
CEU/Design: Insert DOH logo

Unexpected Intraoperative Life Threatening Haemorrhage

National Clinical Guideline No. X

[Template - full version]

Notes:
CEU actions are marked in red.
GDG actions are highlighted in yellow and content write up is flagged in *blue italics*. Font style is Calibri 12 and justified.

CEU - this top section left intentionally blank for addition of logos.
GDG *must provide all the required logos (high definition images sized at 100% and the d.p.i. should be 300. JPGS, TIFFS and EPS are the required format. They must be sent by email as JPEG files. Examples HSE Clinical/National Programmes, Colleges or other. Their use must be appropriate and be reflected in the accompanying sentence immediately below. If logo is not self explanatory, additional text should be added.*

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 a risk of an unexpected intraoperative life threatening haemorrhage can occur. While this is likely to be an uncommon problem in the clinical arena there are no official statistics regarding its incidence – the correct approach in management of these patients should lead to a reduction in mortality from this life threatening complication.

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 is deemed out of scope
d) Life threatening haemorrhage in paediatric patients

This National Clinical Guideline is relevant to all healthcare professionals 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 (hardcopy or softcopy) 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 CEU
Department of Health (yyyy). Title (NCEC National Clinical Guideline No. XX). Available at: http://health.gov.ie/national-patient-safety-office/ncec/

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, the College of Anaesthesiologists of Ireland, National Clinical Programme for Surgery, National Clinical Programme for Anaesthesia and the HSE.

Membership nominations were sought from a variety of clinical and non-clinical backgrounds so as to be representative of all key stakeholders within the theatre and support teams. GDG members included those involved in clinical practice, education, administration, research methodology and two members representing patients and the public.

Name	Job title and affiliation
Professor John Hyland	Consultant Surgeon General/Colorectal, Past President RCSI
Ms Marina Cronin	Head of Quality & Development, National Office of Clinical Audit
Dr Joan Power	Consultant Haematologist, National Clinical Advisor Transfusion Services
Dr Jeremy Smith	Consultant Anaesthesiologist, Clinical Lead with The National Anaesthesia Programme
Dr Naomi Burke	Consultant Obstetrician and Gynaecologist
Dr Norma Reidy	Chief Medical Scientist Haematology
Ms Patsy Kelleher	Senior Medical Scientist Transfusion
Mr Edward Mulkern	Consultant Vascular Surgeon
Mr David Waldron	Consultant General / Colorectal Surgeon
Mr Aiden Devitt	Consultant Trauma & Orthopaedic Surgeon
Mr Barry McGuire	Consultant Urologist
Dr Cormac Farrelly	Consultant Radiologist
Ms Fiona Hanrahan	Theatre Nursing, Director of Midwifery and Nursing
Ms Aileen O Brien	Perioperative Nursing, Nurse Lead, National Clinical Programme for Anaesthesia
Ms Marie Cregan	Patient Representative
Ms Karen Egan	Patient Representative
Dr Vida Hamilton	National Clinical Advisor and Group Lead, Acute Hospital Operations Division
Ms Miriam Kennedy (RCSI)	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 0Development 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 Guideline Development Group 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 Ms 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, Ms Susan Ahern and Ms Natasha Broderick from HRB CICER completed the evidence searches and prepared the Business 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 in 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. Mr 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 Ms 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.

_____

Professor John Hyland Date: 30/06/2021

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.

Table of contents

Section 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.

Table 1.0: Summary of Recommendations

	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.	Very Low	Strong
2	All theatre teams will 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 may have identified specific issues for individual patients however prior to commencement of the operation the multidisciplinary team should identify specific parts of the operation when 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 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 for the management of a life threatening haemorrhage are available Every Patient: • Confirm a blood group and antibody screen (group and hold) has been performed	Very Low	Strong

	• Confirm with the laboratory that the specific blood order for a particular patient is available where required • 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 will be provided to surgical 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. As a minimum an introductory skills training module should be completed in advance of trainees undertaking these procedures.	Very Low	Strong
8	All staff working in theatre and the transfusion laboratory 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.	Low	Strong
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.	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 (senior surgeon, vascular surgeon, nursing personnel, interventional radiology etc) according to availability and request this assistance ASAP. 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
11	Serial haemostatic tests, including platelet count, PT, APTT and fibrinogen/Near Patient Testing (NPT), from before and after resuscitation should be taken every 30–60 mins 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.	Low	Strong

<table>
<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).
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. PT/APTT >1.5 times normal, use standard dose 15–20 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. Aim 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 monitoring. Trigger 1.5 g/l / viscoelastic testing. A dose of 4g will increase fibrinogen by 1 g/l in an adult.</td></tr>
<tr><td>TXA</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>Massive Haemorrhage Packs</td><td>Empirical transfusion component support may be helpful where laboratory test results or ROTEM/TEG are unavailable.

<u>Pack 1</u>
4 Red cell, 2 Plasma components. Add 4g Fibrinogen if 1-1.5 Blood volume loss.

<u>Pack 2</u>
4 Red cell, 3 Plasma components add 4g Fibrinogen.</td></tr>
</table>
</td>
<td>Low</td>
<td>Strong</td>
</tr>
<tr>
<td>13</td>
<td>Early mechanical thromboprophylaxis with intermittent pneumatic compression (IPC) while the patient is immobile and has a bleeding risk is recommended. Combined pharmacological and IPC thromboprophylaxis within 24 h after bleeding has been controlled and until the patient is mobile is also recommended.</td>
<td>Low</td>
<td>Strong</td>
</tr>
</table>

14	Two separate reviews are required following a 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 – lead haematologist for transfusion supported by the haemovigilence officer and chief medical scientist should undertake a case review fully engaging the theatre team in a timely manner and a summary reported to the HTC. In addition such incidents may be part of: • Periodic Audit by the Hospital Transfusion Committee reviewing overall trends, outcomes and process for life threatening haemorrhage events • All Hospital Transfusion Committees will feed into an Overarching Transfusion Committee (OTC). The OTC will review and benchmark 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 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.	Very Low	Strong
17	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.	Very Low	Strong

Section 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.

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 of intraoperative life threatening haemorrhage

and associated mortality in Ireland. In response to this lack of available data, the GDG undertook a survey of all Hospital 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.

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 staff & laboratory staff on the prevention, recognition and management of 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
- A reduction in mortality from unexpected life threatening haemorrhage events in Ireland

2.5 Guideline scope

The guideline will span acute clinical specialties where interventions and operations occur:

- The guideline will provide guidance to theatre teams and associated healthcare professionals on the recommended practices for unexpected intraoperative life threatening haemorrhage in the following areas -
  a) Prevention of intraoperative life threatening haemorrhage
  b) Immediate recognition of life threatening haemorrhage
  c) Timely response and management of 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 is deemed out of scope
- Life threatening haemorrhage (Massive/major haemorrhage) in paediatric patients

2.6 Conflict of interest statement

The NCEC Conflicts of Interest Policy was shared with all Guideline Development Group 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 business impact assessment, which were also funded by the Department of Health.

2.8 Guideline methodology

The NCEC Guideline Developers Manual[7] 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 the Health Research Board - Collaboration in Ireland for Clinical Effectiveness Reviews (HRB-CICER). The detailed search strategy is provided in Annex A.

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[8]. 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 Intraoperative Massive 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 intraoperative massive 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 about which recommendations from existing guidelines to adopt and/or adapt were based on GDG consensus. Through a series of 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) BCSH guideline - A practical guideline for the haematological management of major haemorrhage.[9]
   (recommendations 3,8,9,11,12)

d) European guideline on management of major bleeding and coagulopathy following trauma: fifth edition[10]
(recommendation 13)

The GRADE[11](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 4) to assess the quality of evidence and strength of recommendations. The consensus of the GDG is that the **quality of evidence is very low or low** for the recommendations. 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. 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

Note - this section will be completed following the Public Consultation Review:

The GDG endeavored to ensure all interested parties had an opportunity to contribute to the development of this NCG. The GDG would like to acknowledge the significant contribution made by the various stakeholders from professional & academic groups. An advanced draft of the NCG was sent to key stakeholders for a four-week consultation period in July 2021 and the consultation report is presented in Appendix 2.

Key areas noted from the Consultation review included:
a)
b)
c)

2.10 External review

Following discussion with the GDG, a decision was made to make a formal request to the Presidents of RCSI, CAI and the Dean of the Faculty of Pathology in RCPI seeking nominations of international Surgical, Anesthesiology and Haematology reviewers. Nominations were sought by the three colleges and the nominated reviewers accepted the invitation.

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

- 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).

- Haematology: Professor Simon J Stanworth - Consultant Haematologist and lead author on the 2021 revised BCSH guideline 'A practical guideline for the haematological management of major haemorrhage' guideline.

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:

- Xxx
- Xxxx
- xxxx

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 5) 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 6. The implementation plan is designed as a framework to guide actions required to promote effective implementation of recommendations made in this NCG. 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, 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 Hospital Transfusion Committee.

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. Hospital Transfusion Committee or theatre.
- Are benchmarked across sites with a view to practice enhancement

A completed Audit and Monitoring Plan for transfusion is presented in Appendix 8. Figure 1.0 below provides an overview of the data flow from Case Review through to Audit.

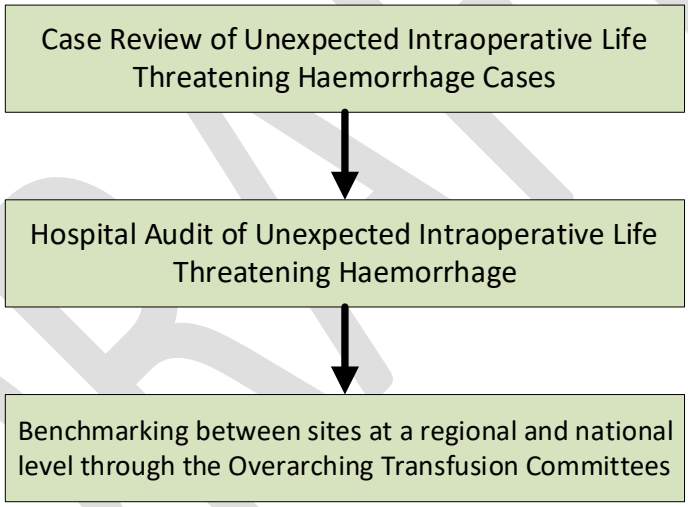


Figure 1.0 - Data Flow

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 (DOH, 2019)[12]. 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. The GDG recommend that audit of this NCG include:

a) Audit of transfusion events
b) Audit of the safe surgery checklist

a) Audit of transfusion events

While a data set is captured for an individual case review (see Appendix 7.3), formal audit of structures, processes and outcomes indicators is recommended (see Appendix 8). 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 hospital transfusion committee (HTC). The responsibilities of the HTC is outlined in the Framework for the management of Unexpected Intraoperative Life Threatening Haemorrhage (Appendix 7.1). 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 Overarching Transfusion Committees (OTC) as outlined in Recommendation 14.

b) Audit of safe surgery checklist

The current National Policy and Procedure for Safe Surgery (HSE, 2013)[13] 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 8 does not refer to the safe surgery checklist audit as this is already covered within the National Policy and Procedure for Safe Surgery[13].

Monitoring

Monitoring is a systematic process of gathering information and tracking over time and seeks to continuously measure compliance (DOH, 2019)[7]. 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 8 - 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).

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 intra-operative 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. Governance and oversight of KPIs is carried out by the Hospital Transfusion Committee.

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 guideline will be updated three years from publication as per the process recommended by NCEC (DOH, 2019)[7].

Joint ownership for the review of the guideline will be shared between the National Clinical Programme for Surgery and a suitable forum convened by the National Clinical Lead for Transfusion (potentially the National Transfusion Advisory Group (NTAG)) – with the understanding that if additional resources are required they will be funded through HSE/DOH.

The group convened for the review should incorporate stakeholder groups represented in the creation of the guideline.

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.

Section 3: National Clinical Guideline

The PICO (Population, Intervention, Comparison/Control, and Outcome) format has been used for all questions and associated recommendations.

3.1 Key questions and evidence statements

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[14]. Centers of care or centers of excellence have the ability to deliver enhanced quality through the application of innovative tools, technologies, and techniques which improve outcomes[15]. 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 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 Surgical Clinical Programme provides a comprehensive framework for the delivery of surgical care[16,17] in addition to the National Women and Infants Health Clinical Programme model of care[18].

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.

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

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 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[19] is a recognised approach in supporting patient safety worldwide. A systematic review conducted by (Treadwell et al, 2014) 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[20]. 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' (HSE, 2013)[13] 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 will 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 (example 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' (Hunt et al, 2015)[9], 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'[9]. 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/SOP the GDG have defined a 'Life Threatening Haemorrhage Framework' which is included as a tool in Appendix 7.1. 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 7.2 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, informed by the National Framework document. 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 under the Transfusion Tab (also available in Appendix 7.1 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 informed should be informed by Protocol/Procedure & Poster
- Each hospital is responsible to populate the local information in the National Life Threatening Haemorrhage Poster (Appendix 7.2)
- 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, Hospital Transfusion Committee, 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 hemorrhage 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'[19]. The first step in mitigating blood loss is prevention. Known coagulation deficits should be corrected before surgery whenever clinically possible[19]. 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[13] 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[13].

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 by (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[21].

Recommendation 4

Consideration should be given to the possibility of unexpected life threatening haemorrhage and if it is a possibility, the team should identify specific parts of the operation when life threatening haemorrhage could occur, particularly 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 lab staff
I (Intervention)	Confirming blood 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[22]. 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 by (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[21]. The GDG reached consensus in determining that if a life threatening haemorrhage event were to take place, confirming blood 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 fulfills 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:

<u>Once per day</u>:

- Confirm 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 for the management of a life threatening haemorrhage are available

<u>Every Patient</u>:

- Confirm a blood group and antibody screen (group and hold) has been performed

- Confirm with the laboratory that the specific blood order for a particular patient is available where required
- 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

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[23]. 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[24].

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

Appropriate supervision and clinical support will be provided to surgical, 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

- It is a judgement call by the consultant surgeon 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 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[25]. 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[26]. 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[27]. 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)[28] 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 gynecologists 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 will complete laparoscopy skills training and simulation drills that include recognition and appropriate response to a life threatening haemorrhage event.

Certainty of evidence: ⨁◯◯◯ **Very Low**
Strength of recommendation: **Strong**

Rational/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. Simulation drills at appropriate simulation sites are required 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
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 hemorrhage 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 BCSH 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[9]. 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 clinical staff working in theatre and the transfusion laboratory 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.

Certainty of evidence: ⊕⊕◯◯ **Low**
Strength of recommendation: **Strong**

Rationale/context for recommendation

A survey undertaken 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 Major 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 major 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 a part of 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
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 BCSH 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[9]. 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[29]. 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[30].

Recommendation 9

Following the trigger of the major or 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
- A communication link between the laboratory and theatre is required
- 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 major 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, embolisation or topical haemostatic agents, or a combination of these approaches[31]. 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 depending as required. This may include vascular or general surgery input[26] 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 (senior surgeon, vascular surgeon, interventional radiology etc.) according to availability and request this assistance ASAP. Whilst waiting for senior assistance to arrive – 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.

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 major 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

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, transfusion 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, consumption of coagulation factors, activation of fibrinolysis and haemodilution by resuscitation fluids. Developing hypothermia, acidosis and hypocalcaemia will further impair coagulopathy. It is important to monitor haemostatic changes to guide the use of blood components after initial 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[9].

Recommendation 11

Serial haemostatic tests, including platelet count, PT, APTT and fibrinogen/NPT thromboelastography, from before and after resuscitation should be taken every 30–60 mins 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.

Certainty of evidence: ⊕⊕◯◯ **Low**
Strength of recommendation: **Strong**

Good Practice Points

- Surgery should not take place in hospitals where haemostatic testing/NPT thromboelastography is not available
- The TAT for tests should be specified in the major haemorrhage protocol
- Near Patient Testing (NPT) is evolving and should only be used by fully trained and competent personnel and the technology should be enrolled in an External Quality Assurance (EQA) scheme
- The laboratory should be kept informed of results from NPT.

The following are responsible for implementation of Recommendation 11:

Lead Transfusion Haematologist, Hospital Transfusion Committee

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[9]. 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[9]. Anticipate need for platelets in on-going bleeding as platelet count falls below 100 x 10^9/l[9]. There should be close communication between the transfusion laboratory and the Blood Transfusion Service to enable timely platelet transfusion[9]. 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 (Hiippala, 1998;Hirshberg et al, 2003)[9,32,33]. The use of tranexamic acid (TXA) should be considered in non-traumatic major bleeding. TXA - 1g over 10 minutes at initial presentation, can be continued at a dose of 1g 8 hourly until bleeding ceases[34]. Empirical use of Massive Haemorrhage Packs may be helpful where laboratory test results or ROTEM/TEG 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 negative red cell components and the timeline to availability (refer to the National Life Threatening Haemorrhage Poster).

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 15–20 ml/kg. Where laboratory results are unavailable and bleeding continues, further transfusion in at least a 1:2 ratio with red cells.
Platelets	Aim to keep >50 x 10^9/l (≥100 x 10^9/l in the case of brain/critical site bleeding). Request where ongoing bleeding and platelet count < 100 x 10^9/l.
Fibrinogen Concentrate	Guided by fibrinogen levels or viscoelastic monitoring. Trigger 1.5 g/l / viscoelastic testing. A dose of 4g will increase fibrinogen by 1 g/l in an adult.

TXA	1g over 10 minutes at initial presentation, can be continued at a dose of 1g 8 hourly until bleeding ceases.
Massive Haemorrhage Packs **(Joan to confirm with BCSH what their planned approach will be)**	Pack 1 4 Red cell, 2 Plasma, 1 platelet components. Add 4g Fibrinogen if 1-1.5 Blood volume loss. Pack 2 4 Red cell, 3 Plasma, 1 platelet components, add 4g Fibrinogen.

Certainty of evidence: ⊕⊕◯◯ **Low**

Strength of recommendation: **Strong**

Good Practice Points

- Familiarity with blood component and product resuscitation availability and location must be a part of drills
- Best practice is that red cell components are available within 10 minutes
- Use of Massive Haemorrhage Packs is encouraged where possible. Pack 1 delivers red cells and plasma at a ratio of 1:2 as a minimum and Pack 2 contains red cells and plasma in a ratio of 1:1.(this is not the correct ratio) For specific conditions (liver impairment or DIC) resuscitation should commence with Pack 2. Platelet components may be added to Pack 1 as required and are included in Pack 2. **(TO BE CONFIRMED!)**
- Requirement for platelets and plasma should be considered early where hospitals do not have the components available on site. Timely and appropriate consultation with Haematology Team/Haematologist if required.
- When a major vessel injury is suspected, assistance should be called for early as per the local major haemorrhage protocol
- Any member of the team should be empowered to ask if assistance is required

The following are responsible for implementation of Recommendation 12:

Lead Haematologist for Transfusion, Chief/Senior Medical Scientist

Question 13

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[10] 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. Combined pharmacological and IPC thromboprophylaxis within 24 h after bleeding has been controlled and until the patient is mobile [10].

Recommendation 13

Early mechanical thromboprophylaxis with intermittent pneumatic compression (IPC) while the patient is immobile and has a bleeding risk is recommended. Combined pharmacological and IPC thromboprophylaxis within 24 h after bleeding has been controlled and until the patient is mobile is also recommended.

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, Haematologist,

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[19]. Debriefing is a means of standardising communication, which has been shown to improve patient outcomes in multiple situations[35]. 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[21]. The British Committee for Standards in Haematology guideline

'A practical guideline for the haematological management of major haemorrhage' (Hunt et al, 2015)[9], 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 hemorrhage should be reviewed to ensure local protocols are applied appropriately and effectively[9]. These cases should be investigated locally and reported to at the Hospital Transfusion Committee. 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 a 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 – lead haematologist for transfusion supported by the haemovigilence officer and chief medical scientist should undertake a case review fully engaging the theatre team in a timely manner and a summary reported to the HTC.

In addition such incidents may be part of:

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

Certainty of evidence: ⊕⊕◯◯ **Low**
Strength of recommendation: **Strong**

Good Practice Point

- A debrief is encouraged to take place within an hour (or as soon as appropriate) after the event.
- Use of facilitators outside the theatre team can be an appropriate approach to take 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 7.3
- 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 following are responsible for implementation of Recommendation 14:
Surgeon, Lead Haematologist for Transfusion, Nurse Manager, Chair of HTC, Chair of OTC

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?	
P (Population)	Med scientists not routinely working in the transfusion lab
I (Intervention)	10 dedicated familiarisation days
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[36]. A survey undertaken by the GDG 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 for medical scientists who are not core transfusion laboratory medical scientists and yet support out of hours transfusion laboratory activity. 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. 26/46 hospitals reported dedicated familiarisation days for non-core blood bank Medical Scientists. The data is available on request.

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**
Responsibility for implementation: Hospital General Manager, Laboratory Management.

Rationale/context for recommendation

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 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 Serious Hazards Of Transfusion 2019 Report (Chapter 9)[37] highlighted 10/29 (34.5%) reports of the wrong component being collected from the storage site where the member of staff selected the wrong component and delivered it to the clinical area. 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.

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'[38].

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 hours medical support. When asked if there a formal arrangement in place to call in additional staff members for MHP activation, 10/47 hospitals reported 'Yes'. Data is available on request.

Recommendation 16
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.

Certainty of evidence: ⨁◯◯◯ **Very Low**
Strength of recommendation: **Strong**

Good practice Points

- A list of available staff for out of hours should be compiled by laboratory management and made available for local arrangements to support call in
- Responsibility 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

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 offsite hospital which did not have appropriate blood products available. There are 11 Hospital Transfusion Laboratories supporting 14 offsite 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 delivery of required blood components and full transparency on the needs of the off-site hospital.

Recommendation 17
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.

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 surgical practice.

Good practice Points

- The Service Level Agreement must allow for O negative blood being available in a timely manner to the theatre
- A risk assessment should to 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 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
- The Service Level Agreement 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 red cell components

The following are responsible for implementation of Recommendation 17:
Hospital Management, Laboratory Management, Lead Haematologist for Transfusion

3.2 Summary budget impact analysis

Note – this section can be ignored for the Public Consultation Review. Work is underway in completing the BIA and will not be finished until the Public Consultation process is completed as the output will feed into the process.

The Budget Impact Analysis (BIA) looks at the resource impact of full implementation of this National Clinical Guideline. The methodology and estimations of the Business Impact Analysis are outlined in Appendix 3.

Seven recommendations will have an associated cost for implementation and have been included as part of the Budget Impact Analysis:

	Recommendation Number	Description
1	3	Poster Design
2	5	Costs associated with increased blood screening
3	7	Gynaecology Trainee Simulation Drills
4	8	Opportunity Cost for Drills in Theatre
5	12	Development of elearning module
6	14	Opportunity Cost for Overarching Transfusion Committee meetings
7	15	Familiarisation Days for Medical Scientists covering out of hours in Transfusion Lab
8	16	Formal out of hours arrangement for Medical Scientists covering out of hours in Transfusion Lab

Additional text to stress Gynaecology Funding case: As directed by NDTP, and in response to the National Maternity Strategy and the requirement for at least 100 new consultant posts by 2026, the IOG RCPI training scheme has undergone a significant overhaul and expansion over the last 8 years. There are just under 80 trainees on the BST scheme, and the HST scheme has expanded from 33 trainees in 2013, to 46 in 2016, and from July 2021 78 trainees will be

on the scheme, with 18 trainees on Out of Programme Experience (OPE). Challenged by the at least 30% reduction in clinical experience as a result of EWTD, appeals were made to the NDTP in 2017 for funding to introduce simulation to the curriculum and were awarded 45,000 euro more per year for advanced gynae surgery, obstetric anal sphincter injury, and advanced practical labour ward emergency skills simulation.

These courses have been highly successful, and won the first Excellence in Medical training award by NDTP in 2018, however, the cost of running these courses has increased, and the number of trainees who need access has almost doubled in the interim.

Unfortunately, no change in SLA funding has occurred despite this massive expansion, and Obstetrics and Gynaecology, as a mostly surgical specialty, is woefully behind in resources and funding compared to other surgical specialties, especially considering the cost of medical negligence claims against maternity services to the exchequer. By 2019, the estimated outstanding liabilities of the Clinical Indemnity Scheme stood at 3.6 billion euro, and while brain injury at birth cases account for 3% of all claims, they make up more than two thirds of the outstanding liability, meanwhile the number of new claims has overtaken the number being resolved. Appropriate funding for training in obstetrics and gynaecology requires urgent attention.

Section 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 Guideline Development Group and together with the Project Manager have responsibility for ensuring the guideline is developed using a robust methodology.

Membership of the Guideline Development Group 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 Guideline Development Group.

3.0 Role and Responsibilities

The primary aim of Guideline Development Group 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

4.0 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
- 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
- Meeting notes will be taken by the Project Manager and will be circulated alongside any other supporting documentation in advance of the next meeting.

5.0 Decision Making

The decision making process for the GDG will endeavor 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.

6.0 Quorum

The Guideline Development Group must have at least one third of its membership present in person or via teleconference (exclusive of the Chair and Project Manager).

7.0 Conflict of Interest

All Guideline Development Group 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: Consultation Report

Note - yet to be completed, you can ignore for this review!

List names of stakeholder/ organisations invited to contribute and noted those that responded (table below can be used).
Outline also the process for stakeholder consultation and any changes made as a result.

Date	
Patients groups	
External review	
Clinical Programmes and healthcare divisions	
National committees	
Professional groups	

Appendix 3: Economic Assessment

Yet to be completed – you can ignore for this review!

Where a commissioned review is used to inform the guideline, the report can be an annex and remain a standalone document (separate to this guideline). Remember the summary BIA remains part of the main guideline.

Appendix 4: Evidence to Decision Framework

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 uncertainly or variability Possibly important uncertainly or variability Probably no important uncertainly 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.
	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.
	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.

	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 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[13]. • WHO Guidelines for Safe Surgery 2009[19].	• 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 uncertainly or variability Possibly important uncertainly or variability Probably no important uncertainly 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.
	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.

	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 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. • BCSH 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 uncertainly or variability Possibly important uncertainly or variability Probably no important uncertainly 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	• 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.

	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.	• Design costs of a national template for poster and making it available.
	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 uncertainly or variability Possibly important uncertainly or variability Probably no important uncertainly 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.
	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.	• 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.

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. • Joan to complete - Serious Hazards Of Transfusion (SHOT) UK Data identifies??	• 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 uncertainly or variability Possibly important uncertainly or variability Probably no important uncertainly 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	• Confirming the following checks will assist with the timeliness of a crisis response: a) blood group and antibody screen b) availability of Group O blood c) any additional required blood components d) senior help (surgery and anaesthesiology) e) availability of equipment f) 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.

	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.	• These checks are common practice in many instances however there may be a cost associated with testing, additional equipment and ensuring availability of Group O blood.
	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.	• All hospitals should already have an efficient system in place for patients at risk of unexpected intraoperative life threatening haemorrhage that fulfills 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 fulfills 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 surgical 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.	
	Is there important uncertainty about how people value the main outcomes	✓	Important uncertainly or variability Possibly important uncertainly or variability Probably no important uncertainly 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.

	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 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.
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 priority?	✓	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 uncertainly or variability Possibly important uncertainly or variability Probably no important uncertainly 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.	• 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.
	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.

	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.	• 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.	
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	• BCSH 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	
	Is there important uncertainty about how people value the main outcomes	✓	Important uncertainly or variability Possibly important uncertainly or variability Probably no important uncertainly 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.
	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.

	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.	• Cost associated with training time of staff assigned to drill preparation, coordination and execution.
	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.
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	• BCSH 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 theatres 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	
	Is there important uncertainty about how people value the main outcomes	✓	Important uncertainly or variability Possibly important uncertainly or variability Probably no important uncertainly 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 fulfill 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.

	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 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.
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	• BCSH 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[9].	• 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	
	Is there important uncertainty about how people value the main outcomes	✓	Important uncertainly or variability Possibly important uncertainly or variability Probably no important uncertainly 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.

	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 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.
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	• BCSH 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 platelet count, PT, APTT and fibrinogen, from before and after resuscitation should be taken every 30–60 mins 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 uncertainly or variability Possibly important uncertainly or variability Probably no important uncertainly 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	• 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.

	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 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	• BCSH 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 O RhD 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 uncertainly or variability Possibly important uncertainly or variability Probably no important uncertainly 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	• Correct 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: 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	• As above	
	Is there important uncertainty about how people value the main outcomes	✓	Important uncertainly or variability Possibly important uncertainly or variability Probably no important uncertainly 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 thrombosus
	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.

	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?	✓	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 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 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. • BCSH 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	• As above	
	Is there important uncertainty about how people value the main outcomes	✓	Important uncertainly or variability Possibly important uncertainly or variability Probably no important uncertainly 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.
	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.

	Criteria	Judgements		Research Evidence	Additional 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 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[19]. • Serious Hazards Of Transfusion (SHOT Report 2019) identifies a number of[39].	• 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	• 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 uncertainly or variability Possibly important uncertainly or variability Probably no important uncertainly 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.
	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.

	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.	• 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 in not place to request out of hours 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	• No evidence specific to life threatening haemorrhage identified.	
	Is there important uncertainty about how people value the main outcomes	✓	Important uncertainly or variability Possibly important uncertainly or variability Probably no important uncertainly 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.
	Are the desirable anticipated effects large	✓	Probably No No Uncertain Yes Varies	• No evidence specific to life threatening haemorrhage identified.	• In many cases an ad hoc arrangement or relying on the goodwill of staff to fulfill out of hours cover is in place. This approach is not safe or sustainable, a formal arrangement caters for the welfare of staff and supports patient safety.
	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.

	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.	• 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.	
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 case of a patient dying in an offsite hospital which did not have appropriate blood products available.	• Survey conducted by GDG of Hospital Transfusion Laboratories identified concerns with 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	• No evidence specific to life threatening haemorrhage identified.	
	Is there important uncertainty about how people value the main outcomes	✓	Important uncertainly or variability Possibly important uncertainly or variability Probably no important uncertainly 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 the transfusion lab 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.

	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.	• 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.	• 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.	• 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 by all clinicians 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 high** for the recommendations presented in Part C.

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

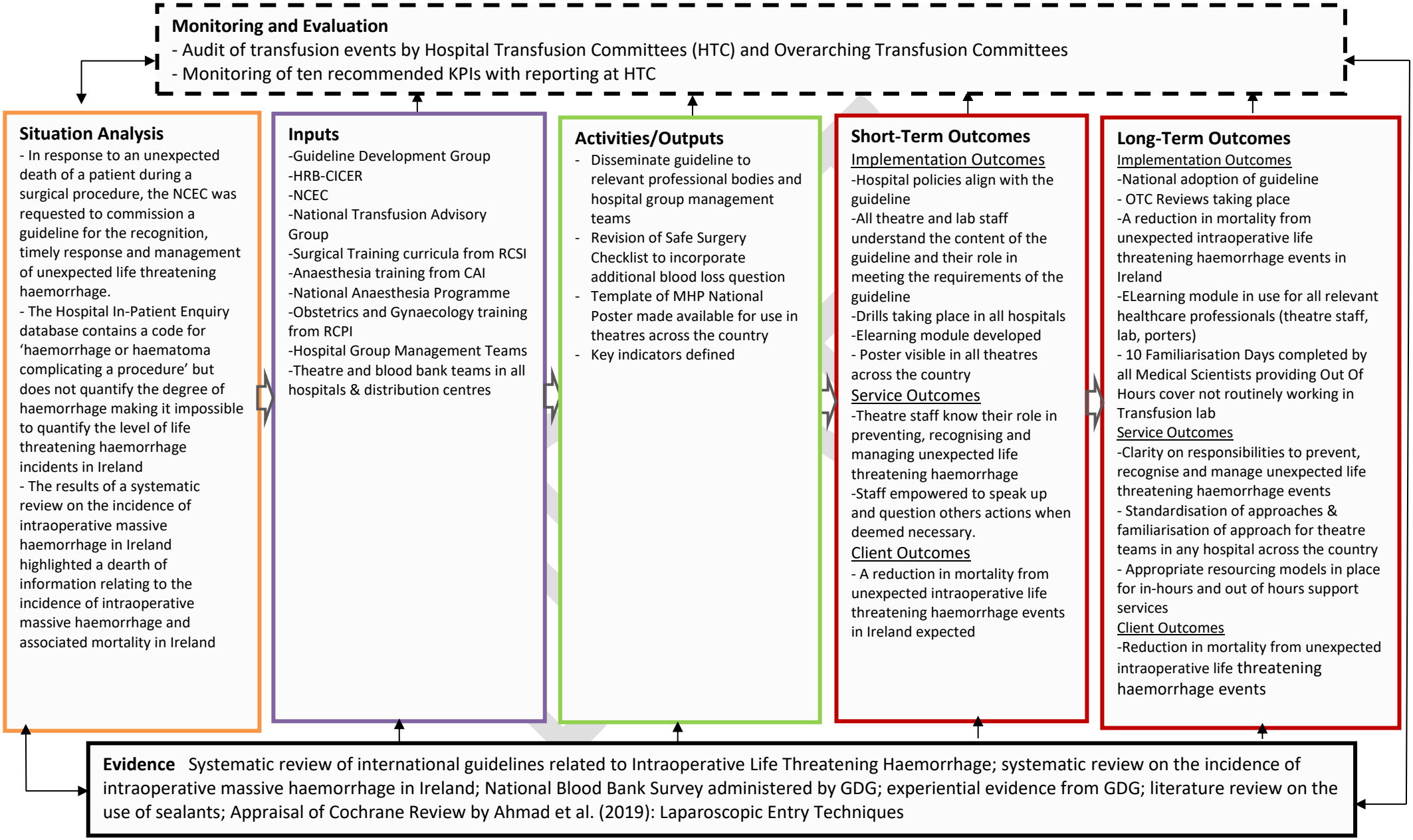
	Recommendation	Quality of evidence	Strength of recommendation	Agreement /Consensus achieved
1	Hospital Group structures already exist for the delivery of healthcare nationally and should designate the appropriate sites for scheduled (elective) and unscheduled (emergency /urgent) surgery and be supported appropriately for life threatening haemorrhage events.	Very Low	Strong	Yes
2	All theatre teams will 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' (WHO Safe Surgery for Private Hospitals).	Low	Strong	Yes
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 Protocol/Procedure 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	Consideration should be given to the possibility of unexpected life threatening haemorrhage and if it is a possibility, the team should identify specific parts of the operation when life threatening haemorrhage could occur, particularly when any operative intervention in the chest, abdomen or pelvis occurs.	Very Low	Strong	Yes

	Recommendation	Quality of evidence	Strength of recommendation	Agreement/ Consensus achieved
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 for the management of a life threatening haemorrhage are available Every Patient: • Confirm a blood group and antibody screen (group and hold) has been performed • Confirm with the laboratory that the specific blood order for a particular patient is available where required • 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	Yes
6	Appropriate supervision and clinical support will be provided to surgical 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 will complete laparoscopy skills training and simulation drills that 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 clinical staff working in theatre and the transfusion laboratory 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.	Low	Strong	Yes
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.	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 (senior surgeon, vascular surgeon, interventional radiology, etc.) and request this assistance ASAP. Whilst waiting for senior assistance to arrive – 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.	Very Low	Strong	Yes
11	Serial haemostatic tests, including platelet count, PT, APTT and fibrinogen, from before and after resuscitation should be taken every 30–60 mins 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.	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). Blood component support for life threatening haemorrhage is guided as per table below: (table not included in this section – refer to section 1.1 recommendation 12)	Low	Strong	Yes
13	Early mechanical thromboprophylaxis with intermittent pneumatic compression (IPC) while the patient is immobile and has a bleeding risk is recommended. Combined pharmacological and IPC thromboprophylaxis within 24 h after bleeding has been controlled and until the patient is mobile is also recommended.	Low	Strong	Yes

	Recommendation	Quality of evidence	Strength of recommendation	Agreement /Consensus achieved
14	Two separate reviews are required following a 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 – lead haematologist for transfusion supported by the haemovigilence officer and chief medical scientist should undertake a case review fully engaging the theatre team in a timely manner and a summary reported to the HTC. In addition such incidents may be part of: • Periodic Audit by the Hospital Transfusion Committee reviewing overall trends, outcomes and process for life threatening haemorrhage events • All Hospital Transfusion Committees will feed into an Overarching Transfusion Committee (OTC). The OTC will review and benchmark life threatening haemorrhage events - overall trends, outcomes and processes.	Low	Strong	Yes
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	Yes
16	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.	Very Low	Strong	Yes
17	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.	Very Low	Strong	Yes

Appendix 5: Logic Model



Appendix 6: 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.	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	• Hospital (and/or Group) Management Teams • Hospital (and/or Group)	✓ ✓	❍ ✓	❍ ❍	*Outcomes:* • Elective and Emergency surgery taking place in appropriate safe hospital sites.

		the hospital sites undertaking elective and emergency surgery to ensure adequate capability to respond to unexpected life threatening haemorrhage events.	Management Teams				
	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 the action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
Recommendation 2 All theatre teams will 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).	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
	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.	<u>Enablers</u> • 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	<u>Poster & Massive Haemorrhage Protocol/SOP</u> • 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	• GDG with support from RCSI • GDG • Clinical Lead for Transfusion/NTAG with appropriate stakeholder engagement • Clinical Lead for Transfusion/NTAG	✓ ✓ ❍ ❍	❍ ❍ ✓ ✓	❍ ❍ ❍ ❍	*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
		• Include local hospital specific details in the National Life Threatening Haemorrhage	• Lead Haematologist for Transfusion	❍	✓	❍	

		Management Poster (e.g. method of communication, location of blood products, turn around times) • 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 & Massive Haemorrhage Protocol/SOP templates reviewed and signed off by this GDG
		• Poster & Protocol included in Induction training and ongoing training for staff – could be included in an online module • Ensure Poster and Protocol form the basis of multi-disciplinary Hospital Drill	• Lead Haematologist for Transfusion/HTC • Lead Haematologist forTransfusion/HTC	❍ ❍	✓ ✓	❍ ❍	• Annual audit to verify that Life Threatening Haemorrhage Posters are prominently displayed in theatres and Life Threatening Haemoorahge 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 the action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
Recommendation 4 The pre-operative assessment of the patient may have identified specific issues for individual patients however prior to commencement of the operation the multidisciplinary team should identify specific parts of the operation when life threatening haemorrhage could occur. This particularly applies when any operative intervention in the chest, abdomen or pelvis occurs.	Enabler: Perioperative briefing as per WHO Safe Surgery recommendations	• 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	• Perioperative Director (for overall Policy responsibility) & Theatre Manager (at individual theatre level) • Theatre team members • National Safe Site Surgery Policy Review Group	❍ ❍ ✓	✓ ✓ ❍	❍ ❍ ❍	*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.
	Barrier: Difficulty in finding time that is agreeable to everyone to conduct a perioperative briefing	• 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	✓	❍	❍	

Guideline Recommendation number	Implementation barriers / enablers	Action / intervention / task to implement recommendation	Lead responsibility for delivery of the 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)	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 fulfills 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 Appropriate supervision and clinical support will be provided to surgical and anaesthesiology trainees in line with their experience and stage of training.	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 Anaesthesiologist 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 will complete laparoscopy skills training and simulation drills that include recognition and appropriate response to a life threatening haemorrhage event.	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
	Barrier: Time constraints at local hospitals for MDT drills	• Hospitals to determine strategy for implementing drills to ensure appropriate attendance (given the balance between service provision and educational activity)	• Hospital Management & Local Hospital Training Coordinator				*Outcomes:* • Regular educational events in relation to managing life threatening haemorrhage • Doctors will have more protected time for education and training *Verification:* • Logbook entries • CPD records

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 clinical staff working in theatre and the transfusion laboratory 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.	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.	• This person might be - (Chairperson of Theatre Users Group / Perioperative Director, Lead for Safe Surgery Group)	✓	❍	❍	*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) as	• 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.	Enabler: Major 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 (senior surgeon, vascular surgeon, interventional radiology etc) according to availability and request this assistance ASAP. Whilst waiting for senior assistance to arrive – methods such as packing to reduce the ongoing haemorrhage and pressure/compression on the bleeding vessel should be applied as a damage limiting approach.	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) • Request required assistance in all cases when life threatening haemorrhage protocol has been activated • Record sequence of events in the operative note within the patient record • 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	• Surgeon and/or anaesthesiologist • Emergency Coordinator • Surgeon • Hospital Group Management	✓ ✓ ✓ ✓	❍ ❍ ❍ ❍	❍ ❍ ❍ ❍	*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.

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 platelet count, PT, APTT and fibrinogen, from before and after resuscitation should be taken every 30–60 mins 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.	Enabler: Availability of TAT of haemostatic tests in the Massive Haemorrhage Protocol/SOP	• Include hospital specific TAT of haemostatic tests in the Massive Haemorrhage Protocol/SOP • Approve content of Massive 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.
	Enabler: Inclusion of this recommendation in local drill	• 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	• Hospital Transfusion Committee • Perioperative Director in close discussion with Lead Transfusion Haematologist/ Hospital Theatre Committee	❍	✓	❍	
	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).	• Laboratory Management • Hospital Management	✓	❍	❍	

		• Efficient delivery of samples to laboratory					• 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. • Designated person/body responsible for NPT in place in all hospitals – which has governance of the EQA scheme.
	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 • Theatre staff must be trained and competent in NPT.	• Communication Lead • Designated trainers from NPT committees/ departments	✓ ✓	❍ ❍	❍ ❍	

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). Blood component support for life threatening haemorrhage is guided as per table below:	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 • Ensure blood components are available • Chief/Senior Medical Scientist to include local information on Poster	• Lead Haematologist for Transfusion working with each of the clinical divisions • Chief/Senior Medical Scientist with responsibility for blood transfusion • Chief/Senior Medical Scientist	❍	✓	❍	*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.
	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	• Postgraduate bodies for all clinical staff prescribing blood components (including RCSI,	❍	✓	❍	

		of blood components – this needs to be included in the relevant undergraduate and postgraduate curriculum • Induction and ongoing training of appropriate prescription of blood delivered at hospital level by	RCPI, PHECC, relevant postgraduate nursing courses) • Induction and ongoing training delivered at hospital level by				

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) while the patient is immobile and has a bleeding risk is recommended**.** Combined pharmacological and IPC thromboprophylaxis within 24 h after bleeding has been controlled and until the patient is mobile.	Enabler: Current practice in many cases	• Pharmacological thromboprophylaxis to prescribed by Surgeon/Anaesthesiologist before handover to ICU • Pharmacological thromboprophylaxis to commence within 24 hours of bleeding being controlled.	• Surgeon/ Anaesthesiologost • 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 Two separate reviews are required following a 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	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 Anaesthesiologist • Surgeon and/or Anaesthesiologist (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 7.3 of guideline outlines data to be captured as part of the Case Review. • HTC to adopt the national Framework for 'Acute Life	• GDG • HTC	❍	✓	❍	*Outcomes:* • National Framework reviewed and adopted as national policy • National Framework

b) Case Review by a wider multi-functional team – lead haematologist for transfusion supported by the haemovigilence officer and chief medical scientist should undertake a case review fully engaging the theatre team in a timely manner and a summary reported to the HTC. In addition such incidents may be part of:		Threatening Haemorrhage Case Review' (Appendix 7.1) • Lead Haematologist for Transfusion to establish local process to implement the national framework for case review • Case review will become the data input for any future proposed National Clinical Audit Programme	• Chair of HTC • Lead Haematologist for transfusion to establish				adopted by Hospitals *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

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

							implementation of the guideline • Regular Updates provided in Quarterly Converse • Academy highlight resourcing concerns with appropriate bodies *Verification* • Annual report to each HTC capturing compliance level • ACSLM Quarterly Converse content showing updates
	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	❍	✓	❍	
	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)	❍	✓	❍	

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 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.	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 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.	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 b) Specify contingency arrangements • SLA to include reciprocal arrangement for communication	• Hospital Management • HTC • Lead Haematologist for Transfusion • Hospital Management at	✓	❍	❍	*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

		and planning of changes to service demand or availability of service	hospital with transfusion laboratory & Hospital Management at off site hospital				

Appendix 7: 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**

7.1 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.

Framework Document for the management of Unexpected Intraoperative Life Threatening Haemorrhage

1.0 Introduction and Development

This Framework document was developed by the Guideline Development Group (GDG) tasked to develop the NCEC approved guideline for the management of unexpected intraoperative life threatening haemorrhage.

This group undertook a survey of 'massive/major haemorrhage' in Ireland for the calendar year 2018 and invited hospitals to share their protocol/poster/procedure. The data capture identified that a significant number of incidents occurred out of hours and the 26 posters submitted showed a wide variation in content and style of documentation supporting massive/major haemorrhage. Such variation is a potential source of reduced effectiveness for the prompt management required to minimise morbidity and mortality. We can anticipate involvement of clinical staff who rotate between hospitals in the management of life threatening haemorrhage and therefore a standardised National Poster could assist a timely response.

The UK National Comparative Audit of Blood Transfusion undertook an audit of the management of adult major haemorrhage in October 2018[40]. This was across the range of UK hospitals/Trusts (94%) and included two hospitals from 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.

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 in the management of unexpected life threatening haemorrhage. The guideline also recommends life threatening haemorrhage 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 future national audit that is undertaken.

2.0 Scope and Purpose

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.

This document refers to organisational, clinical and laboratory approaches in the management of life threatening haemorrhage in the intra-operative setting. It is a requirement for each hospital to have a documented policy and associated procedures/protocols in relation to the management of unexpected life threatening haemorrhage which should address the elements identified in this Framework. The development of these documents should be integrated with the activity of the Hospital Transfusion Committee.

While this framework was developed for the intraoperative setting, it can be applied with appropriate modification to the management of unexpected life threatening haemorrhage in other clinical scenarios including obstetrics, trauma, paediatrics and gastro intestinal haemorrhage. (Note – these clinical areas are outside the scope of the National Clinical Guideline for Unexpected Intraoperative Life Threatening Haemorrhage).

3.0 Roles and Responsibilities

Hospital responsibilities are met through the responsible parties working with hospital management and the Hospital Transfusion Committee (HTC) to develop, review and seek improvement in organisational systems, documentation, training (including drills), communication methods, data capture and review processes (including Audit). The overall aim of these activities will be to enhance practice and improve patient safety. A multi-disciplinary approach is required and the key roles and responsibilities include:

3.1 Hospital Management are responsible for resourcing and supporting 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.

3.2 The Clinical Director should be fully supportive and participate in the development of hospital policies, procedures, training and documentation supporting life threatening haemorrhage.

3.3 The Perioperative Director is responsible for participating in the development of hospital policies, procedures, training and documentation supporting life threatening haemorrhage. They are responsible for ensuring that pre-operative systems are in place to optimise patients' haemoglobin and manage bleeding risks. They are responsible for considering event review reports and trends so as to address any practice enhancements identified. They are responsible for keeping the lead haematologist for transfusion advised of perioperative developments.

3.4 The Director of Nursing/ Midwifery should be fully supportive and participate in the development of hospital policies, procedures, training and documentation supporting life threatening haemorrhage.

3.5 Hospital Support 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.

3.6 Clinical Staff All clinical staff who may be responsible for unexpected life threatening haemorrhage management must be familiar with the hospital documentation, policy, procedures and the relevant NCEC Guidelines. They must be competent in use of Near Patient Testing (NPT) before application in life threatening haemorrhage management. They must participate in relevant case reviews.

3.7 Hospital Transfusion Committee (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 Hospital Transfusion Committee:

- Has senior hospital management support from the CEO/Hospital Manager and Clinical Director
- Authorises the hospital policy for unexpected life threatening haemorrhage on site and considers off-site hospitals for which the 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 protocol as reported from the lead haematologist for transfusion in conjunction with the surgical lead/team with a particular focus on potential improvements
- Monitors life threatening haemorrhage KPIs and reviews life threatening haemorrhage audit reports
- Provides feedback to the hospital staff
- Membership of the Hospital Transfusion Committee should include:
  - Clinical Director
  - Consultant Haematologist with responsibility for Blood Transfusion
  - 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

3.8 The Hospital Transfusion Team (HTT) is responsible for participating in the development of hospital policies, procedures, training and documentation supporting life threatening haemorrhage and prepare and present the periodic audit for the HTC. The HTT is responsible for trending acute life threatening haemorrhage events and informing the Overarching Transfusion Committee.

- Membership of the HTT will include:
  - Consultant Haematologist Lead for Blood Transfusion/Haemovigilance.
  - Chief /Senior Medical Scientist Hospital Transfusion Laboratory
  - Haemovigilance Officer
  - Chair of the Hospital Transfusion Committee

3.8.1 Lead Haematologist for Transfusion:

- The Lead Haematologist for Transfusion is responsible for ensuring relevant hospital Haematology/transfusion policies are current, optimal practices are established to support policies and that training and audit programmes are in place.
- They will ensure, with hospital management that hospital organisational arrangements are in place to support effective communication during management of life threatening haemorrhage. They will be advised of supporting technology in use e.g. cell salvage and 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 relevant parties any out of laboratory blood component storage facilities/ arrangements in the hospital and off-site.
- They are responsible for engaging in risk assessment for the transfusion support of any off-site surgical activity.
- They will authorise the local hospital data entry on the National Poster.
- They lead the multidisciplinary event review with communication of findings to appropriate parties.
- They are responsible with the C/SMS for transfusion sample acceptance policies. They have a central role in the HTC, haemovigilance and hospital participation in benchmarking and any future national audit.
- The lead Haematologist for Transfusion /duty Haematologist should be consulted with regard to life threatening haemorrhage Massive/ major Haemorrhage plan activation, as appropriate, to assist management of transfusion support and as soon as possible where patient anticoagulated.

3.8.2 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 center. 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 at all times, 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.

3.8.3 Haemovigilance Officer(s) (HVO)

- The Haemovigilance officers are responsible for participating in the development of hospital policies, procedures, training and documentation supporting life threatening haemorrhage.
- The HVO has a key role in delivering training for management of life threatening haemorrhage and working with the designated trainer in each clinical area.
- They will support life threatening haemorrhage events if on-site, as appropriate
- They will engage in event review and include life threatening haemorrhage 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

The approach to unexpected life threatening haemorrhage is similar to crisis event management. This includes human factor recognition and role assignment - facilitating early recognition of major blood loss, activation by declaring to team this is a life threatening haemorrhage, agreeing an Emergency Coordinator, assigning a Communication Lead and using closed loop communication.

Emergency Coordinator – The Emergency Coordinator is a senior clinician who is responsible for the overall coordination of the management of the unexpected life threatening haemorrhage event. They are responsible for delegating tasks and assigning roles for those present. They are also responsible for mobilising additional resources. In particular they will appoint a Communication Lead as soon as practical.

Communication Lead – The Communication Lead is responsible for 'Calling for Help'. See section 4.2 below for further clarification on the role of the Communication Lead.

Appropriate management is prompted by the National Poster (see National Poster template in section 7.2 of guideline) which will have local information inserted. Event stand down is declared with communication to all relevant parties including the laboratory as soon as possible.

4.1 Training and Drills - Hospital training plans can be supported by the postgraduate training colleges – including RCPI, RCSI, CAI & Institute of Obstetrics & Gynaecology. Local periodic drills facilitate robust and clearly understood communication channels for contacting all relevant staff and laboratories. KPIs should be monitored and reported to the HTC (see Appendix 8).

4.2 Communication - internal and external. The use of a nationally agreed **'CODE RED'** shorthand for unexpected life threatening haemorrhage as clear and well understood communication is recommended. Each hospital must identify their communication pathway for activation of code red and ensure this is completed and included on the National Poster. Key Personnel must be identified together with the transfusion laboratory for immediate communication. Switchboard availability must be defined. The communication pathway for use of cell salvage technology must be defined where available. 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 style of all those engaged in managing the event should be 'Closed Loop Communication' where the receiver confirms their understanding of the communication. Haematology support should be sought early where patient anticoagulated. It is essential that the laboratory is informed of NPT results. Laboratory communication for additional MS support should be identified. Laboratory communication for IBTS support of stock required, especially early communication re platelet component support must be agreed. 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.

4.3 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 (sourcing required equipment etc) and continued usage of 'Safe Surgical Practice' will support the protocol in the event of unexpected intraoperative life threatening haemorrhage. Cell salvage which is in routine use in theatre may be utilised for unexpected life threatening haemorrhage.

4.4 Resuscitation - Following the CODE RED activation, resuscitation will be commenced by the Anesthesiology team. The key elements include large bore access (may require ultrasonic guidance), high flow oxygen, continuous cardiovascular monitoring, warm fluid - including blood warmer for red cells, pressure infusers & use of 'Bear Hugger'.

4.5 Transfusion support - Blood loss of >40% blood volume is life threatening. Life threatening haemorrhage is also associated with a coagulopathy from coagulation factor use, activation of fibrinolysis and haemodilution with resuscitation. However, coagulopathy can be expected to be less severe in the intraoperative setting than trauma. Transfusion protocols support tissue oxygenation and aim to prevent/ reverse coagulopathy early by rapid transfusion in advance of results from blood science testing.

The National Poster supports blood management and identifies the location and time to availability of transfusion component and pharmacological support in each hospital. This includes use of Tranexamic acid to be administered as a bolus and may be followed by an infusion over 8 hrs.

A correctly labelled blood sample should be taken in advance of transfusion for blood group and antibody screen where unknown – local turnaround times for results should be identified. Haematology advice should be sought early where patient is anti-coagulated. Red cell components should be available for emergency use within 10 mins Group O Rh D negative (and Kell negative) red cell for females < 55yrs of child bearing potential and Group O after 1 BV for older females and for males. Where blood group is known, the patient's group specific blood component should be provided. Major haemorrhage packs containing red cells and plasma may be used empirically where laboratory results or NPT are unavailable. The initial pack will have a ratio of at least 2:1 red cells to plasma and a 1:1 for follow on packs. Plasma content may be increased for DIC and guided by laboratory test results. Platelet component support- while a significant reduction in platelet count is a late feature of major haemorrhage, hypotension/shock are associated with platelet dysfunction. Activation of the Massive Haemorrhage Protocol (MHP)/code red should prompt arrangements to have platelets available on-site. Where platelet count falls below $100 \times 10^{9/l}$ clinicians should order platelets on standby for transfusion to maintain platelets above $50 \times 10^{9/l}$. The concern in relation to platelet transfusion in the case of neonates, ICH and patients on anti-platelet medication is noted. Fibrinogen is available as a pooled concentrate in Ireland which has a therapeutic dose of 4g to be repeated as required. Prevention of hypothermia, acidosis and hypocalcaemia are critical in coagulopathy management.

Cell salvage support is infrequently used even when available (12% of available sites in UK national audit for several reasons). Hospitals should identify if and when available on site and associated communication pathways as stated in 4.2 above.

Each hospital will identify a designated person/ role for transfer of samples to the laboratory (where required) and collection of blood components/ derivatives/ pharmacological agents from storage location for clinical site.

There must be clear arrangements for off-site hospitals as per Service Level Agreement (SLA) with the supporting transfusion laboratory, clearly captured in the local documentation and included in National Poster.

4.6 Patient Monitoring - clinical cardiac/ metabolic/ blood sciences including Near Patient Testing (NPT)

- Sample procurement – valid sample critical to ensure accurate patient ID and avoid delays associated with sample rejection

- Turn Around Time (TAT) for each test should be known to clinical staff
- Coagulation and fibrinogen should be repeated at intervals of 30-60 mins
- Identify relevant compliant NPT availability at hospital including viscoelastic haemostatic assays.
- See National Near-Patient Testing (NPT) Consultative group 'Guidelines for safe and effective near-patient testing (NPT)' v 6.2, April 2021
- Metabolic complications should be prevented/ actively managed

4.7 Stand down – 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.

4.8 Arrangements for De-brief - The Emergency Coordinator should consult, consider and communicate arrangements for theatre de-brief in a timely manner.

5.0 Life Threatening Haemorrhage event review, audit and KPI monitoring

5.1 Life Threatening Haemorrhage event review processes

- A theatre de brief should be undertaken as soon as appropriate
- A wider event review should be led 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 outcome elements should be captured and reported to the HTC utilising the data set presented in Appendix 7.3 of the guideline.
- The Hospital representative to the overarching transfusion committee (OTC) should report on events, trends and practice enhancements.

5.2 Life Threatening Haemorrhage Audit & KPI Monitoring

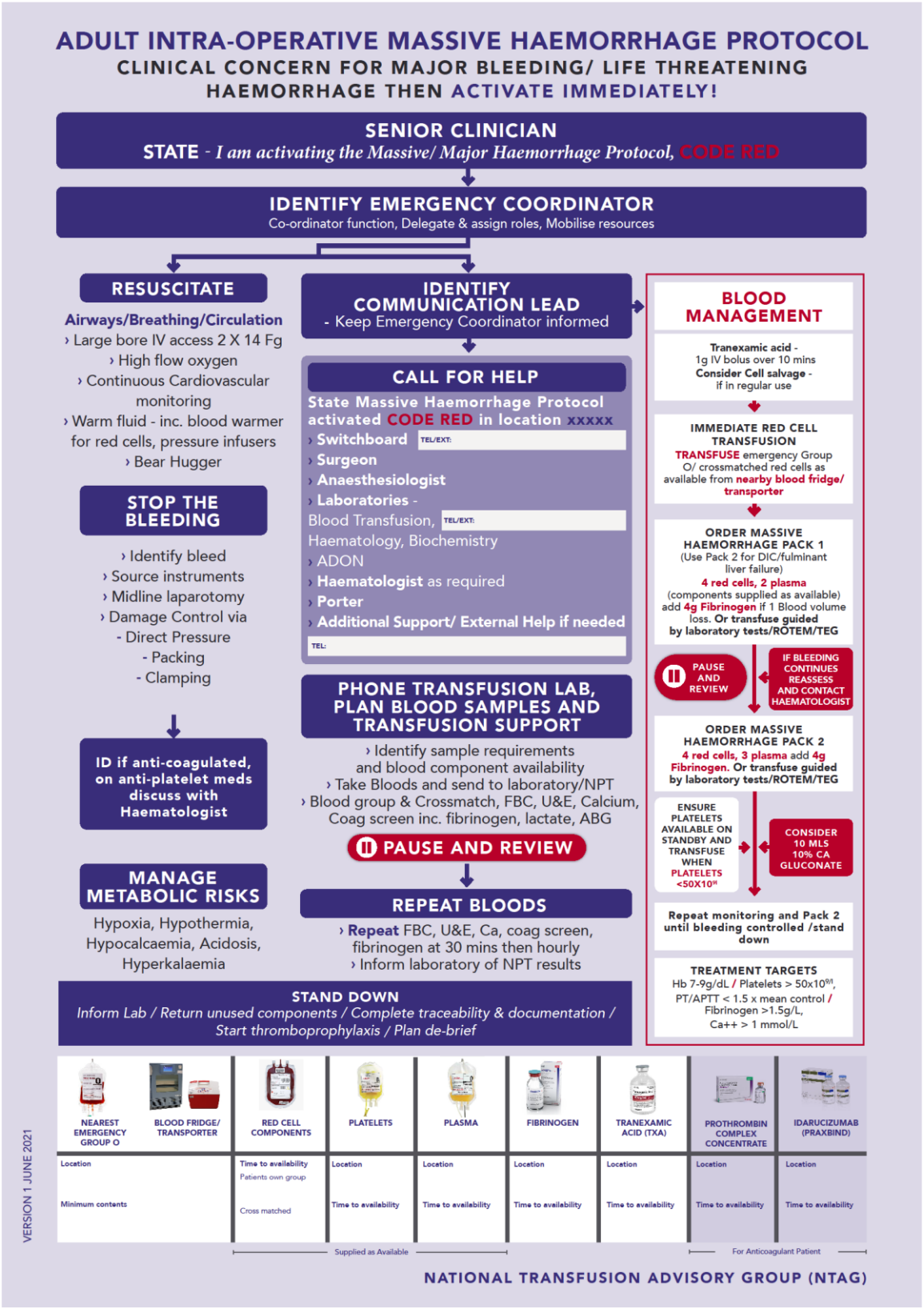
- Management of unexpected life threatening haemorrhage should be included in the hospital Audit cycle (see recommended audit criteria Appendix 8).
- Life threatening haemorrhage KPIs should be reviewed by the HTC on a periodic basis (as set out in Appendix 8).

6.0 Abbreviations Used

CAI – College of Anaesthesiologists of Ireland
CEO – Chief Executive Office
CMS – Chief Medical Scientist
FBC – Full Blood Count
GDG – Guideline Development Group
HCA – Health Care Assistant
HTC – Hospital Transfusion Committee
HTT – Hospital Transfusion Team
HVO – Haemovigilance Officer
IBTS – Irish Blood Transfusion Service
ICH – Intra Cerebral Haemorrhage
ID - Identity

KPI – Key Performance Indicator
MHP – Massive Haemorrhage Protocol
MS – Medical Scientist
NCEC – National Clinical Effectiveness Committee
NHO – National Haemovigilance Office
NPT – Near Patient Testing (formerly Point Of Care Testing)
OTC – Overarching Transfusion Committee
RCSI – Royal College of Surgeons in Ireland
RCPI – Royal College of Physicians of Ireland
SAE - Serious Adverse Events
SAR – Serious Adverse Reactions
SLA – Service Level Agreement
SMS – Senior Medical Scientist
TAT – Turn Around Time

7.2 - National Poster – This National Poster should be adopted by each hospital, customised with local information and displayed in every operating theatre. A PDF of this Poster will be made available to all hospitals for adaptation and distribution to all relevant sites. The Poster should be printed in A1 size.



7.3 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 Lead Haematologist for Transfusion 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 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 (inc. 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)
- 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/ thromboelastography

- 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
- Traceability
- Component wastage and re-use
- Resourcing issues identified

Patient outcome elements of Case Review
- Mortality/ serious morbidity
- Debrief/Review undertaken
- Thromboprophylaxis commenced (inc. timeline)
- Associated serious adverse reactions/events (SAR/SAE) and reporting to NHO

Practice Enhancement Identified elements of Case Review
- Any practice enhancements to be identified in reporting to HTC

Appendix 8: 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 7.3).

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 3.0 below. Periodic trending of these indicators is recommended.

Table 3.0 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 mins 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 Hospital Transfusion Committee. While there are no national level Key Performance Indicators (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 4.0 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 theater 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		
7	Number of non – transfusion medical scientists who have completed 10 familarisation days pa	Familiarisation days for non-transfusion Medical scientists	Laboratory Training Records	15	Annually by HTC Biannually – Hospital Transfusion Lab
8	Average number of familarisation days completed per non transfusion medical scientist		Laboratory Training Records	15	Annually to HTC
9	In date SLA with signatures from provider and recipient hospital	Availability of SLA where a hospital transfusion laboratory provides a transfusion service for offsite hospitals	SLA	17	Annually by HTC

	KPI Description	Title	Data Source	Recommendation Reference	KPI reporting
10	Completion rates of eLearning Crisis Management Training	eLearning Training completion rates		Implementation Plan of recommendation 12	Annually by 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[41] which is available for use.

Appendix 9: 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
BCSH	British Committee for Standards in Haematology
BIA	Business Impact Analysis
CAI	College of Anaesthesiologists in Ireland
CEU	Clinical Effectiveness Unit
CPD	Continuing Professional Development
DIC	Disseminated Intravascular Coagulation
DOH	Department Of Health
EAP	Employee Assistance Programme
EtD	Evidence to Decision
EQA	External Quality Assurance
GDG	Guideine Development Group
HRB CICER	Health Research Board Collaboration in Ireland for Clinical Effectiveness Reviews
HSE	Health Service Executive
HTC	Hosptial Transfusion Committee
HTT	Hospital Transfusion Team
ICU	Intensive Care Unit
IPC	Intermittent Pneumatic Compression
KPI	Key Performance Indicator
MHRA	Medicines and Healthcare products Regulatory Agency
ml	milliliter
mmHg	millimeters of mercury
M&M	Morbidity & Mortality
NCEC	National Clinical Effectiveness Committee
NCG	National Clinical Guideline
NPT	Near Patient Testing
NTAG	National Transfusion Advisory Group
OTC	Overarching Transfusion Committee
PICO	Population, Intervention, Comparison/Control, Outcome
RCPI	Royal College of Pysicians Ireland
RCSI	Royal College of Surgeons in Ireland
SAR	Serious Adverse Reaction
SAE	Serious Adverse Event
SLA	Service Level Agreement
SOP	Standard Operating Procedure
TOR	Terms Of Reference
TXA	Tranexamic Acid
WHO	World Health Organisation

References

1. Norfolk D. *Handbook of Transfusion Medicine* 5th ed. United Kingdom TSO Blackwell; 2013.
2. Irita K. Risk and crisis management in intraoperative hemorrhage: Human factors in hemorrhagic critical events. *Korean journal of anesthesiology.* 2011;60(3):151.
3. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. *New England journal of medicine.* 1991;324(6):370-376.
4. de Vries EN, Ramrattan MA, Smorenburg SM, Gouma DJ, Boermeester MA. The incidence and nature of in-hospital adverse events: a systematic review. *BMJ Quality & Safety.* 2008;17(3):216-223.
5. Anderson O, Davis R, Hanna GB, Vincent CA. Surgical adverse events: a systematic review. *The American Journal of Surgery.* 2013;206(2):253-262.
6. Dutton RP, Lee LA, Stephens LS, Posner KL, Davies JM, Domino KB. Massive HemorrhageA Report from the Anesthesia Closed Claims Project. *Anesthesiology: The Journal of the American Society of Anesthesiologists.* 2014;121(3):450-458.
7. Health DO. How to develop a National Clinical Guideline: A manual for guideline developers. In: Health DO, ed. Dublin2019.
8. Brouwers MC, Kho ME, Browman GP, et al. AGREE II: advancing guideline development, reporting and evaluation in health care. *CMAJ.* 2010;182(18):E839-842.
9. Hunt BJ, Allard S, Keeling D, et al. A practical guideline for the haematological management of major haemorrhage. *British journal of haematology.* 2015;170(6):788-803.
10. Spahn DR, Bouillon B, Cerny V, et al. The European guideline on management of major bleeding and coagulopathy following trauma: fifth edition. *Crit Care.* 2019;23(1):98.
11. Guyatt et al. What is "quality of evidence" and why is it important to clinicians? *BMJ.* 2008;336(7651):995-8.
12. Department Of Health. Department of Health (2019) Patient Safety (Notifiable Patient Safety Incidents) Bill 2019. 2019.
13. HSE QPSD. HSE National Policy and Procedure for Safe Surgery. 2013. https://www.hse.ie/eng/about/who/qid/resourcespublications/safesurg14june.pdf.
14. HSE. Securing the Future of Smaller Hospitals: A Framework for Development. In:2013.
15. Elrod JK, Fortenberry JL, Jr. Centers of excellence in healthcare institutions: what they are and how to assemble them. *BMC Health Serv Res.* 2017;17(Suppl 1):425.
16. Executive HS, Ireland RCoSi, Ireland CoAo, Surgery NCPi. *Model of Care for Acute Surgery.* 2013.
17. Executive HS, Ireland RCoSi, Ireland CoAo, Surgery NCPi. Model of care for elective surgery: including implementation guide. In: Royal College of Surgeons in Ireland (RCSI); 2011.
18. Programme NWaIHC. Model of Care - National Women and Infants Health Clinical Programme 2017.
19. Organisation WH. WHO Guidelines for Safe Surgery 2009: Safe Surgery Saves Lives. In: *WHO Guidelines for Safe Surgery 2009: Safe Surgery Saves Lives.* Geneva2009.
20. Treadwell JR, Lucas S, Tsou AY. Surgical checklists: a systematic review of impacts and implementation. *BMJ Qual Saf.* 2014;23(4):299-318.
21. Leong K, Hanskamp-Sebregts M, van der Wal RA, Wolff AP. Effects of perioperative briefing and debriefing on patient safety: a prospective intervention study. *BMJ Open.* 2017;7(12):e018367.
22. UK SHOT. *2019 Annual SHOT Report - Chapter 11a (Delayed Transfusions).*
23. al Be. The Impact of Operating Surgeon Experience, Supervised Trainee vs. Trained Surgeon, in Vascular Surgery Procedures: A Systematic Review and Meta-Analysis. *European Journal of Vascular and Endovascular Surgery, Volume 58, Issue 2, August 2019, Pages 299.* 2019.

24. Tomlinson J. Using clinical supervision to improve the quality and safety of patient care: a response to Berwick and Francis. *BMC Medical Education volume 15, Article number: 103 (2015).* 2015.
25. Querleu D, Chapron C, Chevallier L, Bruhat MA. Complications of gynecologic laparoscopic surgery--a French multicenter collaborative study. *N Engl J Med.* 1993;328(18):1355.
26. Brierley G, Arshad I, Shakir F, Visvathanan D, Arambage K. Vascular injury during laparoscopic gynaecological surgery: a methodological approach for prevention and management. *The Obstetrician and Gynaecologist.* 2020;Volume22(3).
27. Agha RA, Fowler AJ. The role and validity of surgical simulation. *Int Surg.* 2015;100(2):350-357.
28. Katz D, Blasius K, Isaak R, et al. Exposure to incivility hinders clinical performance in a simulated operative crisis. *BMJ Qual Saf.* 2019;28(9):750-757.
29. Edwards S, Siassakos D. Training teams and leaders to reduce resuscitation errors and improve patient outcome. *Resuscitation.* 2012;83(1):13-15.
30. Siassakos D DT, Crofts JF, Hunt LP, Winter C, Fox R. More to teamwork than knowledge, skill and attitude. *BJOG.* 2010;Sep;117(10).
31. Authority ANB. Critical Bleeding Massive Transfusion: Patient Blood Management Guidelines Module 1. In:2011.
32. Hiippala S. Replacement of massive blood loss. *Vox Sang.* 1998;74 Suppl 2:399-407.
33. Hirshberg A, Dugas M, Banez EI, Scott BG, Wall MJ, Jr., Mattox KL. Minimizing dilutional coagulopathy in exsanguinating hemorrhage: a computer simulation. *J Trauma.* 2003;54(3):454-463.
34. Roberts I, Shakur H, Coats T, et al. The CRASH-2 trial: a randomised controlled trial and economic evaluation of the effects of tranexamic acid on death, vascular occlusive events and transfusion requirement in bleeding trauma patients. *Health Technol Assess.* 2013;17(10):1-79.
35. Bartz-Kurycki MA, Anderson KT, Abraham JE, et al. Debriefing: the forgotten phase of the surgical safety checklist. *J Surg Res.* 2017;213:222-227.
36. Chaffe B, Glencross H, Jones J, et al. UK Transfusion Laboratory Collaborative: minimum standards for staff qualifications, training, competency and the use of information technology in hospital transfusion laboratories 2014. *Transfus Med.* 2014;24(6):335-340.
37. UK SHOT. SHOT Report 2019 - Chapter 9 (Incorrect Blood Component Transfused). 2019:Page 62.
38. Robbie C. Medicines and Healthcare products Regulatory Agency (MHRA) Report on Blood Safety and Quality Regulation (BSQR) in 2019. *SHOT 2019 Report* 2019;Chpater 26:Page 218.
39. (SHOT) SHOT. Serious Hazards Of Transfusion (SHOT). 2019. https://www.shotuk.org/shot-reports/report-summary-and-supplement-2019/2019-annual-shot-report-individual-chapters/.
40. Transplant NBa. UK National Comparative Audit of Blood Transfusion 2018.
41. HSE. National Quality Improvement Toolkit. 2019.