An Roinn Sláinte
Department of Health

Unexpected Intraoperative Life Threatening Haemorrhage

National Clinical Guideline No. 29

SUMMARY May 2022

National Patient Safety Office
Oifig Náisiúnta um Shábháilteacht Othar

NATIONAL CLINICAL EFFECTIVENESS COMMITTEE

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

Using this Summary National Clinical Guideline

This summary should be read in conjunction with the full version NCEC National Clinical Guideline. The full version is available at: https://www.gov.ie/en/collection/c9fa9a-national-clinical-guidelines

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

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

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

b) Post-partum haemorrhage

c) Post-operative bleeding

d) Life threatening haemorrhage in paediatric patients

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

Disclaimer

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

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

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

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Membership of the Guideline Development Group (GDG)

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

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

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Table of contents

Section 1: National Clinical Guideline recommendations		
1.1	Summary of recommendations	1
Section 2: Development of this National Clinical Guideline		
2.1	Background	7
2.2	Clinical and financial impact of condition/disease/topic	8
2.3	Rationale for this National Clinical Guideline	8
2.4	Aim and objectives	9
2.5	Guideline scope	9
2.6	Conflict of interest statement	10
2.7	Sources of funding	10
2.8	Guideline methodology	10
	Step 1: Formulate the key questions	
	Step 2: Search methodology	
	Step 3: Screen and appraise the evidence	
	Step 4: Develop and grade the recommendations	
2.9	Consultation summary	13
2.10	External review	13
2.11	Implementation Plan	14
2.12	Monitoring and audit	15
2.13	Plan to update this National Clinical Guideline	17
Section 3: Appendices		
4	Logic Model	20
5	Implementation plan	21
6	Supporting Tools	44
6.2	National Poster	45
7	Monitoring and audit	46
8	Glossary of abbreviations	49
References		51

1 National Clinical Guideline recommendations

1.1 Summary of recommendations

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

Table 1: Summary of Recommendations

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

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

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

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

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

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

4g fibrinogen, for every blood volume loss

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

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

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

2 Development of the National Clinical Guideline

2.1 Background

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

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

Broad definitions have been suggested and they include;

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

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

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

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

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

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

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

2.2 Clinical and financial impact of condition/disease/topic

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

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

2.3 Rationale for this National Clinical Guideline

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

2.4 Aim and objectives

The aim and objectives of this guideline are as follows:

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

2.5 Guideline scope

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

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

This guideline covers the following areas:

a) Prevention of intraoperative life threatening haemorrhage

b) Immediate recognition of intraoperative life threatening haemorrhage

c) Timely response and management of intraoperative life threatening haemorrhage

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

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

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

2.6 Conflict of interest statement

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

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

2.7 Sources of funding

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

2.8 Guideline methodology

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

Step 1: Formulate the key questions

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

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

A systematic review was completed to answer the following question:

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

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

Step 2: Search methodology

A formal literature search was undertaken by HRB-CICER to determine relevant international guidelines of interest. Electronic searches were conducted in PubMed, Embase, CINAHL (via Ebsco), and the Cochrane Library. Key terms and their variations were associated with the PICOS (Population/Patient/ Problem,

Intervention, Comparison, Outcome, Study design) framework which is applicable when addressing a clearly defined clinical question relevant to a defined population group and clinical context. Key terms included a combination of terms associated with "intraoperative massive haemorrhage". The full search strategy is detailed in Annex A. This search strategy was created *de novo* by the research team and used an expansive approach to identify as many potentially relevant guidelines as possible. Grey literature sources were also searched including guideline repositories, guideline developer websites and specific clinical specialty websites. The full list of grey literature sources is also provided in Annex A.

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

Step 3: Screen and appraise the evidence

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

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

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

Step 4: Develop and grade the recommendations

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

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

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

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

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

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

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

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

Table 2: GRADE Quality Level & Symbols

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

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

A very extensive research exercise was undertaken by HRB-CICER resources to source evidence. The EtD Framework also assessed the desirable and undesirable consequences of implementing the recommendations. The risk to patient safety, which can unfortunately result in patient death, is deemed high for all recommendations. The clinical and professional expertise of the GDG members contributed to a consensus score on the quality of evidence and strength of recommendations.

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

2.9 Consultation summary

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

Key areas noted from the Consultation review included:

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

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

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

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

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

f) Additional references provided and incorporated.

2.10 External review

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

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

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

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

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

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

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

The reviewers were as follows:

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

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

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

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

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

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

2.11 Implementation

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

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

implementation is subject to service planning and estimates process.

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

2.12 Monitoring and audit

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

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

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

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

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

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

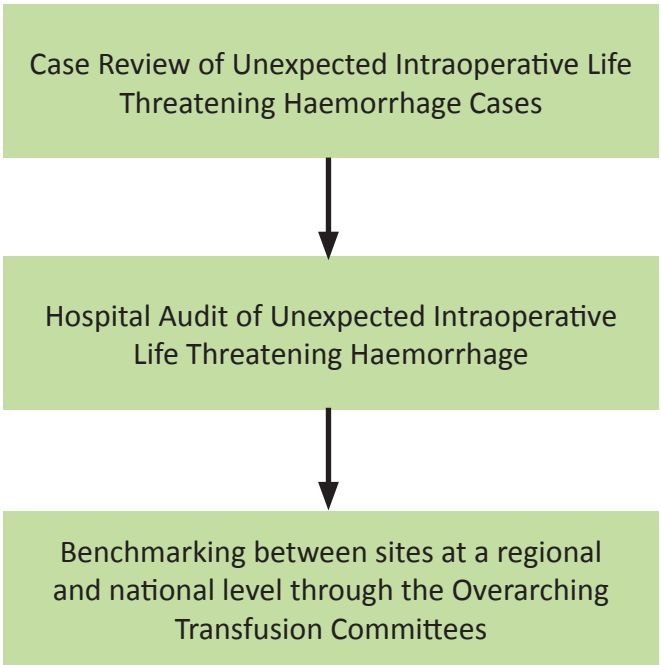


Figure 1: Data Flow

Audit:

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

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

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

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

a) Audit of transfusion events

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

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

b) Audit of safe surgery checklist

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

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

Monitoring

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

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

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

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

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

2.13 Plan to update this National Clinical Guideline

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

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

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

- **Cell Salvage**

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

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

- **National Audit of Practice**

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

- **Medical scientist resourcing**

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

- **Use of Viscoelastic Haemostatic Assays (VHAs)**

  Robust diagnostic studies validating and standardizing diagnostic cut offs for VHA parameters and randomized trials comparing VHA-guided algorithms with standard care on clinical outcomes in massive haemorrhage are urgently needed.

3 Appendices

Only appendices 4, 5, 6, 6.2, 7 and 8 are presented here as they are key to interpreting the recommendations in this summary guideline.

Refer to the full guideline report for the remaining appendices:

Appendix 1: Guideline Development Group Terms of Reference

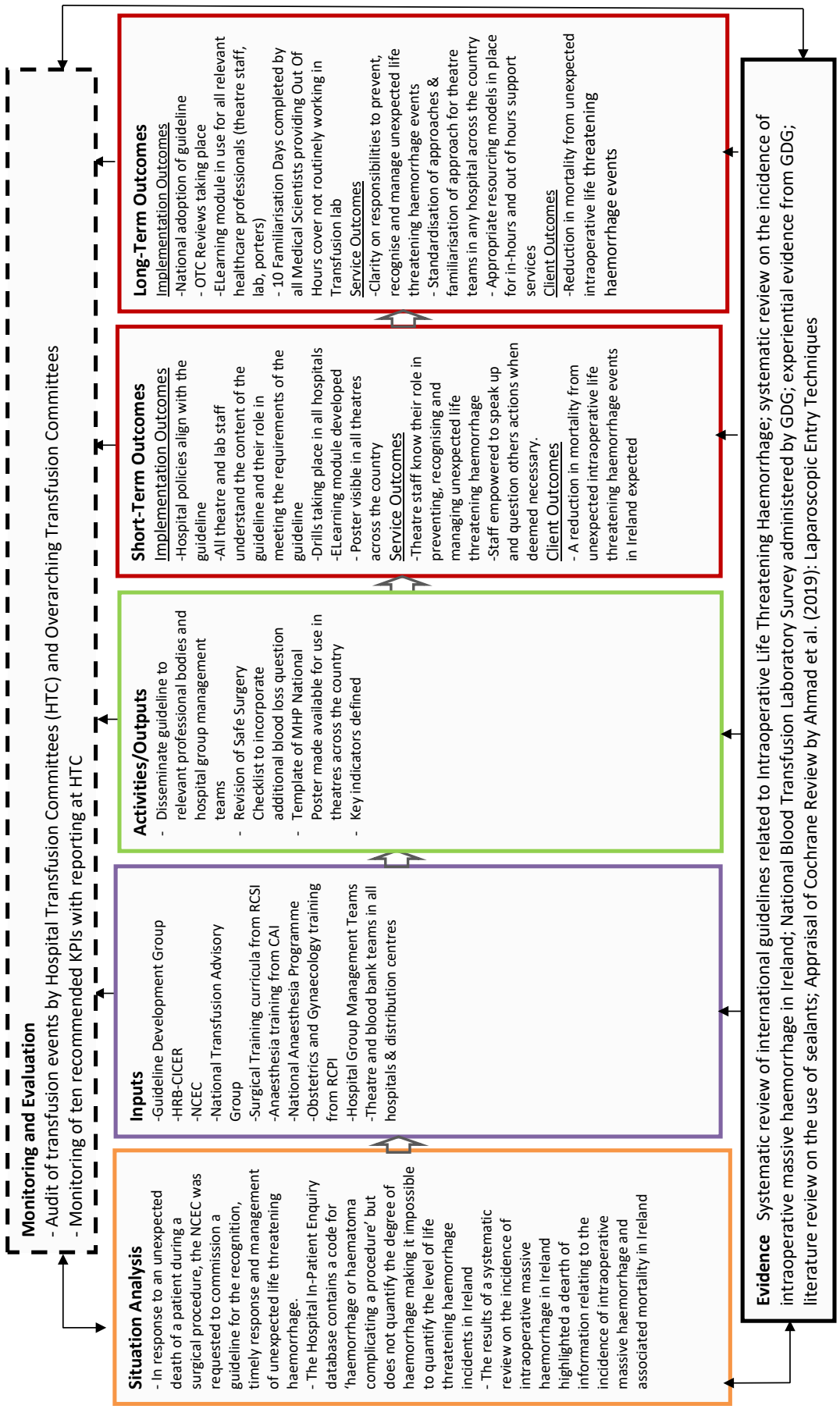
Appendix 2: Evidence to Decision Framework (EtD)

Appendix 3: Consultation Report

Appendix 6.1: Framework Document

Appendix 6.3: Data Capture

Appendix 4: Logic Model



Appendix 5: Implementation plan

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Appendix 6: Supporting tools

The Guideline includes three supporting tools:

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

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

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

6.2 - National Poster

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

Appendix 7: Monitoring and audit

Audit of unexpected intraoperative life threatening haemorrhage events

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

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

Table 3: Recommended audit criteria

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

Monitoring of unexpected intraoperative life threatening haemorrhage events

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

Table 4: KPIs for monitoring at hospital level

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

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

Monitoring compliance of KPIs and audit

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

Appendix 8: Glossary of Abbreviations

The following abbreviations are used in this document:

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

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

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. Li J, Sun SL, Tian JH, Yang K, Liu R, Li J. Cell salvage in emergency trauma surgery. *Cochrane Database Syst Rev.* 2015;1:CD007379.
8. DOH. How to develop a National Clinical Guideline: A manual for guideline developers. In: Health DO, ed. Dublin2019.
9. HSE. Patient Safety Strategy 2019-2024. 2019; https://www.hse.ie/eng/about/qavd/patient-safety/hse-patient-safety-strategy-2019-2024.pdf.
10. 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.
11. 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.
12. 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.
13. Guyatt et al. What is “quality of evidence” and why is it important to clinicians? *BMJ*. 2008;336(7651):995-8.
14. Department Of Health. Department of Health (2019) Patient Safety (Notifiable Patient Safety Incidents) Bill 2019. 2019.
15. HSE QPSD. HSE National Policy and Procedure for Safe Surgery. 2013. https://www.hse.ie/eng/about/who/qid/resourcespublications/safesurg14june.pdf.
16. HSE. Securing the Future of Smaller Hospitals: A Framework for Development. In:2013.
17. 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.
18. HSE, Royal College of Surgeons in Ireland, College of Anaesthetists of Ireland, National Clinical Programme in Surgery. *Model of Care for Acute Surgery*. 2013.
19. Health Service Executive, Royal College of Surgeons in Ireland, College of Anaesthetists of Ireland, National Clinical Programme in Surgery. Model of care for elective surgery: including implementation guide. In: Royal College of Surgeons in Ireland (RCSI); 2011.

20. National Women and Infants Health Clinical Programme. Model of Care - National Women and Infants Health Clinical Programme 2017.
21. World Health Organisation. *WHO Guidelines for Safe Surgery 2009: Safe Surgery Saves Lives. In: WHO Guidelines for Safe Surgery 2009: Safe Surgery Saves Lives*. Geneva2009.
22. Treadwell JR, Lucas S, Tsou AY. Surgical checklists: a systematic review of impacts and implementation. *BMJ Qual Saf*. 2014;23(4):299-318.
23. 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.
24. UK SHOT. 2019 *Annual SHOT Report - Chapter 11a (Delayed Transfusions).*
25. Bath et al. 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.
26. 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.
27. 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.
28. 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).
29. Agha RA, Fowler AJ. The role and validity of surgical simulation. *Int Surg.* 2015;100(2):350-357.
30. 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.
31. Edwards S, Siassakos D. Training teams and leaders to reduce resuscitation errors and improve patient outcome. *Resuscitation*. 2012;83(1):13-15.
32. Siassakos D DT, Crofts JF, Hunt LP, Winter C, Fox R. More to teamwork than knowledge, skill and attitude. *BJOG*. 2010;Sep;117(10).
33. Australian National Blood Authority. Critical Bleeding Massive Transfusion: Patient Blood Management Guidelines Module 1. In:2011.
34. National Near-Patient Testing (NPT) Consultative Group D, Ireland. Guidelines for safe and effective near-patient testing (NPT). 2021.
35. Curry NS, Davenport R, Pavord S, et al. The use of viscoelastic haemostatic assays in the management of major bleeding: A British Society for Haematology Guideline. *Br J Haematol*. 2018;182(6):789-806.
36. Selby R. “TEG talk”: expanding clinical roles for thromboelastography and rotational thromboelastometry. *The American Society of Hematology Education Program*. 2020;2020(1):67-75.
37. Hiippala S. Replacement of massive blood loss. Vox Sang. 1998;74 Suppl 2:399-407.
38. 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.
39. 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.

40. Shalhoub J LR, Hudson J, Baker C, Bradbury A, Dhillon K, et al. Graduated compression stockings as adjuvant to pharmaco-thromboprophylaxis in elective surgical patients (GAPS study): randomised controlled trial. *The BMJ*. 2020;369(8245).

41. 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.

42. 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.

43. Transplant NBa. UK National Comparative Audit of Blood Transfusion - Audit of the Management of Major Haemorrhage 2018.

44. 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.

45. Mauskopf J, Earnshaw S. A Methodological Review of US Budget-Impact Models for New Drugs. *Pharmacoeconomics*. 2016;34(11):1111-1131.

46. HIQA. Guidelines for the Economic Evaluation of Health Technologies in Ireland. 2018.

47. HIQA. Guidelines for the Budget Impact Analysis of Health Technologies in Ireland. 2018.

48. (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/.

49. British Committee for Standards in Haematology, Milkins C, Berryman J, et al. Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories. British Committee for Standards in Haematology. *Transfus Med.* 2013;23(1):3-35.

50. Robinson S, Harris A, Atkinson S, et al. The administration of blood components: a British Society for Haematology Guideline. *Transfus Med*. 2018;28(1):3-21.

51. Heffernan DS, Thakkar RK, Monaghan SF, et al. Normal presenting vital signs are unreliable in geriatric blunt trauma victims. *J Trauma*. 2010;69(4):813-820.

52. UK SHOT. Annual SHOT Report 2020. 2020.

53. Hagler DJ, Jr., Hatton S, Cornejo MD, et al. Image processing and analysis methods for the Adolescent Brain Cognitive Development Study. *Neuroimage.* 2019;202:116091.

54. NICE. Blood Transfusion. 2015;NG24.

55. Crash-trial collaborators. Effects of tranexamic acid on death, disability, vascular occlusive events and other morbidities in patients with acute traumatic brain injury (CRASH-3): a randomised, placebo-controlled trial. *Lancet*. 2019;394(10210):1713-1723.

56. Colomina MJ et al. Clinical use of tranexamic acid: evidences and controversies. *Brazilian Journal of Anesthesiology (English edition*). 2021.

57. Callum JL, Rizoli S. Plasma transfusion for patients with severe hemorrhage: what is the evidence? *Transfusion*. 2012;52 Suppl 1:30S-37S.

58. Rahouma M, Kamel M, Jodeh D, et al. Does a balanced transfusion ratio of plasma to packed red blood cells improve outcomes in both trauma and surgical patients? A meta-analysis of randomized controlled trials and observational studies. *Am J Surg*. 2018;216(2):342-350.

59. Theusinger OM, Baulig W, Seifert B, Emmert MY, Spahn DR, Asmis LM. Relative concentrations of haemostatic factors and cytokines in solvent/detergent-treated and fresh-frozen plasma. *Br J Anaesth*. 2011;106(4):505-511.

60. Kalsi AS, Al-Azzawi O, Gill R. Comparison of the Coagulation Effect Achieved by OctaplasLG Versus Fresh Frozen Plasma in Pediatric Cardiac Surgical Patients. *Clin Appl Thromb Hemost*. 2018;24(8):1327-1332.

61. Stensballe J, Ulrich AG, Nilsson JC, et al. Resuscitation of Endotheliopathy and Bleeding in Thoracic Aortic Dissections: The VIPER-OCTA Randomized Clinical Pilot Trial. *Anesth Analg*. 2018;127(4):920-927.

62. Napolitano LM. Hemostatic defects in massive transfusion: an update and treatment recommendations. *Expert Rev Hematol*. 2021;14(2):219-239.

63. Levy JH, Welsby I, Goodnough LT. Fibrinogen as a therapeutic target for bleeding: a review of critical levels and replacement therapy. *Transfusion*. 2014;54(5):1389-1405; quiz 1388.

64. Estcourt LJ, Malouf R, Hopewell S, et al. Pathogen-reduced platelets for the prevention of bleeding. *Cochrane Database Syst Rev*. 2017;7:CD009072.

65. Strandenes G, Sivertsen J, Bjerkvig CK, et al. A Pilot Trial of Platelets Stored Cold versus at Room Temperature for Complex Cardiothoracic Surgery. *Anesthesiology*. 2020;133(6):1173-1183.

66. Huish S, Green L, Kempster C, et al. A comparison of platelet function in cold-stored whole blood and platelet concentrates. *Transfusion*. 2021.

67. Mooney C, Byrne M, Kapuya P, et al. Point of care testing in general haematology. *Br J Haematol.* 2019;187(3):296-306.

68. Harney M. Statutory Instrument - European Communities (Human Blood and Blood Components Traceability Requirements and Notification of Serious Adverse Reactions and Events) Regulations. In: Children Ha, ed. Vol S.I. No 5472006.

69. HSE. National Quality Improvement Toolkit. 2019.

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