An Roinn Sláinte
Department of Health

Unexpected Intraoperative Life Threatening Haemorrhage

National Clinical Guideline No. 29

Annex C: Budget impact analysis – National Clinical Guideline Unexpected Intraoperative Life Threatening Haemorrhage Guideline.

National Patient Safety Office
Oifig Náisiúnta um Shábháilteacht Othar

NATIONAL CLINICAL EFFECTIVENESS COMMITTEE

CICER
Collaboration in Ireland for Clinical Effectiveness Reviews

Budget impact analysis –

National Clinical Guideline Unexpected Intraoperative Life Threatening Haemorrhage Guideline

REPORT

October 2021

Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

HRB Health Research Board

NATIONAL CLINICAL EFFECTIVENESS COMMITTEE

RCSI

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About HRB-CICER

In 2016, the Department of Health requested the Health Research Board (HRB) to fund a dedicated multidisciplinary research group to support the activities of the Ministerial appointed National Clinical Effectiveness Committee (NCEC). Called HRB-CICER (Collaboration in Ireland for Clinical Effectiveness Reviews), a five-year contract (2017 to 2022) was awarded following a competitive process to the Health Information and Quality Authority (HIQA). The HRB-CICER team comprises a dedicated multidisciplinary research team (including expertise in health economics, qualitative and quantitative research methods and epidemiology) supported by staff from the Health Technology Assessment (HTA) team in HIQA and the HRB Centre for Primary Care Research at the Royal College of Surgeons in Ireland (RCSI), as well as national and international clinical and methodological experts.

Guideline development groups submit clinical guidelines for appraisal and endorsement by the NCEC as National Clinical Guidelines. HRB-CICER provides independent scientific support to guideline development groups tailored according to their specific needs. The main role of the HRB-CICER team is to undertake systematic reviews of the clinical effectiveness and cost-effectiveness of interventions included in the guidelines and to estimate the budget impact of implementing the guidelines. Additional support can be provided by HRB-CICER to guideline development groups including; providing tailored training sessions and working closely with the guideline development groups to develop clinical questions and search strategies; performing systematic reviews of international clinical guidelines; supporting the assessment of their suitability for adaption to Ireland and assisting in the development of evidence-based recommendations.

Membership of the evaluation team

The members of the HRB-CICER and HIQA Evaluation Team were: Susan Ahern, Natasha Broderick, Michelle O'Neill, Prof. Susan Smith and Dr. Máirín Ryan.

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Table of Contents

About HRB-CICER **2**

Membership of the evaluation team **2**

Table of Contents **3**

1 Introduction **6**

1.1 Scope of work 6

1.2 Intraoperative Massive Haemorrhage 6

2 Methods **8**

2.1 Study perspective 8

2.2 Time horizon 8

2.3 Measurement and valuation of resources 8

2.4 Rationale for included and excluded interventions 9

2.5 Target population 11

2.6 Summary of assumptions and data requirements for BIA 12

3 Economic Model Inputs **13**

3.1 National life threatening haemorrhage management poster 13

3.1.1 Poster design, printing and lamination 13

3.2 Simulation drills for life threatening haemorrhage events for trainee gynaecologists 13

3.2.1 Faculty training 13

3.2.2 Trainee gynaecologists training 14

3.3 Multi-disciplinary drills and e-learning module on the recognition and management of major blood loss 15

3.3.1 Training time for multi-disciplinary drills 15

3.3.2 Training material for e-learning module 17

3.3.3 Training time for e-learning module 17

3.4 Overarching Transfusion Committees 18

3.4.1 Meeting time 18

3.5 Familiarisation days for medical scientists supporting out of hours transfusion laboratory activity 19

3.5.1 Staff posts 19

4 Analysis 21

4.1 National life threatening haemorrhage management poster 21

4.2 Simulation drills for life threatening haemorrhage events for trainee gynaecologists 21

4.3 Multi-disciplinary drills and an e-learning module in the recognition and management of major blood loss22

4.4 Overarching Transfusion Committees 23

4.5 Familiarisation days for medical scientists supporting out of hours transfusion laboratory activity 23

5 Results 25

5.1 Overall budget impact 25

5.2 Budget impact according to each intervention 26

5.2.1 Familiarisation days for medical scientists supporting out of hours transfusion laboratory activity 26

5.2.2 Multi-disciplinary drills and an e-learning module on the recognition and management of major blood loss 26

5.2.3 Overarching Transfusion Committees 27

5.2.4 Simulation drills for life threatening haemorrhage events for trainee gynaecologists 27

5.2.5 National life threatening haemorrhage management poster 27

6 Discussion 28

6.1 Conclusion 30

References 31

Appendix 1: National clinical guideline recommendations 33

Appendix 2: Staff numbers and salary mean/midpoint for Recommendation 8 40

List of abbreviations that appear in this report

BIA	Budget Impact Analysis
GDG	Guideline Development Group
HIQA	Health Information and Quality Authority
HRB-CICER	Health Research Board Collaboration in Ireland for Clinical Effectiveness Reviews
HSE	Health Service Executive
HTC	Hospital Transfusion Committee
NCEC	National Clinical Effectiveness Committee
OTC	Overarching Transfusion Committee
PPE	Personal Protective Equipment
PRSI	Pay Related Social Insurance
RCPI	Royal College of Physicians of Ireland
SLA	Service Level Agreement
WTE	Whole-Time Equivalent

1 Introduction

1.1 Scope of work

A budget-impact analysis (BIA), addresses the expected changes in the expenditure of a healthcare system after the adoption of a new intervention.[1] The completion of a BIA is a required step in the development of NCEC National Clinical Guidelines in Ireland.[2] In the context of guideline development, the purpose of the BIA is to quantify the resource implications of implementing the recommendations. That is, to synthesise the best available knowledge in order to estimate the additional resources and costs for the healthcare system.[3] This BIA is developed to support the guideline development group (GDG), who are preparing the National Clinical Guideline, *Unexpected Intraoperative Life Threatening Haemorrhage Guideline*, for the Irish healthcare system.

1.2 Intraoperative Massive Haemorrhage

The Unexpected Intraoperative Life Threatening Haemorrhage GDG considers intraoperative massive haemorrhage to be intraoperative bleeding that is catastrophic in nature and difficult to control even for an experienced practitioner.[4] As outlined in Annex A in broad terms, intraoperative massive haemorrhage is associated with clinical features including tachycardia (>110 beats per minute),[5] hypotension (<90mmHg systolic blood pressure)[5] and suggests a sudden loss of at least 50% of blood volume.

Intraoperative massive haemorrhage has the potential for significant morbidity and mortality.[6] Dependent on the root cause, an intraoperative massive 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 healthcare management and not by the patient's underlying disease'.[7] 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.[8, 9] Surgical care, and specifically care provided in operating theatres, is associated with a notably high incidence of adverse events,[8] with haemorrhage being a frequently encountered complication.[9] 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.[10]

To date, there has been no guidance in Ireland to inform practice where there is a risk that an unexpected intraoperative life threatening haemorrhage can occur. The *Unexpected Intraoperative Life Threatening Haemorrhage Guideline* will apply to patients undergoing interventions and operations where there is a risk of an unexpected intraoperative life

threatening haemorrhage occurring. It will not apply to intraoperative life threatening haemorrhage for:

- trauma patients (that is patients where life threatening haemorrhage has not arisen from the procedure or intervention itself)
- post-partum haemorrhage
- post-operative bleeding
- paediatric patients.

The recommendations outlined in the *Unexpected Intraoperative Life Threatening Haemorrhage Guideline* will provide all healthcare professionals working in acute clinical specialties where interventions and operations occur, with evidence based recommendations to assist with preventing, recognising, managing and responding to a life threatening haemorrhage event.[11]

2 Methods

In clinical guideline development, a budget impact analysis (BIA) addresses the expected changes following the implementation of the guideline recommendations. The BIA aims to quantify the resource implications of all recommendations identified as representing a change to standard clinical practice. The purpose of this analysis is to estimate the likely ongoing financial consequences for the Irish healthcare system of the clinical recommendations outlined in the *Unexpected Intraoperative Life Threatening Haemorrhage Guideline*.

The BIA was conducted in accordance with HIQA guidelines for budget impact analysis and economic evaluation in Ireland,[12, 13] using Microsoft Excel 2013.[14]

2.1 Study perspective

In line with national guidelines, costs and benefits were assessed from the perspective of the publicly-funded health and social care system, the Health Service Executive (HSE).[12, 13] As such, only direct medical costs were included. Indirect costs such as decreased productivity associated with morbidity, treatment or death, or out-of pocket expenses incurred were excluded from the analysis.

2.2 Time horizon

The time horizon represents the timeframe over which resource use is planned. In accordance with national guidelines, the annual budget impact was estimated over a five year time horizon.[12, 13]

2.3 Measurement and valuation of resources

Estimation of costs was carried out using a range of methods as appropriate to each item. Where possible, these estimates were informed by the experience of the Unexpected Intraoperative Life Threatening Haemorrhage GDG. Where there was no clear precedent, resource use was estimated by combining available empirical data with expert opinion from within the GDG and relevant external groups. Specific data used to inform resource use and valuation estimates are described separately for each cost item below. All salary costs were based on mid-point of the scale adjusted for pension, pay related social insurance (PRSI) and overheads (such as office space, heating and lighting) as per HIQA guidelines.[12, 13]

2.4 Rationale for included and excluded interventions

The BIA considers the changes to the treatment pathway arising from implementing the clinical recommendations and estimate the financial consequences (in terms of costs and or cost savings) that result. The BIA's comparator comprises the current standard practice. The decision on whether or not a recommendation represented a change to routine clinical practice, and therefore should be included in the BIA, was based on discussion with the GDG and a review of relevant national literature including policy documents and models of care. The rationale for inclusion and exclusion of individual recommendations is summarised in Appendix 1.

The key changes that will result from implementing the clinical recommendations contained in the *Unexpected Intraoperative Life Threatening Haemorrhage* Clinical Guideline are:

1. To assist with responding to a life threatening haemorrhage event, a National Life Threatening Haemorrhage Management Poster will be developed and must be prominently displayed in all operating theatres [Recommendation 3].
2. Simulation drills, to include recognition and appropriate response to a life threatening haemorrhage event, will be provided for all trainee gynaecologists undertaking laparoscopic procedures during the course of their training [Recommendation 7].
3. Regular multi-disciplinary drills and an e-learning module on the recognition of, response to and management of major blood loss, including when to activate/trigger the life threatening haemorrhage protocol and take prompt and appropriate action, will be provided for all staff working in operating theatres and medical scientists involved in a life threatening haemorrhage, including those providing out of hours cover. [Recommendation 8].
4. A number of Overarching Transfusion Committees (OTC) will meet bi-annually to review and benchmark life threatening haemorrhage events including overall trends, outcomes and processes. [Recommendation 14].
5. 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 ten supervised dedicated familiarisation days annually during routine hours in the transfusion laboratory. In order to facilitate familiarisation and ensure there is no interruption to laboratory work in their absence, additional head count will be required. [Recommendation 15].

No changes to the current standard practice arising from implementation of the guideline recommendations were identified for the following areas:

1. The designation of appropriate sites for surgical procedures of different levels of complexity is currently provided for within existing Hospital Group structures where appropriate sites for scheduled (elective) and unscheduled (emergency/urgent)

surgery are already designated. [Recommendation 1].

2. Adhering to a safe surgery practice checklist, to assist with the prevention and management of life threatening haemorrhage events, is covered by the 'Sign In, Time Out and Sign Out - Safe Surgery Checklist'.[15] The GDG confirmed that this Checklist is being updated as part of a wider project of the 'National Safe Surgery Policy Working Group' and a number of changes have been made to the checklist which incorporate the requirements from this Guideline [Recommendation 2].
3. 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, particularly for operative intervention in the chest, abdomen or pelvis. While this may represent a change to current practice, the nature of the consideration is likely to vary considerably by procedure and theatre. Therefore the resource impact has not been quantified in the BIA [Recommendation 4].
4. When any open or laparoscopic/operative intervention in the chest, abdomen or pelvis takes place, it is recommended that a number of criteria, relating to the availability of emergency group O blood and blood components, the availability and location (if relevant) of specific equipment, sterile vascular instruments and haemostatic products, and specific operational procedures, are confirmed in advance of the procedure to support adequate preparation in the event of an unexpected intraoperative life threatening haemorrhage. Confirmation of these criteria is in line with current practice [Recommendation 5].
5. Providing appropriate supervision and clinical support to surgical and anaesthesiology trainees in line with their experience and stage of training is recommended and is already current practice [Recommendation 6].
6. Laparoscopic skills training is already part of the curriculum for trainee surgeons and gynaecologists. Additionally, simulation drills, to include recognition and appropriate response to a life threatening haemorrhage event, are provided for trainee surgeons under the surgical training programme [Recommendation 7].
7. Following the trigger of the life threatening haemorrhage protocol it is recommended that there must be a clear mechanism to contact all relevant team members and a designated emergency coordinator should coordinate further management. This recommendation is current practice [Recommendation 9].
8. Recommended procedures to be undertaken in the event of a major vascular injury, are already current practice. These include urgent request for extra assistance and damage limiting methods in advance of assistance arriving, such as packing to reduce ongoing haemorrhage and pressure/compression or potentially exploring balloon tamponade/covered stenting of the bleeding vessel. [Recommendation 10].

9. In the event of a haemorrhage, the recommended tests (serial haemostatic tests, including full blood count (FBC), prothrombin time (PT), activated partial thromboplastic time (APTT) and fibrinogen or near-patient testing (NPT)), from before and after resuscitation, and frequency of testing (every 30 to 60 minutes depending on the severity of the haemorrhage) are currently conducted as part of standard practice [Recommendation 11].
10. Recommendations relating to the timely access to sufficient and appropriate blood components and products, including access to emergency Group O red cell components, the timeline to availability and systems to monitor use and ensure immediate replacement, are incorporated into current practice [Recommendation 12].
11. Recommendations regarding the administration and timing of thromboprophylaxis following life threatening haemorrhage events do not represent a change to current practice [Recommendation 13].
12. Two reviews are required following an unexpected life threatening haemorrhage; de-brief by the theatre team and a case review by a wider multi-functional team. In addition, these incidents may be reviewed by the Hospital Transfusion Committee (HTC) and by the OTC. Of these reviews, the meeting of the OTC is the only one that represents a change to current practice and therefore the other three have not been costed in the BIA. [Recommendation 14].
13. All hospitals to develop an arrangement so that in the circumstances of a life threatening haemorrhage event, an additional medical scientist can be called in out of hours to support the Transfusion Laboratory where necessary. Given that current arrangements, where in place, differ greatly between hospitals and are the responsibility of each individual hospital, it is not possible to estimate the overall impact of this recommendation. It therefore has not been costed in the BIA [Recommendation 16].
14. Where transfusion laboratories provide a transfusion service for offsite hospitals, it is recommended that a service level agreement (SLA) should identify the requirement and the timeline for provision of blood components at the offsite hospital. As SLAs are part of current practice this recommendation has not been costed in the BIA [Recommendation 17].

2.5 Target population

The *Unexpected Intraoperative Life Threatening Haemorrhage Guideline* will apply to patients undergoing interventions and operations where there is a risk of an unexpected intraoperative life threatening haemorrhage occurring. While not an uncommon problem in the clinical arena, there are no official statistics regarding its incidence. A systematic literature review was conducted in September 2019 to establish the incidence of intraoperative massive haemorrhage in Ireland (Annex B).[(4)] However, included studies referred to retrospective

reviews of patient information from specific surgical procedures (renal and bariatric surgery procedures), within discrete single institutions only. Population-level data were not identified from the grey literature or key data sources. Therefore, the review did not establish incidence rates of intraoperative massive haemorrhage in Ireland.[4] The recommendations outlined in the *Unexpected Intraoperative Life Threatening Haemorrhage Guideline* will provide all healthcare professionals working in acute clinical specialties where interventions and operations occur, with evidence based recommendations to assist with preventing, recognising, managing and responding to a life threatening haemorrhage event.

2.6 Summary of assumptions and data requirements for BIA

- In addition to the development of the National Life Threatening Haemorrhage Management poster, an update will be completed in year four of the BIA.
- Three faculty members will be trained annually, over the course of a single day, to provide simulation drills for life threatening haemorrhage events to trainee gynaecologists.
- A total of 80 trainee gynaecologists will participate in simulation drills for life threatening haemorrhage events annually, with a maximum of 16 trainees per training session.
- The multi-disciplinary drills will be rolled out to 25% of staff in year one, 25% in year two and the remaining 50% in year three.
- The time required to complete the multi-disciplinary drills is estimated to be 7.5 minutes.
- All relevant staff will be required to complete the multi-disciplinary drills twice per annum.
- The e-learning module will be rolled out in year two of the BIA with 50% of relevant staff completing the module in year two and 50% in year three.
- The time required to complete the e-learning module is estimated to be 25 minutes.
- All relevant staff will be required to complete the e-learning module every three years.
- OTC meetings will have 15 attendees, commence in year 1 and will be conducted virtually over the five year time horizon of the BIA.
- To enable medical scientists who support out of hours on-call activity, but who do not routinely work in the transfusion laboratory, to complete the recommended number of familiarisation days annually, 50% of the additional medical scientists required will be hired in year one and 50% in year two of the BIA.

3 Economic Model Inputs

3.1 National life threatening haemorrhage management poster

3.1.1 Poster design, printing and lamination

The GDG provided an indicative cost of €75 per hour for a graphic designer and it is estimated that nine hours will be required to design the poster. This cost will be incurred in year one of the BIA. It is assumed that an update of the poster will be required in year four and will require two hours' work of the graphic designer.

Posters will be distributed to all hospitals electronically and therefore will require printing and lamination locally. An extract from the National Theatre Report[16] for the week ending 28 March 2021 provides a figure of 220 operating theatres (excluding operating theatres at Children's Health Ireland, minor operating theatres and endoscopy suites). It is assumed that half of the posters (n=110) will be A1 size and half A2 size. Printing and lamination costs will be incurred in both year one and year four (following poster review) of the BIA. Inputs for estimating poster design, printing and lamination are detailed in Table 3.1.1.

Table 3.1.1: Unit costs and inputs for estimating the cost of poster development

Description	Detail	Units	Unit cost	Years(s) incurred	Source
Poster development					
Initial design	Graphic designer's time	9 hours	€75	Year 1	GDG
Update of poster		2 hours		Year 4	
Printing and lamination (pricing based on 30 posters per unit)	A1 posters (n=90)	3	€406*	Years 1 & 4	GDG
	A2 posters (n=90)	3	€234*	Years 1 & 4	GDG
Printing and lamination (pricing based on 20 posters per unit)	A1 posters (n=20)	1	€283*	Years 1 & 4	GDG
	A2 posters (n=20)	1	€172*	Years 1 & 4	GDG

* Indicative pricing obtained for printing and lamination of posters was provided on a per unit basis, based on 30 or 20 posters per unit. Given that 110 posters of each of A1 and A2 size are required, 3 units of 30 posters and 1 unit of 20 posters are required of each size.

3.2 Simulation drills for life threatening haemorrhage events for trainee gynaecologists

3.2.1 Faculty training

Faculty (obstetrician and gynaecology staff of the Royal College of Physicians of Ireland (RCPI)) will require training to enable them to deliver laparoscopy skills training and simulation drills for trainee gynaecologists. This training will be conducted on an annual basis, commencing in

year one of the BIA, and will take place over the course of a single day. It is assumed that three faculty members will be trained each year at one training session. The costs incurred in providing faculty training include an individual participant cost, hire of a simulation suite with dedicated technical support, hire of a double tutorial room with live audio visual stream for observers, consumables and personal protective equipment (PPE), and the provision of case programming (of manikins) with four simulation trials. The cost of case programming with four simulation trials is a one-off annual cost. It is assumed that faculty training is part of the role of faculty and therefore no opportunity cost is associated with the time spent receiving or providing training. Inputs for estimating the cost of faculty training are detailed in Table 3.2.1.

Table 3.2.1: Unit costs and inputs for estimating the cost of faculty training

Description	Detail	Units	Unit cost	Years(s) incurred	Source
Faculty training					
Participant cost	Cost per person	3	€200	Years 1-5	GDG
Simulation suite	Full day hire with dedicated technical support	1	€1,000	Years 1-5	GDG
Tutorial room	Full day hire with live audio visual stream for observers	1	€300	Years 1-5	GDG
Consumables and PPE	Cost per person	3	€10	Years 1-5	GDG
Case programming and trials (x4)	Case programming of manikins and running simulation trials	1	€400	Years 1-5	GDG

Key: PPE – personal protective equipment

3.2.2 Trainee gynaecologists training

Simulation drills for trainee gynaecologists will be conducted annually, with a maximum of 16 participants per training session. It is estimated that 80 trainees will require training each year (based on correspondence with the gynaecology training programme at the RCPI), therefore five training days will be provided annually. The costs incurred in providing the training include hire of a simulation suite with dedicated technical support, hire of a double tutorial room with live audio visual stream for observers, consumables and PPE. The cost of case programming is included in the faculty training costs above. Inputs for estimating the cost of skills training and simulation drills for trainees are detailed in Table 3.2.2.

Table 3.2.2: Unit costs and inputs for estimating the cost of simulation drills for life threatening haemorrhage events for trainee gynaecologists

Description	Detail	Units	Unit cost	Years(s) incurred	Source
Trainee training					
Simulation suite	Full day hire with dedicated technical support	5	€1,000	Years 1-5	GDG
Tutorial room	Full day hire with live audio visual stream for observers	5	€300	Years 1-5	GDG
Consumables and PPE	Cost per person	80	€10	Years 1-5	GDG

Key: PPE – personal protective equipment

3.3 Multi-disciplinary drills and e-learning module on the recognition and management of major blood loss

3.3.1 Training time for multi-disciplinary drills

The multi-disciplinary drills will take place bi-annually and the average time required to complete a drill is estimated at between five and ten minutes. It is assumed that the drills will commence for 25% of staff in year one of the BIA, a further 25% in year two and the remaining 50% in year three. The following staff will be required to take part in the drills:

- Consultant surgeons
- Consultant anaesthesiologists
- Theatre nurses and midwives
- Theatre porters
- Transfusion laboratory medical scientists
- Medical scientists who provide out of hours on-call cover for the transfusion laboratory, but do not routinely work there
- Senior house officers working in theatre
- Registrars working in theatre
- Interns working in theatre

Details of the number of staff required to participate in the drills and sources for these data are provided in Appendix 2. Salary costs are calculated using consolidated salary scales available from the Department of Health for public-sector employees.[17] As per HIQA guidelines, midpoint salaries scales are used and are adjusted to account for PRSI, pension costs and overheads.[13] Inputs for estimating the opportunity cost of staff time for participating in the multi-disciplinary drills are detailed in Table 3.3.1.

Table 3.3.1: Unit costs and inputs for estimating staff opportunity costs for completing the multi-disciplinary drills and e-learning module

Description	Salary Scale	Time input (minutes)	Unit cost (per minute)	Year(s) incurred	Source
Multi-disciplinary Drills: Opportunity cost of staff time					
Attendees – see below	See below	7.5	See below	25% Year 1 50% Year 2 100% Years 3-5	
E-learning Module: Opportunity cost of staff time					
Attendees – see below	See below	25	See below	50% in each of Years 2, 3 & 5	
Opportunity cost of staff time					
Consultant Anaesthesia (n=445)	Consultant contracts*	See above	€3.05	See above	(17)
Consultant Surgery (n=592)	Consultant contracts*		€3.05		
Theatre Nurse/Midwife (n=1,647)	Staff nurse/midwife		€0.59		
Clinical Nurse/Midwife Manager I (n=359)	Clinical Nurse Manager I		€0.76		
Clinical Nurse/Midwife Manager II (n=36)	Clinical Nurse Manager II		€0.83		
Clinical Nurse/Midwife Manager III (n=4)	Clinical Nurse Manager III		€0.95		
Clinical Nurse/Midwife Specialist (n=89)	Clinical Nurse/Midwife Specialist		€0.83		
Advanced Nurse/Midwife Practitioner (n=41)	Advanced Nurse/Midwife Practitioner		€0.99		
Theatre Porter (n=212)	Theatre Porter/ Attendants (Dublin and non-Dublin) **		€0.48		
Transfusion Laboratory Medical Scientist (n=155)	Medical Scientist		€0.69		
Transfusion Laboratory Senior Medical Scientist (n=71)	Senior Medical Scientist with and without NFQ Level 9**		€0.89		
Transfusion Laboratory Chief Medical Scientist (n=22)	Chief Medical Scientist		€1.13		
Non-Transfusion Laboratory Medical Scientist (n=128)	Medical Scientist		€0.69		
Non-Transfusion Laboratory Senior Medical Scientist (n=95)	Senior Medical Scientist with and without NFQ Level 9**		€0.89		
Non-Transfusion Laboratory Chief Medical Scientist (n=23)	Chief Medical Scientist		€1.13		

Description	Salary Scale	Time input (minutes)	Unit cost (per minute)	Year(s) incurred	Source
Senior House Officer (n=847)	Senior House Officer		€0.80		
Intern (n=443)	Intern		€0.57		
Registrar (n=685)	Registrar		€0.94		
Senior Registrar (n=43)	Senior Registrar		€1.14		
Specialist Registrar (n=464)	Specialist Registrar		€1.06		

* The mid-point for a consultant's salary has been calculated as the mean of the mean values of 'consultant categories' and 'contract type'.
** Where multiple salary scales are listed for one role, the mid-point has been calculated as the mean of the mid-points for the scales listed.
Key: NFQ-National Framework of Qualifications.

3.3.2 Training material for e-learning module

The estimated cost of developing the new training module on recognising, responding to and managing major blood loss has been estimated at €35,000 (Table 3.3.2). This has been provided by the GDG and is based on the development cost of an e-learning module for Paediatric Sepsis. This is a one-off cost, incurred in year two of the BIA.

Table 3.3.2: Unit costs and inputs for estimating the cost of developing an e-learning module

Description	Detail	Unit(s)	Unit cost	Years(s) incurred	Source
E-Learning: Module Development					
Training Material (Recognition, response to and management of major blood loss)	Development of new e-learning module	1	€35,000	Year 2	GDG

3.3.3 Training time for e-learning module

The estimated time required to complete the e-learning module is 25 minutes. The module will be rolled out in year two of the BIA with 50% of relevant staff completing the module in year two and 50% in year three. All relevant staff will be required to complete the module every three years. The opportunity cost associated with completing the training is determined using salary costs and the following staff will be required to complete the module:

- Consultant surgeons
- Consultant anaesthesiologists
- Theatre nurses and midwives
- Theatre porters
- Transfusion laboratory medical scientists
- Medical scientists who provide out of hours on-call cover for the transfusion laboratory, but do not routinely work there
- Senior house officers working in theatre

- Registrars working in theatre
- Interns working in theatre

Details of the number of staff required to participate in the drills and sources for these data are provided in Appendix 2. Inputs for estimating staff opportunity costs for completing the e-learning module are detailed in Table 3.3.1.

3.4 Overarching Transfusion Committees

3.4.1 Meeting time

A total of seven OTCs will be formed nationally. Each OTC will have 15 members, meeting twice a year, with the duration of each meeting estimated to be 1.5 hours. The opportunity cost of the time associated with attending the meeting are determined using salary costs. The membership of each OTC will include one of each of the staff listed below, with the exception of the Consultant Haematologist with responsibility for Blood Transfusion, where two staff members will be required to attend:

- Chief Hospital Pharmacist
- Chief/ Senior Medical Scientist Hospital Transfusion Laboratory
- Clinical Director
- Consultant Emergency Medicine
- Consultant Haematologist (two required) with responsibility for Blood Transfusion
- Consultant Obstetrics and Gynaecology
- Consultant Paediatrics/Neonatology
- Director of Surgery (Consultant)
- Director of Anaesthesiology (Consultant)
- Director of Nursing/Midwifery
- Haemovigilance Officer (Clinical Nurse Manager 2 or Senior Medical Scientist)
- Operations Manager (Grade VII or Grade VIII Clerical)
- Perioperative Director (Consultant)
- Quality and Risk Management (Grade VII or Grade VIII Clerical)

It is assumed that meetings of the OTCs will commence in year 1 of the BIA and will be conducted virtually over the five year time horizon of the BIA. Inputs for estimating staff opportunity costs for attending the OTCs are detailed in Table 3.4.1.

Table 3.4.1: Unit costs and inputs for estimating staff opportunity costs for attending an Overarching Transfusion Committee meeting

Description	Salary Scale	Time input (minutes)	Unit cost (per minute)	Years(s) incurred	Source
Overarching Transfusion Committee: Opportunity cost of staff time					
Chief Hospital Pharmacist (n=1)	Chief I or II*	90	€1.29	Years 1-5	(17)
Chief/Senior Medical Scientist Transfusion Laboratory (n=1)	Chief or Senior Medical Scientist*	90	€0.98	Years 1-5	
Clinical Director (n=1)	Group Manager (Clinical Director)	90	€3.32	Years 1-5	
Consultant Emergency Medicine (n=1)	Consultant^	90	€3.05	Years 1-5	
Consultant Haematologist with responsibility for Blood Transfusion (n=2)	Consultant^	90	€3.05	Years 1-5	
Consultant Obstetrics and Gynaecology (n=1)	Consultant^	90	€3.05	Years 1-5	
Consultant Paediatrics/Neonatology (n=1)	Consultant^	90	€3.05	Years 1-5	
Director of Anaesthesiology (n=1)	Consultant^	90	€3.05	Years 1-5	
Director of Nursing/Midwifery (n=1)	Hospital Group Director of Nursing and Midwifery	90	€1.72	Years 1-5	
Director of Surgery (n=1)	Consultant^	90	€3.05	Years 1-5	
Haemovigilance Officer (n=1)	Clinical Nurse Manager 2 or Senior Medical Scientist*	90	€0.77	Years 1-5	
Operations Manager (n=1)	Grade VII or VIII Clerical*	90	€1.04	Years 1-5	
Perioperative Director (n=1)	Consultant^	90	€3.05	Years 1-5	
Quality and Risk Management (n=1)	Grade VII or VIII Clerical*	90	€1.04	Years 1-5	

* Where multiple salary scales are listed for one role, the mid-point has been calculated as the mean of the mid-points for the scales listed.
^ The mid-point for a consultant's salary has been calculated as the mean of the mean values of 'consultant categories' and 'contract type'.

3.5 Familiarisation days for medical scientists supporting out of hours transfusion laboratory activity

3.5.1 Staff posts

Data collected from two surveys, both conducted by the GDG (National Blood Transfusion Laboratory Survey 2019[18] and Hospital Transfusion Laboratory Survey 2021[19]), were used to estimate the whole time equivalent (WTE) required per annum to provide cover to enable medical scientists who support out of hours in the transfusion laboratory (but who do not routinely work there) to complete the recommended familiarisation. These surveys provided the following data:

- the number of medical scientists in each hospital who support out of hours in the

transfusion laboratory but do not routinely work there.

- the number of familiarisation days currently provided to each medical scientist who supports out of hours cover for the transfusion laboratory but does not routinely work there.

Based on the recommended 10 days familiarisation per medical scientist per annum, and using the data described above, the total number of familiarisation days required, but not currently provided each year, is estimated at 2,132. This total converts to a WTE figure of 9.6, assuming 224 working days (260 week days less 11 public and bank holidays less 25 days annual leave) in a calendar year for the medical scientist grade. The 9.6 WTE figure is used to estimate the cost of additional staff. It is assumed that 50% of the required staff are hired in year one and 50% in year two of the BIA. The direct cost associated with hiring additional staff is determined using salary costs. Inputs for estimating these costs are provided in Table 3.5.1.

Table 3.5.1: Unit costs and inputs for estimating staff recruitment costs

Description	Salary Scale	Units	Unit cost	Years(s) incurred	Source
Familiarisation: Recruitment of additional staff					
Additional Medical Scientists to support completion of recommended 10 days familiarisation	Medical Scientist	9.6WTE	€64,205	50% Year 1 100% Years 2 - 5	(17)

4 Analysis

Activities related to the introduction of the guideline that are associated with an increased cost to the HSE, and which are included in this BIA, are detailed below by intervention.

4.1 National life threatening haemorrhage management poster

The costs associated with developing, producing and updating the national life threatening haemorrhage poster are provided in Table 4.1.1 below and include the following:

- Poster design and update
- Printing and lamination

Table 4.1.1: Cost of national life threatening haemorrhage poster

Item	Description	Cost (€) Year 1	Cost (€) Year 2	Cost (€) Year 3	Cost (€) Year 4	Cost (€) Year 5	Total (€) Years 1-5
Cost of Poster							
Poster	Design and update	675	0	0	150	0	825
	Printing and Lamination	2,374	0	0	2,374	0	4,748
Total cost (€)		**3,049**	**0**	**0**	**2,524**	**0**	**5,573**

From year one, the poster will be displayed in an estimated 220 operating theatres across Ireland.

4.2 Simulation drills for life threatening haemorrhage events for trainee gynaecologists

The costs associated with providing simulation drills for trainee gynaecologists are provided in table 4.2.1 and include the following:

- Faculty training
- Trainee training

Table 4.2.1: Cost of simulation drills for trainee gynaecologists

Item	Description	Cost (€) Year 1	Cost (€) Year 2	Cost (€) Year 3	Cost (€) Year 4	Cost (€) Year 5	Total (€) Years 1-5
Cost of Simulation Drills							
Faculty Training	Participant cost	600	600	600	600	600	3,000
	Simulation suite	1,000	1,000	1,000	1,000	1,000	5,000
	Tutorial room with live audio visual stream	300	300	300	300	300	1,500
	Consumables and PPE	30	30	30	30	30	150
	Case programming and trial (x4)	400	400	400	400	400	2,000
Total cost of faculty training (€)		**2,330**	**2,330**	**2,330**	**2,330**	**2,330**	**11,650**
	Simulation suite	5,000	5,000	5,000	5,000	5,000	25,000

Item	Description	Cost (€) Year 1	Cost (€) Year 2	Cost (€) Year 3	Cost (€) Year 4	Cost (€) Year 5	Total (€) Years 1-5
Trainee Training	Tutorial room with live audio visual stream	1,500	1,500	1,500	1,500	1,500	7,500
	Consumables and PPE	800	800	800	800	800	4,000
Total cost of trainee training (€)		**7,300**	**7,300**	**7,300**	**7,300**	**7,300**	**36,500**
Total cost of Simulation Drills (€)		**9,630**	**9,630**	**9,630**	**9,630**	**9,630**	**48,150**

Key: PPE - personal protective equipment

It is estimated that a total of 15 faculty members will be trained and 400 trainee gynaecologists will attend simulation drills over the five year time horizon of the BIA (Table 4.2.2).

Table 4.2.2: Impact of simulation drills for trainee gynaecologists

Item	Year 1	Year 2	Year 3	Year 4	Year 5	Years 1-5
Impact of Simulation Drills						
Number of faculty attending training	3	3	3	3	3	15
Number of trainees attending drills	80	80	80	80	80	400

4.3 Multi-disciplinary drills and an e-learning module in the recognition and management of major blood loss

The costs associated with providing multi-disciplinary drills and an e-learning module on the recognition and management of major blood loss are provided in Table 4.3.1 below and include:

- Opportunity cost of staff time required to complete the drills
- Development of the e-learning module
- Opportunity cost of staff time required to complete the e-learning module

Table 4.3.1: Cost of multi-disciplinary drills and e-learning module

Item	Description	Cost (€) Year 1	Cost (€) Year 2	Cost (€) Year 3	Cost (€) Year 4	Cost (€) Year 5	Total (€) Years 1-5
Cost of Multidisciplinary Drills							
Multidisciplinary Drills	Staff time	26,858	53,716	107,432	107,432	107,432	402,868
Cost of E-learning Module							
E-Learning Module	Development	0	35,000	0	0	0	35,000
	Staff time	0	78,498	78,498	0	78,498	235,495
Total cost of E-learning Module (€)		**0**	**113,498**	**78,498**	**0**	**78,498**	**270,495**
Total cost of Multidisciplinary Drills & E-learning Module (€)		**26,858**	**167,214**	**185,930**	**107,432**	**185,930**	**673,364**

The estimated number of staff who will complete the drills and e-learning module each year are provided in Table 4.3.2 below.

Table 4.3.2: Impact of multi-disciplinary drills and e-learning module

Item	Year 1	Year 2	Year 3	Year 4	Year 5	Years 1-5
Impact of Multidisciplinary Drills & E-Learning						
Number of staff attending drills	1,600	3,200	6,401	6,401	6,401	24,004
Number of staff completing e-learning module	0	3,200	6,401	6,401	6,401	22,403

While employment reports and expert opinion from the GDG were used to estimate the number of relevant staff for this recommendation, there is some uncertainty with the numbers. A one-way sensitivity analysis was conducted where the number of relevant staff was varied by ±20%. When the numbers at full roll-out were increased by 20%, the annual opportunity cost associated with the multi-disciplinary drills and e-learning increased from €107,000 and €78,500 to €128,500 and €94,000 respectively, while decreasing the numbers by 20% reduced the annual cost to €85,500 and €63,000 respectively.

4.4 Overarching Transfusion Committees

The cost of one OTC meeting, comprising the opportunity cost of staff time for those attending the committee is estimated at €2,902. With two meetings per OTC per annum, the annual cost of each OTC is €5,804. The total cost for the seven OTCs over the five years of the BIA is provided in Table 4.4.1 below.

Table 4.4.1: Cost of Overarching Transfusion Committees

Item	Description	Cost (€) Year 1	Cost (€) Year 2	Cost (€) Year 3	Cost (€) Year 4	Cost (€) Year 5	Total (€) Years 1-5
Cost of OTC meetings							
OTC Meetings	Committee members' time	40,634	40,634	40,634	40,634	40,634	203,170
Total cost (€)		**40,634**	**40,775**	**40,634**	**40,634**	**40,634**	**203,170**

Note: Figures in the table are rounded.
Key: OTC – Overarching Transfusion Committee

In total, there will be 14 OTC meetings annually and 70 over the five years of the BIA.

4.5 Familiarisation days for medical scientists supporting out of hours transfusion laboratory activity

The costs associated with supporting the completion of the recommended number of familiarisation days for medical scientists who support out of hours in the transfusion laboratory, but do not routinely work there, comprise the cost of hiring additional medical scientists to provide cover and ensure that day-to-day work in the laboratories releasing staff is not impacted. The costs associated with hiring additional staff are provided in Table 4.5.1 below.

Table 4.5.1: Cost of Familiarisation

Item	Description	Cost (€) Year 1	Cost (€) Year 2	Cost (€) Year 3	Cost (€) Year 4	Cost (€) Year 5	Total (€) Years 1-5
Cost of Familiarisation							
Staff posts	Medical Scientists (n=9.6)	308,433	616,866	616,866	616,866	616,866	2,775,895
Total cost (€)		**308,433**	**616,866**	**616,866**	**616,866**	**616,866**	**2,775,895**

Note: Figures in the table are rounded.

The annual cost of one WTE medical scientist is estimated at €64,205 and the annual cost of 9.6 WTEs is estimated at €617,000. Hiring 9.6 WTE medical scientists would address the current shortfall of 2,132 familiarisation days per annum. However, the figure of 9.6 WTEs is a cumulative figure across 24 hospitals, where the estimated WTEs required to address the shortfall ranges from 0.1 WTE to 1.2 WTEs. In recognising that hiring 0.1 WTE is not feasible, a scenario analysis was conducted where individual hospital WTE requirements were rounded up or down to the nearest 0.5 WTE. This resulted in a cumulative requirement of 13 WTEs across the 24 hospitals, with an annual cost of €835,000 and a total budget impact over five years of €3.8 million (assuming 50% are hired in year one and 50% in year two). The timing and annual impact of this cost will be dependent on identifying the staff requirement at an individual hospital level, securing funding to support the posts and the associated recruitment timeline.

5 Results

5.1 Overall budget impact

The overall budget impact of the Unexpected Intraoperative Life Threatening Haemorrhage Guideline was estimated at €3.7 million over five years, of which 77.3% (€2.86 million) related to direct costs and 22.7% (€842k) to the opportunity cost of staff time for training and committee attendance. This estimate includes:

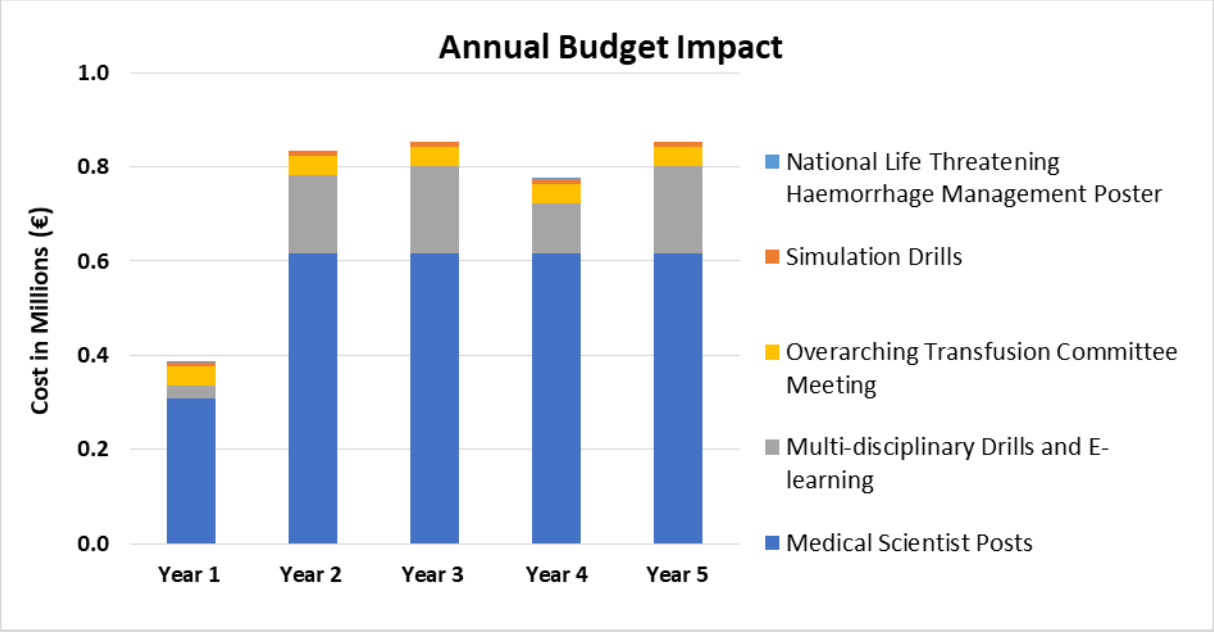
- Development, distribution and review of the national life threatening haemorrhage management poster.
- Provision of simulation drills for life threatening haemorrhage events annually for trainee gynaecologists.
- Provision of bi-annual multi-disciplinary drills and an e-learning module on the recognition and management of major blood loss for all staff working in operating theatres and medical scientists involved in a life threatening haemorrhage, including those providing out of hours cover.
- Bi-annual meetings of seven OTCs.
- Appointment of 9.6 WTE medical scientists to support the completion of the recommended number of familiarisation days for those medical scientists who do not routinely work in the transfusion laboratory but who do support out of hours on-call activity.

The annual costs applicable to each intervention are summarised in Table 5.1.1 and illustrated in Figure 5.1.1 below.

Table 5.1.1: Incremental budget impact over a five year time horizon

Intervention	Cost (€) Year 1	Cost (€) Year 2	Cost (€) Year 3	Cost (€) Year 4	Cost (€) Year 5	Total (€) Years 1-5
Medical Scientist Posts	308,301	616,603	616,603	616,603	616,603	2,774,712
Multi-disciplinary Drills and E-learning	26,858	167,214	185,930	107,432	185,930	673,364
Overarching Transfusion Committee Meeting	40,634	40,634	40,634	40,634	40,634	203,170
Simulation Drills	9,630	9,630	9,630	9,630	9,630	48,150
National Life Threatening Haemorrhage Management Poster	3,049	0	0	2,524	0	5,573
Total Cost (€)	**388,472**	**834,081**	**852,797**	**776,822**	**852,797**	**3,704,968**

Figure 5.1.1: Incremental budget impact of Unexpected Intraoperative Life Threatening Haemorrhage Clinical Guideline



5.2 Budget impact according to each intervention

In descending order, the budget impact of each intervention is provided in further detail below.

5.2.1 Familiarisation days for medical scientists supporting out of hours transfusion laboratory activity

The largest budget impact, totalling €2.8 million (74.9% of total budget impact), was estimated for hiring additional medical scientists to provide cover and enable the recommended annual familiarisation (10 days) to be completed by medical scientists who do not routinely work in the transfusion laboratory, but who support out of hours on-call activity. It has been estimated that across 24 laboratories there is currently an annual shortfall of 2,132 familiarisation days when compared with the recommended ten days familiarisation per medical scientist per year. Hiring an additional 9.6 WTE medical scientists would enable this shortfall to be addressed. However, the scenario analysis, where the estimated FTE requirement for each hospital was rounded up or down to nearest 0.5 WTE, indicated that this requirement could be up to 13 WTEs.

5.2.2 Multi-disciplinary drills and an e-learning module on the recognition and management of major blood loss

The total incremental cost of the bi-annual multi-disciplinary drills for theatre staff and medical scientists involved in a life threatening haemorrhage event and the development and

roll-out of the e-learning module was estimated at €0.67 million, 18.2% of total budget impact. This largely comprised (95%) the opportunity cost of time spent participating in the drills (€403k) and completing the e-learning module (€235K). The remaining 5% was the development cost of the module (€35k). Once the programmes have been fully rolled out, it has been estimated that 6,401 members of staff will complete both the drills and the e-learning module annually.

5.2.3 Overarching Transfusion Committees

The opportunity cost of committee members attending bi-annual OTC meetings was estimated at €200,000 (5.5% of total budget impact). This cost was estimated based on 15 committee members attending each of 14 meetings per annum and a total of 70 meetings over the time horizon of the BIA.

5.2.4 Simulation drills for life threatening haemorrhage events for trainee gynaecologists

The direct cost associated with providing simulation drills for trainee gynaecologists was estimated at €48,000 (1.3% of total budget impact). This comprised the cost of training for an estimated 400 trainees (75.8%) and 15 faculty members (24.2%) over the five year time horizon of the BIA.

5.2.5 National life threatening haemorrhage management poster

The direct cost associated with designing, distributing and updating the national life threatening haemorrhage management poster was estimated at €5,600 (0.2% of total budget impact). The poster will be displayed in an estimated 220 operating theatres across the country.

6 Discussion

Intraoperative massive haemorrhage has the potential for significant morbidity and mortality.[6] Surgical care, and specifically care provided in operating theatres, is associated with a notably high incidence of adverse events,[8] with haemorrhage being a frequently encountered complication.[9] 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.[10] However, until now there has been no guidance in Ireland to inform practice where there is a risk that an unexpected intraoperative life threatening haemorrhage can occur. The recommendations outlined in the *Unexpected Intraoperative Life Threatening Haemorrhage Guideline* will provide all healthcare professionals working in acute clinical specialties where interventions and operations occur, with recommendations to assist with preventing, recognising, managing and responding to a life threatening haemorrhage event.

It is recommended that medical scientists who support out of hours transfusion laboratory activity, but who do not routinely work there, undertake ten supervised dedicated familiarisation days annually to ensure the appropriate skill set, including in relation to unexpected life threatening haemorrhage. Currently there is a significant shortfall (estimated 2,132 days) in the number of familiarisation days provided to an estimated 246 medical scientists who do not routinely work in the transfusion laboratory but who do provide out of hours support to on-call activity. This BIA demonstrates that an additional 9.6 WTE medical scientists are required to provide cover to enable all 246 medical scientists to complete the recommended ten familiarisation days in the transfusion laboratory. The annual staff cost per WTE is estimated at €64,000 with a total direct annual cost of €617,000 for 9.6 WTEs. The budget impact of these staff posts over the course of the BIA has been estimated at €2.8 million. However, the figure of 9.6 WTEs is a cumulative figure across 24 hospitals, where the estimated WTEs required to address the shortfall ranges from 0.1 WTE to 1.2 WTEs. In recognising that hiring 0.1 WTE is not feasible, a scenario analysis was conducted where individual hospital WTE requirements were rounded up or down to the nearest 0.5 WTE. This resulted in a cumulative requirement of 13 WTEs, with an annual cost of €835,000 and a total budget impact over five years of €3.8 million (assuming 50% are hired in year one and 50% in year two). The timing and annual impact of this cost will be dependent on identifying the staffing requirements at an individual hospital level, securing funding to support the posts and the associated recruitment timeline.

The opportunity cost of staff time associated with both the multi-disciplinary drills and the e-learning module has been estimated at €638,000 over the five years of the BIA. The annual cost when both are fully rolled out has been estimated at €107,000 for the multi-disciplinary drills and €78,500 for the e-learning module. In both cases, it has been estimated that a total of 6,401 theatre and laboratory staff will attend the drills and complete the module as

required. A one-way sensitivity analysis was conducted where the number of relevant staff was varied by 20%. Increasing the number of staff by 20% at full roll-out, would result in the annual opportunity cost of both the drills and e-learning module rising to €222,500, while decreasing the numbers by 20% would reduce the annual cost to €148,500.

The incremental cost associated with the OTCs solely comprises the opportunity cost of staff time required to attend the meetings. At an estimated cost of €3,000 per OTC, the annual incremental cost for 14 OTCs was estimated at €40,500 and the total incremental cost of 70 OTCs over the course of the BIA, was estimated at €203,000. This estimate is based on an assumption that each OTC will have 15 members and therefore may be subject to change when the composition of each OTC is finalised.

The provision of simulation drills for life threatening haemorrhage events to trainee gynaecologists represents a direct cost in the BIA. While this training is already provided to trainee surgeons as part of the surgical training programme, extending the simulation drills to trainee gynaecologists is required to ensure that they have the skills to recognise and respond appropriately to a life threatening haemorrhage event. The annual incremental cost associated with this training was estimated at €9,500 with a total incremental cost of €48,000. The incremental cost of €5,600 associated with the initial development and update of the national life threatening haemorrhage management poster also represents a direct cost.

There are a number of limitations associated with this BIA. The rarity of unexpected intraoperative massive haemorrhage events presents difficulty in providing robust evidence to underpin the clinical and cost-effectiveness of the guideline recommendations. Therefore, no benefits or associated cost savings have been included in the BIA. However, in the context of severe morbidity and mortality that can result from intraoperative massive haemorrhage,[(6)] there are potential savings from successful management and or mitigation, where the guideline will provide guidance to theatre teams and associated healthcare professionals on the recommended practices for the recognition, response to and management of unexpected intraoperative life threatening haemorrhage.

There are three guideline recommendations where variations in current practice have impacted on identifying if the recommendation represents a change to current practice. As a result, there are potential additional costs (both direct costs and opportunity costs) associated with the implementation of the guideline that are not included in the BIA. There is considerable variation in current pre-operative assessment practice between both individual theatres and procedures, therefore identifying if Recommendation 4 represents a change to current practice is difficult, and quantifying the opportunity cost associated with the time taken to conduct the assessment in line with the recommendation has not been possible. While Recommendation 12 largely does not represent a change to current practice, there may be a cost associated with introducing massive haemorrhage packs as part of blood component

support for life threatening haemorrhage. However, given the use of such packs is not mandatory and practice varies across hospitals, it has not been possible to identify where this recommendation would represent a change to current practice and to quantify the direct cost associated with its introduction. Lastly, current arrangements for additional out of hours medical scientist support for a transfusion laboratory are the responsibility of each individual hospital and practice differs between hospitals. Given this variability, it has not been possible to identify where Recommendation 16 would represent a change to current practice and to quantify the associated direct cost.

The BIA is costed based upon the implementation plan developed by the GDG. However, as funding has not yet been secured for those recommendations with a direct cost, that is, the hiring of additional medical scientists, providing simulation drills for trainee gynaecologists, development of an e-learning module and development and distribution of the national life threatening haemorrhage poster, the timelines of the anticipated costs should be regarded as estimates and considered to represent the anticipated rollout which may change over time. While 9.6 WTEs has been estimated as the base case requirement to enable medical scientists to complete recommended familiarisation, this is a cumulative number across 24 hospitals and therefore is subject to revision based on individual hospital laboratory requirements. Costs for the OTC are based on virtual meetings and while it is recognised that this may change over the five years, consideration of a change to in-person meetings should incorporate the additional costs associated with this change. The cost of providing simulation drills for life threatening haemorrhage events for trainee gynaecologists is driven by the estimated number of faculty and trainees requiring training. Any future changes in these numbers and the timing of such changes will impact these costs. While the cost of one review of the national life threatening haemorrhage management poster has been included in these estimates, any further reviews will incur additional costs. Furthermore, while estimates were determined based on best available data and expert opinion of the GDG, these data and assumptions underpinning the BIA are subject to change.

6.1 Conclusion

The budget impact of the *Unexpected Intraoperative Life Threatening Haemorrhage Guideline* was estimated at €3.7 million over a five year period. Direct costs totalled €2.86 million (77.3%) and opportunity costs totalled €0.84 million (22.7%). The majority of the total cost (74.9%) provides for hiring additional medical scientists to support eliminating the current shortfall in the recommended number of familiarisation days for those medical scientists who do not routinely work in the transfusion laboratory but who support out of hours on-call activity. The opportunity costs account for time spent away from usual duties to participate in the OTCs and in training for theatre staff and medical scientists in recognising, responding to and managing major blood loss.

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Appendix 1: National clinical guideline recommendations

No.	Recommendation	BIA Implications
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.	None. The GDG has confirmed that structures are already in place to designate the appropriate sites for scheduled (elective) and unscheduled (emergency /urgent) surgery.[20, 21] Therefore this recommendation is not included in the BIA.
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).	None. The Safe Surgery Checklist[15] is currently being updated as part of a wider project of the 'National Safe Surgery Policy Working Group' and the GDG has confirmed that the update incorporates the requirements from this Guideline. The GDG has also confirmed that clinical teams are already familiar with the 'Safe Surgery Checklist'. Therefore this recommendation is not included in the BIA.
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.	The cost of developing and displaying a National Life Threatening Haemorrhage Management Poster for the operating theatres of all hospitals is included in the BIA.
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.	None. While this recommendation may represent a change to current practice, the GDG has confirmed that the nature of the consideration is likely to vary considerably by procedure and theatre and therefore its impact cannot be quantified.

No.	Recommendation	BIA Implications
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 a 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.	None. The GDG has confirmed that this recommendation does not represent a change to current standard practice and therefore it is not costed in the BIA.

No.	Recommendation	BIA Implications
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.	None. Per the guideline recommendation, it is acknowledged that all hospitals have trainee surgeons, gynaecologists and anaesthesiologists and this model is essential for the delivery and development of the health service. Within the health system currently, many out of hours emergency cases are managed by trainees. Under current practice, the consultant surgeon and anaesthesiologist are responsible for ensuring the individuals performing the procedure are receiving the correct level of supervision in line with their experience and stage of training is recommended and is already current practice. Therefore this recommendation is not included in the BIA.
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.	The cost of providing simulation drills, to include recognition and appropriate response to a life threatening haemorrhage event, for all trainee gynaecologists undertaking laparoscopic procedures during the course of their training is included in the BIA. Given that trainee surgeons already receive this training, the cost of providing it is not included in the BIA. Additionally, laparoscopic skills training is already part of the curriculum for trainee surgeons and gynaecologists and therefore the cost of providing this training is not included in the BIA.

No.	Recommendation	BIA Implications
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.	The cost of providing regular multi-disciplinary drills and an e-learning module to support recognition, response to and management of major blood loss for all staff working in theatre and the transfusion laboratory is included in the BIA.
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.	None. The GDG has confirmed that this is currently standard practice. Therefore this recommendation is not included in the BIA.
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.	None. The GDG has confirmed that this is currently standard practice. Therefore this recommendation is not included in the BIA.
11	Serial haemostatic tests, including FBC (Hb, platelet count), PT, APTT and fibrinogen or compliant near patient testing (NPT), from before and after resuscitation should be taken every 30–60 minutes depending on the severity of the haemorrhage. The results of these tests will guide and ensure the appropriate use of blood components. Calcium must also be monitored and replaced as appropriate.	None. The GDG has confirmed that required tests and frequency of testing recommended in the event of haemorrhage are currently conducted as part of standard practice. Therefore this recommendation is not included in the BIA.

<table>
<tr><th>No.</th><th>Recommendation</th><th>BIA Implications</th></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. 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. Aim to keep >50 x 10^9/l (≥100 x 10^9/l in the case of brain/critical site bleeding).</td></tr>
<tr><td>Fibrinogen Concentrate</td><td>Guided by fibrinogen levels or viscoelastic haemostatic monitoring. Trigger 1.5 g/l. A dose of 4g will increase fibrinogen by 1 g/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 Packs</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>None.
The GDG has confirmed that with the exception of the use of ‘Massive Haemorrhage Packs’, this recommendation does not represent a change to current practice. The GDG has advised that the practice of using ‘Massive Haemorrhage Packs’ is not applied across all hospitals. Additionally, there is one component (platelets) of the Massive Haemorrhage Pack that has a limited shelf life. Therefore, if this practice is to be introduced as a result of this guideline, there is a potential cost associated with component wastage if the packs are not used. However, given that practice currently varies between hospitals and past wastage has not been monitored, it is not possible to quantify the potential future wastage associated with employing ‘Massive Haemorrhage Packs’. Therefore this recommendation is not included in the BIA.</td></tr>
</table>

No.	Recommendation	BIA Implications
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.	None. Per the GDG, recommendations with regard to the administration and timing of thromboprophylaxis following life threatening haemorrhage events do not represent a change to current practice. Therefore this recommendation is not included in the BIA.
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 Hospital Transfusion Committee (HTC). In addition such incidents may be part of: • Periodic Audit by the HTC reviewing overall trends, outcomes and processes for life threatening haemorrhage events. • All HTCs will feed into an Overarching Transfusion Committee (OTC). The OTC will review and benchmark unexpected life threatening haemorrhage events - overall trends, outcomes and processes.	The establishment of the OTCs (seven committees nationally) is the only change to current practice arising from this recommendation. The cost of running the OTCs to review and benchmark unexpected life threatening haemorrhage events including overall trends, outcomes and processes, is included in the BIA.

No.	Recommendation	BIA Implications
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.	In order to facilitate medical scientists undertaking the recommended 10 familiarisation days annually, and to ensure that work in their laboratory is not impacted by their absence, additional headcount will be required. The cost of hiring additional medical scientists is included in the BIA.
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 Transfusion Laboratory where necessary.	None The GDG has confirmed that current arrangements, where in place, differ greatly between hospitals and are the responsibility of each individual hospital. Therefore it is not possible to estimate the budget impact of this 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.	None. The GDG has confirmed that Service Level Agreements are part of current practice and therefore this recommendation is not included in the BIA.

Appendix 2: Staff numbers and salary mean/midpoint for Recommendation 8

Staff Posts	Headcount for Hospital Groups (if used in calculations)[22]	Theatre and Transfusion Laboratory Headcount for Recommendation 8 of BIA	Salary Scale Mean/Mid-point[17]
Consultants			
Consultant Surgeon	445	445	€199,015[‡]
Consultant Anaesthesiologist	592	592	€199,015[‡]
Registrars			
Registrar	2,001	685[*]	€63,201
Senior Registrar	127	43[*]	€76,801
Specialist Registrar	1,356	464[*]	€71,488
SHOs and Interns			
SHO	2,473	847[*]	€53,493
Intern	1,294	443[*]	€38,252
Theatre Nurses			
Staff Nurse/Midwife	N/A	1,647[**]	€39,317
Clinical Nurse/Midwife Manager I	N/A	359[**]	€50,798
Clinical Nurse/Midwife Manager II	N/A	36[**]	€54,920
Clinical Nurse/Midwife Manager III	N/A	4[**]	€63,251
Clinical Nurse/Midwife Specialist	N/A	89[**]	€54,920
Advanced Nurse/Midwife Practitioner	N/A	41[**]	€65,862
Medical Scientists			
Medical Scientist (Transfusion Laboratory)	N/A	155[^]	€45,943
Senior Medical Scientist (Transfusion Laboratory)	N/A	71[^]	€58,427[‡‡]
Chief Medical Scientist (Transfusion Laboratory)	N/A	22[^]	€73,184
Medical Scientist (Non-Transfusion Laboratory)[†]	N/A	128[†]	€45,943
Senior Medical Scientist (Non-Transfusion Laboratory)[†]	N/A	95[†]	€58,427[‡‡]
Chief Medical Scientist (Non-Transfusion Laboratory)[†]	N/A	23[†]	€73,184
Others			
Porters	1,412	706[††]	€32,625[‡‡]

[*]Figure for the % of WTE consultants in surgery and anaesthesia (34.2%) within the Hospital Groups (excluding Children's Health Ireland) was applied to the total number of registrars, SHOs and interns (per the Hospital Group Employment Reports) to estimate how many work in surgery.

[**]A figure of 2,000 theatre nurses for the non-maternity hospitals and a figure of 176 theatre nurses/midwives for maternity hospitals were provided by the GDG. The split by grade was estimated using proportions calculated from the Hospital Group Employment Reports.[22]
[^]Numbers sourced from the GDG's Hospital Laboratory Survey2019.[18]
[†]Medical scientists who do not routinely work in the transfusion laboratory but support out of hours on-call activity. Numbers sourced from the GDG's Hospital Transfusion Laboratory Survey. 2021.[19]
[††]Assumed that the number of theatre porters is 15% of total number of porters based on numbers from CUH and expert opinion from the GDG.
[‡]Mean salary for a consultant calculated as the mean across all 'consultant categories' and 'contract types'.
[‡‡]Where multiple salary scales are listed for one role, the mid-point has been calculated as the mean of the mid-points for the scales listed.

Key: GDG – Guideline Development Group; HSE – Health Service Executive; SHO – Senior house officer; WTE – whole time equivalent;
Note: Figures in the table are rounded.

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