An Roinn Sláinte
Department of Health

Unexpected Intraoperative Life Threatening Haemorrhage

National Clinical Guideline No. 29

Annex B: Intraoperative Massive Haemorrhage – Irish incidence.

National Patient Safety Office
Oifig Náisiúnta um Shábháilteacht Othar

NATIONAL CLINICAL EFFECTIVENESS COMMITTEE

CICER
Collaboration in Ireland for Clinical Effectiveness Reviews

Intraoperative Massive Haemorrhage– Irish incidence

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RCSI

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About HRB-CICER

In 2016, the Department of Health requested that the Health Research Board (HRB) fund an evidence synthesis service called HRB-CICER (Collaboration in Ireland for Clinical Effectiveness Reviews) to support the activities of the Ministerial appointed National Clinical Effectiveness Committee (NCEC). Following a competitive process, the Health Information and Quality Authority (HIQA) was awarded the contract for the five-year period from 2017 to 2022. The HRB-CICER team comprises a dedicated multidisciplinary research team 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.

With regard to clinical guidelines, the role of the HRB-CICER team is to independently review evidence and provide scientific support for the development, by guideline development groups, of National Clinical Guidelines for the NCEC. The HRB-CICER team undertakes systematic reviews of the clinical effectiveness and cost-effectiveness of interventions included in the guidelines as well as estimating the budget impact of implementing the guidelines. The HRB-CICER team also works closely with the guideline development groups; provides tailored training sessions; assists in the development of clinical questions and search strategies; performs systematic reviews of international clinical guidelines and supports the assessment of their suitability for adaption to Ireland; and supports the development of evidence-based recommendations informed by the evidence produced by HRB-CICER within the National Clinical Guidelines.

Membership of the evaluation team

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List of abbreviations that appear in this report

AXIS	Appraisal tool for cross-sectional studies
CoCoPop	Condition, Context, Population
GDG	Guideline development group
HRB-CICER	Health Research Board – Collaboration in Ireland for Clinical Effectiveness Reviews
HSE	Health Service Executive
NCEC	National Clinical Effectiveness Committee
NCG	National Clinical Guideline
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
WHO	World Health Organisation

1 Background

1.1 Description of the condition

This review will focus on the incidence of massive haemorrhage in Ireland. Massive haemorrhage is difficult to define with no universally accepted definition and a need to consider clinical context. However, broad definitions have been suggested and they include; [1, 2]

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.

The Unexpected Intraoperative Life Threatening Haemorrhage guideline development group (GDG) consider intraoperative massive haemorrhage to be intraoperative bleeding that is catastrophic in nature and difficult to control even for an experienced practitioner. In broad terms, it is associated with clinical features including tachycardia (>110 beats per minute),[2] hypotension (<90mmHg systolic blood pressure)[2] 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 massive haemorrhage has the potential for significant morbidity and mortality.[3] 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'.[4] 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.[5, 6] Surgical care, and specifically care provided in operating theatres, is associated with a notably high incidence of adverse events,[5] with haemorrhage being a frequently encountered complication.[6] 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.[7]

The potential that intraoperative massive haemorrhage has for patient morbidity and mortality denotes that it is an adverse event of key concern in healthcare delivery. Such an event would appear to meet the criteria for a reportable patient safety incident within the guidance of the Health Service Executive (HSE) in Ireland,[8] defined as any event which could

have or did result in unintended or unnecessary harm to the patient. These include adverse events which result in serious harm and near misses which could have resulted in serious harm, but did not cause harm, either by chance or timely intervention.[8] The World Health Organisation (WHO) patient safety initiative advocates the systematic reporting and analysis of such patient safety events, at both local and national levels, to enable learning opportunities and the prospective improvement of patient safety.[9]

1.2 Purpose of this systematic review

For massive haemorrhages which occur intraoperatively, no national guidance exists in Ireland regarding strategies and pathways for their prevention, recognition or management. The Minister for Health mandated, as a matter of priority, the commissioning and quality assurance of a National Clinical Guideline (NCG) for Unexpected Intraoperative Life Threatening Haemorrhage through the National Clinical Effectiveness Committee (NCEC). A guideline development group (GDG) has been set up to develop this NCG for the Irish healthcare system. This NCG will focus on the prevention, recognition and management of intraoperative massive haemorrhage in adults. This NCG does not cover intraoperative massive haemorrhage resulting from obstetric or acute trauma related causes.

The purpose of this systematic review is to summarise evidence relating to the incidence of intraoperative massive haemorrhage, and associated mortality, in Ireland to support the work of the Unexpected Intraoperative Life Threatening Haemorrhage GDG.

2 Methods

This review will adhere to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria.[10]

2.1 Review Question

This systematic review aims to answer the following questions:

- What is the incidence of intraoperative massive haemorrhage in Ireland?
- What is the incidence of mortality related to intraoperative massive haemorrhage in Ireland?

The modified Condition, Context and Population (CoCoPop) for the review questions is provided in Table 2.1 below. The specific objectives of this systematic review are:

- To determine the incidence of intraoperative massive haemorrhage across all surgical care in Ireland, including any potential subpopulations from discrete surgical

procedures or specialities excluding those related to acute trauma and obstetric causes.

- To determine the incidence of associated mortality from intraoperative haemorrhage across all surgical care in Ireland, including any potential subpopulations from discrete surgical procedures or specialities excluding those related to acute trauma and obstetric causes.

Table 2.1 Modified Condition, Context and Population (CoCoPop)

Condition	Incidence of: ▪ intraoperative massive* haemorrhage ▪ mortality related to intraoperative massive* haemorrhage.
Context	Surgical procedures performed in the acute Irish healthcare setting, excluding those related to acute trauma and obstetric causes.
Population	Adults (aged ≥ 18 years)
Study design	▪ observational studies ▪ routine data collections including audits, registers and surveys.
Search period	No time restriction

*Note: Or a related synonym such as major, critical, excessive, severe, profound or catastrophic.

2.2 Search strategy

Electronic searches were conducted in PubMed, Embase, CINAHL (via Ebsco), and The Cochrane Library. The search terms utilised for each database are provided in Appendix 1 and included database specific thesauri and free-text terms. This search strategy was created *de novo* by the research team. These searches were supplemented using the key data and grey literature sources highlighted in Appendix 2. Further search methods included forward citation searching of relevant articles and hand searching of reference lists. Members of the GDG were also consulted by email to identify any other potential sources of data relevant to this review.

2.3 Eligibility criteria

The specific inclusion and exclusion criteria for this systematic review are provided in Table 2.2.

Table 2.2 Inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
▪ Adults (aged ≥ 18 years) who have undergone a surgical procedure in Ireland.	▪ Specific to paediatric populations, or obstetrics or trauma related causes.
▪ Observational study designs and routine data collection such as audits, registers and surveys.	▪ All other study designs.
▪ Clear statement that data was collected in an Irish healthcare setting.	▪ Data from countries outside of Ireland.
▪ Clear statement of massive (or related synonym) haemorrhage.	▪ No clear statement of massive (or related synonym) haemorrhage.
▪ Reports frequency data related to intraoperative massive haemorrhage.	▪ Data from the surgical continuum of care other than intraoperative (for example postoperative).
	▪ Studies which refer to intraoperative massive haemorrhage where the index admission was bleeding, for example upper gastrointestinal bleeding.

2.4 Selection of eligible studies

All studies identified from the collective search strategy were exported to EndNote (Version X8) for reference management, where duplicates were identified and removed. Using Covidence, two reviewers independently screened the titles and abstracts of the remaining citations to identify those eligible for 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. Citations excluded during the full-text review stage were documented alongside the reasoning for their exclusion and included in a study flow diagram.

2.5 Data extraction and management

Data extraction was performed independently by two members of the research team. Where disagreements occurred, discussions were held to reach consensus. Relevant data from each study were extracted including patient characteristics, surgical discipline, procedures, description of haemorrhage, and frequency of intraoperative massive haemorrhage and associated mortality. Data extraction was conducted in Microsoft Excel, using a data extraction table.

2.6 Quality appraisal

Methodological quality of included studies was independently assessed by two reviewers. Given the cross-sectional nature of the included studies, the Appraisal tool for Cross-Sectional studies (AXIS)[11] was used. The AXIS contains a checklist of criteria across the introduction, methodology, results and discussion of cross-sectional studies and further examines factors such as ethical approval and funding. Where disagreements occurred between the reviewers, discussions were held to reach consensus. There is a dearth of tools for appraising cross-sectional studies, and to the author's knowledge no robustly validated or recommended tool exists. Therefore, the AXIS tool was first piloted and discussed between the two members of the research team to assess applicability with modifications made where necessary. Questions relating to sampling (questions 5-7) were removed from the appraisal given the census type data provided within the studies, as advised by the developers of the AXIS tool.[11]

2.7 Data synthesis

As intraoperative massive haemorrhage is a rare and typically unforeseen clinical outcome, pooling of data was not deemed to be appropriate and is presented in descriptive terms using a narrative synthesis of included studies.

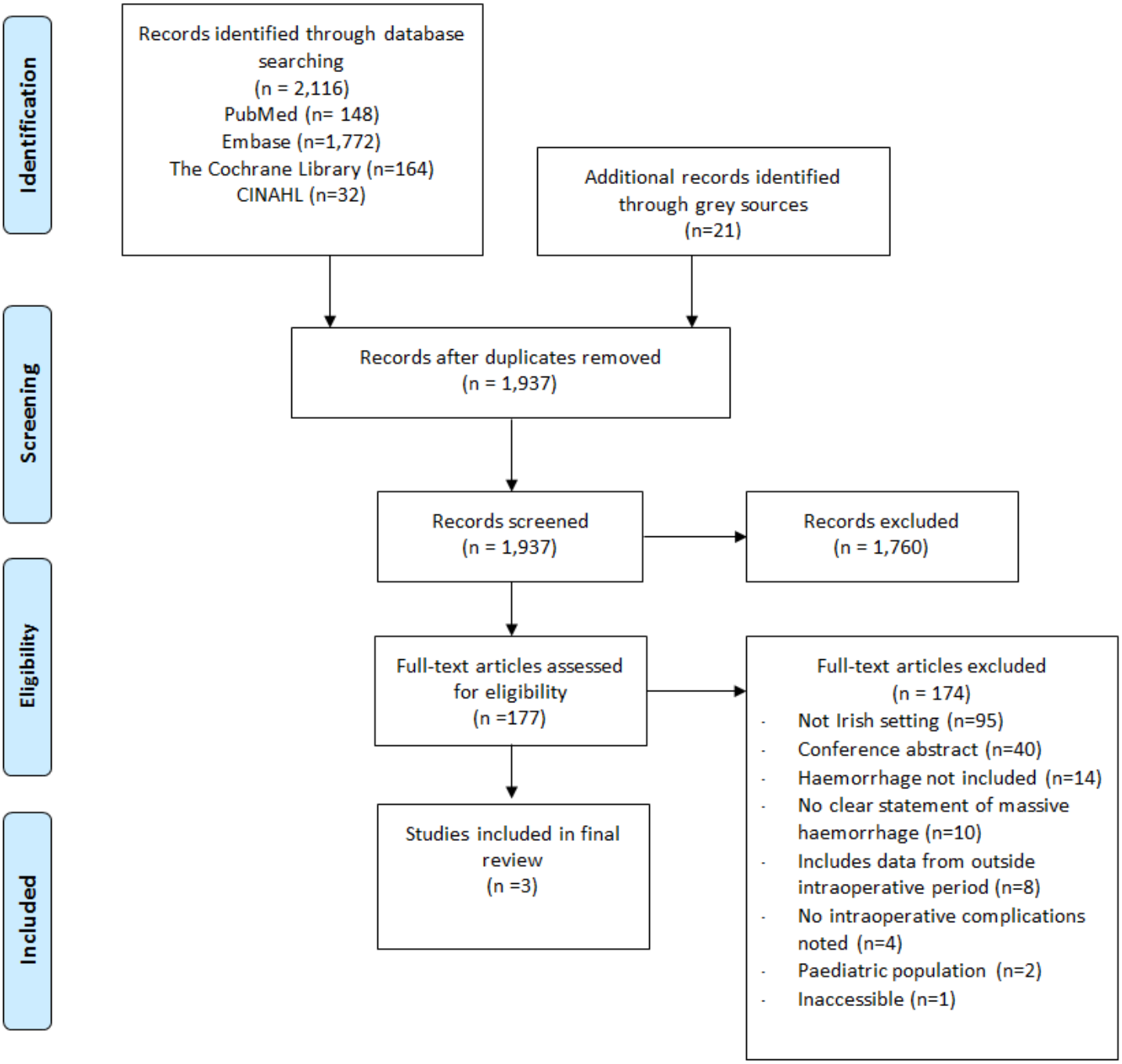
3 Results

3.1 Search results

The search of electronic databases was conducted on the 2 and 3 September 2019 (Appendix 1). Grey literature and key data sources were searched on the 3 and 4 September 2019 (Appendix 2)**.** Members of the GDG further identified a number of potentially relevant sources of information which were searched and any potentially relevant reports screened (Appendix 2).

Collectively, the search of electronic databases and grey literature sources identified 2,137 citations. After removal of duplicates, the titles and abstracts of 1,937 records were independently screened by two reviewers and 1,760 records excluded at this stage. A total of 177 full-texts were independently assessed by the two reviewers for eligibility based on the predefined inclusion and exclusion criteria (Table 2.2). One hundred and seventy-four records were subsequently excluded, with a detailed overview of their reasons for exclusion provided in Appendix 3, the primary reason for exclusion was data being from outside of the Republic of Ireland. This resulted in three studies [12-14] being included in this systematic review. A PRISMA flow-chart summarising the search process and subsequent results is provided in Figure 3.1.

Figure 3.1 PRISMA flow chart



3.2 Characteristics of included studies

A summary of the characteristics of the three included studies [12-14] is provided in Table 3.1. All three studies were retrospective reviews of patient records for specific surgical procedures in single acute care institutions in Ireland. The sample sizes of the studies ranged from 24[12] to 215,[13] with the retrospective review of patient information ranging from 1998-2002[13] to 2001-2012,[12] and one study identifying their sample as the first 100 patients undergoing a procedure within a new service (2001-2008).[14] Two of the included studies[12, 13] concerned urological procedures using open entry techniques, with the third[14] examining bariatric procedures using predominantly laparoscopic entry techniques.

3.3 Frequency of intraoperative massive haemorrhage and associated mortality

As the included studies[12-14] refer to retrospective reviews of patient information from specific surgical procedures (renal and bariatric surgery procedures), within discrete single institutions and no population-level data was identified from the grey literature or key data sources, the presentation of true incidence rates of intraoperative massive haemorrhage in Ireland is not possible. The frequency of intraoperative massive haemorrhage and associated mortality for each included study is provided in Table 3.1 and described below**.**

Casey et al.[12] analysed information relating to procedures, complications and outcomes of radical nephrectomies with inferior vena cava thrombectomy from all patients undergoing this procedure across a ten-year period. Indications for surgery were renal cell carcinoma with concurrent inferior vena cava thrombus. Surgical access techniques included were laparotomies with or without sternotomy and cardiopulmonary bypass. The authors reported one occurrence of intraoperative haemorrhage across 24 open nephrectomies with inferior vena cava thrombectomy. The individual required a massive transfusion of 21 units of red blood cells secondary to a prolonged surgery and cross clamping of the vena cava and aorta. This intraoperative complication resulted in the death of the patient 28 days post-operatively.

Connolly et al.[13] examined complications and outcomes of all patients who had undergone open nephrectomy surgeries (simple and radical) across a four-year period with indications for surgery including chronic pain, recurrent infection complicating a poorly functioning renal unit, diagnosis of xanthogranulomatous pyelonephritis and suspected malignancy. The authors reported one occurrence of major blood-loss (defined as greater than 1.5 litres estimated blood-loss) in 89 cases of simple nephrectomy and 10 occurrences in 126 cases of radical nephrectomy, with no perioperative mortality reported. No description of the contributing factors to these intraoperative complications was provided.

The remaining study conducted by Smith et al. [14] examined complications and outcomes for the first 100 patients undergoing surgical procedures in a newly-established bariatric service. Surgical procedures performed were Roux-en-Y gastric bypasses, sleeve gastrectomies and duodenal switches. The majority of procedures documented were performed laparoscopically. The authors reported one occurrence of very heavy bleeding which resulted in conversion to open surgery and transfusion of blood. The bleeding resulted from the gastric artery whilst creating a pouch jejunosotomy. The outcome of this specific case was not provided.

Table 3.1 Study characteristics

Author and year	Study design and period	Study setting Surgical specialty	Population characteristics	Surgical Procedure(s)	Definition/ description of massive haemorrhage	Frequency of intraoperative massive haemorrhage	Frequency of mortality related to intraoperative massive haemorrhage
Casey et al.[12] 2013	**Design:** Retrospective chart review **Time period:** 2001-2012	**Setting:** Single centre acute hospital **Specialty:** Surgical urology with cardiothoracic and vascular support as required	All patients surgically managed for Renal Cell Carcinoma with inferior vena cava thrombus (n=24) Median age (Range): 58 years (33-78) Percentage male: 82% (n=18)	**Open nephrectomy with inferior vena cava thrombectomy (n=24):** Laparotomy (n=9) Laparotomy combined with sternotomy (n=5) Laparotomy combined with sternotomy and veno-venous cardiopulmonary bypass (n=10)	The incident was described as a patient requiring massive transfusion of 21 units of red blood cells due to intraoperative blood-loss.	**Frequency:** 1/24 cases **Description:** Inferior vena cava thrombus adherent to vena cava resulting in prolonged surgery, the cava and aorta were cross clamped.	**Frequency:** 1/1 case **Description:** Twenty-eight days post-surgery due to multi-organ failure.
Connolly et al.[13] 2011	**Design:** Retrospective review **Time period:** 1998-2002	**Setting:** Single centre acute hospital **Specialty:** Not exclusively stated	All patients who underwent nephrectomy (n=215) **Simple nephrectomy (n=89):**	**Open nephrectomy (n=215):** Simple nephrectomy (n=89)	Major intraoperative blood-loss >1.5 litres estimated blood-loss.	**Frequency:** Simple nephrectomy: 1/89 cases	**Frequency:** No resultant mortality.

			Mean age (Range): 43 years (14-82) Percentage female: 70% (n=62) **Radical nephrectomy (n=126):** Mean age (range): 60 years (23-83) Percentage female: 35% (n=44)	Radical nephrectomy (n=126)		Radical nephrectomy: 10/126 cases **Description:** No information provided.	
Smith et al.[14] 2010	**Design:** Retrospective chart review **Time period:** 2001-2008	**Setting:** Single centre acute hospital **Specialty:** Bariatric surgical service	The first 100 patients surgically managed by a bariatric service (n=100) Mean age (range): 45 years (20-69) Percentage female: 68% (n=68) Average Body Mass Index (range): 55 (40-70)	**Bariatric procedures (n=100):** Roux-en-Y gastric bypass (n=87) Sleeve gastrectomy (n=11) Duodenal switch (n=2) 87% (n=85) performed laparoscopically with 2(2%) requiring conversion to open surgery.	Very heavy bleeding which resulted in conversion to an open surgery and required intraoperative blood transfusion.	**Frequency:** 1/100 cases **Description:** Bleeding from left gastric artery while creating pouch-jejunostomy.	**Frequency:** No directly applicable data provided.

3.4 Quality of included studies

A summary of the quality of the included studies,[12-14] as indicated by the criteria within the AXIS checklist, is provided in Table 3.2. As previously highlighted, the included studies relate to specific procedural activity in single institutions and hence the quality appraisal provides limited insight in the context of this systematic review. Areas of poor reporting noted across the included studies were:

- adequate justification of sample sizes
- description of methodologies
- declaration of conflicting interests
- attainment of ethical consent.

Table 3.2 Quality appraisal: Appraisal Tool for Cross-sectional Studies (AXIS)

AXIS item	Casey et al. (2013)	Connolly et al. (2011)	Smith et al. (2010)
Item 1: Clear aims and objectives	Yes	Yes	Yes
Item 2: Appropriate study design	Yes	Yes	Yes
Item 3: Justified sample size	No	No	No
Item 4: Population clearly defined	Yes	Yes	Yes
Item 5: Sample frame from appropriate population	N/A	N/A	N/A
Item 6: Selection process likely representative population	N/A	N/A	N/A
Item 7: Measures undertaken to address non-responders	N/A	N/A	N/A
Item 8: Risk factor and outcome variables appropriate to aim	Yes	Yes	Yes
Item 9: Risk and outcome variables measured correctly	No	Yes	No
Item 10: Clear method to determine statistical significance or precision estimates	No	Yes	Yes
Item 11: Methods sufficiently described to repeat	No	Yes	Yes
Item 12: Basic data adequately described	Yes	Yes	Yes
Item 13: Response rate raises concerns about bias	N/A	N/A	N/A
Item 14: Information about non-responders provided	N/A	N/A	N/A
Item 15: Results are internally consistent	Yes	Yes	Yes
Item 16: Results presented for all analyses described	Yes	Yes	Yes
Item 17: Discussions and conclusions justified	Yes	Yes	Yes
Item 18: Limitations discussed	Yes	Yes	No
Item 19: Funding and sources of conflict disclosed	No	No	No
Item 20: Ethical approval and informed consent	No	No	No

N/A- non-applicable

4 Discussion

This systematic review aimed to summarise the evidence relating to the incidence of intraoperative massive haemorrhage and associated mortality in Ireland. The search of electronic databases, grey literature and key data sources did not return any large-scale data to inform incidence rates. Three single institution studies[12-14] met the inclusion criteria and provide limited frequency data relating to intraoperative massive haemorrhage and associated mortality from specific surgical procedures at a local level. 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 cannot be determined by this review.

The reporting of adverse events relating to patient safety is a valuable activity, which can allow learning and development opportunities within healthcare systems to improve patient care and safety over the long term.[9] It is particularly important when collecting data relating to patient safety, that an adequate definition of an adverse event and the criteria which accompany it are well defined.[9] This consideration was a factor which limited this review as individual studies, institution-level reports and national-level data did not provide definitions of the degree of haemorrhage experienced or the timeframe in which they occurred. For example, the Coombe Women and Infant's University Hospital produces an annual report summarising the institution's clinical statistics. Within these reports there is a section on complications relating to gynaecological procedures with one complication 'Blood transfusion of greater than five units' having an incidence ranging from one to four per approximately 8,500 procedures performed in the institution annually.[15-20] However, although this definition infers a relatively large degree of blood-loss, whether these occurrences of transfusion are for the treatment of massive haemorrhage or if they occur specifically in the intraoperative period cannot be inferred. 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.

Future reporting of intraoperative massive haemorrhage should be guided by clear and well-defined criteria to enable the collection of data which can be compared and amalgamated across institutions. These data should be collected in a form which enables the generation of incidence rates such as consistent reporting of numerators and denominators for each surgical procedure performed, which can be analysed collectively to provide accurate and reliable information.[6]

The significance of adverse event reporting has received a growing level of attention in Ireland in recent years with the implementation of the National Incident Management System to collect data relating to patient safety incidents across healthcare settings and the emergence of studies such as the Irish National Adverse Events study conducted by the Royal College of Surgeons in Ireland.[21] The addition of well-defined criteria for intraoperative massive haemorrhage to such programmes of work may produce fruitful data to enable monitoring and surveillance. Similarly, a large scale clinical audit of surgical mortality in Ireland proposed by the National Office of Clinical Audit was postponed in 2013 and may offer a further source of information when resumed, should a clear definition of intraoperative massive haemorrhage be included.

Overall, the results of the systematic review highlight a lack of information relating to the incidence of intraoperative massive haemorrhage and associated mortality in Ireland. Future monitoring and surveillance may prove beneficial to provide learning and development opportunities to improve patient safety. However, these activities need to utilise a clear definition for intraoperative massive haemorrhage and collect data in a consistent fashion to allow synthesis and comparison across institutions.

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Appendix 1: Electronic database search terms and search results

PubMed 2 September 2019		Results = 148
1.	haemorrhage[Title/Abstract]	34007
2.	hemorrhage[Title/Abstract]	145777
3.	bleeding[Title/Abstract]	191145
4.	blood-loss[Title/Abstract]	48868
5.	exsanguinati*[Title/Abstract]	2450
6.	"vessel injury"[Title/Abstract]	1321
7.	"vascular injury"[Title/Abstract]	10242
8.	"adverse event"[Title/Abstract]	24659
9.	complication*[Title/Abstract]	924961
10.	"adverse events"[Title/Abstract]	130961
11.	bleeding[MeSH Terms]	318811
12.	surgical hemorrhage[MeSH Terms]	16992
13.	exsanguinating hemorrhage[MeSH Terms]	332
14.	hemorrhagic shock[MeSH Terms]	11235
15.	intraoperative complication[MeSH Terms]	50979
16.	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #15 OR #16	1494525
17.	Massive*	99716
18.	Major*	1748178
19.	Excessive*	126991
20.	Severe*	984462
21.	Catastrophic*	15547
22.	Critical*	896907
23.	Profound*	103339
24.	#17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23	3644260
25.	intraoperative*[Title/Abstract]	126203
26.	intra-operative*[Title/Abstract]	13885
27.	perioperative*[Title/Abstract]	89194

PubMed 2 September 2019		**Results = 148**
28.	peri-operative*[Title/Abstract]	6591
29.	surg*[Title/Abstract]	1892372
30.	#25 OR #26 OR #27 OR #28 OR #29	1962279
31.	ireland[Title/Abstract]	19793
32.	irish[Title/Abstract]	8856
33.	dublin[Title/Abstract]	4453
34.	limerick[Title/Abstract]	175
35.	cork[Title/Abstract]	1768
36.	galway[Title/Abstract]	397
37.	waterford[Title/Abstract]	70
38.	#31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37	2979
39.	#16 AND #24 AND #30 AND #38	148
	Total	**148**

Embase 2 September 2019		**Results = 1772**
1.	Haemorrhage: ab,ti	48361
2.	hemorrhage: ab,ti	184707
3.	bleeding: ab,ti	301772
4.	'blood loss' : ab,ti	77578
5.	exsanguinati*: ab,ti	2929
6.	'vessel injury': ab,ti	1934
7.	'vascular injury': ab,ti	13999
8.	'adverse event': ab,ti	42858
9.	complication*: ab,ti	1245728
10.	'adverse events': ab,ti	228899
11.	Bleeding/de	283127
12.	Operative blood loss/de	20153

Embase 2 September 2019		**Results = 1772**
13.	Exsanguination/de	942
14.	Hemorrhagic shock/de	16940
15.	Adverse event/de	59614
16.	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #15 OR #16	1977989
17.	Massive*	128863
18.	Major*	5538140
19.	Excessive*	171731
20.	Severe*	1411172
21.	Catastrophic*	19844
22.	Critical*	1253704
23.	Profound*	133316
24.	#17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23	7779553
25.	intraoperative*: ab,ti	174618
26.	'Intra operative*': ab,ti	26171
27.	perioperative*: ab,ti	127026
28.	'peri-operative*': ab,ti	14116
29.	surg*: ab,ti	2507874
30.	#25 OR #26 OR #27 OR #28 OR #29	2601452
31.	ireland: ab,ti	160596
32.	irish: ab,ti	13561
33.	dublin: ab,ti	6357
34.	limerick: ab,ti	532
35.	cork: ab,ti	2572
36.	galway: ab,ti	889
37.	waterford: ab,ti	135
38.	#31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37	175349
39.	#16 AND #24 AND #30 AND #38	1772
	Total	**1772**

CINAHL (via Ebsco) 3 September 2019		**Results = 32**
1.	TI Haemorrhage OR AB Haemorrhage	25396
2.	TI haemorrhage OR AB hemorrhage	28142
3.	TI bleeding OR AB bleeding	33884
4.	TI "blood loss" OR AB "blood loss"	9542
5.	TI exsanguinat* OR AB exsanguinat*	407
6.	TI "vessel injury" OR AB "vessel injury"	205
7.	TI "vascular injury" OR AB "vascular injury"	1289
8.	TI "adverse event" OR AB "adverse event"	7612
9.	TI complication* OR AB complication*	159074
10.	TI "adverse events" OR AB "adverse events"	40889
11.	MH Hemorrhage+	55062
12.	MH Surgical blood loss	278
13.	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12	272254
14.	Massive*	10376
15.	Major*	252302
16.	Excessive*	20957
17.	Severe*	169165
18.	Catastrophic*	4050
19.	Critical*	180955
20.	Profound*	14005
21.	S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20	599826
22.	TI intraoperative* OR AB intraoperative*	21685
23.	TI intra-operative* OR AB intra-operative*	2670
24.	TI perioperative* OR AB perioperative*	23383
25.	TI peri-operative* OR AB peri-operative*	1734
26.	TI surg* OR AB surg*	339134
27.	S22 OR S23 OR S24 OR S25 OR S26	356254
28.	TI ireland OR AB ireland	9222

CINAHL (via Ebsco) 3 September 2019		**Results = 32**
29.	TI irish OR AB irish	3879
30.	TI Dublin OR AB Dublin	1055
31.	TI Limerick OR AB Limerick	139
32.	TI cork OR AB cork	337
33.	TI galway OR AB galway	177
34.	TI waterford OR AB waterford	47
35.	S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34	12476
36.	S13 AND S21 AND S37 AND S35	32
	Total	**32**

The Cochrane Library 3 September 2019		**Results = 164**
1.	("hæmorrhage"):ti,ab,kw	4343
2.	(hemorrhage):ti,ab,kw	27283
3.	(bleeding):ti,ab,kw	40022
4.	(‘blood loss’):ti,ab,kw	27130
5.	(exsanguinat*):ti,ab,kw	121
6.	('vessel injury'):ti,ab,kw	910
7.	('vascular injury'):ti,ab,kw	2356
8.	('adverse event'):ti,ab,kw	28976
9.	(complication*):ti,ab,kw	172400
10.	('adverse events'):ti,ab,kw	98581
11.	MeSH descriptor: [Hemorrhage] explode all trees	13241
12.	MeSH descriptor: [Hemorrhage] explode all trees	2469
13.	MeSH descriptor: [Exsanguination] explode all trees	16
14.	MeSH descriptor: [Shock, Hemorrhagic] explode all trees	92
15.	MeSH descriptor: [Intraoperative Complications] explode all trees	4108
16.	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15	311375

The Cochrane Library 3 September 2019		**Results = 164**
15.	Massive*	1908
16.	Major*	285000
17.	Excessive*	9371
18.	Severe*	169165
19.	Catastrophic*	494
20.	Critical*	44065
21.	Profound*	3997
22.	#15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21	325847
23.	(intraoperative*):ti,ab,kw	24404
24.	(perioperative*):ti,ab,kw	17533
25.	(Surg*):ti,ab,kw	225918
26.	#23 OR #24 OR #25	232189
27.	(Ireland):ti,ab,kw	3372
28.	(irish):ti,ab,kw	390
29.	(dublin):ti,ab,kw	457
30.	(limerick):ti,ab,kw	27
31.	(cork):ti,ab,kw	122
32.	(galway):ti,ab,kw	118
33.	(waterford):ti,ab,kw	5
34.	#27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33	3850
35.	#16 AND #22 AND #26 AND #34	164
	Total	**164**

Appendix 2: Key data and grey literature sources search results

Grey literature sources

Source	Date searched	Number of citations added to screening
Lenus: The Irish Health Repository www.lenus.ie	3 September 2019	16
Health Service Executive www.hse.ie	3 September 2019	0
State Claims Agency www.stateclaims.ie	3 September 2019	2
Central Statistics Office www.cso.ie	4 September 2019	0
National Office of Clinical Audit www.noca.ie	4 September 2019	3
The Irish Coroner's Service www.coroners.ie	4 September 2019	0

Key data sources

Source	Editions searched	Number of relevant codes
Hospital Inpatient-Enquiry Database	ICD10 6th and 10th Edition	0

Additional sources following consultation with GDG

Source	Date searched	Number of potentially relevant reports
Coombe Women and Infants University Hospital Annual Reports	10 September 2019	5
The Rotunda Hospital Annual Reports	9 September 2019	6
Cork University Maternity Hospital Annual Reports	9 September 2019	4
National Maternity Hospital, Holles Street Annual Reports	9 September 2019	3

National Haemovigilence Office Annual Reports	10 September 2019	10
National Perinatal Epidemiology Centre Reports	10 September 2019	0

Data sources awaiting response or collection

Source	Progress
National Incident Management System	Requested data (4 September 2019) and awaiting response.
Information from individual hospital laboratories on 2018 massive haemorrhage protocol activation	Collection of data from individual hospitals on 2018 rates of activation of massive haemorrhage protocols and rates from surgical/procedural settings. Data collection being led by two GDG members with HRB-CICER support as required.

Appendix 3: Excluded citations following full-text review

Reason for exclusion	References
Data clearly from outside of Republic of Ireland or no clear statement that presented data is from the Republic of Ireland (n=95)	(22-116)
No intraoperative complications included (n=8)	(117-120)
Haemorrhage not included or mentioned as complication (n=14)	(21, 121-132)
No clear statement of massive (or synonym) haemorrhage (n=10)	(133-142)
Includes amalgamating data from continuum of care outside on intraoperative (e.g. postoperative) (n=8)	(143-150)
Conference abstract without identified corresponding full-text article(n=40)	(151-189)
Inaccessible article due to discontinuation of journal (n=1)	(190)
Paediatric population (n=2)	(191, 192)

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