An Roinn Sláinte
Department of Health

Unexpected Intraoperative Life Threatening Haemorrhage

National Clinical Guideline No. 29

May 2022

National Patient Safety Office
Oifig Náisiúnta um Shábháilteacht Othar

NATIONAL CLINICAL EFFECTIVENESS COMMITTEE

This National Clinical Guideline has been developed by the Unexpected Intraoperative Life Threatening Haemorrhage Guideline Development Group (GDG). The NCEC was requested by the Minister for Health to commission this guideline arising from a significant patient safety/policy matter.

Using this National Clinical Guideline

This National Clinical Guideline applies to patients undergoing interventions and operations where there is a risk that an unexpected intraoperative life threatening haemorrhage can occur.

It does not apply to intraoperative life threatening haemorrhage in patients that have presented as:

a) Trauma patients (i.e. patients where life threatening haemorrhage has not arisen from the procedure/ intervention itself)

b) Post-partum haemorrhage

c) Post-operative bleeding

d) Life threatening haemorrhage in paediatric patients

The guideline is relevant to the core theatre team of surgeons, anaesthesiologists, nurses and porters in addition to haematologists and medical scientists supporting transfusion activities working in acute clinical specialties where interventions and operations occur.

Disclaimer

NCEC National Clinical Guidelines do not replace professional judgment on particular cases, whereby the clinician or health professional decides that individual guideline recommendations are not appropriate in the circumstances presented by an individual patient, or whereby an individual patient declines a recommendation as a course of action in their care or treatment plan. In these circumstances the decision not to follow a recommendation should be appropriately recorded in the patient's healthcare record.

Users of NCEC National Clinical Guidelines must ensure they have the current version by checking the relevant section in the National Patient Safety Office on the Department of Health website: https://www.gov.ie/en/collection/c9fa9a-national-clinical-guidelines/

Whilst every care has been taken to ensure that all information contained in this publication is correct, the Department of Health cannot accept responsibility for any errors or omissions which may have occurred.

Published by:

The Department of Health, Block 1, Miesian Plaza, 50-58 Lower Baggot Street, Dublin 2, D02 XW14, Ireland.
Tel: +353 (1) 6354000 www.health.gov.ie ISSN 2009-6259.

Citation text

Department of Health (2022). Unexpected Intraoperative Life Threatening Haemorrhage (NCEC National Clinical Guideline No. 29). Available at: https://www.gov.ie/en/collection/c9fa9a-national-clinical-guidelines

Membership of the Guideline Development Group (GDG)

The GDG was chaired by Professor John Hyland. This National Clinical Guideline is supported by the Royal College of Surgeons in Ireland (RCSI), the College of Anaesthesiologists of Ireland (CAI), the National Clinical Programme for Surgery, the National Clinical Programme for Anaesthesia and the Health Services Executive (HSE).

Membership nominations were sought from a variety of clinical and non-clinical backgrounds so as to be representative of all key stakeholders within theatre and support teams. GDG members included those involved in clinical practice, education, administration, research methodology and two members representing patients and the public. The methodology experts from the Health Research Board Collaboration in Ireland for Clinical Effectiveness Reviews (HRB-CICER) completed the evidence searches and prepared the Budget Impact Analysis to support the implementation of the guideline (as presented in Annex A, B and C accompanying the guideline). Hospital management representatives provided input through the consultation process and through direct membership of the National Clinical Advisor and Group Lead, Acute Hospital Operations Division within the HSE. See Appendix 1 for Terms of Reference for the GDG.

Name	Job title and affiliation
Professor John Hyland	Consultant Surgeon General/Colorectal, Past President RCSI
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Ms Karen Egan	Patient Representative
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Ms Miriam Kennedy	Project Manager

Credits

The role of the NCEC is to prioritise, quality assure and recommend clinical guidelines to the Chief Medical Officer for endorsement by the Minister for Health. It is intended through Ministerial endorsement that full implementation of the guideline will occur through the relevant service plans.

The NCEC and the Department of Health acknowledge and recognise the Chair and members of the Guideline Development Group (GDG) for development of the guideline. The NCEC and Department of Health wish to express thanks and sincere gratitude to all persons contributing to this National Clinical Guideline; especially those that give of their time on a voluntary basis.

Acknowledgments

The Chair of the GDG, Professor John Hyland wishes to acknowledge all members of the GDG for their professionalism and expertise as contributors to the development of this guideline. All members of the group worked effectively in bringing wide specialty input for the common goal of improved patient safety.

The HRB-CICER Team under the direction of Michelle O'Neill provided invaluable support and guidance throughout the entire guideline development process and the GDG are especially grateful for their input. Dr Laura Comber, Dr Sinead O'Neill, Susan Ahern and Natasha Broderick from HRB-CICER completed the evidence searches and prepared the Budget Impact Analysis to support the implementation of the guideline. The Chief/Senior medical scientists of all hospital transfusion laboratories across Ireland participated in two separate data gathering exercises which informed some of the content of this guideline and we are grateful for their time and input throughout this process. Fergus Guilfoyle from the Academy of Clinical Science and Laboratory Medicine (ACSLM) assisted the survey distribution process through communication with the Academy's Transfusion Advisory Body.

Nicola Williams from the Quality & Patient Safety Division supported the GDG by assisting with selecting appropriate patient representatives to participate in the GDG. Professor Eva Doherty from RCSI participated in a subgroup of the GDG providing Human Factors input in relation to the poster design that will be used in all theatres across the country. Tony Temple from RCSI worked with the poster subgroup to develop the poster design and we appreciate his expertise and willingness to assist. We are grateful to Maureen Nolan also in providing additional external input to the poster design process.

I am very grateful for the extensive participation of all those that contributed in the public consultation process, their input has added to the quality of this guideline. The external international review carried out by Professors Sibylle Kietaibl, Rob Sayers and Simon Stanworth is also appreciated.

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Professor John Hyland

Date: 30/09/2021

National Clinical Guidelines

Providing standardised clinical care to patients in healthcare is challenging. This is due to a number of factors, among them diversity in environments of care and complex patient presentations. It is self-evident that safe, effective care and treatment are important in ensuring that patients get the best outcomes from their care.

The Department of Health is of the view that supporting evidence-based practice, through the clinical effectiveness framework, is a critical element of the health service to deliver safe and high quality care. The National Clinical Effectiveness Committee (NCEC) is a Ministerial committee set up in 2010 as a key recommendation of the report of the Commission on Patient Safety and Quality Assurance (2008). The establishment of the Commission was prompted by an increasing awareness of patient safety issues in general and high profile health service system failures at home and abroad.

The NCEC on behalf of the Department of Health has embarked on a quality assured National Clinical Guideline development process linked to service delivery priorities. Furthermore, implementing National Clinical Guidelines sets a standard nationally, to enable healthcare professionals to deliver safe and effective care and treatment while monitoring their individual, team and organisation's performance.

The aim of these National Clinical Guidelines is to reduce unnecessary variations in practice and provide an evidence base for the most appropriate healthcare in particular circumstances. As a consequence of Ministerial mandate, it is expected that NCEC National Clinical Guidelines are implemented across all relevant services in the Irish healthcare setting.

The NCEC is a partnership between key stakeholders in patient safety. NCEC's mission is to provide a framework for national endorsement of clinical guidelines and clinical audit to optimise patient and service user care. The NCEC has a remit to establish and implement processes for the prioritisation and quality assurance of clinical guidelines and clinical audit so as to recommend them to the Minister for Health to become part of a suite of National Clinical Guidelines and National Clinical Audit. The aim of the suite of National Clinical Guidelines is to provide guidance and standards for improving the quality, safety and cost-effectiveness of healthcare in Ireland. The implementation of these National Clinical Guidelines will support the provision of evidence-based and consistent care across Irish healthcare services.

NCEC Terms of Reference

1. Provide strategic leadership for the national clinical effectiveness agenda.
2. Contribute to national patient safety and quality improvement agendas.
3. Publish standards for clinical practice guidance.
4. Publish guidance for National Clinical Guidelines and National Clinical Audit.
5. Prioritise and quality assure National Clinical Guidelines and National Clinical Audit.
6. Commission National Clinical Guidelines and National Clinical Audit.
7. Align National Clinical Guidelines and National Clinical Audit with implementation levers.
8. Report periodically on the implementation and impact of National Clinical Guidelines and the performance of National Clinical Audit.
9. Establish sub-committees for NCEC workstreams.
10. Publish an annual report.

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1 National Clinical Guideline recommendations

1.1 Summary of recommendations

A summary list of the guideline recommendations are presented below together with the quality of evidence and strength of each recommendation. (Refer to Appendix 8 for full glossary of abbreviations). The views or interests of the funding body have not influenced the final recommendations.

Table 1: Summary of Recommendations

No.	Recommendation	Quality of evidence	Strength of recommendation
1	Hospital Group structures already exist for the delivery of healthcare nationally and should continue to designate the appropriate sites for scheduled (elective) and unscheduled (emergency/urgent) surgery. Consideration of timely access to blood transfusion support and turnaround times (TATs) for critical tests or availability of near patient testing (NPT), should be included in the designation of appropriate sites so as to support life-threatening haemorrhage.	Very Low	Strong
2	All theatre teams must follow the agreed 'Sign In, Time Out and Sign Out - Safe Surgery Checklist' as presented in the 'HSE National Policy and procedure for safe surgery' (Private Hospitals to use WHO Safe Surgery Guideline).	Low	Strong
3	All hospitals must have the National Life Threatening Haemorrhage Management Poster prominently on display in the operating theatre. All hospitals must also have an underpinning life threatening haemorrhage policy & procedure/protocol which incorporates the recommendations of this guideline. All clinical, laboratory and support staff to maintain their competency must be familiar with the contents of the life threatening haemorrhage protocol/ procedure.	Low	Strong

4	The pre-operative assessment of the patient should identify specific issues for individual patients which need to be addressed to reduce the risk of life threatening haemorrhage. In addition, prior to commencement of the operation the multidisciplinary team should identify specific parts of the operation where life threatening haemorrhage could occur. This particularly applies when any operative intervention in the chest, abdomen or pelvis occurs.	Very Low	Strong
5	When any open or laparoscopic/operative intervention in the chest, abdomen or pelvis is to take place or where there is potential to inadvertently enter one of these cavities during surgery - the following criteria will be confirmed in advance of the procedure to support adequate preparation in the event of an unexpected intraoperative life threatening haemorrhage: Once per day: • Confirm emergency Group O blood is available in the specified fridge/cold storage known to the theatre staff and documented on the National Life Threatening Haemorrhage Poster • Confirm other blood components (see poster) for the management of a life threatening haemorrhage are available Every patient: • Confirm blood group and antibody screen (group and hold) or crossmatch has been performed as per hospital Maximum Surgical Blood Ordering Schedule (MSBOS) /specific blood order for a particular patient is available • Confirm where senior help is and how they can be contacted • Confirm placement of at least one peripheral wide bore cannula • Confirm the availability of equipment for the placement of central access catheters (including ultrasound) • Confirm location and availability of sterile vascular instruments and haemostatic products	Very Low	Strong

6	To ensure patient safety appropriate supervision and clinical support should be provided to surgery, gynaecology and anaesthesiology trainees in line with their experience and stage of training.	Very Low	Strong
7	All trainee surgeons and gynaecologists undertaking laparoscopic procedures during the course of their training must complete laparoscopy skills training and simulation drills - these include recognition and appropriate response to a life threatening haemorrhage event.	Very Low	Strong
8	All staff working in theatre and all medical scientists involved in a life threatening haemorrhage (including those providing out of hours cover) should participate in regular multi-disciplinary drills in the recognition and management of major blood loss. Participants should know when to activate/trigger the life threatening haemorrhage protocol and take prompt and appropriate action. Those participating in the multi-disciplinary drills should complete the eLearning training content on life threatening haemorrhage when it becomes available.	Low	Strong
9	Following the trigger of the life threatening haemorrhage protocol there must be a clear mechanism to contact all relevant team members and a designated emergency coordinator should then coordinate further management.	Low	Strong
10	In the event of a major vascular injury the designated Emergency Coordinator in association with the surgeon and anaesthesiologist should request extra assistance as appropriate to the procedure and if promptly available locally (senior surgeon, vascular surgeon, interventional radiology, etc.) and request this assistance ASAP. Once a Red Alert (activation of the Life Threatening Haemorrhage Protocol) has been called, progression to laparotomy should be considered. Whilst waiting for senior assistance to arrive – methods such as packing to reduce the ongoing haemorrhage and pressure/compression or potentially exploring balloon tamponade/ covered stenting of the bleeding vessel should be applied as a damage limiting approach. This might allow time for further resuscitation of the patient.	Very Low	Strong

<table>
<tr><td>11</td><td>Serial haemostatic tests, including FBC (Hb, platelet count), PT, APTT and fibrinogen or compliant Near Patient Testing (NPT), from before and after resuscitation should be taken every 30–60 minutes depending on the severity of the haemorrhage. The results of these tests will guide and ensure the appropriate use of blood components. Calcium must be monitored and replaced as appropriate.</td><td>Low</td><td>Strong</td></tr>
<tr><td>12</td><td>Ensure access to sufficient and appropriate blood components and products in a timely manner. Staff should know where to access emergency Group O red cell components and the timeline to availability (refer to the National Life Threatening Haemorrhage poster). Hospitals must have systems in place that reliably inform the laboratory on use of emergency Group O red cell components so as to assure immediate replacement.

Blood component support for life threatening haemorrhage is guided as per table below:
<table>
<tr><th>Component</th><th>Comment</th></tr>
<tr><td>Red cell components</td><td>4-6 units initially, rate guided by blood loss.</td></tr>
<tr><td>Plasma</td><td>At least 1:2 unit ratio with red cells as part of initial resuscitation until results from coagulation monitoring available. Once bleeding controlled guided by haemostatic test results i.e. Trigger PT/APTT >1.5 times normal, use standard dose 15 ml/kg. Where laboratory results are unavailable and bleeding continues, further transfusion in at least a 1:2 ratio with red cells.</td></tr>
<tr><td>Platelets</td><td>Request where ongoing bleeding and platelet count <100 x 10^9/l to have on standby. Transfuse to keep >50 x 10^9/l (≥100 x 10^9/l in the case of brain/critical site bleeding).</td></tr>
<tr><td>Fibrinogen Concentrate</td><td>Guided by fibrinogen levels or viscoelastic haemostatic monitoring. Trigger 1.5 g/l.

A dose of 4g will increase fibrinogen by 1g/l in an adult.</td></tr>
<tr><td>Tranexamic Acid</td><td>1g over 10 minutes at initial presentation, can be continued at a dose of 1g 8 hourly until bleeding ceases.</td></tr>
<tr><td>Empiric Approach: Massive Haemorrhage Pack</td><td>4 Red Cell Components
4 units of Plasma (currently IBTS provides Solvent Detergent Plasma (SDP))

4g fibrinogen, for every blood volume loss

1 unit platelets if 1.5 blood volume loss</td></tr>
</table>
</td><td>Low</td><td>Strong</td></tr>
</table>

13	Early mechanical thromboprophylaxis with intermittent pneumatic compression (IPC) should be applied while the patient is immobile and has a bleeding risk. This should be combined with pharmacological and IPC thromboprophylaxis within 24 hours after bleeding has been controlled and until the patient is mobile.	Low	Strong
14	Two separate reviews are required following an unexpected life threatening haemorrhage in addition to hospital specific processes which are in place for adverse events/risk management / open disclosure: a) De-brief by the theatre team to ensure all staff members are supported, discuss and learn from the life threatening haemorrhage event b) Case Review by a wider multi-functional team – led by perioperative director and supported by lead haematologist for transfusion, Haemovigilance officer and chief medical scientist should be undertaken, fully engaging the theatre team in a timely manner. A summary should be reported to the HTC. In addition, such incidents may be part of: • Periodic audit by the Hospital Transfusion Committee reviewing overall trends, outcomes, and processes for life threatening haemorrhage events • All Hospital Transfusion Committees will feed into an Overarching Transfusion Committee (OTC). The OTC will review and benchmark unexpected life threatening haemorrhage events - overall trends, outcomes and processes.	Low	Strong
15	It is recommended that all medical scientists supporting out of hours transfusion laboratory activity, who do not work routinely in the Transfusion laboratory should undertake supervised dedicated familiarisation days annually. It is recommended that this familiarisation consist of 10 days during routine hours in the Transfusion laboratory to ensure the appropriate skill set.	Very Low	Strong

16	All hospitals must develop an arrangement so that in the circumstances of a life threatening haemorrhage event, an additional medical scientist can be called in out of hours to support the laboratory practice where necessary.	Very Low	Strong
17	Hospitals which provide a transfusion service for offsite hospitals should identify as part of the Service Level Agreement(s) the requirement and the timeline for provision of blood components at the offsite hospital.	Very Low	Strong

2 Development of the National Clinical Guideline

2.1 Background

The NCEC was requested by the Minister for Health to commission this guideline arising from a significant patient safety/policy matter and RCSI were subsequently requested to lead the guideline development process. Prior to this guideline, no national guidance existed in Ireland regarding strategies and pathways for the prevention, recognition or management of life threatening haemorrhages which occur intraoperatively.

In clinical practice, unexpected intraoperative life threatening haemorrhage can be catastrophic in nature and difficult to control, even for an experienced practitioner. Other terms commonly used to describe life threatening haemorrhage and which are used interchangeably are massive haemorrhage or major haemorrhage. Due to inconsistency in definition, the GDG have chosen to adopt the term life threatening haemorrhage which implies less ambiguity as to the level of blood loss observed. Massive or major haemorrhage is difficult to define with no universally accepted definition and a need to consider clinical context.

Broad definitions have been suggested and they include;

1. Loss equivalent to a person's total blood volume in a 24-hour period.
2. Loss equivalent to 50% of a person's total blood volume over a three-hour period.
3. Loss of blood volume at a rate of 150ml/minute.

However, these are in the main retrospective considerations and do not assist prompt recognition which would best manage unexpected life threatening haemorrhage (also termed 'exsanguinating haemorrhage' in the literature). Life threatening haemorrhage is associated with clinical features including tachycardia (>110 beats per minute),[1] hypotension (<90mmHg systolic blood pressure)[1] or significant change in vital signs from baseline and suggests a sudden loss of at least 50% of blood volume. The term does not encompass slow haemorrhage which presents without sudden or acute onset of these clinical signs.

Intraoperative life threatening haemorrhage has the potential for significant morbidity and mortality.[2] Dependent on the root cause, an intraoperative life threatening haemorrhage may fall within the definition of an adverse event in the hospital setting, defined as 'unintended injury or complication resulting in prolonged length of hospital stay, disability at the time of discharge or death caused by clinical management of the injury and not by the patient's underlying disease'.[3] Adverse events present a significant threat to patient safety and can be categorised as preventable or unpreventable, with a considerable proportion of all in-hospital adverse events categorised as potentially preventable.[4,5] Surgical care, and specifically care provided in operating theatres, is associated with a notably high incidence of adverse events,[4] with haemorrhage being a frequently encountered complication.[5] Although all surgical procedures inherently carry a risk of haemorrhage this can range from anticipated, such as in major cardiac or hepatic procedures, to unexpected in more routine surgeries where large quantities of blood-loss are not typically predicted.[6]

The potential that intraoperative life threatening haemorrhage has for patient morbidity and mortality denotes that it is an adverse event of key concern in healthcare delivery.

A systematic review was undertaken to determine the incidence of mortality in Ireland related to intraoperative life threatening haemorrhage (see Annex B) and the results highlighted a lack of information relating to the incidence and associated mortality in Ireland. Most surgeons/gynaecologists in their professional life will have come across several life threatening haemorrhage events and often the outcome has been fatal. This of course is devastating for the patient's relatives and the medical team caring for the patient. In response to this lack of available data, the GDG undertook a survey of all blood transfusion laboratories in Ireland (47 in total) to gather data to support the guideline development process. A response rate of 100% was achieved with this data gathering exercise and the results of the survey are available on request. Data gathered included structural, process and outcomes data such as: assigned blood distribution centres, services supported by blood banks, resourcing, out of hours supports, laboratory activity level, drills, massive haemorrhage protocol activations and free text comments.

The recommendations outlined in this guideline will provide clinical staff with evidence based actions to assist with preventing, recognising, managing and responding to a life threatening haemorrhage event.

Current evidence does not support the universal policy of 24-hour cell salvage (process by which blood from the surgical field is collected, filtered, and washed to produce autologous blood for transfusion back to the patient) for patients with major bleeding in the context of improved mortality.[7] There is however a reduction in donor exposure which assists the sustainability of the national blood supply. While not currently a common practice in emergency situations in Ireland there are a number of clinical sites where this is available for elective cases and the guideline development group support this continued practice where available with trained personnel.

2.2 Clinical and financial impact of condition/disease/topic

A systematic review (Annex B) was undertaken to determine the level of incidence of intraoperative life threatening haemorrhage and the incidence of mortality related to intraoperative life threatening haemorrhage in Ireland.

The included studies related to specific procedural activity in single institutions and hence the quality appraisal provided limited insight in the context of this systematic review. As no sources of population-level data were identified and the included studies provided limited data from discrete surgical procedures within single institutions, the true incidence of intraoperative massive haemorrhage and associated mortality in Ireland could not be determined. Similarly, the Hospital In-Patient Enquiry database contains a code for 'haemorrhage or haematoma complicating a procedure' but does not quantify the degree of haemorrhage experienced.

2.3 Rationale for this National Clinical Guideline

In response to an unexpected death of a patient due to haemorrhage while undergoing a surgical procedure, the National Clinical Effectiveness Committee (NCEC) was requested by the Minister for Health to commission and quality assure a guideline for the recognition, timely response and management of life threatening haemorrhage.

2.4 Aim and objectives

The aim and objectives of this guideline are as follows:

- Provide evidence based recommendations for theatre & laboratory staff on the prevention, recognition and management of unexpected intraoperative life threatening haemorrhage.
- Outline Good Practice Points for each recommendation to provide additional information for healthcare professionals on how each recommendation can be implemented in their hospital environment.

2.5 Guideline scope

This guideline was commissioned by the Minister for Health to address unexpected intraoperative life threatening haemorrhage. Therefore, this guideline will span acute clinical specialties where interventions and operations occur:

The guideline will provide guidance to theatre teams, haematologists and medical scientists on the recommended practices for unexpected intraoperative life threatening haemorrhage. The core theatre team is made of surgeons, anaesthesiologists, nurses and porters. Additional input from other healthcare professionals (haematologists and medical scientists) will be required at an early stage.

This guideline covers the following areas:

a) Prevention of intraoperative life threatening haemorrhage

b) Immediate recognition of intraoperative life threatening haemorrhage

c) Timely response and management of intraoperative life threatening haemorrhage

The clinical scenarios deemed out of scope for the "Unexpected Intraoperative Life Threatening Haemorrhage" Guideline are as follows:

- Life threatening haemorrhage (massive/major haemorrhage) in patients that have presented as trauma patients (i.e. patients where massive/major haemorrhage has not arisen from the procedure/ intervention itself)
- Post-partum massive haemorrhage
- Post-operative bleeding
- Life threatening haemorrhage (massive/major haemorrhage) in paediatric patients. (Note – any adolescent patient who attends an adult public hospital and is accepted by the hospital will be covered under this guideline).

The GDG recognises the morbidity and mortality associated with life threatening haemorrhage in other clinical scenarios for example severe abdominal trauma, gastrointestinal bleeding and postpartum haemorrhage. The overall practical management of life threatening haemorrhage may overlap in terms of clinical practice yet there may be variation. It is important to state that this GDG has specifically focused on the scenario of unexpected intraoperative life threatening haemorrhage as commissioned by the Minister of Health. However, in parallel with the development of this guideline there is a "Postpartum Haemorrhage" Guideline in development by the National Women and Infants Health Programme (NWIHP) and the Institute of Obstetrics and Gynaecology. In addition, the National Transfusion Advisory Group (NTAG) have also convened a GDG to draft a guideline on "Acute Life Threatening Haemorrhage" in other clinical scenarios. There is cross-representation from this GDG with these other two groups to ensure a standard National approach is adopted.

2.6 Conflict of interest statement

The NCEC Conflicts of Interest Policy was shared with all GDG Members and two signed copies (covering the two years of the guideline development process) were received. No conflicts of interest were recorded by members of the GDG.

At the start of all GDG meetings (face to face and virtual) the first item on the Agenda requested that any conflicts of interest from members of the GDG were identified.

2.7 Sources of funding

The Department of Health funded the appointed project management resource for the duration of this project. As this was a commissioned guideline, HRB-CICER resources were assigned to assist with literature reviews and completion of the budget impact analysis. The views or interests of the funding body have not influenced the final recommendations.

2.8 Guideline methodology

The NCEC Guideline Developers Manual[8] was a key resource used to ensure the appropriate guideline methodology was followed. Reproduced below is an extract of the 'Clinical Guidelines for the Management of Massive Haemorrhage: a systematic review' (Annex A). The full systematic review was written by HRB-CICER and the detailed search strategy is provided in Annex A. The review was conducted to ascertain if there were existing high-quality guidelines with recommendations that could be potentially adopted or adapted for the Irish setting, or if *de novo* development was required. Inclusion and exclusion criteria are included in Table 2.2 (page 10) of Annex A. The commitments outlined in the HSE Patient Safety Strategy 2019-2024[9] were considered as part of the recommendation development process also.

Step 1: Formulate the key questions

The scope of the guideline was identified at early meetings of the GDG. In identifying the guideline 'scope', the 'out of scope' areas were also identified by the GDG. It was agreed that the broad areas of focus for a literature review would cover the following areas:

- Recognition of massive/major/life threatening haemorrhage
- Organisational aspects of massive haemorrhage management (use of protocols, communication, training of personnel)
- Surgical management of massive/major/life threatening haemorrhage
- Transfusion/haematological management of life threatening haemorrhage
- Audit of management
- Definition or description of massive haemorrhage.

A systematic review was completed to answer the following question:

- What recommendations do clinical guidelines, which make reference to the management of massive haemorrhage, make relating to one or more of the above topics?

Annex A, Table 2.1 outlines the modified PICO format used for the research question.

Step 2: Search methodology

A formal literature search was undertaken by HRB-CICER to determine relevant international guidelines of interest. Electronic searches were conducted in PubMed, Embase, CINAHL (via Ebsco), and the Cochrane Library. Key terms and their variations were associated with the PICOS (Population/Patient/ Problem, Intervention, Comparison, Outcome, Study design) framework which is applicable when addressing a clearly defined clinical question relevant to a defined population group and clinical context. Key terms included a combination of terms associated with "intraoperative massive haemorrhage". The full search strategy is detailed in Annex A. This search strategy was created *de novo* by the research team and used an expansive approach to identify as many potentially relevant guidelines as possible. Grey literature sources were also searched including guideline repositories, guideline developer websites and specific clinical specialty websites. The full list of grey literature sources is also provided in Annex A.

Members of the GDG were also consulted to identify relevant national and international clinical guidelines based on their expert knowledge.

Step 3: Screen and appraise the evidence

All citations identified from the collective search of electronic databases, grey literature sources and GDG consultation were exported to EndNote® (Version X8) for reference management, where duplicates were identified and removed. Using Covidence®, two reviewers independently reviewed the titles and available summaries of the remaining citations to identify those which warranted full-text review. The full texts were obtained and independently evaluated by two reviewers applying the defined inclusion and exclusion criteria. Where disagreements occurred, discussions were held to reach consensus and where necessary, a third reviewer was involved. Citations excluded during the full-text review stage were documented alongside the reasoning for their exclusion and included in a study flow diagram.

Data extraction was performed independently by two members of the research team. Where disagreements occurred, discussions were held to reach consensus. Relevant information from each clinical guideline was extracted including the definition or description of massive haemorrhage, details of the evidence base, methods used to formulate recommendations and the specific recommendations of interest to the Intraoperative Massive Haemorrhage GDG. Where a structured process of development was not described in detail within the guideline document, authors were contacted to request this information. Data extraction was conducted in Microsoft Excel, using a data extraction table.

Two reviewers independently assessed the quality of the included guidelines using the Appraisal of Guidelines for Research and Evaluation Two (AGREE-II) tool[10]. AGREE-II scores were calculated and reported as scaled domain scores in accordance with the AGREE-II manual. Inter-rater agreements were assessed by subtracting the scores of the two reviewers; differences of more than two for any item were discussed to reach consensus.

Step 4: Develop and grade the recommendations

Nine guidelines, which possessed one or more recommendations on the specific topics of interest to the Unexpected Intraoperative Life Threatening Haemorrhage GDG, were evaluated in this review. The included guidelines predominantly focused on the transfusion or haematological management of bleeding or massive haemorrhage, with no guidelines identified providing specific guidance on unexpected intraoperative life threatening haemorrhage as the primary topic. The majority of recommendations extracted from the included guidelines were formulated based on expert opinion and or low quality evidence.

Decisions regarding which recommendations from existing guidelines to adopt and/or adapt were based on GDG consensus. Through a series of meetings and workshops the GDG identified 17 recommendations covering the scope of 'Unexpected Intraoperative Life Threatening Haemorrhage'. The 17 recommendations were informed by:

a) The expert opinion of members of the Guideline Development Group:
(recommendations 1,2,4,5,6,7,10,14)

b) Survey undertaken by GDG of all hospital transfusion blood banks across the country:
(recommendations 15,16,17) - survey results available on request

c) BSH guideline - A practical guideline for the haematological management of major haemorrhage.[11]
(recommendations 3,8,9,11,12)

d) European guideline on management of major bleeding and coagulopathy following trauma: fifth edition[12]
(recommendation 13)

The GRADE[13](Grading of Recommendations Assessment, Development and Evaluation) approach was used by the GDG to assess the quality of evidence for all recommendations. Domains included priority of the problem, equity, feasibility, etc.)

- GRADE categorises the certainty in evidence as high, moderate, low or very low

Table 2: GRADE Quality Level & Symbols

Symbol	Quality Level	Definition
⨁⨁⨁⨁	High	The GDG is very confident that the true effect lies close to that of the estimate of the effect.
⨁⨁⨁◯	Moderate	The GDG is moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
⨁⨁◯◯	Low	The GDG confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
⨁◯◯◯	Very Low	The GDG has very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of the effect.

A series of workshops took place with GDG members to develop an Evidence to Decision Framework (EtD) (Appendix 2) to assess the quality of evidence and strength of recommendations. Consensus was reached by the GDG through informal consensus discussion. A common scoring approach was used which scored the type of evidence available. All GDG reviewed these scores offline and then came together in a larger group to discuss and adapt as necessary. The consensus of the GDG is that the quality of evidence is very low or low for the recommendations. This type of event is so rare that high quality evidence is unlikely to ever be published to guide recommendations – the pathway for response has higher quality evidence though not specifically focused on life threatening haemorrhage.

A very extensive research exercise was undertaken by HRB-CICER resources to source evidence. The EtD Framework also assessed the desirable and undesirable consequences of implementing the

recommendations. The risk to patient safety, which can unfortunately result in patient death, is deemed high for all recommendations. The clinical and professional expertise of the GDG members contributed to a consensus score on the quality of evidence and strength of recommendations.

Although this may be a rare event the impact is significant, adherence to these recommendations is strongly recommended by all clinicians to ensure patient safety. The consensus of the GDG is that the strength of recommendation is high for all recommendations.

2.9 Consultation summary

The GDG endeavoured to ensure all interested parties had an opportunity to contribute to the development of this guideline. The GDG would like to acknowledge the significant contribution made by the various stakeholders from professional & academic groups which contributed greatly to the content of the guideline. An advanced draft of the guideline was sent to key stakeholders for a four-week consultation period in July 2021 and the consultation report is presented in Appendix 3.

Key areas noted from the Consultation review included:

a) Greater clarity on the scope and objectives of the guideline incorporated.

b) Input to the re-wording of a number of recommendations and good practice points to provide greater clarity.

c) Challenge from stakeholders on a number of recommendations which again assisted in improving the content of recommendations.

d) Many stakeholder groups highlighted their approval in having a standardised national approach to life threatening haemorrhage.

e) Concern due to the lack of high quality evidence and the narrow scope of the guideline – additional text included to further qualify the strength of recommendations.

f) Additional references provided and incorporated.

2.10 External review

Following discussion with the GDG, a decision was made to make a formal request to the Presidents of Royal College of Surgeons Ireland (RCSI), College of Anaesthesiologists of Ireland (CAI) and the Dean of the Faculty of Pathology in Royal College of Physicians of Ireland (RCPI) seeking nominations of international Surgical, Anaesthesiology and Haematology reviewers.

A letter was drafted and signed by the Chair of the GDG and sent to the relevant Presidents and Dean mentioned above outlining the request of the GDG and providing details of the guideline scope. The letter also highlighted that the international nomination(s) should be recognised leaders in the field and possibly have a special interest in any of the specific areas of consideration in the guideline scope.

The letter was acknowledged as received by all parties and nominations were then sought by the three colleges.

Within a few weeks of making the request of the colleges, an email was received by the Chair and Project Manager of the GDG outlining the respective colleges' international nominee.

All proposed nominees were also confirmed by the GDG to ensure alignment of their expertise (Search undertaken to qualify their areas of research and expertise).

When each nomination was received, the nominees were sent an email from the Chair and Project Manager thanking them for their interest in participating in the process and outlining the projected project timelines.

Contact was maintained with the international reviewers in the intervening process to inform them of any changes in timeline.

The reviewers were as follows:

a) Surgery: Professor Rob Sayers - Vascular surgeon - Chair NHS England National Clinical Reference Group (CRG) for Vascular Services.

b) Anaesthesiology: Professor Sibylle Kietaibl - Coordinated the European guidelines on the management of severe bleeding during surgery as well as the Austrian quality standard on Patient Blood Management (PBM).

c) Haematology: Professor Simon J Stanworth - Consultant haematologist and lead author of the BSH guideline currently under revision 'A practical guideline for the haematological management of major haemorrhage'.

A draft guideline was sent to the three international reviewers at the same time as the Public Consultation process outlined in Section 2.9.

Feedback from the panel of international reviewers informed the content of the guideline in the following manner:

- Greater clarity on the scope of the guideline incorporated.
- Amendment to the aims of the guideline as a reduction in mortality could not be measured due to there being a lack of current measures to determine if an improvement had been achieved.
- Greater clarity to the content of National Poster captured in Section 6.2.
- Additional reference sources identified to support recommendations.
- Commentary on Cell Salvage included in sections 2.1, 2.13 and 6.1 of the guideline – due to a lack of supporting evidence on the use of Cell Salvage for unexpected life threatening haemorrhage events, a decision was made not to include Cell Salvage as a recommendation at this time but as an area for further research in the future. This further research may lead to changes in the direction of travel of Cell Salvage practices in Ireland if supported by evidence.

2.11 Implementation

To inform the development of the implementation plan and logic model, GDG members participated in training to gain insight on the appropriate methodology to use.

The logic model (Appendix 4) provides a summary graphic representation of the guideline in terms of situation analysis, inputs, activities/outputs, and outcomes. A plan for the implementation of the guideline is provided in Appendix 5. The implementation plan is designed as a framework to guide actions required to promote effective implementation of recommendations made in this guideline. Funding for guideline implementation is subject to service planning and estimates process.

The Chief Executive Officer or General Manager of each hospital (and their associated Hospital Group Management Teams) have the corporate responsibility for ensuring implementation of the recommendations in this guideline. There are many individual roles that have responsibility to aid the implementation including - perioperative directors, surgical directors, theatre teams, lead haematologist for transfusion, transfusion laboratory staff and the Hospital Transfusion Committees (HTC). Audit of transfusion events will be coordinated and managed locally in each acute setting by the relevant local HTC.

2.12 Monitoring and audit

The overall objective of this National Clinical Guideline (NCG) is to improve patient safety. Audit and monitoring with systematic feedback improves healthcare by:

a) Reviewing performance against explicit recommendations captured in the guideline.

b) Focusing improvement activities towards areas not meeting the required standard.

The GDG recommends regular audit and monitoring to support implementation of the recommendations and to assess the efficacy of the guideline in both theatre and across the hospital setting. It is recommended that the audit and monitoring processes:

- Involve multidisciplinary stakeholders within the acute setting.
- Are planned and continuous.
- Coordinated locally in each acute setting with oversight from appropriate local governance committee e.g. HTC or theatre.
- Are benchmarked across sites with a view to practice enhancement.

A completed audit and monitoring plan for transfusion is presented in Appendix 7. Figure 1 below provides an overview of the data flow from case review through to audit.

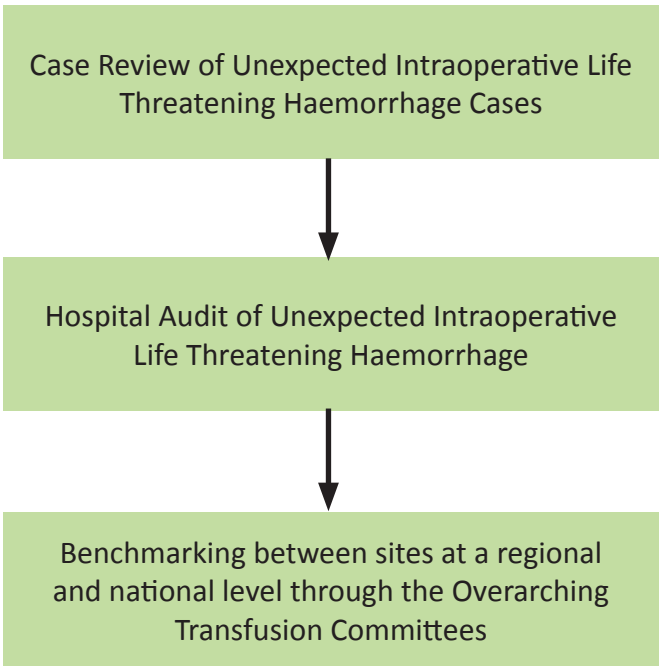


Figure 1: Data Flow

Audit:

Audit is a quality improvement methodology, which assesses clinical practice against standards. It aims to deliver improved processes and outcomes for patients. Audit criteria are a mixture of structure criteria (what is needed), process criteria (what is done) and outcome criteria (what is expected to happen as a result).

Only clinical audit carried out with the intent of improvement of patient outcomes and patient safety and published in an aggregated form can avail of the protection of the proposed patient safety legislation[14]. Within this context, the GDG recommend that audit of this NCG include:

- Audit of transfusion events
- Audit of the safe surgery checklist

A recommendation for national clinical audit has not been included. There is currently no process for prioritisation of national clinical audit at this time. However, the HSE is establishing a National Audit Office and Committee to address this and national audit relevant to this guideline should be proposed through this process.

a) Audit of transfusion events

While a data set is captured for an individual case review (see Appendix 6.3), formal audit of structures, processes and outcomes indicators is recommended (see Appendix 7). Periodic trending of structure, process and outcome indicators will take place. How often trending of events is carried out is determined by the frequency of events at a site e.g. quarterly, biannually, annually.

The audit of transfusion events is coordinated and managed locally in each acute setting by the relevant local HTC. The responsibilities of the HTC is outlined in the "Framework for the management of Unexpected Intraoperative Life Threatening Haemorrhage" (Appendix 6.1). The HTC will be responsible for overseeing audits of transfusion practices, seeking to improve patient care and outcomes through systematic review of care against explicit audit criteria and the implementation of change. Local transfusion audit is further enhanced by benchmarking between sites at a regional and national level through the OTC as outlined in Recommendation 14.

b) Audit of safe surgery checklist

The current HSE National Policy and Procedure for Safe Surgery[15] outlines that hospitals are responsible for local audit. An audit tool and recommendation for annual report is already included in this policy & procedure document. Audit findings and action plans are overseen by the operating theatre manager, clinical director for surgery and the hospital Clinical Governance Committee. While this policy and procedure is currently under revision, it will include similar recommendations for audit.

The audit plan in Appendix 7 does not refer to the safe surgery checklist audit as this is already covered within the HSE National Policy and Procedure for Safe Surgery.[15]

Monitoring

Monitoring is a systematic process of gathering information and tracking over time and seeks to continuously measure compliance.[8] While there are no national level Key Performance Indicators (KPI), the GDG have identified a number of KPIs which can be used to monitor the implementation of selected guideline recommendations at hospital level. These KPIs are detailed in Appendix 7 - they focus on measurement performance to support safe transfusion practice (areas such as personnel and training and are monitored within the Hospital Transfusion Quality System). These KPIs were developed from the recommendations outlined in the guideline (specifically recommendations 3, 8, 15 & 17, further details provided in Appendix 7).

It is important that the implementation of the guideline be monitored to ensure it positively impacts on patient care and safety. Care of the patient with a life threatening intraoperative haemorrhage involves a multidisciplinary healthcare team working across different departments and potentially different sites. The audit and monitoring plan is therefore broad-ranging and focused on ownership for quality and safety of patient care and improvement of patient outcomes firstly at front line level.

The specific recommendation owners are responsible for the implementation of the recommendations which includes relevant KPI monitoring. There are 4 recommendations that have defined KPIs and the table below provides details of these recommendations and their associated owners.

Recommendation Number	Owner
3	Lead haematologist for transfusion
8	Perioperative director
15	Laboratory management
17	Laboratory management

Recommendation owners may delegate data gathering and analysis tasks. Governance and oversight of KPIs is carried out by the HTC. Monitoring of KPIs provides assurance to the HTC and the hospital itself that the recommendations have been implemented. Where there is non-compliance a quality improvement plan should be put in place. See Appendix 7 for a listing of all KPIs.

2.13 Plan to update this National Clinical Guideline

NCEC National Clinical Guidelines need to be kept up to date to ensure the recommendations remain reliable and useful for the public, health professionals and policy makers. The GDG agreed that the guideline should be reviewed after three years from publication and updated in line with NCEC processes. The group convened for the review may incorporate stakeholder groups represented in the creation of the guideline including the National Clinical Programme for Surgery and a forum convened by National Clinical Lead for Transfusion.

If there is a major change in evidence prior to the planned review of this NCG, a rapid update may be conducted as per NCEC procedures.

The GDG propose that future reviews consider additional evidence in areas such as:

- **Cell Salvage**
  Current evidence does not support the universal policy of 24-hour cell salvage for patients with major bleeding in the context of improved mortality. There is however a reduction in donor exposure which assists the sustainability of the national blood supply. While not currently a common practice in emergency situations in Ireland there are a number of units where this is available for elective cases. Cell salvage to support life threatening haemorrhage requires training and on-going competence assessment and availability on a 24 hour basis.

  A recommendation on the use and roll out of Cell salvage practices in Ireland should be informed by participation in national and international randomised control trials.

- **National Audit of Practice**
  Data capture as outlined in section 6.2 should inform a national audit on life threatening haemorrhage outcome and process measures (to include a review of the plasma discard rates associated with the current recommendation of a single massive haemorrhage pack).

- **Medical scientist resourcing**
  A review of medical scientist resourcing for out of hours laboratory demand is recommended.

- **Use of Viscoelastic Haemostatic Assays (VHAs)**
  Robust diagnostic studies validating and standardizing diagnostic cut offs for VHA parameters and randomized trials comparing VHA-guided algorithms with standard care on clinical outcomes in massive haemorrhage are urgently needed.

3 National Clinical Guideline

3.1 Key questions and evidence statements

The PICO (Population, Intervention, Comparison/Control, and Outcome) format has been used for all questions and associated recommendations. The GDG wish to highlight that the rarity of unexpected intraoperative life threatening haemorrhage events presents difficulty in providing robust evidence to underpin the clinical and cost-effectiveness of the guideline. For all recommendations a number of Good Practice Points have been identified – these are best practice guidance points based on the experience of the GDG and are supplementary notes to support the implementation of each recommendation.

Question 1	Is it important to decide where surgical procedures of different levels of complexity should be performed?
P (Population)	All patients undergoing emergency and elective surgical procedures
I (Intervention)	Designated hospital sites
C (Comparison/control)	Non-designated hospital sites
O (Outcome)	Safe surgery sites

Evidence statement:

It is very important that all hospitals provide care in the right way, at the right location and in a manner that ensures a safe, high quality service for all.[16] Centres of care or centres of excellence have the ability to deliver enhanced quality through the application of innovative tools, technologies and techniques which improve outcomes.[17] The GDG are in agreement that surgery should only take place in suitable sites where appropriate resources and supports are available. This needs to be on a 24 hours, 7 days a week basis if the hospital is providing emergency care. Designation of surgical sites is already in place and the GDG believe this should continue – Hospital Group Management Teams should attend to further consolidation of the hospital sites through appropriate resource allocation.

The ability to deliver a safe clinical service is difficult across the high number of hospital sites that exist presently in Ireland. Additionally it is proving very difficult to staff these hospitals with the appropriately skilled personnel and the cost associated with delivering this service across so many sites is significant. The risk of life threatening haemorrhage is present in all surgical procedures accessing the chest, abdomen or pelvis or where there is potential to inadvertently enter one of these cavities during surgery. These scenarios account for a high percentage of emergency and elective surgical procedures. The models of care for Acute and Elective Surgery as defined by the HSE Surgical Clinical Programme provides a comprehensive framework for the delivery of surgical care[18,19] in addition to the HSE National Women and Infants Health Clinical Programme model of care.[20]

Recommendation 1:
Hospital Group structures already exist for the delivery of healthcare nationally and should continue to designate the appropriate sites for scheduled (elective) and unscheduled (emergency /urgent) surgery. Consideration of timely access to blood transfusion support and turnaround times (TATs) for critical tests or availability of near patient testing (NPT), should be included in the designation of appropriate sites so as to support life-threatening haemorrhage.

Certainty of evidence: Very Low
Strength of recommendation: Strong

Good Practice Points:

- Local Hospital Group management teams to take responsibility for designating appropriate surgical sites.
- Review and evaluate the current designation of sites and their suitability to perform particular surgical procedures, this will ensure that patient safety remains central.
- An appropriate site will have pre-operative assessment to identify patients with clinical conditions, medication or prior treatments (e.g. radiotherapy) which would place patients at increased risk of bleeding and structure an appropriate management plan.
- A designated site should have timely access to appropriate transfusion support and appropriate TATs for tests to support management of unexpected life threatening haemorrhage.

The following are responsible for implementation of Recommendation 1:

Hospital Group management teams

Question 2	Will following a safe surgery practice checklist assist with the prevention and management of life threatening haemorrhage events?
P (Population)	Theatre staff
I (Intervention)	Use of the safe surgery checklist
C (Comparison/control)	No safe surgery checklist completed
O (Outcome)	Safer surgical practice resulting in the prevention or better management of life threatening haemorrhage events in patients undergoing elective or emergency surgical procedures.

Evidence statement:

With the aim of improving the safety of surgical procedures for patients, a checklist was developed by the World Health Organization (WHO) patient safety programme, similar to those used in aviation, aeronautics and product manufacturing. The WHO Guidelines for Safe Surgery[21] is a recognised approach in supporting patient safety worldwide. A systematic review conducted on the impacts and implementation of surgical checklists highlighted that surgical safety checklists were associated with increased detection of potential safety hazards, decreased surgical complications and improved communication among operating room staff.[22] By providing guidance for safe practice throughout the surgical patient pathway and introducing key safety steps that can be incorporated into the operating theatre routine, the most common and avoidable risks associated with surgical error can be minimised. The 'HSE National Policy and procedure for safe surgery'[15] which is based on the WHO Guidelines for Safe Surgery is already in use within the Irish health system and provides a sample safe surgery checklist for use.

This policy applies to all staff involved in the surgical patient pathway and should form part of the care provided to all patients undergoing a surgical procedure within the operating theatre environment in their organisation.

Recommendation 2:
All theatre teams must follow the agreed 'Sign In, Time Out and Sign Out - Safe Surgery Checklist' as presented in the 'HSE National Policy and procedure for safe surgery' (Private Hospitals to use WHO Safe Surgery Guideline).

Certainty of evidence: Low
Strength of recommendation: Strong

Good Practice Points:

- Checklists are simple reminders of what to do, it is important to adopt a 'safety first' attitude when completing the checklist.
- It is essential that the operating surgeon or a nominated senior delegate is present for all phases of checklist completion.

The following are responsible for implementation of Recommendation 2:

Hospital management teams, theatre teams.

Question 3	Will documented guidance and visual guidance/instructions for theatre staff assist with responding to a life threatening haemorrhage event?
P (Population)	Theatre and transfusion laboratory staff
I (Intervention)	Visual guidance/instructions (e.g. Poster and Protocol)
C (Comparison/control)	No visual guidance or instructions provided
O (Outcome)	Improved response and management by theatre staff to a life threatening haemorrhage event

Evidence statement:

The British Committee for Standards in Haematology guideline 'A practical guideline for the haematological management of major haemorrhage'[11], outlines a recommendation that 'Hospitals must have local major haemorrhage protocols with adaptations for specific clinical areas. All medical, nursing, laboratory and support staff must know where to find the haemorrhage protocol in relevant areas and be familiar with the contents; their knowledge should be supported by training and regular drills'[11]. The provision of emergency blood to a bleeding patient requires the use of specifically designed protocols, which include robust and clearly understood communication channels between clinical staff and those in the blood transfusion laboratory. The life threatening haemorrhage protocol should enable the release of blood and blood components for initial resuscitation with clear pathways between the transfusion laboratory and the theatre. Having a documented plan provides clarity as to the key activities and responsibilities in managing the crisis. An investigation report from the index case which was a driver for this guideline identified delays in sourcing blood products.

A survey undertaken by the GDG of all blood transfusion laboratories across the country identified gaps in the availability of a Life Threatening Haemorrhage Protocol/Procedure. The survey also identified that in addition to the Protocol, most hospitals summarised information from the Protocol in a single page format (one page poster). Many hospitals had a poster available in theatre but a lack of standardisation

in the content displayed on this poster was apparent. Having a standard format will be helpful for theatre staff and all rotating trainees.

To assist in guiding hospitals on what specific content to include in the local life threatening haemorrhage protocol/procedure the GDG have defined a 'Life Threatening Haemorrhage Framework' which is included as a tool in Appendix 6.1. This Framework document should be referenced when creating local life threatening haemorrhage policy, protocols/sop's. A template of the proposed National Poster for Life Threatening Haemorrhage which will be placed in all theatres is provided in Appendix 6.2 also.

Recommendation 3:
All hospitals must have the National Life Threatening Haemorrhage Management Poster prominently on display in the operating theatre. All hospitals must also have an underpinning life threatening haemorrhage policy & procedure/protocol which incorporates the recommendations of this guideline. All clinical, laboratory and support staff to maintain their competency must be familiar with the contents of the life threatening haemorrhage protocol/procedure.

Certainty of evidence: Low
Strength of recommendation: Strong

Good Practice Points:

- All hospitals must develop their life threatening haemorrhage protocol/procedure according to the national framework which will be available on the HSE repository/Dr Steeven's Library under the Transfusion Tab (also available in Appendix 6.1 of this guideline).
- The life threatening haemorrhage protocol/procedure should be accessible to all relevant staff including the transfusion and haematology laboratory.
- Adoption of terminology 'Life Threatening Haemorrhage/CODE RED' is recommended for clarity of communication.
- Content of drills should be informed by protocol/procedure & poster.
- Each hospital is responsible to populate the local information in the 'Adult Intraoperative Life Threatening Haemorrhage Protocol Poster' (Appendix 6.2).
- Lead haematologist for transfusion has ultimate responsibility (Owner) for protocol/procedure & poster including updates as appropriate.

The following are responsible for implementation of Recommendation 3:

Lead haematologist for transfusion, HTC, National Transfusion Advisory Group.

Question 4	Will considering the possibility or risk of an unexpected life threatening haemorrhage taking place in advance of a procedure (perioperative briefing) by theatre staff lead to an improved response and management of life threatening haemorrhage events?
P (Population)	Theatre staff
I (Intervention)	Considering risk of life threatening haemorrhage in advance of procedure (preoperative briefing)
C (Comparison/control)	Lack of advance discussion on risk of life threatening haemorrhage event (no preoperative briefing)
O (Outcome)	Improved response and management of life threatening haemorrhage events and a potential reduction in the possibility of life threatening haemorrhage events

Evidence statement:

The WHO Guidelines for Safe Surgery 2009 outlines that 'a discussion of critical or non-routine steps is intended to inform all team members of any steps that put the patient at risk for rapid blood loss, injury or major morbidity'.[21] The first step in mitigating blood loss is prevention. Known coagulation deficits should be corrected before surgery whenever clinically possible.[21] The risk is present in all surgical procedures accessing the chest, abdomen or pelvis accounting for a high percentage of surgical procedures. The brief of this guideline covers 'unexpected' life threatening haemorrhage, i.e. a life threatening haemorrhage event that may not have been considered in advance of the procedure. Reducing risk for this scenario is challenging but the GDG see an opportunity of capturing this as a question in the HSE Safe Surgery Checklist[15] to ensure this risk is considered in advance of all surgical procedures.

A National Safe Site Surgery Policy Review Group (independent of this guideline) was established of which three members of the GDG are also members. A proposal from the GDG was made to this policy review group to amend the HSE Safe Surgery Checklist to capture a question related to considering the possibility of unexpected life threatening haemorrhage at the 'Sign In' stage of the checklist. This proposal was accepted and will be captured in a revised version of the HSE Safe Surgery Checklist.[15]

Further amendments to the HSE Safe Surgery Checklist will include a requirement that a preoperative briefing will take place with members of the theatre team - the timing of the briefing may vary from theatre to theatre. As part of the briefing any team member should be empowered to highlight their concerns with regards to the possibility of life threatening haemorrhage. A study undertaken (Leong et al, 2017) concluded that preoperative briefing and debriefing improved the team climate of surgical teams and the efficiency of their work within the operating theatre.[23]

Recommendation 4:
The pre-operative assessment of the patient should identify specific issues for individual patients which need to be addressed to reduce the risk of life threatening haemorrhage. In addition, prior to commencement of the operation the multidisciplinary team should identify specific parts of the operation where life threatening haemorrhage could occur. This particularly applies when any operative intervention in the chest, abdomen or pelvis occurs.

Certainty of evidence: Very Low
Strength of recommendation: Strong

Good Practice Points:

- When an intra-thoracic, abdominal or pelvic operation takes place the possibility of unexpected life threatening haemorrhage should be considered – the surgeon or anaesthesiologist should communicate the specific parts of the operation where the risk is highest to the team.
- Identifying the point where there is a possibility of a haemorrhage event taking place in advance of a procedure will place all theatre staff on alert.
- Preoperative briefing to take place with members of the theatre team - the timing of the briefing may vary from theatre to theatre.
- All team members should feel empowered to voice any concerns that they may have at any stage.

The following are responsible for implementation of Recommendation 4:

Perioperative director, theatre manager, surgeon, anaesthesiologist.

Question 5	Which items would be helpful to consider in advance of any operative intervention in the chest, abdomen or pelvis procedure to assist in responding to a life threatening haemorrhage event?
P (Population)	Theatre staff and transfusion laboratory staff
I (Intervention)	Confirming blood group and antibody screening, blood component availability, senior help and equipment in advance of procedure
C (Comparison/control)	Not planning in advance of procedure
O (Outcome)	Improved ability to respond to and manage a life threatening haemorrhage event

Evidence statement:

The 2019 "Serious Hazards Of Transfusion Report" outlined that poor communication between the clinical and laboratory settings and staff shortages were the main contributory factors for delays in transfusion.[24] This report also found that there is continued evidence of poor understanding and activation of major haemorrhage procedures resulting in delayed transfusion. A study undertaken concluded that preoperative briefing and debriefing improved the team climate of surgical teams and the efficiency of their work within the operating theatre.[23] The GDG reached consensus in determining that if a life threatening haemorrhage event were to take place, confirming blood group and antibody screening, blood component availability, senior help and equipment in advance of the procedure will assist with the response to the life threatening haemorrhage event. All hospitals should already have an efficient system in place for patients at risk of unexpected intraoperative life threatening haemorrhage that fulfils the criteria of required blood testing, theatre equipment, availability of blood and senior help.

It was decided not to create an additional checklist to confirm that this information is checked in advance of an operative intervention in the chest, abdomen or pelvis.

Recommendation 5:
When any open or laparoscopic/operative intervention in the chest, abdomen or pelvis is to take place or where there is potential to inadvertently enter one of these cavities during surgery - the following criteria will be confirmed in advance of the procedure to support adequate preparation in the event of an unexpected intraoperative life threatening haemorrhage:

Once per day:

- Confirm emergency Group O blood is available in the specified fridge/cold storage known to the theatre staff and documented on the National Life Threatening Haemorrhage Poster
- Confirm other blood components (see Poster) for the management of a life threatening haemorrhage are available

Every Patient:

- Confirm blood group and antibody screen (group and hold) or crossmatch has been performed as per hospital Maximum Surgical Blood Ordering Schedule (MSBOS) /specific blood order for a particular patient is available
- Confirm where senior help is and how they can be contacted
- Confirm placement of at least one peripheral wide bore cannula
- Confirm the availability of equipment for the placement of central access catheters (including ultrasound)
- Confirm location and availability of sterile vascular instruments and haemostatic products

Certainty of evidence: Very Low
Strength of recommendation: Strong

Good Practice Points:

- This discussion could take place at the preoperative team briefing which allows for shared learning and transfer of information as outlined by WHO guidelines for Safer Surgery 2009.
- All emergency equipment/instruments should be checked for availability and functionality where possible.
- Use of cell salvage equipment may be used if available by staff who are trained and competent in its use.
- Where an antibody screen is found to be positive with a clinically relevant antibody, compatible components should be available as appropriate prior to surgery.

The following are responsible for implementation of Recommendation 5:

Perioperative director, theatre manager.

Question 6	Does supervisory support provided to trainee surgeons, gynaecologists and anaesthesiologists lead to improved surgical skills?
P (Population)	All patients undergoing surgical procedures
I (Intervention)	Supervisory support from an experienced clinician for trainee surgeons, gynaecologists and anaesthesiologists providing exposure to the operating theatre
C (Comparison/control)	Lack of or no supervisory support from an experienced surgeon for trainee surgeons, gynaecologists and anaesthesiologists
O (Outcome)	Improved surgical skills and knowledge due to exposure to the operating theatre under the guidance of an experienced surgeon

Evidence statement:

The operative caseload of a surgeon has a positive influence on post-operative outcomes. For trainees to progress effectively, maximising operating room exposure is essential. In select cases, with appropriate training and suitable experience, supervised trainees can perform surgical procedures without any detriment to patient care. To ensure high standards for patients of the future, supported training programmes are essential for today's surgical trainees.[25] Clinical supervision has patient safety and the quality of patient care as its primary purposes. After training is completed, doctors may practice for the rest of their career without any clinical supervision, the implication being that the difficulties dealt with in clinical supervision are no longer difficulties, or are better dealt with some other way. Clinical supervision should be sufficiently flexible to adapt to the needs of experienced clinicians as its forms can be varied, though its functions remain focused on patient safety, good quality clinical care and professional wellbeing.[26]

Supervision is already a common practice within the Irish health system and should be continued where trainees are supervised as part of their training journey. Appropriate supervision and clinical support should be provided to surgical, gynaecological and anaesthesiology trainees in line with their experience and stage of training.

Recommendation 6:
To ensure patient safety appropriate supervision and clinical support should be provided to surgery, gynaecology and anaesthesiology trainees in line with their experience and stage of training.

Certainty of evidence: Very Low
Strength of recommendation: Strong

Rationale/Context for Recommendation

It is acknowledged that all hospitals have trainee surgeons, gynaecologists & anaesthesiologists and this model is essential for the delivery and development of the health service. Within the health system currently, many out of hours emergency cases are managed by trainees. It is the responsibility of the consultant surgeon and anaesthesiologist to ensure the individuals performing the procedure are receiving the correct level of supervision.

Good Practice Points:

- Appropriate supervision will vary for each trainee and is directed at the individual trainee doctor's needs and abilities at a point in time.
- It is a judgement call by the consultant surgeon, gynaecologist and anaesthesiologist as to the correct level of supervision required by the trainee.
- The consultant surgeon does not necessarily need to be in the operating room but attendance is dependent on the trainees level of experience and competency.
- The trainee should feel they have attained the level of competency required to undertake the procedure and be empowered to request support if needed.
- The supervisor and trainee should be aware of all local procedures and policies related to the major haemorrhage protocol.

The following are responsible for implementation of Recommendation 6:

Supervising consultant surgeon, supervising consultant gynaecologist, supervising consultant anaesthesiologist.

Question 7	Would laparoscopic skills training and simulated drills on life threatening haemorrhage be of assistance to trainees?
P (Population)	Surgery and gynaecology trainees
I (Intervention)	Laparoscopic skills training and simulated drills on life threatening haemorrhage
C (Comparison/control)	No laparoscopic skills training or simulated drills on life threatening haemorrhage taking place
O (Outcome)	Improved patient safety resulting from trainees receiving laparoscopic skills training and simulated drills on life threatening haemorrhage

Evidence statement:

Vascular injury complicates approximately 0.1–1.1% of all laparoscopic procedures.[27] Laparoscopic vascular injury is a serious and potentially fatal event. Prevention of injury involves the appropriate use of surgery, a good knowledge of anatomy and the safe use of abdominal entry techniques. Management of vascular injury depends on the vessel injured and the experience of the operating surgeon.[28] Evidence suggests that skills obtained in simulation training are applicable in real clinical scenarios. Simulation allows trainees to make mistakes, to ask the 'what if' questions, and to learn and reflect on such situations without risking patient safety.[29] Effective communication is critical for patient safety. One potential threat to communication in the operating room is incivility. A study undertaken by Katz et al, 2019[30] identified that incivility had a negative impact on performance. Multiple areas were impacted including vigilance, diagnosis, communication and patient management even though participants were not aware of these effects. It is imperative that these behaviours be eliminated from operating room culture and that interpersonal communication in high-stress environments be incorporated into medical training. Laparoscopic skills training is already part of the curriculum for trainee surgeons and gynaecologists and the GDG are stating that this practice should continue. Simulation training for life threatening haemorrhage events currently takes place for surgeons and needs to be developed for gynaecology trainees.

Recommendation 7:
All trainee surgeons and gynaecologists undertaking laparoscopic procedures during the course of their training must complete laparoscopy skills training and simulation drills - these include recognition and appropriate response to a life threatening haemorrhage event.

Certainty of evidence: Very Low
Strength of recommendation: Strong

Rationale/Context for Recommendation

Simulation drills that include the recognition and appropriate response to a life threatening haemorrhage event are currently included in the curriculum of surgical trainees undertaking laparoscopic procedures. The GDG are recommending that simulation drills take place at appropriate simulation sites for gynaecology trainees also.

Good Practice Points:

- Senior clinicians should have the opportunity to participate in the faculty simulation courses.

The following are responsible for implementation of Recommendation 7:

RCPI, RCSI & CAI - Directors of training, supervising consultant surgeon & supervising consultant gynaecologist

Question 8	Do regular life threatening haemorrhage drills among theatre staff result in an improved response to and management of life threatening haemorrhage events?
P (Population)	Theatre staff, medical scientists
I (Intervention)	Regular life threatening haemorrhage drills
C (Comparison/control)	No life threatening haemorrhage drills taking place
O (Outcome)	Improved response to and management of life threatening haemorrhage events.

Evidence statement:

When critical events develop in the operating room, communication among the staff concerned is important to avoid exacerbation of critical conditions caused by haemorrhage and to minimise the adverse effects of massive haemorrhage on patients.[2] A drill allows an opportunity for the theatre team to practice effective communication approaches in a safe environment. The BSH guideline 'A practical guideline for the haematological management of major haemorrhage' outlines a recommendation that all medical, nursing, laboratory and support staff should participate in regular drills.[11] The survey undertaken by the GDG of hospital transfusion labs identified a desire from hospitals to participate in drills to support their training. This is already a practice in a number of hospitals but not a standardised practice.

Recommendation 8:
All staff working in theatre and all medical scientists involved in a life threatening haemorrhage (including those providing out of hours cover) should participate in regular multi-disciplinary drills in the recognition and management of major blood loss. Participants should know when to activate/ trigger the life threatening haemorrhage protocol and take prompt and appropriate action.

Those participating in the multi-disciplinary drills should complete the eLearning training content on life threatening haemorrhage when it becomes available.

Certainty of evidence: Low
Strength of recommendation: Strong

Rationale/Context for Recommendation

A survey undertaken by the GDG in 2019 demonstrated that the majority of hospitals did not undertake cross functional major haemorrhage protocol drills. Drills or simulation events provide an opportunity to clarify roles and responsibilities and provide experience that will be helpful should a life threatening haemorrhage event take place.

Good Practice Points:

- All hospitals should schedule cross functional drills (appropriate to their setting) to provide participants - theatre staff, laboratory staff, porters & switch with the opportunity to practice activation of the local life threatening haemorrhage protocol. These drills should incorporate elements such as clarity on roles and responsibilities, communication & team working.
- A review should take place following all drills to determine learnings and opportunities for improvement.
- The decision to trigger a life threatening haemorrhage protocol is one for senior clinical staff to call but all theatre staff should know when to consider the possibility that a major haemorrhage is occurring and feel empowered to suggest that it be considered.
- Familiarity with blood component resuscitation, availability and location must be included in drills.

The following are responsible for implementation of Recommendation 8:

Chairperson of Theatre Users Group / perioperative director, lead for Safe Surgery Group

Question 9	Does an assigned emergency coordinator lead to an improved response to and management of a life threatening haemorrhage event?
P (Population)	Theatre staff, transfusion/haematology laboratory staff
I (Intervention)	Emergency coordinator assigned following triggering of major haemorrhage protocol
C (Comparison/control)	No emergency coordinator assigned
O (Outcome)	Improved response to and management of a life threatening haemorrhage event

Evidence statement:

Good communication between those in theatre is essential to assist clinical outcomes. Professional pride, fear of criticism of calling many staff unnecessarily can cause indecision in declaring an emergency. Survival of the patient has to be prioritized in taking action against critical bleeding.[2] Following the activation of the major haemorrhage protocol, nominating an emergency coordinator will assist with coordinating the response activities. The BSH guideline 'A practical guideline for the haematological management of major haemorrhage' outlines a recommendation that 'following the trigger of the major haemorrhage protocol there must be a clear mechanism for contacting all relevant team members and a designated team leader should then coordinate further management.[11] Critical tasks should be allocated to specific team members with closed loop communication, this approach is associated with higher team efficiency in the performance of critical tasks and administration of essential drugs.[31] It has been shown that it is not simply the knowledge, skills and attitudes of leaders (or in fact of other team members) that affect teams' ability to manage catastrophic medical emergencies efficiently, it is the way teams apply these to practice through teamwork.[32]

Recommendation 9:
Following the trigger of the life threatening haemorrhage protocol there must be a clear mechanism to contact all relevant team members and a designated emergency coordinator should then coordinate further management.

Certainty of evidence: Low
Strength of recommendation: Strong

Rationale/Context for Recommendation

Clear communication between those in theatre and the transfusion laboratory is essential to assist clinical outcomes. The emphasis is to stop the haemorrhage and stabilise the patient – the emergency coordinator will confirm if assistance is required and coordinate the response.

Good Practice Points:

- A designated emergency coordinator will be appointed when the event is recognised to direct and coordinate the overall response – this may be a senior nurse.
- The emergency coordinator needs to be in/outside the theatre where the emergency is unfolding and not in an office. They need to be able to co-ordinate with means of communication (mobile etc.) with all relevant parties.
- During such a case, the clinical decision making is mainly between the anaesthesiologist and surgeon.
- A communication link between the laboratory and theatre is required. Closed loop communication is recommended to confirm instructions/information understood.
- Timely and appropriate consultation with haematology team/haematologist is required.
- In some hospitals the switchboard may play a role in alerting key staff.
- A defined or designated resource to transfer blood components from the laboratory to theatre is required - this may be an assigned porter.

The following are responsible for implementation of Recommendation 9:

Perioperative directorate/ hospital management, theatre manager

Question 10	Does the request for additional assistance when the life threatening haemorrhage protocol is activated lead to better management of a life threatening haemorrhage event?
P (Population)	Theatre staff and surgical patient
I (Intervention)	Extra assistance requested when major haemorrhage protocol activated
C (Comparison/control)	No additional assistance requested
O (Outcome)	Bleeding controlled

Evidence statement:

Following the recognition of a life threatening haemorrhage the emphasis is to stop the haemorrhage and stabilise the patient and it is essential to stop the bleeding as soon as possible. This can be achieved using compression, tourniquet, packing, surgical control, embolization or topical haemostatic agents, or a combination of these approaches.[33] The emergency coordinator in association with the surgeon and anaesthesiologist will confirm if assistance is required and coordinate the response. A multidisciplinary team approach is advocated, seeking early senior surgical help as required. This may include vascular or general surgery input[28] or interventional radiology if available.

Recommendation 10:
In the event of a major vascular injury the designated emergency coordinator in association with the surgeon and anaesthesiologist should request extra assistance as appropriate to the procedure and if promptly available locally (senior surgeon, vascular surgeon, interventional radiology, etc.) and request this assistance ASAP. Once a Red Alert (activation of the Life Threatening Haemorrhage Protocol) has been called, progression to laparotomy should be considered where appropriate. Whilst waiting for senior help to arrive control of bleeding is critical – methods such as packing to reduce the ongoing haemorrhage and pressure/compression or potentially exploring balloon tamponade/ covered stenting of the bleeding vessel should be applied as a damage limiting approach. This may allow time for further resuscitation of the patient.

Certainty of evidence: Very Low
Strength of recommendation: Strong

Good Practice Points:

- When a major vessel injury is suspected, assistance should be called for early as per the local life threatening haemorrhage protocol.
- Any member of the team should be empowered to ask if assistance is required.
- To effectively manage a life threatening haemorrhage it is important that the surgeon stops the bleeding as quickly as possible using their skills which are informed by their training and modern methods of controlling haemorrhage.
- Ensure a vascular set is available.
- The attending consultant surgeon should be informed.
- Potentially exploring balloon tamponade should only be attempted by skilled senior vascular surgeons.

The following are responsible for implementation of Recommendation 10:

RCPI, RCSI & CAI - Directors of Training, supervising consultant surgeon, supervising consultant gynaecologist, nurse manager

Question 11	What type of haemostatic testing should take place and how often for a life threatening haemorrhage event?
P (Population)	Theatre staff and haematology laboratory and patient
I (Intervention)	Haemostatic testing
C (Comparison/control)	No haemostatic testing taking place
O (Outcome)	Haemostatic testing taking place at defined intervals when a life threatening haemorrhage event occurs to guide and ensure the appropriate use of blood components

Evidence statement:

It is important to establish whether the patient is receiving anticoagulant or antiplatelet medication. Coagulopathy is related to loss of blood (tissue hypoxia), consumption of coagulation factors, activation of fibrinolysis and haemodilution by resuscitation fluids. Developing hypothermia, acidosis and hypocalcaemia will further impair coagulation. It is important to monitor haemostatic changes to guide the use of blood components after initial empiric resuscitation, with coagulation and platelet testing performed every 30–60 min/Near Patient Testing (NPT) depending on the severity of blood loss, until bleeding ceases. There is a need for rapid turnaround times (TAT) for coagulation tests in a major haemorrhage and these times should be regularly audited.[11]

Near patient testing should be in compliance with the national NPT guidelines standards, policies and protocols with defined governance structures (includes device procurement, equipment verification, training and competency assessment of operators, quality assurance programmes, adverse incident reporting and traceability and connectivity of results to patient records)[34].

The use of Viscoelastic Haemostatic Assays (VHA) should be in compliance with the relevant BSH guideline.[35] However, the GDG notes that clinical application in this clinical setting is extrapolated from cardiac surgery and at present the evidence base to guide practice is limited.[35] The popularity of VHAs for other indications is also driven by the drawbacks of conventional coagulation assays and by institution-specific preferences.[36] Robust diagnostic studies validating and standardizing diagnostic cut offs for VHA parameters and randomized trials comparing VHA-guided algorithms with standard care on clinical outcomes are urgently needed. Lack of such studies represents the biggest barrier to defining the role and impact of VHA in clinical care.[36]

Recommendation 11:
Serial haemostatic tests, including FBC (Hb, platelet count), PT, APTT and fibrinogen or compliant Near Patient Testing (NPT), from before and after resuscitation should be taken every 30–60 minutes depending on the severity of the haemorrhage. The results of these tests will guide and ensure the appropriate use of blood components. Calcium must be monitored and replaced as appropriate.

Certainty of evidence: Low
Strength of recommendation: Strong

Good Practice Points:

- Near Patient Testing (NPT) is evolving and MUST adhere to current National NPT Guidelines[34] with particular emphasis on service governance, participation in an external quality assurance scheme, used only by fully trained and competency assessed clinical staff and accreditation to ISO 22870 standards.
- At risk surgery should not take place in hospitals where haemostatic testing or compliant NPT viscoelastic haemostatic assays (VHA) are not available.
- The TAT for tests should be specified in the major haemorrhage protocol.
- The laboratory medical scientists should be kept informed of results from NPT and have real time access to test results through interfacing.

The following are responsible for implementation of Recommendation 11:

Clinical theatre staff supported by perioperative director/surgical lead, consultant haematologist, HTC, Hospital MPT steering group, laboratory manager.

Question 12	Does access to sufficient and appropriate blood components and products in a timely manner lead to an improved response to a life threatening haemorrhage?
P (Population)	All patients undergoing surgical procedures
I (Intervention)	Access to sufficient and appropriate blood components and products in a timely manner
C (Comparison/control)	No access to blood components made available following a life threatening haemorrhage event
O (Outcome)	Improved response to a life threatening haemorrhage event.

Evidence statement:

Although red cell transfusion can be lifesaving, there are potential risks including increased morbidity and mortality and so exposure to red cells should be minimized.[11] Rate of administration of red cells to be guided by rate of blood loss and haemodynamic compromise, aiming to maintain oxygen delivery to tissues. At high rates, blood should be given through a warming device.[11] Anticipate need for platelets in on-going bleeding as platelet count falls below 100 x 10^9/l[11]. There should be close communication between the transfusion laboratory and the Blood Transfusion Service to enable timely platelet transfusion[11]. Hypofibrinogenaemia is common in massive haemorrhage and it is reported that fibrinogen is the first factor to fall to critical levels; fibrinogen levels of <1 g/l are likely after 1–1.5 times blood volume replacement.[11,37,38] The use of tranexamic acid should be considered in non-traumatic major bleeding. Tranexamic acid - 1g over 10 minutes at initial presentation, can be continued at a dose of 1g 8 hourly until bleeding ceases.[39] Empirical use of massive haemorrhage packs may be helpful where laboratory test results or VHA are unavailable.

Recommendation 12:
Ensure access to sufficient and appropriate blood components and products in a timely manner. Staff should know where to access emergency Group O red cell components and the timeline to availability (refer to the National Life Threatening Haemorrhage Poster). Hospitals must have systems in place that reliably inform the laboratory on use of emergency Group O red cell components so as to assure immediate replacement.

Blood component support for life threatening haemorrhage is guided as per table below:

Component	**Comment**
Red cell components	4-6 units initially, rate guided by blood loss.
Plasma	At least 1:2 unit ratio with red cells as part of initial resuscitation until results from coagulation monitoring available. Once bleeding controlled guided by haemostatic test results i.e. PT/APTT >1.5 times normal, use standard dose 15 ml/kg. Where laboratory results are unavailable and bleeding continues, further transfusion in at least a 1:2 ratio with red cells.
Platelets	Request where ongoing bleeding and platelet count <100 x 10^9/l to have on standby. Transfuse to keep >50 x 10^9/l (≥100 x 10^9/l in the case of brain/critical site bleeding).
Fibrinogen Concentrate	Guided by fibrinogen levels or viscoelastic haemostatic monitoring. Trigger 1.5 g/l / viscoelastic testing. A dose of 4g will increase fibrinogen by 1 g/l in an adult.
Tranexamic Acid	1g over 10 minutes at initial presentation, can be continued at a dose of 1g 8 hourly until bleeding ceases.
Empiric Approach: Massive Haemorrhage Pack	4 Red Cell Components 4 units of Plasma (currently IBTS provides Solvent Detergent Plasma (SDP)) 4g fibrinogen, for every blood volume loss 1 unit platelets if 1.5 blood volume loss

Certainty of evidence: Low
Strength of recommendation: Strong

Good Practice Points:

- Familiarity with blood component and product resuscitation availability including timeline and location must be a part of drills as per the hospital specific information included in the National Life Threatening Haemorrhage Poster.
- Best practice is that emergency red cell components are available within 10 minutes.
- Timeline to availability of plasma will vary depending on availability of thawed plasma on site or frozen plasma which has to be thawed on demand. The thawing process may take 20-40 minutes depending on the technology available.
- Requirement for platelets should be considered early especially where hospitals do not have the components available on site. Where platelets are not stored on site, the timeline will depend on the distance from the IBTS distribution site. Timely and appropriate consultation with haematology team/haematologist if required.

- Use of a massive haemorrhage pack is encouraged as empirical treatment until laboratory testing results are available.
- When a major vessel injury is suspected, assistance should be called for early as per the local life threatening haemorrhage protocol.
- Any member of the team should be empowered to ask if assistance is required.
- IBTS should develop an internal plan to support code red component distribution to hospitals across the country.
- Request platelet components early, consider geographical distance from distribution centre. Platelet availability on site should reflect patient profile and surgical activity in discussion with lead consultant haematologist for transfusion.
- Arrangements should be in place to allow redistribution of unused platelet components where they are unlikely to be used in that hospital in recognition of the finite platelet resource.
- Make note of the critical need to reinforce frequent blood tests to guide dosing.

The following are responsible for implementation of Recommendation 12:

Lead haematologist for transfusion, chief/senior medical scientist

Question 13	What are best practices on administering and timing of thromboprophylaxis following life threatening haemorrhage events?
P (Population)	All patients undergoing surgical procedures
I (Intervention)	Early mechanical thromboprophylaxis with intermittent pneumatic compression (IPC)
C (Comparison/control)	No early mechanical thromboprophylaxis with intermittent pneumatic compression (IPC)
O (Outcome)	Improved management and response to a life threatening haemorrhage event and (improved patient outcome?)

Evidence statement:

Input was sought from the Irish Haematology Society Coagulation Special Interest Group to inform best evidence for thromboprophylaxis. The 'European guideline on management of major bleeding and coagulopathy following trauma: fifth edition[12] was identified as the primary evidence source. Early mechanical thromboprophylaxis with intermittent pneumatic compression (IPC) while the patient is immobile and has a bleeding risk is recommended. This should be combined pharmacological and IPC thromboprophylaxis within 24 hours after bleeding has been controlled and until the patient is mobile.[12] For patients who have elective surgery and are at moderate or high risk of venous thromboembolism, administration of pharmaco-thromboprophylaxis alone is non-inferior to a combination of pharmaco-thromboprophylaxis and graduated compression stockings. These findings indicate that graduated compression stockings might be unnecessary in most patients undergoing elective surgery.[40]

Recommendation 13:
Early mechanical thromboprophylaxis with intermittent pneumatic compression (IPC) should be applied while the patient is immobile and has a bleeding risk. This should be combined with pharmacological and IPC thromboprophylaxis within 24 hours after bleeding has been controlled and until the patient is mobile.

Certainty of evidence: Low
Strength of recommendation: Strong

Good Practice Points:

- Patient should be assessed by the anaesthesiologist in conjunction with the surgeon for thromboprophylaxis and it should be prescribed before handover of patient to ICU.
- The use of graduated compression stockings for thromboprophylaxis is not recommended.
- The routine use of inferior vena cava filters as thromboprophylaxis is not recommended.

The following are responsible for implementation of Recommendation 13:

Surgeon for individual case, haematologist for policy/protocol

Question 14	Do reviews undertaken following a life threatening haemorrhage event ensure that effective systems are in place for major haemorrhage management in the future?
P (Population)	Theatre teams & members of hospital transfusion committee
I (Intervention)	Reviews following a life threatening haemorrhage event
C (Comparison/control)	No reviews taking place following a life threatening haemorrhage event
O (Outcome)	Ensures that effective systems are in place for major haemorrhage management

Evidence statement:

The WHO Safe Surgery Guidelines states that post-procedure debriefings consisting of an exchange of information at the conclusion of an operation gives the team an opportunity to review what was done, share critical events that arose during the case and develop management plans for recovery.[21] Debriefing is a means of standardising communication, which has been shown to improve patient outcomes in multiple situations.[41] A study undertaken by Leong et al, 2017 concluded that perioperative briefing and debriefing improved the team climate of surgical teams and the efficiency of their work within the operating theatre. Surgical teams with alternating team compositions have the most benefit from briefing and debriefing.[23] The British Society for Haematology guideline 'A practical guideline for the haematological management of major haemorrhage'[11], outlines a recommendation that case review should be undertaken to ensure that effective systems are in place for major haemorrhage management. Audit of major haemorrhage management is essential to assess timeliness of blood component support, patient outcome and component wastage. All cases of life threatening intraoperative haemorrhage should be reviewed to ensure local protocols are applied appropriately and effectively.[11] These cases should be investigated locally and reported to at the HTC. Data and information collated from a case review will allow for further trending and analysis at a hospital and regional level.

Recommendation 14:
Two separate reviews are required following an unexpected life threatening haemorrhage in addition to hospital specific processes which are in place for adverse events/risk management /open disclosure:

a) De-brief by the theatre team to ensure all staff members are supported, discuss and learn from the life threatening haemorrhage event

b) Case review by a wider multi-functional team – led by Perioperative Director and supported by lead haematologist for transfusion, haemovigilance officer and chief medical scientist should be undertaken, fully engaging the theatre team in a timely manner. A summary should be reported to the HTC.

In addition such incidents may be part of:

- Periodic audit by the Hospital Transfusion Committee reviewing overall trends, outcomes and processes for life threatening haemorrhage events
- All Hospital Transfusion Committees will feed into an Overarching Transfusion Committee (OTC). The OTC will review and benchmark unexpected life threatening haemorrhage events - overall trends, outcomes and processes.

Certainty of evidence: Low
Strength of recommendation: Strong

Good Practice Points:

- A debrief is encouraged to take place in a timely manner (as soon as appropriate) after the event - virtual meetings could facilitate other participation e.g. laboratory staff.
- It may be appropriate to use facilitators outside the theatre team in conducting a debrief.
- Access to an EAP (Employee Assistance Programme) should be available for staff.
- Data capture for case reviews performed as per Appendix 6.3.
- Case reviews and periodic audits should be brought to the Hospital Transfusion Committee for consideration of trends and a quality improvement process.
- All case reviews should be reviewed at the hospital Morbidity and Mortality (M&M) meetings.
- The membership of the HTC should be appropriately populated by all specialities involved in major haemorrhage. Surgical and anaesthetic representatives need to be present at scheduled HTC meetings alongside all other relevant specialties.

The following are responsible for implementation of Recommendation 14:

Perioperative director, surgeon, lead haematologist for transfusion, nurse manager, chair of HTC, chair of OTC

Question 15	Do dedicated familiarisation days for medical scientists not normally based in the transfusion lab for out of hours cover lead to an improved response by medical scientists not routinely working in the transfusion lab in the event of a life threatening haemorrhage?
P (Population)	Medical scientists not routinely working in the transfusion lab
I (Intervention)	Dedicated familiarisation days, 10 days recommended
C (Comparison/control)	No dedicated familiarisation days
O (Outcome)	Improved response by medical scientists not routinely working in the transfusion lab in the event of a life threatening haemorrhage.

Evidence statement:

Section 3.3 of the UK Transfusion Laboratory Collaborative identifies that medical scientists must complete and document at least 10 working days per annum of autonomous, independent or lone-working in a hospital blood transfusion laboratory.[42] A survey undertaken by the GDG of blood transfusion laboratories across the country identified less than 50% of laboratories undertake supervised dedicated familiarisation days for medical scientists supporting out of hours transfusion laboratory activity who are not core transfusion laboratory medical scientists. The survey also identified expressions of concern from medical scientists in relation to life threatening haemorrhage out of hours in the absence of adequate familiarisation and that included their willingness to participate in on-call rosters, notwithstanding that training for medical scientists in Ireland has a compulsory transfusion component. 26/46 hospitals reported some number of dedicated familiarisation days for non-core blood bank medical scientists. The data is available on request.

Familiarisation days allow familiarisation with laboratory environment, processes and troubleshooting over and above specific task/skills training.

Recommendation 15:
It is recommended that all medical scientists supporting out of hours transfusion laboratory activity who do not work routinely in the Transfusion Laboratory should undertake supervised dedicated familiarisation days annually.

It is recommended that this familiarisation consist of 10 days during routine hours in the Transfusion Laboratory to ensure the appropriate skill set.

Certainty of evidence: Very Low
Strength of recommendation: Strong

Good Practice Points:

- Hospitals must plan and support laboratory resources to ensure compliance with this requirement – funding and post fulfilment. This is a key patient safety issue.
- In addition to transfusion laboratory requirements - a risk assessment should be undertaken by all hospitals to determine the number of familiarisation days for non-core haematology medical scientists in the haematology laboratory required for the out of hours service demand in the hospital, considering the complexity of the service.

The following are responsible for implementation of Recommendation 15:

Hospital management teams, laboratory management

Question 16	Does a formal out of hours cover process/system lead to improved support and access to expertise in out of hours cover for medical scientists?
P (Population)	Medical scientists providing out of hours cover in transfusion laboratory
I (Intervention)	Formal out of hours cover process in place
C (Comparison/control)	No formal out of hours cover process in place
O (Outcome)	Improved support and access to expertise in out of hours cover for medical scientists?

Evidence statement:

The UK National Comparative Audit of Blood Transfusion undertook an audit of the management of adult major haemorrhage in October 2018. This was across the range of UK hospitals/trusts (94% participation) and included two hospitals in the Republic of Ireland. 54% of these occurred out of hours. This study demonstrates that the opportunity for error exists out of hours as well as during normal working hours and should be mitigated where possible.[43]

The Medicines and Healthcare products Regulatory Agency (MHRA) Report on Blood Safety and Quality Regulation (BSQR) in 2019 outlines a recommendation that 'All training must include a robust competency assessment to ensure competency of individuals both during routine and out-of-hours'.[44]

The GDG undertook a survey of 'massive/major haemorrhage in Ireland' for the calendar year 2018 and invited the 45 hospitals with transfusion laboratories to participate. The data showed that a significant number of incidents occurred out of hours - the majority of such events in stand-alone maternity hospitals, near to half of the events in level 3 hospitals and a quarter of these at level 4 hospitals. Qualitative data returned noted the impact of medical scientist's expertise out of hours on the management of life threatening haemorrhage. In the majority of hospitals it was noted that a formal arrangement was not in place to request out of hours medical scientist support. Survey data available on request.

Recommendation 16:
All hospitals must develop an arrangement so that in the circumstances of a life threatening haemorrhage event, an additional medical scientist can be called in out of hours to support the laboratory practice where necessary.

Certainty of evidence: Very Low
Strength of recommendation: Strong

Good Practice Points:

- A list of available staff for out of hours call in should be compiled by laboratory management and made available for local arrangements to support call in.
- It is important that arrangements recognise the requirement for staff to arrive at the laboratory in a timely manner when called.
- Responsibility for the arrangement to call for assistance should not rest with the on-call medical scientist and should be a formal arrangement by the laboratory management/hospital management.
- This requirement may be met by rostering two medical scientists on call out of hours.

The following are responsible for implementation of Recommendation 16:

Hospital management, laboratory management

Question 17	What content should be included in a Service Level Agreement (SLA) to assist with the provision of transfusion services to off-site hospitals?
P (Population)	Transfusion laboratory managers
I (Intervention)	An appropriate SLA between transfusion lab and off-site hospitals
C (Comparison/control)	No specified requirement or timeline for transfusion support captured in SLA in place between transfusion lab and off site hospitals
O (Outcome)	Blood components arriving in off-site hospitals within agreed timeframes.

Evidence statement:

A survey undertaken by the GDG of blood transfusion laboratories across the country identified an off-site hospital with significant surgical activity which did not appear to routinely have emergency blood components available. There are 11 hospital transfusion laboratories supporting 14 off-site hospitals undertaking significant surgical activity and a number of additional facilities undertaking minor surgery. Data available on request. Having an appropriate SLA between the transfusion lab and any off-site hospitals supported by the lab will assist in ensuring timely availability of required blood components and full transparency on the needs of the off-site hospital.

Recommendation 17:
Hospitals which provide a transfusion service for offsite hospitals should identify as part of the Service Level Agreement(s) the requirement and the timeline for provision of blood components at the offsite hospital.

Certainty of evidence: Very Low
Strength of recommendation: Strong

Rationale/Context for Recommendation

A survey undertaken by the GDG of blood transfusion laboratories across the country identified a gap in the availability of emergency Group O red cell components to support appropriate surgical practice in offsite hospitals.

Good Practice Points:

- The SLA must allow for emergency Group O blood being available in a timely manner to the theatre.
- A risk assessment should be undertaken for the availability of other blood components on site/ available in a timely manner when any open or laparoscopic operative intervention in the chest, abdomen and pelvis is undertaken as well as where there is potential to inadvertently enter one of these cavities during surgery.
- The SLA should take into consideration the services provided at the off-site hospital, distance/ time from the transfusion laboratory and the possibility of life threatening haemorrhage.
- Inventory management should optimise the use of Group O RhD negative red cell components.
- Patient transfer protocols should be in place as appropriate.

The following are responsible for implementation of Recommendation 17:

Hospital management supported by laboratory management, lead haematologist for transfusion

3.2 Summary budget impact analysis

A budget impact analysis (BIA) (Annex C) addresses the expected changes in the expenditure of a healthcare system after the adoption of a new intervention.[45] In the context of guideline development, the purpose of the BIA is to quantify the resource implications of implementing the guideline recommendations. In line with national guidelines, direct costs and benefits were assessed from the perspective of the publicly-funded health and social care system, the HSE, over a five year time horizon.[46,47]

The key changes that will result from implementing the guideline recommendations include:

- additional medical scientists to support the completion of the recommended ten familiarisation days for those medical scientists who do not routinely work in the transfusion laboratory but who do support out of hours on-call activity. (Recommendation 15).

There are five main laboratory disciplines, Histology, Blood Transfusion, Haematology, Microbiology and Biochemistry. All except for Histology provide a 24/7, 365 emergency out of hours service. Medical scientists are routinely employed based on their qualifications and experience in one of the five laboratory disciplines. In smaller hospitals the laboratories are multi discipline, medical scientists carry out basic tests in all four disciplines in the one laboratory.

To staff an emergency (out of hours) service in the Blood Transfusion (BT) laboratory from 8pm to 8am weekdays and 24hrs Saturday/Sunday and Bank Holiday Mondays, medical scientists from other disciplines (e.g. Haematology) are trained to work in Blood Transfusion out of hours. These staff maintain their competency records in BT every two years. Staff work alone during the emergency out of hours service and therefore need to be very familiar with the BT laboratory and the tests performed. The BSH guidelines recommend that all non-routine BT staff trained for out of hours duties have 10 working days annually in the transfusion lab (familiarisation days). Our survey of Blood Transfusion laboratories for this guideline, highlighted that the majority of laboratories do not meet the recommended 10 days familiarisation (some laboratories have 0 familiarisation days) as staffing levels from 8am to 8pm in the routine lab do not allow for the person trained out of hours in the BT laboratory to be released for these 10 days. For each BT laboratory the gap between the current level of familiarisation days provided and the recommended 10 days familiarisation was costed which comprises the cost of hiring additional medical scientists to provide cover and ensure that routine day-to-day work in the laboratories releasing staff is not impacted. Additional medical scientist staff will be required nationally to ensure there is no gap in service provided.

- training for gynaecology trainees, theatre staff and transfusion laboratory staff (including those providing out of hours cover) in recognising, responding to and managing major blood loss. (Recommendation 8)
- the introduction of OTCs to review and benchmark life threatening haemorrhage events including overall trends, outcomes and processes. (Recommendation 14)
- a National Life Threatening Haemorrhage Management Poster to be displayed in all operating theatres to assist with responding to a life threatening haemorrhage event. (Recommendation 3)

The total incremental cost of implementing the guideline recommendations was estimated at €3.7 million over five years, of which 77.3% (€2.86 million) related to direct costs, mostly for hiring additional medical scientists (€2.77 million), and 22.7% (€842k) related to the opportunity cost of staff time for attending training and the OTCs. The estimate included the following over a five year period:

- the recruitment of 9.6 whole-time equivalent medical scientists (€2.77 million) to address the estimated annual shortfall of 2,132 familiarisation days across 24 transfusion laboratories when compared with the recommended ten days familiarisation per medical scientist per year.
- the provision of multi-disciplinary drills and an e-learning module (€670k) for an estimated 6,401 members of theatre and transfusion laboratory staff annually.
- bi-annual meetings of seven OTCs, each attended by 15 members (€200k).
- the provision of simulation drills for life threatening haemorrhage events for an estimated 80 gynaecology trainees annually (€48k).
- the development and dissemination of the National Life Threatening Haemorrhage Management poster (€5.6k) to an estimated 220 operating theatres across the country.

The BIA captures the costs and impact of implementing the Unexpected Intraoperative Life Threatening Haemorrhage Guideline over a five year period. There are three guideline recommendations (Recommendations 4, 12 and 16) where variations in current practice have impacted on identifying if the recommendation represents a change to current practice. As a result, there are potential additional costs (both direct costs and opportunity costs) associated with the implementation of the guideline that have not been included in the BIA. Given the rarity of unexpected intraoperative massive haemorrhage events, there is little robust evidence to underpin the clinical and cost-effectiveness of the guideline recommendations and therefore no benefits and associated cost savings have been included in the BIA. However, there are potential savings in the context of severe morbidity and mortality that can result from unexpected intraoperative massive haemorrhage, where the guideline will provide guidance to theatre teams and associated healthcare professionals on the recommended practices for the recognition, response to and management of such an event.

4 Appendices

Appendix 1: Guideline Development Group Terms of Reference (TOR)

1.0 Governance Overview

The 'Unexpected Intraoperative Life Threatening Haemorrhage Guideline' is a commissioned guideline and has been prioritised by the National Clinical Effectiveness Committee (NCEC). Prof John Hyland is the nominated Chair of the GDG and together with the project manager have responsibility for ensuring the guideline is developed using a robust methodology.

Membership of the GDG comprises: clinical experts and patient representatives and has come by nominations from the appropriate professional bodies. HRB-CICER are assigned to provide research methodology resources supporting the work of the GDG.

2.0 Role and Responsibilities

The primary aim of GDG members is to develop a National Clinical Guideline on 'Unexpected Intraoperative Life Threatening Haemorrhage' using an evidence-based approach where possible. Additional responsibilities are as follows:

- Provide input into the scope of the guideline
- Provide feedback on relevant areas of expertise when required
- Use the findings from the literature search and economic assessment provided by HRB-CICER to develop and agree recommendations appropriately
- Review and approve the final guideline document before submission to the NCEC
- Work within required time frame of two years

3.0 Meeting Format

- Meetings of the GDG will take place every two months in RCSI however more frequent meetings of working groups may be required at critical stages of the process (Pre COVID-19 pandemic format)
- The time period for the overall process is estimated as two years – the goal is to produce an approved guideline within this time period and will be planned for accordingly.
- An extension to this deadline was provided by the DOH due to the impact of the COVID-19 pandemic where all healthcare professionals were assigned to COVID related tasks for approximately 6 months.
- Meeting notes will be taken by the project manager and will be circulated alongside any other supporting documentation in advance of the next meeting.
- Virtual meetings arranged as required using appropriate technology

4.0 Decision Making

The decision making process for the GDG will endeavour to:

- Encourage the participation and empowerment of all GDG members
- Be transparent, open and clear

GDG decisions will be made by consensus following discussion by GDG members. However, in the absence of consensus, members will be requested to vote on the decision with the Chair having the casting vote.

5.0 Quorum

The GDG must have at least one third of its membership present in person or virtual (exclusive of the Chair and Project Manager).

6.0 Conflict of Interest

All GDG members will be asked to sign a form declaring any conflicts of interest. Any conflict of interest that arises during the term of membership must be disclosed as soon as possible.

Appendix 2: Evidence to Decision Framework (EtD)

An Evidence to Decision (EtD) Framework was developed by the GDG to assist with rating the quality of evidence and strength of all recommendations. The EtD has been broken down to three sections:

Part A – Question and associated evidence underpinning all recommendations

Part B - GRADE approach to assess quality of evidence & strength of recommendation

Part C – GDG assessment of quality of evidence and strength of recommendation

Part A – Question and associated evidence

Guideline Question 1: Is it important to decide where surgical procedures of different levels of complexity should be performed?

	Criteria	Judgements		Research Evidence	Additional Considerations
Problem	Is there a problem priority?		Probably No No Uncertain ✓ Yes Varies	• No evidence specific to life threatening haemorrhage identified	• The risk of life threatening haemorrhage is present in all surgical procedures accessing the chest, abdomen or pelvis • Surgery should only take place in suitable sites where appropriate resources and supports are available. • Designation of sites is already in place and the GDG believe this should continue
Benefits & Harms of Options	What is the overall certainty of this evidence?	✓	No included studies Very Low Low Moderate High	• No evidence specific to life threatening haemorrhage identified	
	Is there important uncertainty about how people value the main outcomes?		Important uncertainty or variability Possibly important uncertainly or variability Probably no important uncertainty or variability ✓ No known uncertainty or variability	• No evidence specific to life threatening haemorrhage identified	• The potential outcome is death of a patient if the correct supports and resources are not in place.

	Criteria	Judgements		Research Evidence	Additional Considerations
	Are the desirable anticipated effects large	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified	• Although this may be a rare event the impact is significant • Improvement in patient safety and a reduction in unexpected life threatening haemorrhage events are likely.
	Are the undesirable anticipated effects small	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified	The undesirable effects are expected to be low: • Initial travel time for patients may be longer to specified hospitals. • Life threatening haemorrhage events could take place in smaller hospitals and appropriate transfer processes will be required.
Resources/ Costs	Are the resources required small?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified	• This is already an existing practice within the health system where Hospital Group Management Teams designate surgical sites. • The GDG are stating that this practice should continue.
	Is the incremental cost small relative to the net benefits	✓	Probably No No Uncertain Yes Varies		
Equity	What would be the health impact on the health inequities?	✓	Increased Probably Increased Uncertain Probably Reduced Reduced None known	• No evidence specific to life threatening haemorrhage identified	• The GDG does not anticipate any impact on health inequities.
Acceptability	Is the option acceptable to key stakeholders?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified	• Hospital Group Management Teams are already striving to achieve safe and appropriate patient management practices.
Feasibility	Is the option feasible to implement	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified	• Already current practice and should continue. • Hospital Group Management Teams should attend to further consolidation of the hospital sites through appropriate resource allocation.

Guideline Question 2: Will following a safe surgery practice checklist assist with the prevention and management of life threatening haemorrhage events?

	Criteria	Judgements		Research Evidence	Additional Considerations
Problem	Is there a problem priority?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified. • HSE National Policy and procedure for safe surgery' already in place[15]. • WHO Guidelines for Safe Surgery 2009[21].	• Already current practice and should continue. • Safe Surgery practices assist in providing a safer surgical environment.
Benefits & Harms of Options	What is the overall certainty of this evidence	✓	No included studies Very Low Low Moderate High Probably No	• No evidence specific to life threatening haemorrhage identified. • This is already an existing practice within the health system following on from the WHO Safe Surgery guidelines 2009.	
	Is there important uncertainty about how people value the main outcomes	✓	Important uncertainty or variability Possibly important uncertainty or variability Probably no important uncertainty or variability No known uncertainty or variability	• No evidence specific to life threatening haemorrhage identified.	• The potential outcome is death of a patient – patients and theatre staff value having a safe surgical environment.
	Are the desirable anticipated effects large	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Following safe surgery practices cannot guarantee the prevention of a life threatening haemorrhage event but will assist with providing a safer surgical environment to respond.
	Are the undesirable anticipated effects small	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• The GDG believe that following safe surgery practices can only have a positive impact on patient outcomes.

	Criteria	Judgements		Research Evidence	Additional Considerations
	Are the desirable effects large relative to the undesirable effects	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Patient safety outweighs other considerations.
Resources/ Costs	Are the resources required small?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• This is already an existing practice within the health system following on from the WHO Safe Surgery guidelines 2009. • The GDG are recommending that this practice continue.
	Is the incremental cost small relative to the net benefits	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	
Equity	What would be the health impact on the health inequities?	✓	Increased Probably Increased Uncertain Probably Reduced Reduced	• No evidence specific to life threatening haemorrhage identified.	• The GDG does not anticipate any difference for different users of the health system. The same process will be followed across the health system.
Acceptability	Is the option acceptable to key stakeholders?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Already current practice and should continue.
Feasibility	Is the option feasible to implement	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Already current practice and should continue.

Guideline Question 3: Will documented guidance and visual guidance/instructions for theatre staff assist with responding to a life threatening haemorrhage event?

	Criteria	Judgements		Research Evidence	Additional Considerations
Problem	Is there a problem priority?		Probably No No Uncertain ✓ Yes Varies	• GDG conducted an audit of all hospital transfusion blood banks and identified significant variability in the availability and content of life threatening haemorrhage protocols and posters in theatre. • BSH guideline – 'A practical guideline for the haematological management of major haemorrhage' outlines a recommendation for having a local major haemorrhage protocol available. • Investigation Report from Index case which was a driver for the guideline identified delays in sourcing blood products.	• Having a standardised documented plan of what needs to happen will provide clarity as to the key activities and responsibilities in managing the life threatening haemorrhage event. • When staff move between hospitals – the standardisation of the poster and protocol will make it clearer on the exact process to follow in responding to an emergency event.
Benefits & Harms of Options	What is the overall certainty of this evidence		No included studies Very Low Low ✓ Moderate High Probably No	• As above	
	Is there important uncertainty about how people value the main outcomes		Important uncertainty or variability Possibly important uncertainty or variability Probably no important uncertainty or variability ✓ No known uncertainty or variability	• As above	• The potential outcome is death of a patient.

	Criteria	Judgements		Research Evidence	Additional Considerations
	Are the desirable anticipated effects large		Probably No No Uncertain Yes Varies	• As above	• Patients and theatre staff are aligned in having clarity on knowing the steps to follow in a crisis scenario.
	Are the undesirable anticipated effects small	✓	Probably No No Uncertain Yes Varies	• As above	• The GDG believe that having a visual reminder of what steps to follow in a crisis can only have a positive impact on patient outcomes.
	Are the desirable effects large relative to the undesirable effects	✓	Probably No No Uncertain Yes Varies	• As above	• Patient safety outweighs other considerations.
Resources/ Costs	Are the resources required small?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Design costs of a national template for poster • Printing and laminating costs for Poster
	Is the incremental cost small relative to the net benefits	✓	Probably No No Uncertain Yes Varies		
Equity	What would be the health impact on the health inequities?	✓	Increased Probably Increased Uncertain Probably Reduced Reduced	• No evidence specific to life threatening haemorrhage identified.	• The GDG does not anticipate any difference for different users of the health system. The same process will be followed across the health system.
Acceptability	Is the option acceptable to key stakeholders?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Currently undertaking buy-in and engagement activities with stakeholders to understand acceptability of proposed recommendation.
Feasibility	Is the option feasible to implement	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	

Guideline Question 4: Will considering the possibility or risk of an unexpected life threatening haemorrhage taking place in advance of a procedure (perioperative briefing) by theatre staff leading to an improved response and management of life threatening haemorrhage events?

	Criteria	Judgements		Research Evidence	Additional Considerations
Problem	Is there a problem priority?		Probably No No Uncertain ✓ Yes Varies	• No evidence specific to life threatening haemorrhage identified - however the risk is present in all surgical procedures accessing the chest, abdomen or pelvis accounting for a high percentage of surgical procedures.	• Identifying the point where there is a possibility of a haemorrhage event taking place in advance of a procedure will place all theatre staff on alert. • Preoperative briefing to take place with members of the theatre team - the timing of the briefing may vary from theatre to theatre.
Benefits & Harms of Options	What is the overall certainty of this evidence		No included studies ✓ Very Low Low Moderate High Probably No	• As above	
	Is there important uncertainty about how people value the main outcomes		Important uncertainty or variability Possibly important uncertainty or variability Probably no important uncertainty or variability ✓ No known uncertainty or variability	• As above	• The potential outcome is death of a patient.
	Are the desirable anticipated effects large		Probably No No Uncertain ✓ Yes Varies	• As above	• The theatre team having awareness of the parts of the procedure when a life threatening haemorrhage event could take place.
	Are the undesirable anticipated effects small		Probably No No Uncertain ✓ Yes Varies	• As above	• The amount of time taken to discuss and identify the likely points in a procedure where a life threatening haemorrhage event could take place may vary in duration depending on the complexity of the surgical procedure.

	Criteria	Judgements		Research Evidence	Additional Considerations
	Are the desirable effects large relative to the undesirable effects	✓	Probably No No Uncertain Yes Varies	• As above	• Patient safety outweighs other considerations.
Resources/ Costs	Are the resources required small?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Time taken to discuss and identify the likely points in a procedure where a life threatening haemorrhage event could take place.
	Is the incremental cost small relative to the net benefits	✓	Probably No No Uncertain Yes Varies		
Equity	What would be the health impact on the health inequities?	✓	Increased Probably Increased Uncertain Probably Reduced Reduced	• No evidence specific to life threatening haemorrhage identified.	• The GDG does not anticipate any difference for different users of the health system. The same process will be followed across the health system.
Acceptability	Is the option acceptable to key stakeholders?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Already a common practice in most cases. • Where it is not a common practice, no anticipated difficulty from stakeholders foreseen.
Feasibility	Is the option feasible to implement	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Very easy to implement - Perioperative briefing to take place with members of the theatre team - the timing of the briefing may vary from theatre to theatre.
	Is the incremental cost small relative to the net benefits	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	

Guideline Question 5: Which items would be helpful to consider in advance of any operative intervention in the chest, abdomen or pelvis procedure to assist in responding to a life threatening haemorrhage event?

	Criteria	Judgements		Research Evidence	Additional Considerations
Problem	Is there a problem priority?		Probably No No Uncertain ✓ Yes Varies	• No evidence specific to life threatening haemorrhage identified. • Serious Hazards of Transfusion (SHOT) UK Data identifies communication issues as a significant source of delay to the appropriate management of life threatening haemorrhage.	• When any operative intervention in the chest, abdomen or pelvis takes place – a number of checks will assist with the management of a crisis event should it occur.
Benefits & Harms of Options	What is the overall certainty of this evidence		No included studies ✓ Very Low Low Moderate High Probably No	• As above	
	Is there important uncertainty about how people value the main outcomes		Important uncertainty or variability Possibly important uncertainty or variability Probably no important uncertainty or variability ✓ No known uncertainty or variability		

	Criteria	Judgements		Research Evidence	Additional Considerations
	Are the desirable anticipated effects large	✓	Probably No No Uncertain Yes Varies	• As above	• Confirming the following checks will assist with the timeliness of a crisis response: a) availability of emergency Group O blood b) any additional required blood components c) senior help (surgery and anaesthesiology) d) availability of equipment e) location of vascular equipment • These checks are common practice across the health system.
	Are the undesirable anticipated effects small	✓	Probably No No Uncertain Yes Varies	• As above	• The GDG believe that confirming the criteria above can only have a positive impact on patient safety and outcomes.
	Are the desirable effects large relative to the undesirable effects	✓	Probably No No Uncertain Yes Varies	• As above	• Patient safety outweighs other considerations.
Resources/ Costs	Are the resources required small?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• These checks are common practice in many instances.
	Is the incremental cost small relative to the net benefits	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	
Equity	What would be the health impact on the health inequities?	✓	Increased Probably Increased Uncertain Probably Reduced Reduced	• No evidence specific to life threatening haemorrhage identified.	• The GDG does not anticipate any difference for different users of the health system. The same process will be followed across the health system.

	Criteria	Judgements		Research Evidence	Additional Considerations
Acceptability	Is the option acceptable to key stakeholders?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• All hospitals should already have an efficient system in place for patients at risk of unexpected intraoperative life threatening haemorrhage that fulfils the criteria of required blood testing, theatre equipment and availability of blood.
Feasibility	Is the option feasible to implement	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• All hospitals should already have an efficient system in place for patients at risk of unexpected intraoperative life threatening haemorrhage that fulfils criteria of required blood testing, theatre equipment and availability of blood.

Guideline Question 6: Does supervisory support provided to trainee surgeons, gynaecologists and anaesthesiologists lead to improved surgical skills?

	Criteria	Judgements		Research Evidence	Additional Considerations
Problem	Is there a problem?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Appropriate supervision and clinical support should be provided to surgery, gynaecology and anaesthesiology trainees in line with their experience and stage of training. • This is already a common practice and should be continued
Benefits & Harms of Options	What is the overall certainty of this evidence	✓	No included studies Very Low Low Moderate High Probably No	• No evidence specific to life threatening haemorrhage identified.	

	Criteria	Judgements		Research Evidence	Additional Considerations
	Is there important uncertainty about how people value the main outcomes	✓	Important uncertainty or variability Possibly important uncertainty or variability Probably no important uncertainty or variability No known uncertainty or variability	• No evidence specific to life threatening haemorrhage identified.	• The potential outcome is death of a patient.
	Are the desirable anticipated effects large	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Access to appropriate back-up and support to trainees supports patient safety.
	Are the undesirable anticipated effects small	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Time required from supervisors to support trainees – this is implicit in the trainer/trainee relationship and already common practice.
	Are the desirable effects large relative to the undesirable effects	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Patient safety outweighs other considerations.
Resources/ Costs	Are the resources required small?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• This is already a common practice and should be continued.
	Is the incremental cost small relative to the net benefits	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	
Equity	What would be the health impact on the health inequities?	✓	Increased Probably Increased Uncertain Probably Reduced Reduced	• No evidence specific to life threatening haemorrhage identified.	• The GDG does not anticipate any difference for different users of the health system. The same process will be followed across the health system.

	Criteria	Judgements		Research Evidence	Additional Considerations
Acceptability	Is the option acceptable to key stakeholders?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• This is already a common practice and should be continued.
Feasibility	Is the option feasible to implement		Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• This is already a common practice and should be continued.

Guideline Question 7: Would laparoscopic skills training and simulated drills on life threatening haemorrhage be of assistance to trainees?

	Criteria	Judgements		Research Evidence	Additional Considerations
Problem	Is there a problem?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Laparoscopic skills training already part of the curriculum for trainee surgeons and gynaecologists - the GDG are stating that this practice should continue. • Simulated drills on life threatening haemorrhage already taking place for surgeons and yet to start for gynaecologists.
Benefits & Harms of Options	What is the overall certainty of this evidence	✓	No included studies Very Low Low Moderate High Probably No	• No evidence specific to life threatening haemorrhage identified.	
	Is there important uncertainty about how people value the main outcomes	✓	Important uncertainty or variability Possibly important uncertainty or variability Probably no important uncertainty or variability No known uncertainty or variability	• No evidence specific to life threatening haemorrhage identified.	• The potential outcome is death of a patient.

	Criteria	Judgements		Research Evidence	Additional Considerations
	Are the desirable anticipated effects large	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Participating in life threatening haemorrhage simulation scenarios can provide an opportunity for trainees to practice skills in a safe environment. • GDG members are supportive of laparoscopic skills training continuing for surgeons and gynaecologists. • Simulated drills can assist critical communication pathways in management of life threatening haemorrhage.
	Are the undesirable anticipated effects small	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Participating in life threatening haemorrhage simulation scenarios can provide an opportunity for trainees to practice skills in a safe environment. • GDG members are supportive of laparoscopic skills training continuing for surgeons and gynaecologists. • Simulated drills can assist critical communication pathways in management of life threatening haemorrhage.
	Are the undesirable anticipated effects small	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Time required to complete training
	Are the desirable effects large relative to the undesirable effects	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Patient safety outweighs other considerations.
Resources/ Costs	Are the resources required small?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• There will be additional costs to cover life threatening haemorrhage simulation training for Gynaecology trainees.
	Is the incremental cost small relative to the net benefits	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	

	Criteria	Judgements		Research Evidence	Additional Considerations
Equity	What would be the health impact on the health inequities?	✓	Increased Probably Increased Uncertain Probably Reduced Reduced	• No evidence specific to life threatening haemorrhage identified.	• The GDG does not anticipate any difference for different users of the health system. The same process will be followed across the health system.
Acceptability	Is the option acceptable to key stakeholders?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Already plans in place to commence simulated drills for gynaecology trainees.
Feasibility	Is the option feasible to implement	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Funding required to deliver the simulation training for gynaecology trainees • This is a current practice already for surgical trainees.

Guideline Question 8: Do regular life threatening haemorrhage drills among theatre staff result in an improved response to and management of life threatening haemorrhage events?

	Criteria	Judgements		Research Evidence	Additional Considerations
Problem	Is there a problem priority?	✓	Probably No No Uncertain Yes Varies	• BSH guideline 'A practical guideline for the haematological management of major haemorrhage' outlines a recommendation that all medical, nursing, laboratory and support staff should participate in regular drills.	• Survey undertaken by GDG of hospital transfusion labs identified a desire to participate in drills to support their training. • This is already a practice in a number of hospitals but not a standardised practice.
Benefits & Harms of Options	What is the overall certainty of this evidence	✓	No included studies Very Low Low Moderate High Probably No	• As above	

	Criteria	Judgements		Research Evidence	Additional Considerations
	Is there important uncertainty about how people value the main outcomes	✓	Important uncertainty or variability Possibly important uncertainty or variability Probably no important uncertainty or variability No known uncertainty or variability	• As above	• The potential outcome is death of a patient. • Drills provide an opportunity for staff to practice their response to a crisis in a safe environment. • Simulated drills can assist critical communication pathways in management of life threatening haemorrhage.
	Are the desirable anticipated effects large	✓	Probably No No Uncertain Yes Varies	• As above	• Drills provide an opportunity for staff to practice their response to a crisis in a safe environment.
	Are the undesirable anticipated effects small	✓	Probably No No Uncertain Yes Varies	• As above	• Time required to undertake drills mean staff will be unavailable for other tasks at that time.
	Are the desirable effects large relative to the undesirable effects	✓	Probably No No Uncertain Yes Varies	• As above	• Patient safety outweighs other considerations.
Resources/ Costs	Are the resources required small?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Cost associated with training time of staff assigned to drill preparation, coordination and execution. • Costs associated with the development of an eLearning module
	Is the incremental cost small relative to the net benefits	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	
Equity	What would be the health impact on the health inequities?	✓	Increased Probably Increased Uncertain Probably Reduced Reduced	• No evidence specific to life threatening haemorrhage identified.	• The GDG does not anticipate any difference for different users of the health system. The same process will be followed across the health system.
Acceptability	Is the option acceptable to key stakeholders?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• The survey undertaken by the GDG identified an appetite from staff for drills on a response to a life threatening haemorrhage event.

	Criteria	Judgements		Research Evidence	Additional Considerations
Feasibility	Is the option feasible to implement	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified. • Time for drills will need to be scheduled • A nominated person will be required to ensure drills take place and are attended by the required staff.	

Guideline Question 9: Does an assigned emergency coordinator lead to an improved response to and management of a life threatening haemorrhage event?

	Criteria	Judgements		Research Evidence	Additional Considerations
Problem	Is there a problem priority?	✓	Probably No No Uncertain Yes Varies	• BSH guideline 'A practical guideline for the haematological management of major haemorrhage' outlines that there must be a clear mechanism for contacting all relevant team members.	• GDG members state that all theatre lists should have a designated emergency coordinator who can implement the Life Threatening Haemorrhage Protocol when required • Communication techniques such as 'Closed Loop Communication' should be used by theatre staff to confirm instructions are understood and confirmed • Request immediate assistance when Life Threatening Haemorrhage Protocol is triggered - scribe, runners, senior assistance etc.
Benefits & Harms of Options	What is the overall certainty of this evidence	✓	No included studies Very Low Low Moderate High Probably No	• As above	

	Criteria	Judgements		Research Evidence	Additional Considerations
	Is there important uncertainty about how people value the main outcomes	✓	Important uncertainty or variability Possibly important uncertainty or variability Probably no important uncertainty or variability No known uncertainty or variability	• As above	• The potential outcome is death of a patient.
	Are the desirable anticipated effects large	✓	Probably No No Uncertain Yes Varies	• As above	• Coordinating activities and requesting assistance from all relevant team members outside the theatre will greatly support patient safety.
	Are the undesirable anticipated effects small	✓	Probably No No Uncertain Yes Varies	• As above	• Time required for the emergency co-ordinator to undertake tasks. • The emergency co-ordinator will be unable to fulfil other duties in the theatre.
	Are the desirable effects large relative to the undesirable effects	✓	Probably No No Uncertain Yes Varies	• As above	• Patient safety outweighs other considerations.
Resources/ Costs	Are the resources required small?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• This is already a common practice in theatres. • No additional costs anticipated.
	Is the incremental cost small relative to the net benefits	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	
Equity	What would be the health impact on the health inequities?	✓	Increased Probably Increased Uncertain Probably Reduced Reduced	• No evidence specific to life threatening haemorrhage identified.	• The GDG does not anticipate any difference for different users of the health system. The same process will be followed across the health system.

	Criteria	Judgements		Research Evidence	Additional Considerations
Acceptability	Is the option acceptable to key stakeholders?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Already current practice and should continue.
Feasibility	Is the option feasible to implement	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Already current practice and should continue.

Guideline Question 10: Does the request for additional assistance when the major haemorrhage protocol is activated lead to controlled bleeding in the event of a life threatening haemorrhage event?

	Criteria	Judgements		Research Evidence	Additional Considerations
Problem	Is there a problem priority?	✓	Probably No No Uncertain Yes Varies	• BSH guideline 'A practical guideline for the haematological management of major haemorrhage' outlines that there must be a clear mechanism for contacting all relevant team members[11].	• Good communication between those in theatre is essential to assist clinical outcomes. • The emphasis is to stop the haemorrhage and stabilise the patient • The emergency coordinator in association with the surgeon and anaesthesiologist will confirm if assistance is required and coordinate the response. • Methods such as packing to reduce the ongoing haemorrhage and pressure/ compression on the bleeding vessel should be applied as a damage limiting approach. This might allow time for further resuscitation of the patient.
Benefits & Harms of Options	What is the overall certainty of this evidence	✓	No included studies Very Low Low Moderate High Probably No	• As above	

	Criteria	Judgements		Research Evidence	Additional Considerations
	Is there important uncertainty about how people value the main outcomes	✓	Important uncertainty or variability Possibly important uncertainty or variability Probably no important uncertainty or variability No known uncertainty or variability	• As above	• The potential outcome is death of a patient.
	Are the desirable anticipated effects large	✓	Probably No No Uncertain Yes Varies	As above	• Coordinating activities within the theatre and requesting assistance from all relevant team members outside the theatre will greatly support patient safety.
	Are the undesirable anticipated effects small	✓	Probably No No Uncertain Yes Varies	• As above	• If staff are called to theatre to assist they may be leaving other activities.
	Are the desirable effects large relative to the undesirable effects	✓	Probably No No Uncertain Yes Varies	• As above	• Patient safety outweighs other considerations.
Resources/ Costs	Are the resources required small?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• This is already a common practice in theatres.
	Is the incremental cost small relative to the net benefits	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	
Equity	What would be the health impact on the health inequities?	✓	Increased Probably Increased Uncertain Probably Reduced Reduced	• No evidence specific to life threatening haemorrhage identified.	• The GDG does not anticipate any difference for different users of the health system. The same process will be followed across the health system.

	Criteria	Judgements		Research Evidence	Additional Considerations
Acceptability	Is the option acceptable to key stakeholders?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Already current practice and should continue.
Feasibility	Is the option feasible to implement	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Already current practice and should continue.

Guideline Question 11: What type of haemostatic testing should take place and how often for a life threatening haemorrhage event?

	Criteria	Judgements		Research Evidence	Additional Considerations
Problem	Is there a problem priority?	✓	Probably No No Uncertain Yes Varies	• BSH guideline 'A practical guideline for the haematological management of major haemorrhage' outlines haemostatic test requirements in response to a life threatening haemorrhage event	• Serial haemostatic tests, including Hb, platelet count, PT, APTT and fibrinogen, from before and after resuscitation should be taken every 30–60 minutes depending on the severity of the haemorrhage. • The results of these tests will guide and ensure the appropriate use of blood components. There is also a need for monitoring and replacement of calcium.
Benefits & Harms of Options	What is the overall certainty of this evidence	✓	No included studies Very Low Low Moderate High Probably No	• As above	
	Is there important uncertainty about how people value the main outcomes	✓	Important uncertainty or variability Possibly important uncertainty or variability Probably no important uncertainty or variability No known uncertainty or variability	• As above	• The potential outcome is death of a patient.

	Criteria	Judgements		Research Evidence	Additional Considerations
	Are the desirable anticipated effects large	✓	Probably No No Uncertain Yes Varies	As above	• Completion of haemostatic tests will assist in stabilizing and guiding management of the patient
	Are the undesirable anticipated effects small	✓	Probably No No Uncertain Yes Varies	• As above	• Costs of performing tests
	Are the desirable effects large relative to the undesirable effects	✓	Probably No No Uncertain Yes Varies	• As above	• Patient safety outweighs other considerations.
Resources/ Costs	Are the resources required small?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• This is already a common practice in hospitals.
	Is the incremental cost small relative to the net benefits	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	
Equity	What would be the health impact on the health inequities?	✓	Increased Probably Increased Uncertain Probably Reduced Reduced	• No evidence specific to life threatening haemorrhage identified.	• The GDG does not anticipate any difference for different users of the health system. The same process will be followed across the health system.
Acceptability	Is the option acceptable to key stakeholders?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Already current practice and should continue.
Feasibility	Is the option feasible to implement	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified. d by the required staff.	• Already current practice and should continue.

Guideline Question 12: Does access to sufficient and appropriate blood components and products in a timely manner lead to an improved response to a life threatening haemorrhage?

	Criteria	Judgements		Research Evidence	Additional Considerations
Problem	Is there a problem priority?		Probably No No Uncertain ✓ Yes Varies	• BSH guideline 'A practical guideline for the haematological management of major haemorrhage' outlines the type of blood components and their ratio to respond to a life threatening haemorrhage event.	• Ensure access to sufficient and appropriate blood components and products in a timely manner. • Staff should know where to access emergency Group O negative red cell components and the timeline to availability (refer to the National Life Threatening Haemorrhage Poster).
Benefits & Harms of Options	What is the overall certainty of this evidence		No included studies ✓ Very Low Low Moderate High Probably No	• As above	
	Is there important uncertainty about how people value the main outcomes		Important uncertainty or variability Possibly important uncertainty or variability Probably no important uncertainty or variability ✓ No known uncertainty or variability	• As above	• The potential outcome is death of a patient.
	Are the desirable anticipated effects large		Probably No No Uncertain ✓ Yes Varies	As above	• Appropriate and timely blood components and associated ratios will support patient safety.
	Are the undesirable anticipated effects small		Probably No No Uncertain ✓ Yes Varies	• As above	• Requested blood products may not be used.
	Are the desirable effects large relative to the undesirable effects		Probably No No Uncertain ✓ Yes Varies	• As above	• Patient safety outweighs other considerations.

	Criteria	Judgements		Research Evidence	Additional Considerations
Resources/ Costs	Are the resources required small?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• This is already a common practice in hospitals.
	Is the incremental cost small relative to the net benefits	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	
Equity	What would be the health impact on the health inequities?	✓	Increased Probably Increased Uncertain Probably Reduced Reduced	• No evidence specific to life threatening haemorrhage identified.	• The GDG does not anticipate any difference for different users of the health system. The same process will be followed across the health system.
Acceptability	Is the option acceptable to key stakeholders?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Already current practice and should continue.
Feasibility	Is the option feasible to implement	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Already current practice and should continue.

Guideline Question 13: What are best practices on administering and timing of Thromboprophylaxis following life threatening haemorrhage events?

	Criteria	Judgements		Research Evidence	Additional Considerations
Problem	Is there a problem priority?	✓	Probably No No Uncertain Yes Varies	• European guideline on management of major bleeding and coagulopathy following trauma: fifth edition details the recommended practice	• Risk of Thrombus formation
Benefits & Harms of Options	What is the overall certainty of this evidence	✓	No included studies Very Low Low Moderate High Probably No	• As above	

	Criteria	Judgements		Research Evidence	Additional Considerations
	Is there important uncertainty about how people value the main outcomes	✓	Important uncertainty or variability Possibly important uncertainty or variability Probably no important uncertainty or variability No known uncertainty or variability	• As above	• The potential outcome is death of a patient.
	Are the desirable anticipated effects large	✓	Probably No No Uncertain Yes Varies	As above	• Preventative action to reduce risk of thrombosis
	Are the undesirable anticipated effects small	✓	Probably No No Uncertain Yes Varies	• As above	• Rare risk for reaction to thromboprophylaxis
	Are the desirable effects large relative to the undesirable effects	✓	Probably No No Uncertain Yes Varies	• As above	• Significant risk of thrombus if preventative measures not taken.
Resources/ Costs	Are the resources required small?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• This is already a common practice in some hospitals.
	Is the incremental cost small relative to the net benefits	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	
Equity	What would be the health impact on the health inequities?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• The GDG does not anticipate any difference for different users of the health system. The same process will be followed across the health system.
Acceptability	Is the option acceptable to key stakeholders?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Already current practice in some hospitals and should continue.

	Criteria	Judgements		Research Evidence	Additional Considerations
Feasibility	Is the option feasible to implement	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Already current practice in some hospitals and should continue.

Guideline Question 14: Do reviews undertaken following a life threatening haemorrhage event ensure that effective systems are in place for major haemorrhage management in the future?

	Criteria	Judgements		Research Evidence	Additional Considerations
Problem	Is there a problem priority?	✓	Probably No No Uncertain Yes Varies	• WHO Safe Surgery Guidelines outlines the purpose of a debriefing process. • BSH guideline – 'A practical guideline for the haematological management of major haemorrhage' outlines a recommendation that 'Multidisciplinary audit and case review should be undertaken to ensure that effective systems are in place for major haemorrhage management'.	• A debrief with the theatre team should take place where possible soon after the event - (this is to support all members of the team, to discuss the event and establish the sequence of events) • Audit of life threatening haemorrhage management is essential to assess adverse events, timeliness of blood component support, patient outcome and component wastage • Performing a Case Review, HTC and OTC review will assist in identifying trends and informing best practices.
Benefits & Harms of Options	What is the overall certainty of this evidence	✓	No included studies Very Low Low Moderate High Probably No	• As above	
	Is there important uncertainty about how people value the main outcomes	✓	Important uncertainty or variability Possibly important uncertainty or variability Probably no important uncertainty or variability No known uncertainty or variability	• As above	• Reviews will assist all those involved in a life threatening haemorrhage event to learn from experience and reduce occurrences.

	Criteria	Judgements		Research Evidence	Additional Considerations
	Are the desirable anticipated effects large	✓	Probably No No Uncertain Yes Varies	As above	• Performing reviews will allow staff to learn from experience and inform future practices. • Analysing trends will assist with identifying root causes and potentially reduce occurrences.
	Are the undesirable anticipated effects small	✓	Probably No No Uncertain Yes Varies	• As above	• Time taken to gather, record and review relevant life threatening haemorrhage data.
	Are the desirable effects large relative to the undesirable effects	✓	Probably No No Uncertain Yes Varies	• As above	• Patient safety outweighs other considerations.
Resources/ Costs	Are the resources required small?	✓	Probably No No Uncertain Yes Varies	• As above	• In most hospitals debriefs, case reviews and HTC meetings already take place. • An OTC meeting will be new and will have a time impact for those that attend – possibly a quarterly or 6 monthly meeting with minimal cost impact.
	Is the incremental cost small relative to the net benefits	✓	Probably No No Uncertain Yes Varies	• As above	
Equity	What would be the health impact on the health inequities?	✓	Probably No No Uncertain Yes Varies	• As above	• The GDG does not anticipate any difference for different users of the health system. The same process will be followed across the health system.
Acceptability	Is the option acceptable to key stakeholders?	✓	Probably No No Uncertain Yes Varies	• As above	• The GDG does not anticipate any disagreement to the recommendation from stakeholders.
Feasibility	Is the option feasible to implement	✓	Probably No No Uncertain Yes Varies	• As above	• National Transfusion Advisory Group (NTAG) developing a national framework for acute life threatening haemorrhage review (which will include guidance on case review, HTC and OTC review).

Guideline Question 15: Do dedicated familiarization days for medical scientists not normally based in the transfusion lab for out of hours cover lead to an improved response by Medical Scientists not routinely working in the transfusion lab in the event of a life threatening haemorrhage?

	Criteria	Judgements		Research Evidence	Additional Considerations
Problem	Is there a problem priority?		Probably No No Uncertain ✓ Yes Varies	• Section 3.3 - UK Transfusion Laboratory Collaborative identifies that Medical Scientists must complete and document at least 10 working days per annum of autonomous, independent or lone-working in a hospital blood transfusion laboratory[21]. • Serious Hazards Of Transfusion (SHOT Report 2019) outlined that a lack of adequate training contributed to numerous incidents reported to SHOT[48].	• Familiarisation days are when you typically don't work routinely in a laboratory but are assigned a set number of days per annum to make yourself familiar with the laboratory. • A survey undertaken by the GDG of blood transfusion laboratories across the country identified less than 50% of laboratories undertaking supervised dedicated familiarisation days for medical scientists supporting out of hours transfusion laboratory activity.
Benefits & Harms of Options	What is the overall certainty of this evidence		No included studies Very Low ✓ Low Moderate High Probably No	• No evidence specific to life threatening haemorrhage identified.	• The survey undertaken identified expressions of concern from medical scientists in relation to life threatening haemorrhage out of hours in the absence of adequate familiarisation.
	Is there important uncertainty about how people value the main outcomes		Important uncertainty or variability Possibly important uncertainty or variability Probably no important uncertainty or variability ✓ No known uncertainty or variability	• No evidence specific to life threatening haemorrhage identified.	• The potential outcome is death of a patient.
	Are the desirable anticipated effects large		Probably No No Uncertain ✓ Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Medical Scientists providing out of hours cover who are not normally based in the transfusion laboratory having acquired experience.

	Criteria	Judgements		Research Evidence	Additional Considerations
	Are the undesirable anticipated effects small	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Medical Scientist staff will be unable to complete regular assigned tasks in order to complete the familiarisation days.
	Are the desirable effects large relative to the undesirable effects	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Patient safety outweighs other considerations.
Resources/ Costs	Are the resources required small?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• HSE may need to recruit additional Medical Scientists to cover familiarisation days. • Academy of Clinical Scientists and Laboratory Medicine to consider additional laboratory scientist requirement in work force planning.
	Is the incremental cost small relative to the net benefits	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	
Equity	What would be the health impact on the health inequities?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• The GDG does not anticipate any difference for different users of the health system. The same process will be followed across the health system.
Acceptability	Is the option acceptable to key stakeholders?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Medical Scientists will support a formalised approach rather than an ad hoc
Feasibility	Is the option feasible to implement	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Laboratory management will need to develop a roster to include 10 familiarisation days for non-transfusion laboratory staff participating in a transfusion on call roster

Guideline Question 16: Does a formal out of hours cover process/system lead to improved support and access to expertise in out of hours cover for medical scientists?

	Criteria	Judgements		Research Evidence	Additional Considerations
Problem	Is there a problem priority?		Probably No No Uncertain ✓ Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• A survey undertaken by the GDG of blood transfusion laboratories across the country identified that barriers to timely support included the expertise of medical scientists out of hours. • In many cases it was noted that a formal arrangement was not in place to request out of hour's medical support. • All hospitals to develop an arrangement so that in the circumstances of a life threatening haemorrhage event, an additional medical scientist can be called in out of hours to support the Transfusion Laboratory where necessary.
Benefits & Harms of Options	What is the overall certainty of this evidence	✓	No included studies Very Low Low Moderate High Probably No	• No evidence specific to life threatening haemorrhage identified.	
	Is there important uncertainty about how people value the main outcomes		Important uncertainty or variability Possibly important uncertainty or variability Probably no important uncertainty or variability ✓ No known uncertainty or variability	• No evidence specific to life threatening haemorrhage identified.	• The potential outcome is death of a patient. • Without a formal arrangement Scientists are slow to call their colleagues for help on their days off and very often carry the burden of an overly busy on call themselves and are exhausted at the end of their shift.

	Criteria	Judgements		Research Evidence	Additional Considerations
	Are the desirable anticipated effects large	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• There will be an increased cost for the HSE • There are no known other undesirable effects from having a formal arrangement in place for out of hours cover.
	Are the undesirable anticipated effects small	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• There will be an increased cost for the HSE • There are no known other undesirable effects from having a formal arrangement in place for out of hours cover.
	Are the desirable effects large relative to the undesirable effects	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Patient safety outweighs other considerations. • With a formalised roster in place medical scientists would be more inclined to call in help when the workloads warrant it as they know exactly who to call.
Resources/ Costs	Are the resources required small?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• There will be an additional cost to formalise out of hours cover for medical scientists. • With a formal rota a scientist has to be paid to be on standby for a call in as they are not free to do what they wish when they are on the standby rota. • The ad hoc system means no one is officially available but hopefully someone will respond when an urgent call is sent out for help. • If there were a formalised roster in place medical scientists would be more inclined to call in help when the workloads warrant it as they know exactly who to call.
	Is the incremental cost small relative to the net benefits	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	

	Criteria	Judgements		Research Evidence	Additional Considerations
Equity	What would be the health impact on the health inequities?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• The GDG does not anticipate any difference for different users of the health system. The same process will be followed across the health system.
Acceptability	Is the option acceptable to key stakeholders?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• There is buy-in from Medical Scientists to make this happen
Feasibility	Is the option feasible to implement	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• All hospitals to establish an agreed process for additional out of hours emergency medical scientist call in cover • Recompense needs to be in place for out of hours emergency call in.

Guideline Question 17: What content should be included in a Service Level Agreement (SLA) to assist with the provision of transfusion services to off-site hospitals?

	Criteria	Judgements		Research Evidence	Additional Considerations
Problem	Is there a problem priority?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified. • Survey identified a fatal outcome for a life threatening haemorrhage event in an offsite hospital and this hospital did not appear to routinely have emergency Group O red cell components on site.	• Survey conducted by GDG of Hospital Transfusion Laboratories identified concerns with availability and timing of blood components to offsite hospitals • Transfusion laboratories which provide a transfusion service for offsite hospitals should identify as part of the Service Level Agreement(s) the requirement and the timeline for provision of blood components at the offsite hospital.
Benefits & Harms of Options	What is the overall certainty of this evidence	✓	No included studies Very Low Low Moderate High Probably No	• No evidence specific to life threatening haemorrhage identified.	

	Criteria	Judgements		Research Evidence	Additional Considerations
	Is there important uncertainty about how people value the main outcomes	✓	Important uncertainty or variability Possibly important uncertainty or variability Probably no important uncertainty or variability No known uncertainty or variability	• No evidence specific to life threatening haemorrhage identified.	• The potential outcome is death of a patient.
	Are the desirable anticipated effects large	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Having an appropriate SLA between hospital with the transfusion laboratory and any off-site hospitals supported by the lab will assist in ensuring timely delivery of required blood components and full transparency on the needs of the off-site hospital.
	Are the undesirable anticipated effects small	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• There are no known undesirable effects from having an SLA in place.
	Are the desirable effects large relative to the undesirable effects	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• Patient safety outweighs other considerations.
Resources/ Costs	Are the resources required small?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• SLA's are already current practice but will require resourcing to consider the required elements of this guideline. Already a current practice and no additional costs expected.
	Is the incremental cost small relative to the net benefits	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	
Equity	What would be the health impact on the health inequities?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• This should improve equity in service delivery.

	Criteria	Judgements		Research Evidence	Additional Considerations
Acceptability	Is the option acceptable to key stakeholders?	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• This is already a common practice but SLA's should be reviewed to confirm satisfaction with content and amend if necessary.
Feasibility	Is the option feasible to implement	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• This is already a common practice but SLA's should be reviewed to confirm satisfaction with content and amend if necessary.

Part B – GRADE approach to assess quality of evidence & strength of recommendation

GRADE:
The GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach was used by the GDG to assess the quality of evidence for all recommendations. GRADE categorises the certainty in evidence as high, moderate, low or very low.

Quality Level	Definition
High	The GDG is very confident that the true effect lies close to that of the estimate of the effect.
Moderate	The GDG is moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low	The GDG confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very Low	The GDG has very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of the effect.

Strength of recommendations:
The strength of a recommendation expresses the degree to which the GDG is confident in the balance between the desirable and undesirable consequences of implementing the recommendation. When a GDG is very certain about the balance (i.e. the desirable consequences clearly outweigh the undesirable consequences), it issues a strong recommendation in favour of an intervention. When the GDG is uncertain about this balance, however, it issues a conditional (or 'weak') recommendation. See definitions below:

- Strong Recommendations: A strong recommendation is one for which the panel (GDG) is confident that the desirable effects of adherence to a recommendation outweigh the undesirable effects. This can be both in favour of an intervention and against it.

- Conditional/weak recommendations: A conditional recommendation is one for which the panel (GDG) concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, but the panel is not confident about these trade-offs. Reasons for not being confident can include: absence of high-quality evidence; presence of imprecise estimates of benefits or harms; uncertainty or variation in how different individuals value the outcomes; small benefits; the benefits may not be worth the costs (including the costs of implementing the recommendation.

GDG Consensus on Quality of Evidence and Strength of Recommendation

The consensus of the GDG is that the quality of evidence is very low or low for the recommendations. The risk to patient safety, which can unfortunately result in patient death, is deemed high for all recommendations. Although this may be a rare event the impact is significant, adherence to these recommendations is strongly recommended to ensure patient safety. The risk to patient safety, which can unfortunately result in patient death, is deemed high for all recommendations. The consensus of the GDG is that the strength of recommendation is strong for the recommendations presented in Part C.

PART C – GDG assessment of quality of evidence and strength of recommendation

	Recommendation	Quality of evidence	Strength of recommendation	Agreement/ Consensus achieved
1	Hospital Group structures already exist for the delivery of healthcare nationally and should continue to designate the appropriate sites for scheduled (elective) and unscheduled (emergency /urgent) surgery. Consideration of timely access to blood transfusion support and turnaround times (TATs) for critical tests or availability of near patient testing (NPT), should be included in the designation of appropriate sites so as to support life-threatening haemorrhage.	Very Low	Strong	Yes
2	All theatre teams must follow the agreed 'Sign In, Time Out and Sign Out - Safe Surgery Checklist' as presented in the 'HSE National Policy and procedure for safe surgery' (Private Hospitals to use WHO Safe Surgery Guideline).	Low	Strong	Yes

	Recommendation	Quality of evidence	Strength of recommendation	Agreement/ Consensus achieved
3	All Hospitals must have the National Life Threatening Haemorrhage Management Poster prominently on display in the operating theatre. All hospitals must also have an underpinning Life Threatening Haemorrhage Policy & Procedure/Protocol which incorporates the recommendations of this guideline. All clinical, laboratory and support staff to maintain their competency must be familiar with the contents of the Life Threatening Haemorrhage Protocol/ Procedure.	Low	Strong	Yes
4	The pre-operative assessment of the patient should identify specific issues for individual patients which need to be addressed to reduce the risk of life threatening haemorrhage. In addition, prior to commencement of the operation the multidisciplinary team should identify specific parts of the operation where life threatening haemorrhage could occur. This particularly applies when any operative intervention in the chest, abdomen or pelvis occurs.	Very Low	Strong	Yes
5	When any open or laparoscopic/operative intervention in the chest, abdomen or pelvis is to take place or where there is potential to inadvertently enter one of these cavities during surgery - the following criteria will be confirmed in advance of the procedure to support adequate preparation in the event of an unexpected intraoperative life threatening haemorrhage: Once per day: • Confirm emergency Group O blood is available in the specified fridge/cold storage known to the theatre staff and documented on the National Life Threatening Haemorrhage Poster	Very Low	Strong	Yes

	Recommendation	Quality of evidence	Strength of recommendation	Agreement/ Consensus achieved
	• Confirm other blood components (see Poster) for the management of a life threatening haemorrhage are available Every patient: • Confirm blood group and antibody screen (group and hold) or crossmatch has been performed as per hospital Maximum Surgical Blood Ordering Schedule (MSBOS) /specific blood order for a particular patient is available • Confirm where senior help is and how they can be contacted • Confirm placement of at least one peripheral wide bore cannula • Confirm the availability of equipment for the placement of central access catheters (including ultrasound) • Confirm location and availability of sterile vascular instruments and haemostatic products			
6	To ensure patient safety appropriate supervision and clinical support should be provided to surgery, gynaecology and anaesthesiology trainees in line with their experience and stage of training.	Very Low	Strong	Yes
7	All trainee surgeons and gynaecologists undertaking laparoscopic procedures during the course of their training must complete laparoscopy skills training and simulation drills - these include recognition and appropriate response to a life threatening haemorrhage event.	Very Low	Strong	Yes

	Recommendation	Quality of evidence	Strength of recommendation	Agreement/ Consensus achieved
8	All staff working in theatre and all Medical Scientists involved in a life threatening haemorrhage (including those providing out of hours cover) should participate in regular multi-disciplinary drills in the recognition and management of major blood loss. Participants should know when to activate/ trigger the life threatening haemorrhage protocol and take prompt and appropriate action. Those participating in the multi-disciplinary drills should complete the eLearning training content on life threatening haemorrhage when it becomes available.	Low	Strong	Yes
9	Following the trigger of the life threatening haemorrhage protocol there must be a clear mechanism to contact all relevant team members and a designated emergency coordinator should then coordinate further management.	Low	Strong	Yes
10	In the event of a major vascular injury the designated Emergency Coordinator in association with the surgeon and anaesthesiologist should request extra assistance as appropriate to the procedure and if promptly available locally (senior surgeon, vascular surgeon, interventional radiology, etc.) and request this assistance ASAP. Once a Red Alert (activation of the Life Threatening Haemorrhage Protocol) has been called, progression to laparotomy should be considered. Whilst waiting for senior assistance to arrive – methods such as packing to reduce the ongoing haemorrhage and pressure/ compression or potentially exploring balloon tamponade/covered stenting of the bleeding vessel should be applied as a damage limiting approach. This might allow time for further resuscitation of the patient.	Very Low	Strong	Yes

	Recommendation	Quality of evidence	Strength of recommendation	Agreement/ Consensus achieved
11	Serial haemostatic tests, including FBC (Hb, platelet count), PT, APTT and fibrinogen or Near Patient Testing (NPT), from before and after resuscitation should be taken every 30–60 minutes depending on the severity of the haemorrhage. The results of these tests will guide and ensure the appropriate use of blood components. Calcium must be monitored and replaced as appropriate.	Low	Strong	Yes
12	Ensure access to sufficient and appropriate blood components and products in a timely manner. Staff should know where to access emergency Group O red cell components and the timeline to availability (refer to the National Life Threatening Haemorrhage Poster). Hospitals must have systems in place that reliably inform the laboratory on use of emergency Group O red cell components so as to assure immediate replacement.	Low	Strong	Yes
13	Early mechanical thromboprophylaxis with intermittent pneumatic compression (IPC) should be applied while the patient is immobile and has a bleeding risk. This should be combined with pharmacological and IPC thromboprophylaxis within 24 h after bleeding has been controlled and until the patient is mobile.	Low	Strong	Yes
14	Two separate reviews are required following an unexpected life threatening haemorrhage in addition to hospital specific processes which are in place for adverse events/risk management /open disclosure: a) De-brief by the theatre team to ensure all staff members are supported, discuss and learn from the life threatening haemorrhage event	Low	Strong	Yes

	Recommendation	Quality of evidence	Strength of recommendation	Agreement/ Consensus achieved
	b) Case Review by a wider multi-functional team – led by Perioperative Director and supported by lead haematologist for transfusion, haemovigilance officer and chief medical scientist should be undertaken, fully engaging the theatre team in a timely manner. A summary should be reported to the HTC. In addition such incidents may be part of: • Periodic Audit by the Hospital Transfusion Committee reviewing overall trends, outcomes and processes for life threatening haemorrhage events • All Hospital Transfusion Committees will feed into an Overarching Transfusion Committee (OTC). The OTC will review and benchmark unexpected life threatening haemorrhage events - overall trends, outcomes and processes.			
15	It is recommended that all medical scientists supporting out of hours transfusion laboratory activity, who do not work routinely in the Transfusion Laboratory should undertake supervised dedicated familiarisation days annually. It is recommended that familiarisation consist of 10 days during routine hours in the Transfusion Laboratory to ensure the appropriate skill set.	Very Low	Strong	Yes
16	All hospitals must develop an arrangement so that in the circumstances of a life threatening haemorrhage event, an additional medical scientist can be called in out of hours to support the laboratory practice where necessary.	Very Low	Strong	Yes
17	Hospitals which provide a transfusion service for offsite hospitals should identify as part of the Service Level Agreement(s) the requirement and the timeline for provision of blood components at the offsite hospital	Very Low	Strong	Yes

Appendix 3: Consultation Report

A template was prepared capturing all sections of the guideline to seek feedback as part of the public consultation process. Due to the HSE ransomware attack efforts were made to ensure emails were received by all stakeholders. The feedback template and guideline was emailed to all identified stakeholders which included the following:

- **3 x International Reviewers** - Haematology, surgery & anaesthesiology as nominated by Royal College of Physicians of Ireland (RCPI), Royal College of Surgeons in Ireland (RCSI) & College of Anaesthesiologists of Ireland (CAI)
- **Academy of Clinical Science and Laboratory Medicine (ACLMS)** – the Academy representing medical scientists in Ireland circulated the guideline to their Council Members, Haematology Advisory Body Members & Transfusion and Transplantation Advisory Body Members. They provided detailed feedback to the draft guideline which included the diverse opinion of its members. As a follow-up with the Academy, a sub group of the GDG organised meetings with Academy members to discuss feedback and provide an opportunity to discuss, reflect and amend guideline content. Many Academy members contributed to the content of the guideline through their participation in a number of data gathering surveys also.
- **Irish Haematology Society (IHS)** – Transfusion & Coagulation Special Interest Groups. The IHS are a significant stakeholder that was informed of progress throughout the guideline development process. The IHS provided a single response from their representatives to reflect the consensus of opinion in addition to individual haematologists taking the opportunity to provide feedback. They provided much valued input to a number of recommendations related to transfusion and provided robust challenge to reduce ambiguity in the guideline.
- **Faculty of Pathology – RCPI** – The Dean of the Faculty of Pathology was sent the guideline and feedback template and requested to circulate to anyone they thought should have sight on the draft guideline and could offer relevant input. The audience here would have included the IHS members mentioned above.
- **Irish Blood Transfusion Service (IBTS)** – The Medical and Scientific Director in the IBTS and a Consultant Haematologist in the IBTS were both sent the guideline and feedback template. Their input provided additional references and challenge to the guideline content.
- **Hospital Group CEOs** – All Hospital Group CEOs were sent the guideline and requested to circulate the guideline to the relevant members of their teams for input. A follow-up took place to ensure that this happened with all PA's to the Hospital Group CEO's.
- **Nursing** – With the assistance of the nursing representatives on the GDG, the Chair of Hospital Group Directors of Nursing and Midwifery (HGDONMs) & Office of the Nursing and Midwifery Services Director (ONMSD) were sent the guideline and template and requested to share the guideline with their representatives. Eight individual responses from Nurses were received.
- **Clinical Programme** – **Anaesthesiology** – Two members of the Clinical Programme for Anaesthesia were represented on the GDG and the guideline and template was sent to additional members of the National Anaesthesia Programme for their input.
- **Clinical Programme – Surgery** – The guideline and template were shared with the co-leads of the Surgical Clinical Programme and the assigned programme manager for comment. Consolidated response received providing surgical input.
- **Clinical Programme for Trauma & Orthopaedic Surgery** - The guideline and associated feedback template was sent to the Clinical Leads and requested to circulate to all relevant parties for input.

- **National Women's and Infants Health Programme (NWIHP)** - The guideline and associated feedback template was sent to the Clinical Lead of the NWIHP Programme and requested to circulate to all relevant parties for input.
- **Obstetrics & Gynaecology Training – RCPI** - The guideline and associated feedback template was sent to the Lead for Obstetrics & Gynaecology training in RCPI and requested to circulate to all relevant parties for input.
- **Institute of Obstetrics & Gynaecology** - The guideline and associated feedback template was sent to Institute of Obstetrics and Gynaecology and requested to circulate to all relevant parties for input. Feedback was received from a number of the maternity hospitals.
- **Private Hospitals Association (PHA)** - The guideline and associated feedback template was sent to the PHA and requested to circulate to all relevant parties for input.
- **Faculty of Radiologists** - The guideline and associated feedback template was sent to the Faculty of Radiologists and requested to circulate to all relevant parties for input.
- **Irish Society of Interventional Radiology** The guideline and associated feedback template was sent to the Irish Society of Interventional Radiology and requested to circulate to all relevant parties for input.
- **National Transfusion Advisory Group (NTAG)** – The NTAG group were informed of progress throughout the guideline development process and provided valuable input on items such as poster design and a review of the transfusion data gathering exercises undertaken throughout the process. They also provided a consolidated feedback form providing input to improve the guideline quality.
- **National Office of Clinical Audit (NOCA) –** The guideline and associated feedback template was sent to the Executive Director of NOCA and requested to circulate to all relevant parties for input. NOCA were also represented on the GDG.

The public consultation process was opened for 4 weeks – from July 1st 2021 through to July 30th 2021. An extension was provided to a small number of bodies that requested additional time. 35 responses were received in total which ranged from individual feedback or feedback on behalf of an organisation. All feedback received was collated in an excel spreadsheet clearly denoting the section of the guideline with the respective feedback received. The collated feedback was circulated to all GDG members for review. A series of meetings took place with the entire GDG and subgroups of the GDG to address specific areas of the feedback.

The public consultation process informed a revision of the guideline through consideration of the feedback received and consensus being reached on any required amendments. Some of these amendments included the following:

- Section 2.5 'Guideline Scope' amended to provide greater clarity on how the narrow scope of the guideline will be built upon for other clinical scenarios
- Section 2.8 'Guideline Methodology' amended to provide further clarification on the fact that high quality evidence is unlikely to ever be published to guide recommendations for this clinical scenario and to justify the 'Strong' rating of recommendations
- Section 2.13 amended with additional areas requiring further research as part of future guideline review
- Recommendation 1 amended to incorporate the consideration of timely access to blood transfusion support and TATs for critical tests or availability of NPT, in designating appropriate sites so as to support life threatening haemorrhage.

- Recommendation 5 revised to remove a requirement for a group and antibody screen for all laparoscopic/operative interventions in the chest, abdomen or pelvis or where there is potential to inadvertently enter one of these cavities during surgery outside of requirement defined by MSBOS. Additional evidence was sourced by the GDG which outlined the minimal risk/benefit for conducting these tests and aligned with the concerns of a number of stakeholders.
- A number of changes were made to the "National Poster for Adult Intra-operative Life Threatening Haemorrhage Protocol" to provide greater clarity and consistency of content. These included:
  a) Lines 2 & 3 in the title of the poster changed to state 'Clinical concern for life threatening bleeding then activate immediately!'
  b) In the Resuscitate section the following amendments were captured for the relevant points – Large bore IV access 2 x 14 gauge, High f_iO_2, Active pressure warming – environment, fluids, blanket
  c) Discuss reversal with haematologist added to relevant step
  d) Removal of as many acronyms as possible – ID, ADON, NPT, FBC, CA etc
  e) ROTEM/TEG replaced with VHAs
  f) Blood Management heading replaced to say – Empiric Blood Management or transfuse by laboratory tests/NPT
  g) Immediate Red Cell Transfusion box – accompanying text replaced with Transfuse Group O/cross matched red cells whichever is available from nearby blood fridge/transporter
  h) Contents of Massive Haemorrhage Pack re-defined
- Recommendation 8 amended to state that those participating in multi-disciplinary drills should complete the eLearning training content on life threatening haemorrhage when it is available
- Recommendation 10 amended to include the following text: 'Once a Red Alert (activation of the Massive Haemorrhage Protocol) has been called, progression to laparotomy should be considered'
- Recommendation 11 – evidence base expanded in relation to NPT and VHAs
- Contents of the Massive Haemorrhage Pack as outlined in Recommendation 12 informed by feedback and discussion with the Irish Haematology Society and available evidence
- Recommendation 16 amended to replace the term 'transfusion laboratory' with 'laboratory practice' to capture the broad responsibility of laboratory support required in a life threatening haemorrhage event
- Recommendation 17 amended to specify the 'Hospital' rather than 'Transfusion Laboratory' having responsibility for off-site hospital arrangements
- The wording of a number of recommendations revised by replacing passive language with stronger language – e.g. use of the word 'will' changed to read 'must'.
- Additional Good Practice Points were included across many of the recommendations to provide greater clarity and support in implementing the guideline recommendations
- Responsibilities for actions in the Implementation Plan were amended – Appendix 5
- Framework Document - Appendix 6.1 amended to provide greater details of the Irish experience as reported through the Blood Transfusion Laboratory Survey conducted by the GDG. Amendments to reflect the responsibilities and authority of the Perioperative Director & Lead Haematologist for Transfusion, seeking clinical user support for the HTC, the role availability and evidence in relation to cell salvage & contents of massive haemorrhage pack. Inclusion of Patient Transfer protocol. In relation to blood components – hospital discard rates to be monitored and hospitals to identify the timelines to emergency availability of components from the IBTS.

Appendix 4: Logic Model

Appendix 5: Implementation plan

Guideline Recommendation number	Implementation barriers / enablers	Action / intervention / task to implement recommendation	Lead responsibility for delivery of action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
Recommendation 1 Hospital Group structures already exist for the delivery of healthcare nationally and should continue to designate the appropriate sites for scheduled (elective) and unscheduled (emergency /urgent) surgery. Consideration of timely access to blood transfusion support and turnaround times (TATs) for critical tests or availability of near patient testing (NPT), should be included in the designation of appropriate sites so as to support life-threatening haemorrhage. **Overall Lead – Hospital (and/or Group Management Teams**	Enabler: Broad representation of Colleges and Programmes on GDG	• Clinical Programmes updated on the guideline recommendations • Hospital Group Management Teams to seek guidance of the various colleges (CAI, RCSI, RCPI) as to ongoing suitability of facilities to carry out surgical procedures.	• GDG • Hospital Group Management Teams	✓ ✓	◯ ◯	◯ ◯	*Outcomes:* • Clinical Programmes and Colleges informed of recommendations as the guideline development process progresses • Engagement of the Hospital Management Teams with the Colleges *Verification:* • Colleges endorsing the guideline recommendations
	Enabler: Hospital Group Management Teams already in place	• Review and evaluate the current designation of sites and their suitability to perform particular surgical procedures, this will ensure that patient safety remains central. • Going forward, Hospital Group Management Teams to consider the hospital sites undertaking elective and emergency surgery to ensure adequate capability to respond to unexpected life threatening haemorrhage events.	• Hospital (and/or Group) Management Teams • Hospital (and/or Group) Management Teams	✓ ✓	◯ ✓	◯ ◯	*Outcomes:* • Elective and Emergency surgery taking place in appropriate safe hospital sites.

Guideline Recommendation number	Implementation barriers / enablers	Action / intervention / task to implement recommendation	Lead responsibility for delivery of action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
	Barrier: Lack of funding could be a barrier to making changes	• Designated centres may require additional resources and if this is the case they should be adequately funded	• Hospital Management Teams in consultation with HSE & DOH	✓	✓	✓	*Outcomes:* • Appropriate resources in place – right operation in right hospital with right resources *Verification:* • Resource constraints captured on Hospital Risk Register
	Barrier: International bodies are responsible for the accreditation of most private hospitals	• Ensure accreditation bodies for Private Hospitals are informed of national guideline recommendations • Ensure Private Hospitals implement the recommendations of the guideline	• DOH • Private Hospital Management Teams	✓ ✓	◯ ◯	◯ ◯	*Outcomes:* • Accreditation Bodies informed • Accreditation bodies assessing against recommendations of guideline *Verification:* • Accreditation reports of Private Hospitals

Guideline Recommendation number	Implementation barriers / enablers	Action / intervention / task to implement recommendation	Lead responsibility for delivery of action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
Recommendation 2 All theatre teams must follow the agreed 'Sign In, Time Out and Sign Out - Safe Surgery Checklist' as presented in the 'HSE National Policy and procedure for safe surgery' (Private Hospitals to use WHO Safe Surgery Guideline). **Overall Lead – Hospital General Manager**	Enabler: Clinical teams are already familiar with the Safe Surgery Checklist	• All hospitals to implement the HSE National Policy and procedure for safe surgery' (WHO Safe Surgery Policy in Private Hospitals) • Amend existing Safe Surgery checklist to include question on the likelihood of Unanticipated Life Threatening Haemorrhage • All hospital versions of the safe surgery checklist to include the question on the likelihood of Unanticipated Life Threatening Haemorrhage	• Hospital General Manager • National Safe Surgery Policy Working Group • Hospital General Manager	✓ ◯ ◯	◯ ✓ ✓	◯ ◯ ◯	*Outcomes:* • Safe Surgery Checklist completed correctly for all operations • Amended HSE National policy and procedure for safe surgery published and accessible • Audit criteria as set out in the 'HSE National Policy and procedure for safe surgery' *Verification:* • Audit undertaken as per the criteria of HSE National Safe Surgery Policy or WHO Safe Surgery Guidelines
		• Implement the minimum standard of the HSE Safe Surgery Policy (WHO Policy for the private Hospitals)	• Hospital General Manager • All theatre staff	✓	◯	◯	*Outcomes:* • Checklist completed for all surgical patients *Verification:* • Audit undertaken against criteria of HSE National Safe Surgery Policy or WHO Safe Surgery

Guideline Recommendation number	Implementation barriers / enablers	Action / intervention / task to implement recommendation	Lead responsibility for delivery of action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
	Enabler: Support from Hospital (Group) Management Team	• Hospital Group Management Teams to action checklist audit results	• Hospital Management Teams	✓	◯	◯	*Outcome:* • Checklist Audits reviewed and actioned as necessary *Verification:* • Audit Results

Guideline Recommendation number	Implementation barriers / enablers	Action / intervention / task to implement recommendation	Lead responsibility for delivery of action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
Recommendation 3 All Hospitals must have the National Life Threatening Haemorrhage Management Poster prominently on display in the operating theatre. All hospitals must also have an underpinning Life Threatening Haemorrhage Policy & Procedure/Protocol which incorporates the recommendations of this guideline. All clinical, laboratory and support staff to maintain their competency must be familiar with the contents of the Life Threatening Haemorrhage Protocol/ Procedure. **Overall Lead – Perioperative Surgical Lead supported by Lead Haematologist for Transfusion**	Enablers • National Clinical Lead for Transfusion is a member of the GDG • Seeking NCAGL agreement to enable the development of the national life threatening haemorrhage poster and making it accessible. • NTAG Acute Life Threatening Haemorrhage working group is working in parallel with this GDG	Poster & Massive Haemorrhage Protocol/SOP • Develop national templates for Life Threatening Haemorrhage Management Poster (to include clinical, communication and human factor requirements) & Framework Document • National Poster template & Framework Document reviewed and signed off by GDG • National template for Life Threatening Haemorrhage Poster & Framework Document reviewed after a year when first developed and every two years thereafter or when any significant changes have been highlighted • National Poster published on HSELand • Include local hospital specific details in the National Life Threatening Haemorrhage Management Poster (e.g. method of communication, location of blood products, turnaround times)	• GDG with support from RCSI • GDG • Perioperative Surgical Lead supported Clinical Lead for Transfusion/ NTAG with appropriate stakeholder engagement • Clinical Lead for Transfusion/ NTAG • Lead Haematologist for Transfusion	✓ ✓ ◯ ◯ ◯	◯ ◯ ✓ ✓ ✓	◯ ◯ ◯ ◯ ◯	*Outcomes:* • National template for Life Threatening Haemorrhage Management Poster available • Life Threatening Haemorrhage Framework Document available • Life Threatening Haemorrhage Poster on display in all hospital operating theatres • Life Threatening Haemorrhage Protocol/ SOP available in all hospitals • Induction training and on-going training including content related to Life Threatening Haemorrhage

Guideline Recommendation number	Implementation barriers / enablers	Action / intervention / task to implement recommendation	Lead responsibility for delivery of action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
		• Review local specific information captured in the poster on a periodic basis to ensure correct details are captured	• Lead Haematologist for Transfusion/ HTC	◯	✓	◯	*Verification:* • National Poster & Life Threatening Haemorrhage Protocol/ SOP templates reviewed and signed off by this GDG • Annual audit to verify that Life Threatening Haemorrhage Posters are prominently displayed in theatres and Life Threatening Haemorrhage Protocol/ SOP is available • Records available of drills completed and attendance • HTC review of drill records – attendance, multi-disciplinary participation, close out of any noted gaps

Guideline Recommendation number	Implementation barriers / enablers	Action / intervention / task to implement recommendation	Lead responsibility for delivery of action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
Recommendation 4 The pre-operative assessment of the patient should identify specific issues for individual patients which need to be addressed to reduce the risk of life threatening haemorrhage. In addition, prior to commencement of the operation the multidisciplinary team should identify specific parts of the operation where life threatening haemorrhage could occur. This particularly applies when any operative intervention in the chest, abdomen or pelvis occurs. **Overall Lead: Perioperative Director**	Enabler: Timely Pre-operative assessment Enabler: Perioperative briefing as per WHO Safe Surgery recommendations	• All hospitals should have arrangements in place for timely pre-operative assessments of elective surgical patients to enable identification and pre-operative management of risk relating to life threatening haemorrhage • Perioperative briefing to take place with members of the theatre team - the timing of the briefing may vary from theatre to theatre. • As part of the perioperative briefing any team member should be empowered to highlight their concerns with regards to the possibility of life threatening haemorrhage. • Amend existing Safe Surgery checklist to include question on the likelihood of Unanticipated Life Threatening Haemorrhage • Theatre team to make efforts to find an appropriate time for a perioperative briefing. Perioperative Director to assist with seeking agreement on an appropriate time.	• Perioperative Director (for overall Policy responsibility) & Theatre Manager (at individual theatre level) • Theatre team members • National Safe Site Surgery Policy Review Group • Perioperative Director	◯ ◯ ✓ ✓	✓ ✓ ◯ ◯	◯ ◯ ◯ ◯	*Outcomes:* • Perioperative briefing takes place • Safe Surgery checklist capturing risk of Unanticipated Life Threatening Haemorrhage *Verification:* • If a risk of life threatening haemorrhage is identified, this should be documented in the patient chart & safe surgery checklist.

Guideline Recommendation number	Implementation barriers / enablers	Action / intervention / task to implement recommendation	Lead responsibility for delivery of action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
Recommendation 5 When any open or laparoscopic/operative intervention in the chest, abdomen or pelvis is to take place or where there is potential to inadvertently enter one of these cavities during surgery - the following criteria will be confirmed in advance of the procedure to support adequate preparation in the event of an unexpected intraoperative life threatening haemorrhage: (confirmations as outlined in section 1.1) **Overall Lead: Perioperative Director**	Enabler: Good Hospital Governance structures to support and fund this recommendation	• All hospitals should have an efficient system in place for patients at risk of unexpected intraoperative life threatening haemorrhage that fulfils all criteria in this recommendation. • Each hospital to establish mechanism to ensure all criteria of this recommendation have been fulfilled (examples could include Hospital Safety Committee or Risk Committee monitoring compliance)	• Perioperative Director or Theatre Manager • Perioperative Director	✓ ✓	◯ ◯	◯ ◯	*Outcomes:* • System in place fulfilling all criteria of this recommendation *Verification:* • Hospital Safety Committee Review
	Barrier: Cost of testing, additional equipment and ensuring availability of emergency Group O blood	• Funding made available to cover testing, additional equipment and ensuring availability of emergency Group O blood should additional funding be required.	• Hospital Management (at Group and local level)	✓	◯	◯	

Guideline Recommendation number	Implementation barriers / enablers	Action / intervention / task to implement recommendation	Lead responsibility for delivery of action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
Recommendation 6 To ensure patient safety appropriate supervision and clinical support should be provided to surgery, gynaecology and anaesthesiology trainees in line with their experience and stage of training. **Overall Lead: Perioperative Director**	Enabler: Culture of education and supervision in the theatre	• Appropriate back-up and support available to trainees 24/7 • Contact details of supervising personnel confirmed in advance of procedure • Organisation and scheduling of operating lists should be cognisant of the need for training opportunities such that junior trainees receive appropriate training and supervision	• Supervising Consultant Surgeon • Consultant Surgeon, Consultant Anaes-thesiologist and Head Nurse. • Surgical Team in consultation with Perioperative Directorate	✓	◯	◯	*Outcomes:* • Improvement in life threatening haemorrhage morbidity and mortality stats • Trainee competent in performing procedure *Verification:* • Site assessment for training by SAC (Specialist Advisory Committee of Royal Colleges) • Log book assessment – training records.
	Enabler: Support from Postgraduate Colleges is strong	• Postgraduate Colleges recognising their high performing Trainers	• RCSI, CAI, RCPI Training Units	✓	◯	◯	
	Enabler: Specialist Advisory Committee of Royal Colleges	• Continued ongoing assessment of the training units by the Specialist Advisory Committees of Royal Colleges (SAC)	• Supervising Consultants assigned from RCSI, CAI, RCPI Training Units	✓	◯	◯	
	Barrier: Over emphasis on service provision versus education on a background of limited resources	• If scheduled surgery is cancelled - HSE and individual hospitals to provide support for training such as access to simulation facilities.	• HSE CCO • Hospital Management Teams	◯	✓	◯	

Guideline Recommendation number	Implementation barriers / enablers	Action / intervention / task to implement recommendation	Lead responsibility for delivery of action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
Recommendation 7 All trainee surgeons and gynaecologists undertaking laparoscopic procedures during the course of their training must complete laparoscopy skills training and simulation drills - these include recognition and appropriate response to a life threatening haemorrhage event **Overall Lead: Perioperative Director**	Enabler: RCSI, RCPI, CAI high fidelity simulation facilities	• Appropriate financial support to organise and execute simulation training for gynaecological trainees (facilities and dedicated personnel) – gynaecologists, anaesthesiologists, technicians. • Funding should be in place to ensure all gynaecology trainees have access to simulation sites – simulation on life threatening haemorrhage • Confirm that one session of training is devoted to life threatening haemorrhage in curriculum	• RCPI, RCSI & CAI- Directors of Training at national and local level	◯	✓	◯	*Outcomes:* • Possibility of life threatening haemorrhage event and management highlighted to trainees *Verification* • Curriculum showing simulation content • Certification of competence
	Enabler: Local hospital facilities	• Hospitals should have local educational facilities available to train trainees (an empty room or a theatre can make this work)	• Supervising Consultant, Local Training Coordinator	✓	◯	◯	*Outcomes:* • Improved local training on management of life threatening haemorrhage events *Verification:* • Audit of training events
	Barrier: Lack of funding	• Review funding approach for delivery of training for high fidelity simulation training • Medical Philanthropy to be considered	• RCSI, RCPI, CAI training units • R&D at hospital (will be linked to academic partners)	✓ ◯	◯ ✓	◯ ◯	*Outcomes:* • Colleges receive adequate funding to ensure all trainees receive simulation training *Verification* • Spend on simulation training for life threatening haemorrhage reviewed by training bodies

Guideline Recommendation number	Implementation barriers / enablers	Action / intervention / task to implement recommendation	Lead responsibility for delivery of action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
Recommendation 8 All staff working in theatre and all Medical Scientists involved in a life threatening haemorrhage (including those providing out of hours cover) should participate in regular multi-disciplinary drills in the recognition and management of major blood loss. Participants should know when to activate/ trigger the major haemorrhage protocol and take prompt and appropriate action. Those participating in the multi-disciplinary drills should complete the eLearning training content on life threatening haemorrhage when it is available. **Overall Lead: Perioperative Director**	Enabler: Local Hospital Management Teams and Lab Management involvement	• Regular multidisciplinary drills should take place for entire theatre teams. All hospitals should nominate a person who ensures that these drills take place. • Sign-off on policy/commitment to undertake periodic drills across the relevant clinical/ service areas to include intraoperative life threatening haemorrhage. • Ensure schedule of drills is in place and communicate with surgical, anaesthesiology, theatre nursing and laboratory	• This person might be - (Chairperson of Theatre Users Group / Perioperative Director, Lead for Safe Surgery Group) • Hospital Transfusion Committee • Perioperative Director in close discussion with Lead Transfusion Haematologist / Hospital Theatre Committee	◯	✓	◯	*Outcomes:* • Regular drills taking place *Verification:* • Drill/training records
	Enabler: Education culture existing within hospitals	• Hospitals to determine approach required for multidisciplinary drills. A skilled person is required to design a drill to ensure local hospital specific practices are captured. Roles and responsibilities of all teams to be defined (Theatre team, laboratory, porter, switch etc.) • Develop an eLearning training module or video on Crisis Event Management (i.e. acute life threatening haemorrhage) • Support implementation by small group teaching/lectures and raising awareness	• Perioperative Director supported by Lead Haematologist / HTC • HSE Land Developers (needs to be available to all healthcare staff)	✓ ◯	◯ ✓	◯ ◯	*Outcomes:* • Drill approach defined • ELearning module or video available for the management of life threatening haemorrhage. *Verification:* • HTC or Quality and Safety Committee monitoring attendance. 1/4ly reports to HTC outlining participation at drills

Guideline Recommendation number	Implementation barriers / enablers	Action / intervention / task to implement recommendation	Lead responsibility for delivery of action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
Recommendation 9 Following the trigger of the major haemorrhage protocol there must be a clear mechanism to contact all relevant team members and a designated emergency coordinator should then coordinate further management. **Overall Lead: Perioperative Director**	Enabler: Life Threatneing Haemorrhage Protocol defined and available	• All theatres should have a designated emergency coordinator who can implement the Life Threatening Protocol when required • Communication techniques such as 'Closed Loop Communication' should be used by theatre staff to confirm instructions are understood and confirmed • Request immediate assistance when Life Threatening Haemorrhage Protocol is triggered - scribe, runners, senior assistance etc.	• Perioperative Directorate/ Hospital Management • Theatre Management • Emergency Coordinator	✓ ✓ ✓	◯ ◯ ◯	◯ ◯ ◯	*Outcomes:* • When emergency takes place, relevant team members contacted *Verification:* • Patient record providing details of all events pertaining to the life threatening haemorrhage event.

Guideline Recommendation number	Implementation barriers / enablers	Action / intervention / task to implement recommendation	Lead responsibility for delivery of action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
Recommendation 10 In the event of a major vascular injury the designated Emergency Coordinator in association with the surgeon and anaesthesiologist should request extra assistance as appropriate to the procedure and if promptly available locally (senior surgeon, vascular surgeon, interventional radiology, etc.) and request this assistance ASAP. Once a Red Alert (activation of the Life Threatening Haemorrhage Protocol) has been called, progression to laparotomy should be considered. Whilst waiting for senior assistance to arrive – methods such as packing to reduce the ongoing haemorrhage and pressure/compression or potentially exploring balloon tamponade/ covered stenting of the bleeding vessel should be applied as a damage limiting approach. This might allow time for further resuscitation of the patient. **Overall Lead: Surgeon and/or anaesthesiologist**	Enabler: Theatre team structure	• Trigger and follow the Life Threatening Haemorrhage Protocol - (the surgeon and anaesthesiologist have the ultimate responsibility to trigger the life threatening haemorrhage protocol)	• Surgeon and/ or anaesth-esiologist	✓	◯	◯	*Outcomes:* • Senior assistance requested in all cases when life threatening haemorrhage protocol has been activated *Verification:* • Patient record providing details of activation of life threatening haemorrhage and any additional assistance which attended the event.
		• Request required assistance in all cases when life threatening haemorrhage protocol has been activated	• Emergency Coordinator	✓	◯	◯	
		• Record sequence of events in the operative note within the patient record	• Surgeon	✓	◯	◯	
		• When no additional assistance is available – determine what measures can be implemented to stabilise the patient and transfer the patient safely. Agreements should be in place with local hospitals for assistance and transfer	• Hospital Group Management	✓	◯	◯	

Guideline Recommendation number	Implementation barriers / enablers	Action / intervention / task to implement recommendation	Lead responsibility for delivery of action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
Recommendation 11 Serial haemostatic tests, including FBC (Hb, platelet count), PT, APTT and fibrinogen or Near Patient Testing (NPT), from before and after resuscitation should be taken every 30–60 minutes depending on the severity of the haemorrhage. The results of these tests will guide and ensure the appropriate use of blood components. Calcium must be monitored and replaced as appropriate. **Overall Lead: Clinical Theatre Staff supported by Haematologist & Perioperative Director**	Enabler: Availability of TAT of haemostatic tests in the Massive Haemorrhage Protocol/SOP	• Include hospital specific TAT of haemostatic tests in the Life Threatening Haemorrhage Protocol/SOP • Approve content of Life Threatening Haemorrhage Protocol/SOP	• Lead Transfusion Haematologist • Hospital Transfusion Committee	◯	✓	◯	*Outcomes:* • Tests, TAT and any special sample handling arrangements (in hours and out of hours) for haemostatic tests captured in MHP/SOP • Policy document available capturing policy for undertaking periodic drills • Timely, accurate and complete communication between laboratory and theatre. *Verification:* • HTC will review schedule of drills to ensure they are taking place. • HTC review of events (case review) should include key aspects of sample management including acceptance, delivery to laboratory, testing, TAT and communication between laboratory and theatre.
	Enabler: Inclusion of this recommendation in local drill			◯	✓	◯	
	Enabler: Efficiency of Hospital in TAT of testing.	• Local system in place to identify samples as being part of life threatening haemorrhage protocol when they arrive in laboratory (proper labelling in place or a special transport bag). • Efficient delivery of samples to laboratory	• Laboratory Management • Hospital Management	✓	◯	◯	
	Enabler: Early communication to laboratory as to triggering of acute life threatening haemorrhage protocol	• Activate the life threatening haemorrhage protocol which includes communication with laboratory	• Communication Lead	✓	◯	◯	
	Enabler: Timely communication of NPT results to laboratory staff	• Communication Lead has responsibility for continued bi-directional communication with laboratory	• Communication Lead	✓	◯	◯	

Guideline Recommendation number	Implementation barriers / enablers	Action / intervention / task to implement recommendation	Lead responsibility for delivery of action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
		• Theatre staff must be trained and competent in NPT.	• Designated trainers from NPT Steering Groups / Committees	✓	◯	◯	

Guideline Recommendation number	Implementation barriers / enablers	Action / intervention / task to implement recommendation	Lead responsibility for delivery of action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
Recommendation 12 Ensure access to sufficient and appropriate blood components and products in a timely manner. Staff should know where to access emergency Group O red cell components and the timeline to availability (refer to the National Life Threatening Haemorrhage Poster). Hospitals must have systems in place that reliably inform the laboratory on use of emergency Group O red cell components so as to assure immediate replacement. Blood component support as per section 1.1 recommendation 12) **Overall Lead: Lead Transfusion Haematologist**	Enabler: Availability of poster outlining requirements.	• Poster available in theatre identifying: a) access and timelines to availability of blood components b) access and timelines to availability of emergency Group O red cell components c) blood component support requirements	• Lead Haematologist for Transfusion working with each of the clinical divisions	◯	✓	◯	*Outcomes:* • Hospital specific information on location and timeline to availability of blood components captured in theatre poster • Curriculum in Postgraduate Bodies for prescribing blood components to include content on the appropriate use of blood components. *Verification:* • Curriculum review outlining blood component prescribing.
		• Ensure blood components are available	• Chief/Senior Medical Scientist with responsibility for blood transfusion	◯	✓	◯	
		• Chief/Senior Medical Scientist to include local information on Poster	• Chief/Senior Medical Scientist				
	Enabler: Case review and debrief	• Recommended training content for all theatre staff • All clinical staff prescribing blood must be educated, trained and competent in the appropriate use of blood components – this needs to be included in the relevant undergraduate and postgraduate curriculum	• Postgraduate bodies for all clinical staff prescribing blood components (including RCSI, RCPI, PHECC, relevant postgraduate nursing courses)	◯	✓	◯	

Guideline Recommendation number	Implementation barriers / enablers	Action / intervention / task to implement recommendation	Lead responsibility for delivery of action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
Recommendation 13 Early mechanical thromboprophylaxis with intermittent pneumatic compression (IPC) should be applied while the patient is immobile and has a bleeding risk. This should be combined with pharmacological and IPC thromboprophylaxis within 24 h after bleeding has been controlled and until the patient is mobile. **Overall Lead: Surgeon/ Anaesthesiologist in discussion with Clinical Haematologist**	Enabler: Current practice in many cases	• Pharmacological thromboprophylaxis to be prescribed by Surgeon/ Anaesthesiologist before handover to ICU • Pharmacological thromboprophylaxis to commence within 24 hours of bleeding being controlled.	• Surgeon/ Anaes-thesiologist in discussion with Clinical Haematologist • ICU Nursing	✓	◯	◯	*Outcomes:* • Pharmacological thromboprophylaxis prescribed • IPC in place • No thrombosis detected *Verification:* • Pharmacological thromboprophylaxis prescription captured in patient Drug Record
		• Ensure intermittent pneumatic compression (IPC) device in place	• Theatre Nurse	✓	◯	◯	

Guideline Recommendation number	Implementation barriers / enablers	Action / intervention / task to implement recommendation	Lead responsibility for delivery of action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
Recommendation 14 Refer to Section 1.1 for recommendation 14 details. **Overall Lead:** **a) Debrief: Surgeon and/or Anaesthesiologist** **b) Case Review: Perioperative Director with assistance from Lead Haematologist for transfusion** **c) HTC Review – Chair of HTC** **d) OTC Review**	Enabler: Timely and effective communication	<u>De-brief</u> • A debrief with the theatre team will take place where possible soon after the event - (this is to support all members of the team, to discuss the event and establishing the sequence of events) • A meeting should take place with family members outlining the events that happened and explain why it happened – family should be assured of open disclosure of events. • Follow up meetings may also be required	• Surgeon and/ or Anaes-thesiologist • Surgeon and/ or Anaes-thesiologist (a Hospital Liaison Officer may be appointed) • A Hospital Liaison Officer may be appointed to facilitate this meeting	✓	◯	◯	*Outcomes:* • Debrief takes place and recorded in notes • Meetings with family members take place *Verification:* • Patient Record should state that debrief and meeting with family members took place.
		<u>Case Review</u> • Appendix 6.3 of guideline outlines data to be captured as part of the Case Review. • HTC to adopt the national Framework for 'Acute Life Threatening Haemorrhage Case Review' (Appendix 6.3)	• GDG • Chair of HTC	◯	✓	◯	*Outcomes:* • National Framework reviewed and adopted as national policy • National Framework adopted by Hospitals

Guideline Recommendation number	Implementation barriers / enablers	Action / intervention / task to implement recommendation	Lead responsibility for delivery of action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
		• Perioperative Director to establish local process to implement the national framework for case review and ensure case review is undertaken by the relevant surgical staff assisted by the Lead Haematologist for Transfusion • Case review will become the data input for any future proposed National Clinical Audit Programme	• Perioperative Director with assistance from Lead Haematologist for transfusion • Surgical Clinical Programme				*Verification:* • National Framework available on HSE repository - Dr Stevens Library
		<u>HTC Review</u> • HTC to undertake the annual review of acute life threatening haemorrhage events	• Chair of HTC	◯	✓	◯	*Outcomes:* • Annual review of acute life threatening haemorrhage events undertaken by HTC
		<u>Overarching Transfusion Committee (OTC)</u> • Review of acute life threatening haemorrhage events (biannually) to be part of agenda at OTC meetings • Annual National Report produced by Transfusion Clinical Lead Advisor – based on data from OTCs • Annual National Report presented to NTAG	• Chair of Overarching Transfusion Committee (OTC)	◯	✓	◯	*Outcomes:* • Life Threatening Haemorrhage events reviewed at OTC meetings

Guideline Recommendation number	Implementation barriers / enablers	Action / intervention / task to implement recommendation	Lead responsibility for delivery of action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
Recommendation 15 It is recommended that all medical scientists supporting out of hours transfusion laboratory activity, who do not work routinely in the Transfusion Laboratory should undertake supervised dedicated familiarisation days annually. It is recommended that this familiarisation consist of 10 days during routine hours in the Transfusion Laboratory to ensure the appropriate skill set. **Overall Lead: Laboratory Management**	Enabler: Adequate funding available	• Hospital Management teams to support this necessary change – resource and fund accordingly	• Hospital Management Teams	◯	✓	◯	*Outcomes:* • Laboratory management will have developed roster to include 10 familiarisation days for non-transfusion laboratory staff participating in transfusion on call roster • 10 Familiarisation Days implemented in all hospital laboratories for non-transfusion laboratory staff participating in transfusion on call roster • Academy of Clinical Science and Laboratory Medicine will communicate with their members on the implementation of the guideline • Regular Updates provided in Quarterly Converse • Academy highlight resourcing concerns with appropriate bodies
	Barrier: Resource unavailability	• Laboratory management to identify resource requirements, roster staff for dedicated familiarisation days and undertake an annual review • Academy to consider additional laboratory scientist requirement in work force planning	• Laboratory management • ACSLM	◯	✓	◯	
	Enabler: Adoption of the guideline	• Hospital Transfusion Committee adopt this guideline as hospital transfusion policy	• Hospital Transfusion Committee	◯	✓	◯	
	Enabler: Haematology, Transfusion and Transplantation Advisory Bodies	• Discuss guideline at Haematology, Transfusion and Transplantation Advisory Bodies prior to guideline publication • Update provided in Quarterly Converse as to progress with implementation	• Academy of Clinical Science and laboratory Medicine (ASLM) • ACSLM NTAG Scientific Committee	◯	✓	◯	
	Enabler: National Transfusion Advisory Group (NTAG)	• NTAG members to raise awareness of Intraoperative life threatening haemorrhage and to support the guideline • NTAG Life Threatening Haemorrhage Special Interest Group (SIG) adopt the guideline and seek implementation	• NTAG	◯	✓	◯	

Guideline Recommendation number	Implementation barriers / enablers	Action / intervention / task to implement recommendation	Lead responsibility for delivery of action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
	Enabler: Support from DoH who commissioned these guidelines and from the HSE in their implementation	• 10 Familiarisation Days becomes mandatory in all hospital laboratories for non-transfusion laboratory staff participating in transfusion on call roster	• National Clinical Acute Group Lead Office (NCAGL)	◯	✓	◯	*Verification* • Annual report to each HTC capturing compliance level • ACSLM Quarterly Converse content showing updates

Guideline Recommendation number	Implementation barriers / enablers	Action / intervention / task to implement recommendation	Lead responsibility for delivery of action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
Recommendation 16 All hospitals must develop an arrangement so that in the circumstances of a life threatening haemorrhage event, an additional medical scientist can be called in out of hours to support the laboratory practice where necessary. • **Overall Lead: Laboratory Management**	Enabler: Hospital Management to agree a mechanism with laboratory management for emergency call in cover	• All hospitals to establish an agreed process for additional out of hours emergency medical scientist call in cover • List of staff available to cover emergency out of hours • Recompense in place for out of hours emergency call in • Agreed point of contact in place (e.g. Switch, Night Porter or Lab representative) to request emergency call in • Contact numbers of laboratory management held by point of contact	• Laboratory Management & Hospital Management • Laboratory Management • Hospital Management • Laboratory Management • Laboratory Management & Hospital Management	◯	✓	◯	*Outcomes:* • All hospitals have an emergency cover process in place • Sufficient staff available for call in *Verification:* • Laboratory SOPs capturing emergency call in procedure • As part of the case review for out of hours life threatening haemorrhage, the requirement for and the availability of the additional support will be considered (consider the decision making of not calling someone in)
	Enabler: Implementation of Familiarisation Days	• Implementation of actions captured in Recommendation 15	• As captured in Recommendation 15	◯	✓	◯	
	Enabler: Medical Scientists are empowered to make decision on whether additional support is required	• All hospitals to establish an agreed process for additional out of hours emergency medical scientist call in cover	• Laboratory Management & Hospital Management	◯	✓	◯	

Guideline Recommendation number	Implementation barriers / enablers	Action / intervention / task to implement recommendation	Lead responsibility for delivery of action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
Recommendation 17 Hospitals which provide a transfusion service for offsite hospitals should identify as part of the Service Level Agreement(s) the requirement and the timeline for provision of blood components at the offsite hospital. **Overall Lead: Hospital Management**	Enabler: Reciprocal membership and regular attendance at HTC (primary hospital and offsite hospital)	• Hospital Management to consult the business owner (transfusion laboratory) before SLAs are signed off • HTC to review SLAs for offsite hospitals annually • Review existing SLAs with off-site hospitals to identify transfusion service requirements given the healthcare provided at the off-site hospital. Review to include but not limited to: a) Risk Assessment for requirement of Group O availability on-site b) Specify the timeline for availability of blood components for life threatening haemorrhage c) Specify turn-around times for laboratory testing d) Specify contingency arrangements e) Specify patient transfer protocols • SLA to include reciprocal arrangement for communication and planning of changes to service demand or availability of service	• Hospital Management • HTC • Hospital Management supported by Lead Haematologist for Transfusion • Hospital Management at hospital with transfusion laboratory & Hospital Management at off site hospital	✓	◯	◯	*Outcomes:* • SLA for offsite hospitals to include specific requirements in relation to transfusion support • Risk assessment completed *Verification:* • SLA for off-site hospitals reviewed annually by HTC

Appendix 6: Supporting tools

The Guideline includes three supporting tools:

a) **Framework Document** for the management of Unexpected Intraoperative Life Threatening Haemorrhage

b) **National Poster** for Unexpected Intraoperative Life Threatening Haemorrhage

c) **Data Capture for Life Threatening Haemorrhage events**

Framework Document for the management of Unexpected Intraoperative Life Threatening Haemorrhage

6.1 Framework Document:

The purpose of this Framework Document is to assist hospitals prepare local policy and procedures/ protocol for the management of Unexpected Intraoperative Life Threatening Haemorrhage.

1.0 Introduction, Background and Development

This Framework document was developed as a supporting tool by the GDG tasked to develop the NCEC approved guideline for the management of unexpected intra-operative acute life threatening haemorrhage (ALTH).

The UK National Comparative Audit of Blood Transfusion undertook an audit of the management of adult major haemorrhage in October 2018. This was across the range of UK hospitals/trusts (94% participation) and included two hospitals in the Republic of Ireland. 23% of the 826 major haemorrhage events occurred in theatre, 78% were unexpected and 54% occurred out of hours. 16% of patients were anticoagulated.[43]

The GDG undertook a survey of 'massive/major haemorrhage in Ireland' for the calendar year 2018 and invited the 45 hospitals with transfusion laboratories and the two IBTS transfusion laboratories, to share their protocol/poster/procedure. Data was incomplete as not all hospitals returned a full data set and hospitals were invited to share more comprehensive data for up to 20 activations at the primary site and up to 10 at off-site hospitals supported by the transfusion laboratory. The data capture showed variation in trigger for activation/definition of massive/ major haemorrhage. From the 22 hospitals with activation data returned, <20% occurred in theatre and the overall mortality rate at >10% was similar for intra-operative and total cases. A significant number of incidents occurred out of hours- the majority of events in stand-alone maternity hospitals, near to half of the events in level 3 hospitals and a quarter at level 4 hospitals.

Cell salvage was in use in a third of hospitals with transfusion laboratories however its use was particularly targeted at elective surgical activity and a single surgical specialty in almost all cases. In the very small number of hospitals where there is some application for massive/major haemorrhage, limited hours resourcing was noted. There appears little awareness/review of cell salvage activity at hospital transfusion committees.

A significant majority of hospitals have laboratory medical scientists who do not routinely work in the transfusion (or haematology) laboratory providing on-call out of hours for the transfusion laboratory and the majority work alone with informal arrangements for calling in support where required.

Turn-around times for laboratory tests supporting major/massive haemorrhage varied widely and lack of laboratory staff access to NPT results was raised as an issue.

Twenty six hospital posters were submitted to the GDG, which showed a wide variation in content and style of documentation supporting massive/major haemorrhage from one hospital to another. This reflects significant variation in approach to blood component support. As we can anticipate, for clinical staff who rotate between hospitals and are involved in the management of life threatening haemorrhage, such variation is a potential source of reduced effectiveness for the prompt management required to minimise morbidity and mortality.

In the circumstances it was agreed to set out a framework document and to develop a national poster which would assist a consistent approach across hospitals in Ireland to the management of unexpected ALTH. This guideline also recommends ALTH incident review, hospital level audit with a defined data set and KPI monitoring which may identify further enhancements of life threatening haemorrhage management. Hospitals should engage in any national audit that is undertaken. The GDG recognises the work of NTAG developing a national guideline for acute life threatening haemorrhage in other clinical scenarios, chaired by Mr Morgan McMonagle and the development of national guidelines for post partum haemorrhage through the HSE National Women and Infants' Health Programme and the Institute of Obstetrics and Gynaecology, chaired by Dr Bridgette Byrne. With cross representation across all groups it is envisioned that a consistent national approach can be achieved.

2.0 Scope and Purpose

This Framework was developed by the GDG to support a consistent approach to management of life threatening haemorrhage at hospital level in compliance with this NCEC guideline.

This document refers to the organisational, clinical and laboratory approach at hospital level in the management of acute life threatening haemorrhage in the intra-operative setting. The framework identifies the structures and responsibilities to assist each hospital develop and maintain an acute life threatening haemorrhage policy, associated protocols/procedures and review processes for clinical improvement. The standardised approach is captured in the National Poster (Appendix 6.2) which requires local hospital information to be captured in specified sections.

It is a requirement for each hospital to have a documented policy and associated procedures/protocols in place which should address the management of acute life threatening haemorrhage and that policy should address the elements identified in this Framework, customised to their site. This should be integrated with the activity of the HTC.

While this framework was developed for the intra-operative setting, it can be applied to unexpected life threatening haemorrhage in other clinical scenarios including obstetrics, trauma, paediatrics and gastro intestinal haemorrhage. This will support a consistent approach, practice enhancement and familiarity for staff rotating between hospitals.

3.0 Roles and Responsibilities

Hospital responsibilities are met through the responsible parties working with hospital management through the HTC and other governance systems in place to develop, review and seek improvement in organisational systems, documentation, training (including drills), communication methods, data capture and review processes (including audit) so as to enhance practice. Note – resources vary from hospital to hospital. A multi-disciplinary approach is required and the key roles and responsibilities set out in general terms below should be assigned to relevant staff members in individual hospitals. These include:

3.1 Hospital management

- Hospital management is responsible to support safe surgical practice and risk assess support for off-site facilities.
- Hospital management is responsible to resource and support appropriate policy development, training, documentation, communication and review processes in the management of acute life threatening haemorrhage and support the HTC, hospital transfusion laboratory and hospital personnel in their roles in this regard to comply with the recommendations set out in this guideline.

3.2 Clinical director

- The Clinical director is responsible to participate in the development of hospital policies, procedures, training and documentation supporting ALTH.

3.3 Peri-operative director

- The Peri-operative director is responsible to participate in the development of hospital policies, procedures, training and documentation supporting ALTH.
- They are responsible to ensure that pre-operative systems are in place to optimise patients' haemoglobin, identify and manage bleeding risks, support patient blood management (PBM) initiatives and keep the lead haematologist for transfusion advised of perioperative developments.
- They are responsible to ensure compliance with recommendations of this guideline appropriate to their responsibilities/ authority.
- They are responsible to undertake review of acute intra operative life threatening haemorrhage events with appropriate engagement of the surgical team, preparing reports with a view to addressing any practice enhancements identified.
- They are responsible to report within the hospital morbidity and mortality and risk management systems as appropriate, and report trends to the hospital transfusion committee

3.4 Director of surgery

- The Director of surgery is responsible to participate in the development of hospital policies, MSBOS, procedures, training, documentation and reviews supporting ALTH.
- They are responsible for blood conserving surgical practice including the use of Tranexamic acid where significant bleeding is anticipated.

3.5 Director of nursing/midwifery

- The Director of nursing/midwifery is responsible to participate in the development of hospital policies, procedures, training, documentation and reviews supporting ALTH.

3.6 Hospital support staff/ portering staff/HCA.

- All hospital staff supporting acute life threatening haemorrhage must be trained in the systems agreed and engage in periodic drills, as specified in hospital policies.

3.7 Clinical Service Users

- All clinical staff who may be responsible for acute life threatening haemorrhage management must be familiar with the hospital documentation, policy, procedures and the NCEC Guidelines.
- They must participate in case review.
- Any clinical user of near patient testing (NPT) must work within the national guidelines for NPT.

3.8 Hospital Transfusion Committee

- Has senior hospital management support from the CEO/Hospital manager and Clinical director and active engagement of clinical users of transfusion services.
- The HTC is responsible for the transfusion policies and strategic direction of transfusion service delivery at the hospital, including patient blood management, haemovigilance, audit, staff training and the quality system. The HTC is responsible to authorise hospital ALTH transfusion policies, training, review and audit schedules and review reports and trends relating to ALTH in the hospital.
- Authorises the hospital policy for ALTH on site and supports hospital management in the consideration of off-site hospitals for which the haematologist/hospital transfusion laboratory provides transfusion support.
- Oversees organisational arrangements including communication within the hospital
- Agrees arrangements in relation to training and drills and monitors associated KPIs.
- Reviews all activations of the plan as reported from the perioperative director in consultation with the lead haematologist for transfusion and hospital transfusion team, with a particular focus on practice enhancement.
- Monitors ALTH KPIs and reviews ALTH audit reports.
- Provides feedback to the hospital staff.
- Is informed of technologies in use supporting ALTH including cell salvage and has liaison with the hospital NPT committee.
- Contributes to the relevant OTC
- Membership of the HTC should include:
    - Hospital CEO/Manager or nominee
    - Clinical director
    - Consultant haematologist with responsibility for Blood Transfusion
    - Director of surgery
    - Perioperative director
    - Director of anaesthesiology
    - Director of nursing/midwifery
    - Chief hospital pharmacist
    - Quality and Risk Management
    - Patient Safety Office
    - Chief/ Senior medical scientist hospital transfusion laboratory
    - Operations manager
    - Haemovigilance officer
    - Others as appropriate

3.9 Hospital Transfusion Team (HTT)

- The HTT is responsible to participate in the development of hospital policies, procedures, training and documentation supporting ALTH and prepare and present an annual review for the HTC
- The HTT is responsible, together with relevant clinical directors to complete an annual review of acute life threatening haemorrhage events to present to the HTC and overarching transfusion committee.
- The HTT structure/membership varies across hospitals and should be identified for each surgical site. Membership may include:
  - Consultant haematologist lead for blood transfusion/haemovigilance.
  - Chief /senior medical scientist hospital (c/sms) transfusion laboratory
  - Haemovigilance officer
  - (Chair of the Hospital Transfusion Committee - only in specific circumstances)

3.9.1 Lead haematologist for transfusion:

- The lead haematologist for transfusion is responsible to ensure relevant hospital haematology/ transfusion policies are current, optimal practices are established to support these policies (in line with relevant national and BSH transfusion guidelines https://b-s-h.org.uk/guidelines/?search=transfusion[49,50] and that training and audit programmes are in place).
- They will support hospital management organisational arrangements to support effective communication during management of ALTH. They will support hospital management risk assessment for the transfusion support of any off-site surgical activity.
- They will be advised of supporting technology in use in the hospital e.g. cell salvage. NPT.
- They will agree with the C/SMS and IBTS, stock holding levels by component on-site (and off-site facilities supported by the hospital transfusion laboratory) and arrangements for emergency distribution.
- They will agree with the C/SMS and relevant clinical users any out of laboratory blood component storage facilities/ arrangements in the hospital and any off-site hospitals/facilities.
- They are responsible with the C/SMS for sample acceptance and emergency concessionary release policies.
- They will authorise the local hospital data entry on the national acute life threatening haemorrhage poster.
- They will support the multidisciplinary event review with communication of findings to appropriate parties.
- They have a central role in the HTC consideration of ALTH, hospital participation in benchmarking and any national audit.
- The duty haematologist/haematology team should be consulted when the ALTH Massive/ Major Haemorrhage plan has been activated where they can assist management of transfusion support and as soon as possible where patient is anticoagulated, on anti-platelet medication, has irregular antibodies identified or concessionary release of blood components from the laboratory is required.

3.9.2 Chief/Senior Medical Scientist (C/SMS)

- The Chief/ senior medical scientist is in close communication with the Lead haematologist for blood transfusion, hospital clinical staff and the hospital IBTS distribution centre. They should empower Medical Scientists in their central role in the management of acute life threatening haemorrhage.
- They are responsible for participating in the development of hospital policies, procedures, training and documentation supporting life threatening haemorrhage. They will work with hospital management to ensure communication pathways are optimised in the support of life threatening haemorrhage.
- They are responsible for ensuring laboratory arrangements for the management of life threatening haemorrhage, communication and traceability pathways and associated resourcing are in place. This includes adequate number of laboratory staff competent to support life threatening haemorrhage, participation in hospital training and drills, that MS not routinely working in the transfusion laboratory have scheduled familiarisation days in the transfusion laboratory, that an escalation plan is in place to seek additional resourcing out of hours, as appropriate.
- They are responsible with the Lead haematologist for transfusion for sample acceptance policies.
- They will agree with the Lead haematologist for transfusion and IBTS, stock holding levels by component on-site (and off site facilities supported by the hospital transfusion laboratory as informed by risk assessment) and arrangements for emergency distribution, as appropriate for the hospital's health care delivery. This will include the appropriateness of having thawed plasma available on site.
- They will agree with the Lead haematologist for transfusion any component storage outside the laboratory (e.g. accessibility to theatre). They will ensure that systems are in place for the laboratory to be aware of use of emergency Group O blood in any such storage facility, so as to replace this in a timely manner.
- They are responsible for systems to minimise component wastage and ensure full traceability.
- They are responsible for engaging in surgical blood order schedule review, life threatening haemorrhage data capture and event review and local and national audit.

3.9.3 Haemovigilance Officer(s) (HVO)

- The HVOs are responsible to participate in the development of hospital policies, procedures, training and documentation supporting ALTH.
- HVOs have a key role in delivering training for management of ALTH, working with the designated trainer in each clinical area and supporting drills.
- While HVOs in some hospitals may support ALTH events if on-site, in particular in relation to traceability, it is noted that a significant number of events occur at times when HVOs are not scheduled on-site.
- They will engage in event review and include ALTH in their annual audit schedule. They will participate in any national audit. They will report on KPI monitoring to the HTC.
- They will report any associated serious adverse events (SAE) and serious adverse reactions (SAR) to the National Haemovigilance Office (NHO).

4.0 Approach to unexpected life threatening haemorrhage

4.1 Acute Life Threatening Haemorrhage (ALTH)

While trauma focused, authors of European guidance believe that emerging evidence supports that the greatest outcome improvement can be achieved through education and the establishment of and adherence to local clinical management algorithms.[12]

4.2 National Poster

The National poster empowers clinicians to activate the life threatening haemorrhage protocol early from clinical judgement, rather than the historical approach of retrospective definitions of blood loss or transfusion support. Clinicians should be aware however that the physiological response to blood loss may be blunted in some patients/circumstances e.g. in the elderly.[51] Blood loss of >40% blood volume is life threatening.[12] ALTH is also associated with a coagulopathy from coagulation factor use, activation of fibrinolysis and haemodilution with resuscitation and shock can induce endotheliopathy.

4.3 Clinical crisis event

ALTH is approached as a clinical crisis event which requires human factor recognition and role assignment. These must facilitate early recognition of major blood loss, clear activation by declaring to the team that 'this is a life threatening haemorrhage/CODE RED', agreeing the ALTH co-ordinator/ Team leader and assigning a communication lead. Appropriate follow-on management is prompted by the national poster which has local hospital information inserted. Event stand down is declared with communication to all relevant parties.

4.4 Every minute counts

Critical delays in the setting of acute life threatening haemorrhage have been reported to haemovigilance systems resulting from poor communication, delayed recognition of concealed bleeding severity, lack of knowledge and failure to follow the correct procedure. Concern is noted at increasing number of reports and associated mortality.[52]

4.5 Training and Drills

Hospital training plans can be supported by medical college and national supporting material. This includes filmed material (video) and inclusion of ALTH in simulation exercises. Hospitals should be aware of technological tools in development.[53] Periodic drills facilitate robust and clearly understood communication channels for contacting all relevant staff and laboratories and accessing emergency group O blood. Training KPIs should be monitored and reported to the HTC.

4.6 Communication - internal and external

- The use of nationally agreed 'CODE RED' shorthand for ALTH as clear and well understood communication is recommended. Clear and unambiguous communication between individual staff, departments and IBTS is essential.
- Each hospital must identify their communication pathway for activation of CODE RED and ensure this is completed and in date on the national poster. This may be through switchboard or bleep system, as agreed locally. Key Personnel must be identified together with the transfusion laboratory for immediate communication. Switchboard availability must be defined. External communication pathways for identified support (e.g. vascular surgery, interventional radiology-specific bleeding site expertise) must be documented.
- The guideline recommends assigning the role of communication lead as early as possible who will be the central communicator with the laboratory and other key hospital resources. The communication co-ordinator should identify themselves and provide their contact number in communication with the laboratory and other parties outside of theatre. The patient location and identity should be provided, and in addition their hospital ID number in initial communication with the laboratory to minimise requirement for follow-up communication.

- Haematology support should be sought early where patient is anticoagulated, has irregular antibodies or where concessionary release of blood components from the laboratory is required.
- It is essential that the laboratory is informed of NPT results. Laboratory communication pathways for medical scientist (MS) support and IBTS support of stock required (especially early communication from laboratory re platelet component support) must be known.
- The communication lead will advise of requirement for ICU bed and communicate stand down to the laboratory and all other relevant parties as soon as possible.

4.7 Surgical setting

The potential for unexpected life threatening haemorrhage should be considered where any open or laparoscopic/operative intervention in the chest, abdomen or pelvis is to take place or where there is potential to inadvertently enter one of these cavities during surgery. Theatre preparation in sourcing required equipment (major general/major vascular kit) and personnel together with continued usage of 'Safe Surgical Practice' will support the protocol in the event of unexpected intraoperative life threatening haemorrhage preparation and adopting 'Safe Surgical practice'

4.8 Approach to damage limitation surgery

The priority in management of the crisis is to identify the source of bleeding and control it. Methods to control the bleeding will include midline laparotomy (where appropriate to surgery undertaken), direct pressure on the bleeding source, packing and the use of clamps. Once bleeding has been controlled the surgical focus will be to repair the damaged vessel with the assistance of other colleagues who have arrived to support. Continued communication will take place between the entire team in managing the crisis.

4.9 Resuscitation

With the **CODE RED** activation, the surgeon and anaesthesiologist will be trying to identify the possible sources of the sudden unexpected bleeding and at the same time resuscitation will be commenced by the anaesthesiology team. This will include establishing large bore peripheral and central venous access as appropriate. This may require the use of ultrasound which should be immediately available. The patient's inspired oxygen may need to be increased to ensure adequate oxygenation. Continuous cardiovascular monitoring will be supplemented with more invasive monitoring such as an arterial line or cardiac output measurement. Fluids and red cell components should be infused through a blood warmer. Pressure bags and where available pressure infusers should be used. Body warming blankets and other warming devices/environmental temperature control should be used to maintain the patient's temperature. A red cell salvage system may be set up and used where it is available. Appropriate blood sampling should also be undertaken by the team early in the resuscitation. Communication between all team members should continue during the resuscitation, with frequent re assessment of the situation. This occurs as the surgical team attempt to control the bleeding. Further medical advice and the need to call for specialised assistance along with communication with the laboratory for updates on blood and blood components supply as well as results of tests will be facilitated by the communication lead.

4.10 Transfusion support

Anticipatory empiric transfusion protocols support tissue oxygenation and aim to prevent/ reverse coagulopathy early by rapid transfusion in advance of results from blood science/ near patient testing (NPT). Further transfusion support should be guided by blood science testing/ NPT. Control of bleeding, prevention of hypothermia, acidosis and hypocalcaemia are critical in prevention and management of coagulopathy.

4.10.1 The National poster - the National poster sets out the algorithm for blood management and must have the location and time to availability of transfusion component and pharmacological support in each hospital identified in the specified space on the poster. There must be clear arrangements for transfusion laboratory support for off-site hospitals captured in the local documentation and included in the National poster at the off-site hospital / facility. This should be set out in the hospital SLA with the off-site facility, informed by risk assessment.

4.10.2 Cell salvage - The availability of cell salvage support in Ireland is, in the main, limited to specific surgical specialties and applied in the elective setting. It appears to be infrequently used in support of ALTH, even when available. The UK national comparative audit identified limited use (in 12% of cases) even where the technology was available, for a variety of reasons.[43] Hospitals should identify if and when cell salvage is available on-site and associated communication pathways are required in section 4.6 above. The Cochrane review (2015) considered use of cell salvage in emergency trauma surgery and in the single small study included in the review, showed no impact on mortality.[7] However there is a reduction in exposure to donor blood and extended use of cell salvage in ALTH could, to some small extent, assist the sustainability of the national blood supply.

4.10.3 Early procurement of blood sample - A correctly labelled blood sample should be taken in advance of transfusion for urgent blood group (and antibody screen). This enables change from use of emergency Group O to patient specific blood group. It is important to avoid error which could require re-sampling and associated delay and put patient at risk of mismatch. Turn-around times (TAT) for results should be identified.

4.10.4 Sample and component collection and transportation -Each hospital should identify a designated person/ role for transfer of samples to the laboratory and collection of blood components/ derivatives/ pharmacological agents from storage location for the clinical site for acute life threatening haemorrhage.

4.10.5 Haematology advice - Haematology advice should be sought early where patient is anti-coagulated, on anti-platelet medication, has irregular antibodies or where concessionary release of blood components from the laboratory is required for any reason- Hospitals to identify communication pathway in 4.6 above.

4.10.6 Tranexamic acid - Good Patient Blood Management (PBM) practice supports administration of tranexamic acid where significant surgical bleeding is anticipated (administered at 10 ml/Kg and then 1mg/Kg/hour -NICE transfusion guidelines).[54] In the setting of acute life threatening haemorrhage, Tranexamic acid where significant bleeding is anticipated will be administered at 10 ml/Kg and then 1mg/Kg/hour (NICE transfusion guidelines).[54] Tranexamic acid should be administered early as a bolus and may be followed by an infusion over 8 hrs. This is extrapolated from RCTs which have shown a reduction in mortality in comparison to placebo in trauma and obstetrics and meta-analysis has shown this benefit limited to 3 hours.[39,55,56]

4.10.7 Blood components - Where blood group is known, the patient's group specific blood components should be provided and systems should be in place to urgently type patients where group is unknown. The efforts to control haemorrhage are paramount and active bleeding will reduce the efficacy of the blood components/derivatives transfused.

a) **Red cell components** - Once **CODE RED** is triggered, clinical staff should access emergency group O red cell components (Rh D negative and Kell negative for females of child bearing potential or the patient specific pre-op blood order if available) from the designated storage location nearest theatre- as identified in the national poster. The National Transfusion Advisory Group (NTAG) will support the change of universal use of emergency O RH D negative blood to emergency Group O through policy development and implementation

planning in parallel with implementation of this guideline in hospitals across the country. Red cell components should be available for emergency use within 10 mins. While Hb measurement may not be accurate or reflect actual blood loss in this clinical setting, a target Hb of 7-9g/dL is recommended to keep tissue oxygenated.

b) Major haemorrhage packs - Clinical staff should request the laboratory to provide major haemorrhage packs to support immediate empiric management of ALTH. These are recommended to contain red cells and plasma at a ratio of 1:1 red cells to plasma. Components will be issued from the laboratory as they become available. While the elective surgical evidence base is limited [57,58] this approach has been taken to provide a standardised approach as much as possible, in this acute life threatening haemorrhage setting, in an effort to assist communication, reduce delays and reduce potential for error. Audit of clinical outcome and component wastage should be undertaken after one year. It is expected that patients will have received immediate transfusion of emergency red blood cells from storage near theatre in advance of the issue of major haemorrhage pack from the laboratory. A ratio of 1:1.5 was not associated with increased risk of transfusion associated pulmonary complications.

c) Plasma - Timely plasma transfusion is required to manage coagulopathy in acute life threatening haemorrhage. Where bleeding is controlled a 12-15ml/kg starting dose should increase coagulation factors by 25% and on-going treatment should aim to keep PT/APTT <1.5 x mean control. Time to availability of plasma must be indicated on the National poster. In most hospitals in Ireland, frozen plasma must be thawed over 20-40 minutes. A small number of hospitals have thawed plasma on-site. This should be considered where there is frequent demand to support life threatening and considering the current post thaw shelf life of 5 days.

At time of guideline development, frozen plasma is available as a 200 ml pooled fractionated solvent detergent product (Octaplas LG) sourced from Austrian donors. Fresh frozen plasma (FPP) is not currently routinely available in Ireland (of note in comparison to single donor FFP F V, V111 and X1 0.76-0.88 iu/ml- show a 10-15% reduction). Protein S and plasmin inhibitor are 40-70% lower and as protein S and alpha 2- antiplasmin are labile to solvent detergent treatment, the final product is controlled to ≥0.4iu/ml)[59]. However there is less variability in range of coag factors than FFP[60] and a small RCT showed evidence of reduced markers of endotheliopathy.[61] However with the recent change in policy to re-instate use of Irish donor plasma, a stakeholder engagement will be undertaken to decide on the most suitable preparation into the future.

d) Platelet component support-While a significant reduction in platelet count is a late feature of major haemorrhage, hypotension/shock are associated with platelet dysfunction.[37,62] Activation of the MHP/CODE RED should prompt arrangements to have platelets available on-site as on-site storage in Irish hospitals is limited to level 4 and a minority of level 3 hospitals. Where the platelet count falls below 100 x 10^9/l clinicians should order one adult therapeutic dose of platelets for transfusion to maintain platelets above 50 x 10^9/l. The concern in relation to platelet transfusion in the case of neonates, ICH and patients on anti-platelet medication is noted. Platelet components in Ireland are leucodepleted, room temperature stored and available as apheresis procured components (70%) or as a pooled component (30%), the latter contains less plasma (circa 100 ml) and platelet additive solution (PAS). Of note pathogen reduction of platelet components in Ireland is under active consideration and would be expected to impact the platelet count in final preparation.

e) Fibrinogen- Fibrinogen levels show early reduction to critical levels in life threatening haemorrhage (<1g/L expected with 1-1.5 BV loss).[38,62,63] A therapeutic dose of 4g, to be repeated as required, may be expected to increase fibrinogen by 1g/L. Fibrinogen is available as a pooled concentrate in Ireland. (Cryoprecipitate is available in very limited circumstances for a single hospital site however it shows a significant inter component variability in fibrinogen levels and hence therapeutic effect).

f) Components in development - Component pathogen reduction is under active consideration in Ireland and may require modification to platelet dose.[64] Cold stored platelets are under trial for enhanced efficacy in the management of acute haemorrhage and as a constituent of whole blood for up to 21 days storage.[65,66]

5.0 Patient Monitoring - clinical cardiac/ metabolic/ blood sciences including NPT

- Sample procurement – valid samples are critical to ensure accurate patient ID, avoid ABO errors and delays associated with sample rejection.
- TAT for each test should be known to clinical staff.
- Coagulation and fibrinogen should be repeated q 30-60 mins
- Hospitals should identify relevant compliant NPT availability - see National Near-Patient Testing (NPT) Consultative group 'Guidelines for safe and effective near-patient testing (NPT)' v 6.2, April 202134 and BSH guideline (2018).[35,67] It is noted that the use of viscoelastic haemostatic assays (VHA) remains controversial-see section re VHA above.
- Metabolic complications should be prevented/actively managed as per National Poster algorithm.

6.0 Stand down – The emergency co-ordinator should identify when protocol is to be stood down. The communication lead should communicate to relevant parties and advise the transfusion laboratory early to minimise wastage of blood components and return unused components to controlled storage as appropriate. Arrangements should be made for completion of Traceability, documentation, and commencing thromboprophylaxis. 100% traceability of blood components is a statutory requirement.[68]

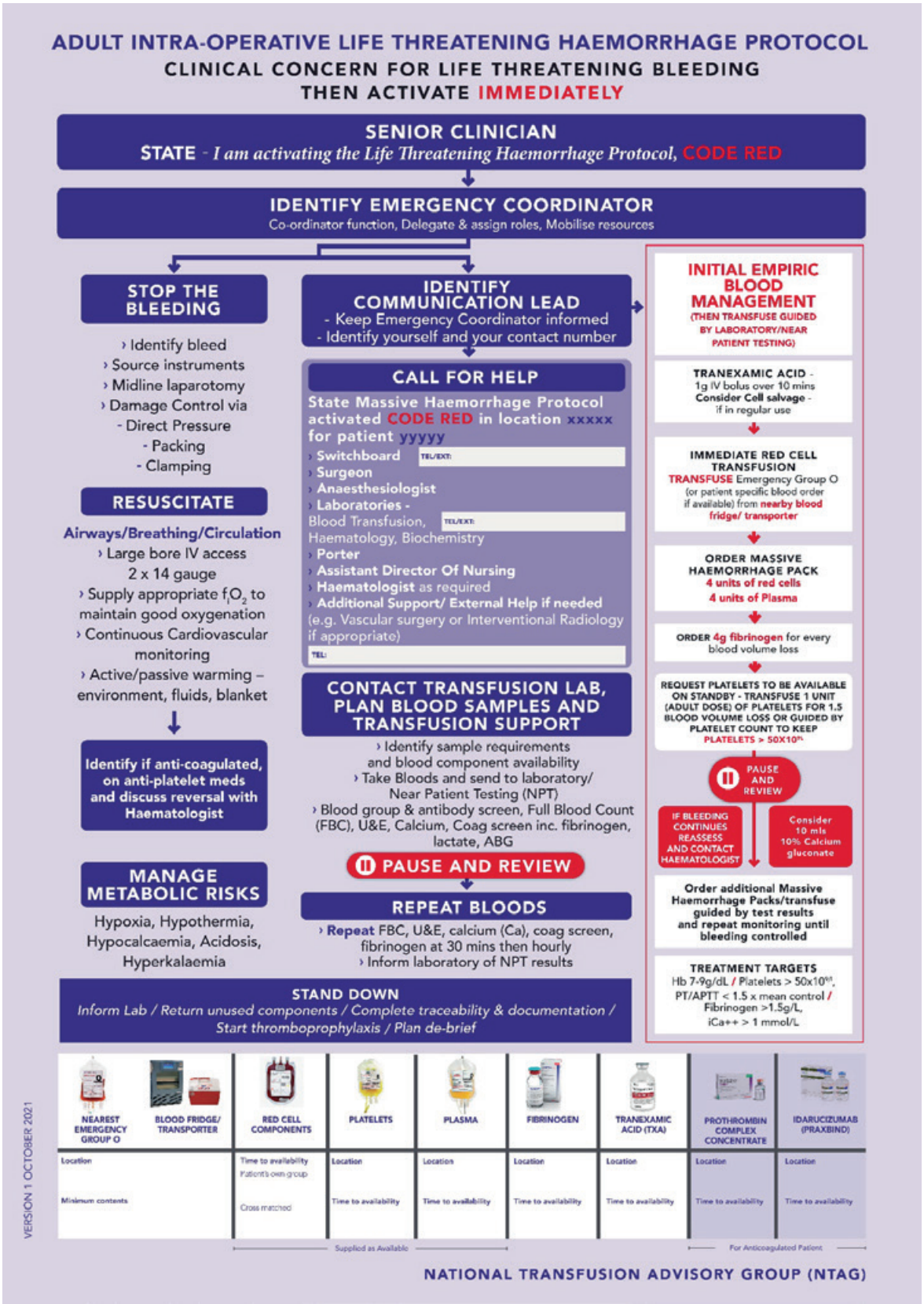
7.0 Arrangements for De-brief - The emergency co-ordinator should consult, consider and communicate arrangements for theatre de-brief in a timely manner. With the availability of virtual communication this may include staff outside of theatre who supported the event.

8.0 ALTH event review, audit and KPI monitoring.

- A theatre de brief should be undertaken as soon as appropriate
- A wider event review should be led by the perioperative director/surgical Lead supported by the Lead haematologist for transfusion with all relevant parties and reported to next HTC including seeking to identify practice enhancements.
- A data set - including structure, process and event outcomes elements, should be captured and reported to the HTC utilising the data set in Appendix 6.3. The hospital representative to the OTC should report on events and trends and practice enhancements.
- Management of acute life threatening haemorrhage should be included in the hospital Audit cycle (see recommended audit criteria Appendix 7).
- ALTH KPIs should be reviewed by the HTC on a periodic basis (as set out in Appendix 7).
- Hospitals should contribute to any national audit on acute life threatening haemorrhage when this is in place.

6.2 - National Poster

This National Poster should be adopted by each hospital, customised with local information and displayed prominently in every operating theatre. A PDF of this Poster will be made available to all hospitals for adaptation and distribution to all relevant sites.



6.3 Data Capture for Case Review of Unexpected Life Threatening Haemorrhage events

Case events are reviewed with the intention of improving practice and outcomes locally in the hospital, the data set out below is intended to assist the case review. Each hospital should record this data and maintain relevant records. It is envisaged that this data will inform the report of the perioperative director to the HTC and contribute in part to the development of a national picture in relation to unexpected intraoperative life threatening haemorrhage through national audit.

NOTE - The National Transfusion Advisory Group (NTAG) proposes to develop a national template which can be used to capture this data in the future.

The data includes Structural, Process and Outcome elements as set out below:

Structural elements of case review

- Hospital Policy for the management of unexpected life threatening haemorrhage is in place together with associated training needs.
- Is the National Poster in place (and customised with local hospital information)

Process elements of case review

- Is staff training in date?
- Was drill undertaken within previous 6 months (did staff involved in **CODE RED** activation participate in drill?)
- Was **CODE RED** activated?
- Was emergency coordinator identified?
- Was Hospital communication satisfactory?

Outcome elements of case review

- Event location
- Team members present
- Time of event
- Staff grades on-site
- Time to senior staff on-site

Patient Specific Information elements of case review

- Patient demographics (age, gender, comorbidities etc.)
- Patient medication (including anti-coagulation)
- Surgical procedure undertaken (specify if return to theatre)
- Source of major haemorrhage

Blood Transfusion and Blood sciences elements of case review

- Patient blood group (+ specify if known pre haemorrhage)
- Estimation of blood loss
- Group sample taken prior to red cell transfusion
- Use of emergency Group O blood (units)
- Use of emergency Group O RhD negative (units)
- Timeline to availability of Group O blood and location

- Use of Group O positive and appropriateness
- Timeline to availability of own blood group.
- Use of massive haemorrhage packs and total components used.
- Ratio of Red cells to Plasma transfused in total
- Any delay to availability of blood components
- Use of Tranexamic acid, fibrinogen, other blood derivatives
- Use of NPT/ VHA
- Number of MS on site
- Support available for call in if required, staff called in
- Laboratory TAT for serial FBC, Bio, coagulation tests
- Use of cell savage
- 100% Traceability
- Component wastage and re-use
- Resourcing issues identified

Patient outcome elements of case review

- Mortality/ serious morbidity (serious morbidity include unplanned ICU/HTU admission, DIC etc)
- Debrief/Review undertaken
- Thromboprophylaxis commenced (including timeline)
- Transfusion associated serious adverse reactions/events (SAR/SAE - including TACO/TRALI etc) and reporting to NHO

Practice enhancement identified elements of case review

- Any practice enhancements to be identified in reporting to HTC

Appendix 7: Monitoring and audit

Audit of unexpected intraoperative life threatening haemorrhage events

All unexpected intraoperative life-threatening haemorrhage events will be reviewed. This information feeds into local hospital audit where some of the data captured from the case review (as presented in Appendix 6.3).

The purpose of the hospital audit is to measure compliance against the recommendations of the unexpected intraoperative life threatening haemorrhage guideline and focus improvement towards areas not meeting the standard. These recommendations with associated audit criteria are set out in Table 3 below. Periodic trending of these indicators is recommended.

Table 3: Recommended audit criteria

Recommendation	Audit Criteria	Description
9	Structure	In all cases of Unexpected Intraoperative Life Threatening Haemorrhage: • A designated emergency coordinator was identified
11 12 13	Process	In all cases of Unexpected Intraoperative Life Threatening Haemorrhage: • CODE RED activated • Serial haemostatic tests before and after resuscitation should be taken every 30–60 minutes depending on the severity of the haemorrhage • Access to sufficient and appropriate blood components and products in a timely manner • Thromboprophylaxis following major haemorrhage and as soon as possible after bleeding ceases.
14	Outcome	In all cases of Unexpected Intraoperative Life Threatening Haemorrhage, clinical outcome at 48 hours are evaluated: • Unplanned return to theatre • Unplanned admission to Intensive care unit / High Dependency Unit • Development other major morbidity e.g. Disseminated Intravascular Coagulopathy, Transfusion Associated Circulatory Overload, Transfusion Related Acute Lung Injury etc. • Survival

Monitoring of unexpected intraoperative life threatening haemorrhage events

Governance and oversight of KPIs will take place by the HTC. While there are no national level KPI, it is recommended that the following 10 KPI's are used to monitor the implementation of key guideline recommendations at hospital level. These KPIs are described below and should be monitored and reported to the HTC at the recommended intervals.

Table 4: KPIs for monitoring at hospital level

	KPI Description	Title	Data Source	Recommendation Reference	KPI reporting
1	All theatres have up to date Poster available (annual reporting)	Planning for National Life Threatening Haemorrhage	Check of surgical theatres	3	Annual reporting for KPI 1&2 Quarterly reporting to HTC of KPI 3
2	All hospitals have up to date policy & procedure available (annual reporting)		Hospital policy repository		
3	All staff fully trained (quarterly)		Training records		
4	Number of drills run per annum	Multi-disciplinary drills in the recognition and management of major blood loss	Training and education department of hospital	8	Reported at HTC annually
5	Percentage attendance of theatre staff at drills		Training records of theatre staff and transfusion staff participation in drills		
6	Percentage attendance of laboratory staff at drills		Training and education department of hospital		

	KPI Description	Title	Data Source	Recommendation Reference	KPI reporting
7	Number of non –transfusion medical scientists who have completed 10 familiarisation days pa	Familiarisation days for non-transfusion Medical scientists	Laboratory Training Records	15	Annually by HTC Biannually – Hospital Transfusion Lab
8	Average number of familiarisation days completed per non transfusion medical scientist		Laboratory Training Records		Annually to HTC
9	In date SLA with signatures from provider and recipient hospital	Availability of SLA where a hospital ttransfusion laboratory provides a transfusion service for offsite hospitals	SLA	17	Annually to HTC
10	Completion rates of eLearning Crisis Management Training	eLearning Training completion rates		Implementation Plan of recommendation 8	Annually to HTC

Monitoring compliance of KPIs and audit

The recommended standard required is 100% compliance. Where the compliance is less than 80% it is proposed that local action plans are put in place, e.g. increase frequency of audits and identify recurring issues. A quality improvement methodology should be applied to implement a sustainable solution. The HSE National Quality Improvement Team have developed a National QI Toolkit[69] which is available for use.

Appendix 8: Glossary of Abbreviations

The following abbreviations are used in this document:

ACSLM	Academy of Clinical Science and Laboratory Medicine
AGREE	Appraisal of Guidelines for Research and Evaluation
ALTH	Acute Life Threatening Haemorrhage
APTT	Abnormal Partial Thromboplastin Time
BSH	British Society for Haematology
BIA	Business Impact Analysis
CAI	College of Anaesthesiologists in Ireland
CEU	Clinical Effectiveness Unit
CINAHL	Cumulative Index to Nursing and Allied Health Literature
C/SMS	Chief/Senior Medical Scientist
CPD	Continuing Professional Development
DIC	Disseminated Intravascular Coagulation
DOH	Department Of Health
EAP	Employee Assistance Programme
EtD	Evidence to Decision
EQA	External Quality Assurance
FBC	Full Blood Count
FFP	Fresh Frozen Plasma
GDG	Guideine Development Group
Hb	Haemoglobin
HGDONM	Hospital Group Directors Of Nursing and Midwifery
HRB CICER	Health Research Board Collaboration in Ireland for Clinical Effectiveness Reviews
HSE	Health Service Executive
HTC	Hosptial Transfusion Committee
HTT	Hospital Transfusion Team
HVO	Haemovigilance Officer
IBTS	Irish Blood Transfusion Service
ICU	Intensive Care Unit
IHS	Irish Haematology Society
IPC	Intermittent Pneumatic Compression
KPI	Key Performance Indicator

MHRA	Medicines and Healthcare products Regulatory Agency
ml	millilitre
mmHg	millimetres of mercury
M&M	Morbidity & Mortality
MS	Medical Scientist
MSBOS	Maximum Surgical Blood Ordering Schedule
NCEC	National Clinical Effectiveness Committee
NCG	National Clinical Guideline
NOCA	National Office of Clinical Audit
NPT	Near Patient Testing
NTAG	National Transfusion Advisory Group
NHO	National Haemovigilance Office
NWIHP	National Women and Infants Health Programme
ONMSD	Office of the Nursing and Midwifery Services Director ONMSD
OTC	Overarching Transfusion Committee
PBM	Patient Blood Management
PHA	Private Hospitals Association
PICO	Population, Intervention, Comparison/Control, Outcome
PT	Partial thromboplastin
RCPI	Royal College of Pysicians Ireland
RCSI	Royal College of Surgeons in Ireland
RCT	Random Control Trials
SAR	Serious Adverse Reaction
SAE	Serious Adverse Event
SDP	Solvent Detergent Plasma
SLA	Service Level Agreement
SOP	Standard Operating Procedure
TACO	Transfusion Assocaited Circulatory Overload
TAT	Turn Around Time
TOR	Terms Of Reference
TRALI	Transufsion Related Acute Lung Injury
TXA	Tranexamic Acid
VHA	Viscoelastic Haemostatic Assays
WHO	World Health Organisation

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