SV, Kitchen D, Klein AA, Maybury H, Collins PW, Laffan M. The use of viscoelastic haemostatic assays in the management of major bleeding: A British Society for Haematology Guideline. Br J Haematol. 2018 Sep;182(6):789-806. doi: 10.1111/bjh.15524. Epub 2018 Aug 2. PMID: 30073664.
- National Institute for Health and Care Excellence (NICE): Intrapartum care for women with existing medical conditions or obstetric complications and their babies. NICE guideline [NG121] Published: 06 March 2019 Last updated: 25 April 2019
- Royal College of Obstetricians & Gynaecologists (RCOG): Jauniaux E, Alfirevic Z, Bhide AG, Belfort MA, Burton GJ, Collins SL, Dornan S, Jurkovic D, Kayem G, Kingdom J, Silver R, Sentilhes L; Royal College of Obstetricians and Gynaecologists. Placenta Praevia and Placenta Accreta: Diagnosis and Management: Green-top Guideline No. 27a. BJOG. 2019 Jan;126(1):e1-e48. doi: 10.1111/1471-0528.15306. Epub 2018 Sep 27. PMID: 30260097.

Australia & New Zealand

- Australian Haemophilia Centre Directors' Organisation (AHCDO): Dunkley, Scott *et al*. "Updated Australian consensus statement on management of inherited bleeding disorders in pregnancy." The Medical journal of Australia vol. 210,7 (2019): 326-332. doi:10.5694/mja2.50123
- Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG): Management of postpartum haemorrhage (PPH) (2017)
- Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG): Green-top guideline for prevention and management of postpartum haemorrhage (2016)
- National Blood Authority (NBA): Patient blood management guidelines – Module 5: Obstetrics and maternity (2015)
- Queensland Health: Maternity and neonatal clinical guideline on primary postpartum haemorrhage (2018, amended 2021)
- Queensland Maternity and Neonatal Clinical Guidelines Primary postpartum haemorrhage. Queensland Clinical Guidelines, 2018.

Appendix 5 (b) search terms

Primary Database	**OVID MEDLINE (all) from 2015**
Additional databases	**EMBASE, Cochrane Library of Systematic Reviews**
Primary search string	Postpartum Hemorrhage/OR postpartum hemorrhage OR post partum hemorrhage OR postpartum haemorrhage OR post partum haemorrhage
	Primary search string combined with 9 separate facets:
1	active management AND third stage labor or Labor Stage, Third
2	Diagnosis or diagnosis or hypotension or Hypotension or tachycardia or Tachycardia or 'blood loss'
3	genital tract or reproductive tract
4	Oxytocin or oxytocin or syntocinon or syntometrine or carbocetin or misoprostol or Misoprostol or ergometrine or prostaglandins
5	retained placenta
6	*Risk or Risk Factors or Risk Management or high risk or risk factor$ or risk assessment
7	uterine compression or intrauterine balloon OR intrauterine tamponade OR baki balloon OR balloon tamponade or B-Lynch compression suture or surgical intervention$
8	uterine atony OR uterine inertia or uterine massage or bladder emptying or IV infusion$ or IV therapy or intravenous therapy or infusion therapy or Uterotonics or Oxytocin or Ergometrine or Misoprostol or Carboprost or tranexamic acid$
9	Uterotonic$ OR cord clamp

Appendix 6: **Grades of Recommendation**[17]

Grade of recommendation	Clarity of risk/ benefit	Quality of supporting evidence	Implications	Suggested Language
1 A. Strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Consistent evidence from well-performed randomised, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk	Strong recommendations can apply to most patients in most circumstances without reservation. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present	We strongly recommend… We recommend that …should be performed/ administered… We recommend that … is indicated/ beneficial/ effective….
1 B. Strong recommendation, moderate-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Evidence from randomised, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate	Strong recommendation and applies to most patients. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present	We recommend… We recommend that … should be performed/ administered… We recommend that … is (usually) indicated/ beneficial/ effective…

17 SMFM adopts GRADE (Grading of Recommendations Assessment, Development, and Evaluation) for clinical guidelines. Society for Maternal-Fetal Medicine (SMFM), Chauhan SP, Blackwell SC. Am J Obstet Gynecol. 2013 Sep;209(3):163-5. doi: 10.1016/j.ajog.2013.07.012. PMID: 23978245

Grade of recommendation	Clarity of risk/ benefit	Quality of supporting evidence	Implications	Suggested Language
1 C. Strong recommendation, low-quality evidence	Benefits appear to outweigh risk and burdens, or vice versa	Evidence from observational studies, unsystematic clinical experience, or from randomised, controlled trials with serious flaws. Any estimate of effect is uncertain	Strong recommendation that applies to most patients. Some of the evidence base supporting the recommendation is, however, of low quality	We recommend… We recommend that … should be performed/ administered… We recommend that … Is (maybe) indicated/ beneficial/ effective…
2A. Weak recommendation, high-quality evidence	Benefits closely balanced with risks and burdens	Consistent evidence from well-performed randomised, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk	Weak recommendation: best action may differ depending on circumstances or patients or societal values	We suggest… We suggest that … may/might be reasonable…
2B. Weak recommendation, moderate-quality evidence	Benefits closely balanced with risks and burdens, some uncertainty in the estimates of benefits, risks and burdens	Evidence from randomised, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate	Weak recommendation; alternative approaches likely to be better for some patients under some circumstances	We suggest… We suggest that … may/might be reasonable…

Grade of recommendation	Clarity of risk/ benefit	Quality of supporting evidence	Implications	Suggested Language
2C. Weak recommendation, low-quality evidence	Uncertainty in the estimates of benefits, risks, and burdens; benefits may be closely balanced with risks and burdens	Evidence from observational studies, unsystematic clinical experience, or from randomised, controlled trials with serious flaws. Any estimate of effect is uncertain	Very weak recommendation: other alternatives may be equally reasonable.	We suggest… is an option We suggest that … may/might be reasonable.
Best practice	A recommendation that is sufficiently obvious that the desirable effects outweigh undesirable effects, despite the absence of direct evidence, such that the grading of evidence is unnecessary			We recommend… We recommend that … should be performed/ administered… We recommend that … Is usually) indicated/ beneficial/effective

Appendix 7: Policies, Procedures, Protocols and Guidelines Checklist

The PPPG Checklists were developed to assist staff to meet standards when developing Clinical PPPGs.

Standards for developing clinical PPPG	
Stage 1 initiation	**Checklist**
The decision making approach relating to the type of PPPG guidance required (policy, procedure, protocol, guideline), coverage of the PPPG (national, regional, local) and applicable settings are described.	☐
Synergies/co-operations are maximised across departments/organisations (Hospitals/ Hospital Groups/Community Healthcare Organisations (CHO)/National Ambulance Service (NAS)), to avoid duplication and to optimise value for money and use of staff time and expertise.	☐
The scope of the PPPG is clearly described, specifying what is included and what lies outside the scope of the PPPG.	☐
The target users and the population/patient group to whom the PPPG is meant to apply are specifically described.	☐
The views and preferences of the target population have been sought and taken into consideration (as required).	☐
The overall objective(s) of the PPPGs are specifically described.	☐
The potential for improved health is described (e.g. clinical effectiveness, patient safety, quality improvement, health outcomes, quality of life, quality of care).	☐
Stakeholder identification and involvement: The PPPG Development Group includes individuals from all relevant stakeholders, staff and professional groups.	☐
Conflict of interest statements from all members of the PPPG Development Group are documented, with a description of mitigating actions if relevant.	☐
The PPPG is informed by the identified needs and priorities of service users and stakeholders.	☐
There is service user/lay representation on PPPG Development Group (as required).	☐
Information and support is available for staff on the development of evidence-based clinical practice guidance.	☐

Stage 2 development	**Checklist**
The clinical question(s) covered by the PPPG are specifically described.	☐
Systematic methods used to search for evidence are documented (for PPPGs which are adapted/ adopted from international guidance, their methodology is appraised and documented).	☐
Critical appraisal/analysis of evidence using validated tools is documented (the strengths, limitations and methodological quality of the body of evidence are clearly described).	☐
The health benefits, side effects and risks have been considered and documented in formulating the PPPG.	☐
There is an explicit link between the PPPG and the supporting evidence.	☐
PPPG guidance/recommendations are specific and unambiguous.	☐
The potential resource implications of developing and implementing the PPPG are Identified e.g. equipment, education/training, staff time and research.	☐
There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated care.	☐
Budget impact is documented (resources required).	☐
Education and training is provided for staff on the development and implementation of evidence- based clinical practice guidance (as appropriate).	☐
Three additional standards are applicable for a small number of more complex PPPGs:	☐
Cost effectiveness analysis is documented.	☐
A systematic literature review has been undertaken.	☐
Health Technology Assessment (HTA) has been undertaken.	☐
Stage 3 governance and approval	**Checklist**
Formal governance arrangements for PPPGs at local, regional and national level are established and documented.	☐
The PPPG has been reviewed by independent experts prior to publication (as required).	☐
Copyright and permissions are sought and documented.	☐
Stage 4 communication and dissemination	**Checklist**
A communication plan is developed to ensure effective communication and collaboration with all stakeholders throughout all stages.	☐
Plan and procedure for dissemination of the PPPG is described.	☐
The PPPG is easily accessible by all users e.g. PPPG repository.	☐

Stage 5 implementation	**Checklist**
Written implementation plan is provided with timelines, identification of responsible persons/ units and integration into service planning process.	☐
Barriers and facilitators for implementation are identified, and aligned with implementation levers.	☐
Education and training is provided for staff on the development and implementation of evidence- based PPPG (as required).	☐
There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated care.	☐
Stage 6 monitoring, audit, evaluation	**Checklist**
Process for monitoring and continuous improvement is documented.	☐
Audit criteria and audit process/plan are specified.	☐
Process for evaluation of implementation and (clinical) effectiveness is specified.	☐
Stage 7 revision/update	**Checklist**
Documented process for revisions/updating and review, including timeframe is provided.	☐
Documented process for version control is provided.	☐

To view in full refer to website: https://www.hse.ie/eng/about/who/qid/nationalframeworkdevelopingpolicies/

Appendix 8: **NWIHP/IOG CAG membership 2022**

Dr Cliona Murphy (Chair). Consultant Obstetrician and Gynaecologist, Coombe Women and Infants University Hospital. Clinical Director, National Women and Infants Health Programme.

Dr Sam Coulter-Smith. Consultant Obstetrician and Gynaecologist, Rotunda Hospital. Chair, Institute of Obstetricians and Gynaecologists.

Angela Dunne. Director of Midwifery, National Women and Infants Health Programme.

Kilian McGrane. Director, National Women and Infants Health Programme.

Dr Peter McKenna. Clinical Lead, Obstetric Event Support Team, National Women and Infants Health Programme.

Prof John Murphy. Clinical Lead Neonatology, National Women and Infants Health Programme.

Prof Maeve Eogan. Consultant Obstetrician and Gynaecologist, Rotunda Hospital. Clinical Lead, Sexual Assault Treatment Units, National Women and Infants Health Programme.

Dr Aoife Mullaly. Consultant Obstetrician and Gynaecologist, Coombe Women and Infants University Hospital. Clinical Lead, Termination of Pregnancy Services, National Women and Infants Health Programme.

Prof Keelin O'Donoghue. Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Clinical Lead, National Guidelines, National Women and Infants Health Programme.

Prof Nóirín Russell. Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Clinical Director, Cervical Check.

Prof Richard Greene. Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Clinical Director, National Perinatal Epidemiology Centre, University College Cork.

Prof John Morrison. Consultant Obstetrician and Gynaecologist, University Hospital Galway. Clinical Director, Saolta Maternity Directorate.

Dr Suzanne O'Sullivan. Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Director of Education and Training, Obstetrics and Gynaecology, Institute of Obstetricians and Gynaecologists.

Prof Fergal Malone. Master, Consultant Obstetrician and Gynaecologist, Rotunda Hospital.

Prof John Higgins. Cork University Maternity Hospital, Consultant Obstetrician and Gynaecologist, Clinical Director, Ireland South Women and Infants Directorate.

Dr Mendinaro Imcha. Clinical Director, Consultant Obstetrician and Gynaecologist, University Maternity Hospital Limerick.

Prof Shane Higgins. Master, Consultant Obstetrician and Gynaecologist, National Maternity Hospital.

Prof Mike O'Connell. Master, Consultant Obstetrician and Gynaecologist, Coombe Women and Infants University Hospital.

Dr Brian Cleary. Chief Pharmacist, Rotunda Hospital. Medications Lead, Maternal and Newborn Clinical Management System Project.

Appendix 9:
PPHQII National Steering Committee

Dr Cliona Murphy(Chair), Consultant Obstetrician and Gynaecologist, Coombe Women and Infants University Hospital. Clinical Director, National Women and Infants Health Programme.

Dr Bridgette Byrne, Senior Lecturer in Obstetrics and Gynaecology, RCSI Dept of Obstetrics and Gynaecology, Coombe Women and Infants University Hospital,

Georgina Cruise, Acting Service Manager, Patient Advocacy Service

Dr Fionán Donohoe, Clinical Fellow

Angela Dunne, Director of Midwifery, National Women and Infants Health Programme.

Cliodhna Grady, Senior Clinical Risk Manager, State Claims Agency

Prof Richard Greene, Director, National Perinatal Epidemiology Centre (NPEC)

Fiona Hanrahan Directory of Midwifery, Rotunda Hospital

Dr Niamh Hayes, Consultant Anaesthesiologist, Rotunda Hospital and Mater Misericordiae University Hospital

Maria Lordan Dunphy, Assistant National Director Quality Improvement, HSE

Kilian McGrane, Director, National Women and Infants Health Programme.

Dr Peter McKenna, Clinical Lead, Obstetric Event Support Team, National Women and Infants Health Programme.

Joye McKernan PhD, Project Manager PPHQII, NPEC

Prof. Fionnuala Ní Áinle, PhD, MB, MRCPI, FRCPath (she/her) Consultant Haematologist, Mater Misericordiae University Hospital and Rotunda Hospital, Dublin

Dr Joan Power, Consultant Haematologist Munster Regional Transfusion Centre, Irish Blood Transfusion Service, Clinical Senior Lecturer UCC

Aideen Quigley, Quality & Safety Manager, Manager