NHS
Health Research Authority

FULL/LONG TITLE OF THE STUDY

Defining and identifying the elective high-risk general surgical patient – do all the relevant parties' perceptions add up?

SHORT STUDY TITLE / ACRONYM

How do we define and identify high-risk surgical patients

PROTOCOL VERSION NUMBER AND DATE

'How do we define and identify high-risk surgical patients' Version 0.7 July 2025

RESEARCH REFERENCE NUMBERS

IRAS Number:	**355125**
SPONSORS Number:	**355125**
FUNDERS Number:	n/a

How do we define and identify high-risk surgical patients

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How do we define and identify high-risk surgical patients

KEY STUDY CONTACTS

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Sponsor	University of Glasgow
Joint-sponsor(s)/co-sponsor(s)	Not applicable
Funder(s)	Awaited
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Committees	N/A

STUDY SUMMARY

Study Title	Defining and identifying the elective high risk general surgical patient – do all the relevant parties' perceptions add up?
Internal ref. no. (or short title)	How do we define and identify high-risk surgical patients
Study Design	Mixed methods, prospective
Study Participants	Focus group work - NHS Greater Glasgow and Clyde (NHS GGC) patients who have undergone colorectal, oesophagectomy or pancreatic surgery in past year
Planned Size of Sample (if applicable)	Literature review- sample size not specified Focus group work – 30 patients (they will be invited to bring along a support person who will be welcome to contribute in the conversation) Database work – sample size not specified Clinician survey – sample size not specified
Follow up duration (if applicable)	No formal follow up is required Participants will be offered opportunity to receive information on how their involvement has influenced the project
Planned Study Period	8 months for the focus group work
Research Question/Aim(s)	Question: How are high-risk elective surgical patients defined and identified? Do clinicians and patients have the same understanding of this definition? Aims: To create a definition for 'high-risk' surgical patients that is more reflective of outcomes and perceptions that are important to patients to enable consistent identification and management of major elective general surgical patients.

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
NHS Greater Glasgow and Clyde	Non-financial support - specialist cancer nurses for colorectal, pancreatic, and oesophagectomy surgeries will assist in identifying patients for focus group work
Safehaven	Non-financial support – providing access to the peri-operative database for Glasgow patients
NERCI	Non-financial support – providing access to the peri-operative database for colorectal patients
University of Glasgow	Non-financial support – providing sponsorship and by extension indemnity for this project

ROLE OF STUDY SPONSOR AND FUNDER

Sponsor

The sponsor will be the University of Glasgow.

Funder

The study is not reliant on external funders. We will aim to apply for a small grant to fund the focus group work.

Roles and responsibilities

Sponsor: The sponsor's primary responsibility is to ensure appropriate arrangements are in place for the governance, management and funding of the project. Whilst the study design has considered guidance from the University of Glasgow, they have not/ will not play a direct role in the design, conduct, analysis, write up or dissemination of the project.

Funder: The funder's primary responsibility will be to provide financial resources for the conduct of the focus group work. They will not play a direct role in the design, conduct, analysis, write up or dissemination of the project. We will ensure that their requirements for ensuring proper utilisation of the funds and dissemination of the results are met.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Not Applicable

PROTOCOL CONTRIBUTORS

Dr Anna-Marie Tiah (Principal investigator) – design of project and protocol

Professor Susan Moug (PhD supervisor and chief investigator) – design of project and protocol

Professor Tara Quasim (PhD supervisor) – design of project and protocol

KEY WORDS: General surgery, peri-operative, high-risk, patients, morbidity, elective

How do we define and identify high-risk surgical patients

STUDY PROTOCOL

Defining and identifying the elective high risk general surgical patient – do all the relevant parties' perceptions add up?

1 BACKGROUND

1.1 ORIGIN OF 'HIGH-RISK' DEFINITION

Pearse et al and The Royal College of Surgeons (RCOS) defines 'high risk' general surgical patients as those with an estimated mortality of 5% or higher (1, 2). Pearse's estimate is informed by the findings of six studies conducted by other researchers including (i) a review of patients undergoing pancreatic debridement in a single district general hospital under the care of one surgeon and (ii) a multicentre cohort study looking at mortality in patients undergoing oesophagectomies and gastrectomies (3, 4).

The mortality rate in these six studies ranges from 3.5% (in hospital mortality for patients suffering a fractured neck of femur in a study carried out by Goldacre et al) to 37% (for patients suffering a rupture aortic aneurysm in analysis carried out by Bradbury et al) (5, 6). Whilst Pearse et al does acknowledge that there are few available estimates for patients considered to be part of the high-risk surgical population, the supporting papers are vastly different in terms of surgical population and study type, limited in numbers, as well as being over twenty years old (1).

1.2 EFFORTS TO REDEFINE 'HIGH-RISK'

In an updated report, RCOS highlights the importance of assessing patients' morbidity and frailty, for patients over the age of sixty-five, in addition to mortality (7). RCOS also point out that the elective and emergency cohort are inherently different acknowledging that factors such as advanced age and increase in comorbidities are more common (2). Attempts have been made to redefine high risk surgical patients based on morbidity, for example by Dyas et al, who proposed defining high-risk patients as those in the tenth decile of risk for prespecified postoperative adverse outcomes, based on using the SURPAS tool to retrospectively analyse the NSQIP database (8). Despite this there is still a paucity of literature which shifts the focus from mortality to morbidity when referring to the 'higher risk' surgical patient. Furthermore, there isn't a definition that considers patients' perceptions of the label of 'high-risk' and its implications for decision making in the context of elective surgery.

2 RATIONALE

Being labelled as 'high-risk' for surgery carries several management implications. Namely patients require active multidisciplinary consultant input in all aspects of their care from diagnosis, vigilance for sepsis, comparison of pre-operative scans with surgical findings, and consideration for admission to critical care (2, 7). This is applicable to all patients who meet the criteria, not just emergency patients. The current definition focuses on a mortality rate of 5% as the threshold for initiating these strategies. The actual mortality rate for elective surgical patients is closer to 1–4%, whereas complications are

estimated to occur in 20% of patients in high-income countries (9, 10). Clinical expertise suggests that complications are likely to affect patients' lifestyles, diminish their quality of life, and ultimately increase their long-term mortality risk. There is a possibility that patients who do not meet the threshold for being classified as 'high-risk' may not fully benefit from the recommended management strategies. The rationale behind this project is to identify discrepancies in how the term 'high-risk' is defined in the literature, among clinicians and patients, and within audit data. It aims to develop a definition that integrates diverse perspectives and more accurately reflects likely outcomes.

3 THEORETICAL FRAMEWORK

The reasoning for this study is based on the theory that there are differences in understanding what constitutes a high-risk surgical patient and therefore variations in management. The existing definition does not consider the key stakeholder in all decision making, the patient. Furthermore, it does not account for the discrepancy in mortality rates for elective and emergency patients, instead utilising 'one size fits all' approach to two very different cohorts. The project is created on the premise that identifying and addressing these differences requires a multifaceted approach that engages the major stakeholders i.e. patients and clinicians to create a more accurate and impactful definition. This will enable a consistent approach to identification and therefore management of this cohort of patients.

Basis of concepts

The following key ideas form the foundation of the project:

1. **Definition not reflective of actual outcomes:** There is a discrepancy between actual outcomes for elective surgery and current threshold of definition for 'high-risk'.
2. **Definition excludes patient perspective:** The very people the current definition impacts does not reflect the factors important to them and its impact on their lives beyond 30 days.
3. **Mismatched target*:*** the cohort who are likely to benefit from the strategies employed may not be identified with the current definition and outcomes may suffer as a result.
4. **Unclear on outcomes for Glasgow population:** Given that the main focus is on mortality and the characterisation of the 'high-risk' surgical patient excluded Scotland, it is unclear what outcomes are likely for patients undergoing elective general surgery in Glasgow.

Implementation of concepts

- Determine if there are potential alternative definitions of 'high-risk' that are focused on morbidity as opposed to mortality.
- Establish patients' and clinicians' perception of the definition, focusing on the factors most important to them, and comparing it with current factors recorded for audit purposes, to distinguish differences in practice.

- Characterise the elective 'high-risk' general surgical population of Glasgow by reviewing the most likely outcomes for major elective general surgery.
- Findings will be integrated into a new definition that is more aligned with outcomes that are probable and important to patients.

4 RESEARCH QUESTION/AIM(S)

Questions

1. How are high-risk general surgical patients in Scotland currently identified?
2. Do patients' and clinicians' definitions and recorded outcomes match the current definition of 'high-risk'?

Aim

To create a definition for 'high-risk' surgical patients that is more reflective of outcomes and perceptions that are important to patients to enable consistent identification and management of major elective general surgical patients.

4.1 Objectives

1. Understand the roles and limitations of frailty and morbidity base preoperative risk scores in identifying and defining high risk general surgical patients
2. Explore patients' understanding of the label of high-risk, the implication of this for the consent process, and outcomes that are important to them
3. Characterise high risk elective general surgical patients in Greater Glasgow and Clyde / determine if database captures meaningful outcomes
4. Determine how clinicians identify high risk patients

4.2 Outcome

1. Create a definition for 'high-risk' surgical patients that is more reflective of outcomes and perceptions that are important to patients.
2. Enable a more uniformed approach to identifying and therefore managing 'high-risk' elective general surgical patients.

5 STUDY DESIGN, METHODS of DATA COLLECTION AND DATA ANALYIS, TIMESCALE

STUDY DESIGN

Mixed methods, combining prospective elements (patient focus groups, clinician survey) and retrospective elements (database analysis).

1. **Literature review of literature for frailty and morbidity based pre-operative scores**

To ascertain how high-risk patients are being identified and defined, it is vital to review the current literature on perioperative surgical risk. Moonesinghe et al completed a qualitative literature review of noncardiac surgical risk stratification tools in 2013, identifying twenty-seven studies and thirty-four risk stratification tools used in non-cardiac and non-neurosurgical surgery (11). The review included various surgical specialties, risk stratification tools used post/ intra/ and pre operatively as well as emergency patients (11). Clinical experience informs risk varies between types of surgery, surgical specialties and elective versus emergency cohorts. The Royal College of Surgeons highlights that 'advanced age and significant co-morbidities' are more prevalent in those requiring emergency surgery(12). These inherent factors associated with emergency surgery are directly related to increased risk of morbidity and mortality, thereby making them distinct from elective patients. Moreover, to optimise patients pre-operatively their risk needs to be assessed prior to surgery, making risk scores that are dependent on intra and post-operative factors ineffective. Therefore, this literature review will be focused on studies that assess the use of morbidity based pre-operative surgical risk scores in the elective general surgical population. It will aim to determine if patients were identified based on morbidity and if they present an alternative definition for the 'higher risk' surgical patient.

The Royal College of Surgeons Working Group highlighted the need for frailty (for those over the age of 65 or who appear frail), morbidity and mortality to be assessed on admission which has influenced the decision to include both frailty and morbidity scores (7). It's logical for this evaluation to be a risk score, as it allows for both assessing and stratifying patients based on the results. Whilst NICE guidelines, published in 2020 looking at validated perioperative risk scores, did not recommend the use of one particular risk tool for utilisation during the pre-operative period, they did acknowledge their usefulness (13). The Centre for Perioperative Care suggests the use of SORT, P-Possum, ACS-NSQIP, Clinical Frailty Scale and Edmonton Frail Scale for risk and frailty scoring (14). Further risk and frailty scores were included based on a preliminary review of literature and clinical acumen.

2. **Focus group work to determine patients' views on the label of 'high-risk' and implications on decision making in context of major elective surgery.**

To ensure that patients remain the centre of the decision-making process, it is critical that their understanding of a term with significant consequences for care, being labelled 'high-risk', is reflected in the definition. Being labelled 'high-risk' has several significant implications for the patient not least a potential major impact on the care they receive and potential consequences of said care. There has been significant emphasis placed on patient centred care, defined by NHS England as a 'collaborative process through which a clinician supports a patient to reach a decision about their treatment' (15). It stands to reason that patients should not only have a say in the care they receive but the 'criteria' reflects patient-centred factors. This is further echoed by Billig et al who emphasise the use of patient reported outcomes to evaluate surgical quality, particularly in light of reduction of surgical mortality and 'traditional' morbidity (16).

Several studies have indicated that there is potentially a discrepancy communication between clinicians and patients. Gardner et al acknowledged the difference in literacy levels amongst patients and the need for adapting communication accordingly (17). In Scotland the average reading age amongst adults is 9 – 11 years old (18). Furthermore, clinicians are often observed to use jargon,

which can lead to misunderstandings with patients. This supports the importance of exploring patients' capacity to understand health information. This can be established by completion of a health literacy questionnaire. The health literacy questionnaire will also allow for an understanding of baseline characteristics of participants and help tailor the discussion accordingly.

3. Clinician survey on current practice for referral to high-risk clinic

The RCOS stress the need for multidisciplinary consultant care for patients who are determined to be 'high-risk' (7). A multidisciplinary team review preoperatively can be done in a variety of ways, ranging from a more ad hoc manner to a formalised setting such as a clinic. The Centre for Perioperative Care and partner organisations reflect the sentiment of the RCOS, emphasising that patients identified as being high-risk may benefit from assessment at a dedicated clinic (19). The high-risk clinic is a well-established route for patients to be reviewed therefore it stands to reason that clinicians who identify and subsequently refer patients to these clinics believe that the patient is high-risk for surgery. Clinical experience dictates that surgeons and anaesthetists are likely to be the ones referring patients to these clinics. Using clinicians' referral patterns to the high-risk clinic serves as a practical way to gain insights into how they define and identify high-risk patients. By examining the reasoning behind their referrals, we can better understand the specific characteristics or criteria they associate with being 'high-risk.' This approach allows us to use referral decisions as a proxy for uncovering clinicians' perspectives on what constitutes a high-risk patient.

4. Review of perioperative and National Enhanced Recovery in Colorectal Initiative (NERCI) database to determine outcomes for patients undergoing major elective general surgery

There has been recent emphasis on the use of data to improve patient care as a population. The Department for Health and Social Care in England illustrated an example of this by highlighting the importance of data in the national fight against coronavirus (20).The Perioperative Medicine Clinic Database (perioperative database) in Glasgow was designed to record anonymised data (including investigations, assessments, interventions etc) from patients who have undergone perioperative assessments to assess and improve the overall service and patient care (21). NERCI is an enhanced recovery after surgery (ERAS) pathway initiated in Scotland in 2016 that collected and synthesized data on colorectal resections with the goal of standardising and improving patient care (22). Both databases are collecting outcomes that will ultimately be audited with view to improving patient care. Reviewing the databases will not only enable insight into the actual outcomes for patients undergoing elective general surgical procedures, NERCI focusing on colorectal cases and the perioperative database on all other procedures, but also determine what variables are being recorded. The definition of a 'high-risk' patients can be refined by considering the likelihood of various outcomes, with suggested outcomes for database recording derived from the patient focus groups and clinician survey findings.

METHODS

Literature review

A list of frailty and morbidity based perioperative risk scores was created based on clinical acumen and a preliminary search of the literature. The search criteria (Appendix 1) were developed with the assistance of one of the University of Glasgow's specialist librarians. Given the nature of the topic, a decision was made to conduct the initial literature search in PubMed with view to expanding to other search engines if the yield was unsatisfactory. A screening protocol was created incorporating the search criteria and relevant inclusion and exclusion criteria (Appendix 2). The literature search criteria and screening protocol will be refined iteratively, based on initial results and emerging insights, to ensure comprehensive coverage of the topic.

Focus group work

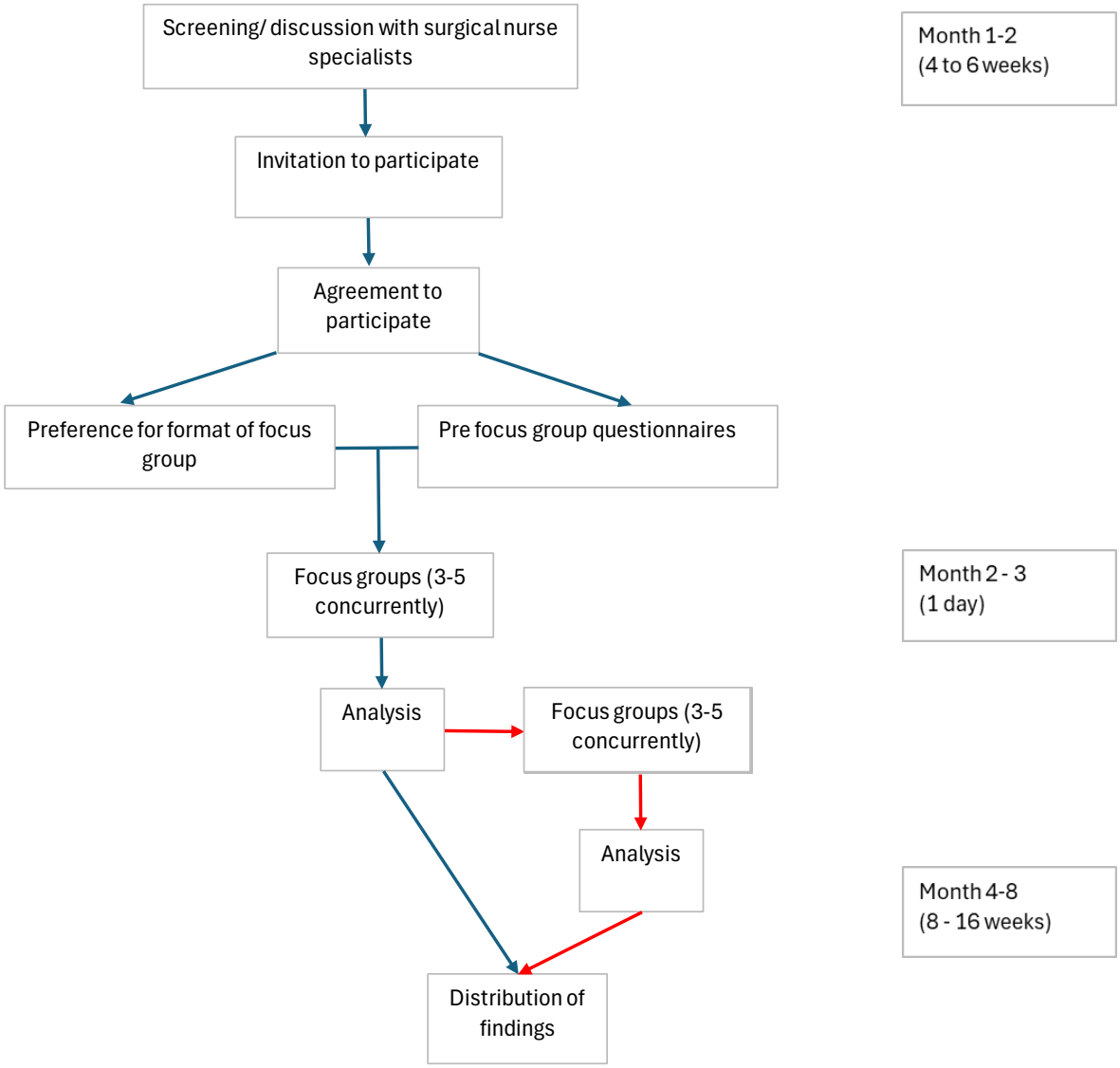
Identification and invitation to participate: Patients who have undergone cancer for surgery are routinely followed up postoperatively, often by cancer nurse specialists. By extension they keep a record of patients who have recently undergone surgery. We plan to enlist the help of the oesophageal, pancreatic and colorectal cancer nurse specialists to identify and invite suitable patients to take part in the focus group work. This is likely to be done in person or over the phone during routine contact. If in person, the patient will be given a patient information pack containing the participant information sheet (Appendix 3), consent form (Appendix 4), questionnaires (Appendix 5, 6). A privacy notice (Appendix 7) will be made available upon request. If over the phone, consent will be obtained verbally to post or email, depending on patient preference, the patient information pack. A number for a secretary will be included so the individual can phone in to confirm willingness to participate and preference for setting. We will then make contact in the upcoming month to help answer any questions, confirm intention to participate and location.

Sample size: Given that this is qualitative research dependent on group discussion in a semi-structured format, sample size is determined by two factors (1) optimum number of participants required to generate but not overwhelm conversation and (2) the number of groups required to meet saturation. The concept of saturation is determined as the point after which no new themes are discovered (23, 24). Several sources indicate that 6 to 8 participants is optimal (25, 26). Evidence suggests that 80% saturation can be achieved with 2 to 3 focus groups and 3 to 6 to achieve 90% saturation (27). Considering this and adopting a pragmatic approach, we plan to recruit 30 patients, ensuring an even distribution across specialties—10 pancreatic, 10 oesophagectomy, and 10 colorectal—to achieve the optimal group size and number of focus groups.

Structure: The setting will be chosen based on the preference of most participants. Sample size will allow for ideally 4 focus groups comprised of 6 to 8 patients. Each group will be led by a dedicated facilitator with sufficient training. Standard questions (Appendix 8) will be used between groups, but conversation will be guided by individual responses. Audio recordings and subsequent transcription will be conducted for each group to facilitate consequent analysis.

Questionnaire: Two questionnaires will be used, one to collect data on participants' understanding of terms related to risk used in consent discussion (interpretation of surgical risk questionnaire) (Appendix 5) and the other a validated health literacy questionnaire (Appendix 6). It will be administered prior to attendance at the focus group and completed via a paper form that can be posted back to Dr Anna-Marie Tiah in a prepaid envelope. It is estimated to take no more than fifteen minutes to complete.

FOCUS GROUP WORKFLOW CHART



Clinician Surveys

Participants: Trainees and consultants in general surgery and anaesthetics

Recruitment: Invitations will be circulated via trainee and consultant networks

Data collection: The survey (Appendix 9) will be distributed online via a secure platform such as Microsoft Forms, accessed via an NHS email account. Participation in the survey will be entirely voluntary, with a clear statement ensuring anonymity of all responses and indicating that the data collected will be presented and potentially published as part of a research project. Participants will have a period of 1 month to complete the survey with a reminder sent out at 2 weeks.

Questionnaire design: The questionnaire will be developed using insights from discussion with experts in the area and review of the literature. The questions will capture data on the following:

- Demographics
- Criteria for defining high risk
- Awareness and knowledge
- Clarity and consensus on high-risk definitions
- Sources of information
- Use objective versus subjective measures
- Influence of risk tools/ scores
- Specialty specific considerations
- Barriers / pitfalls for identification

Database review

Inclusion/ exclusion criteria: Data for all elective general surgical patients over the age 18 will be gathered.

Data extraction: Databases are accessed in a secure manner with all information anonymised prior to review. The format of the perioperative database is made accessible via a secure VPN and the data in in excel spreadsheets. Using various filtering techniques data for elective general surgical patients can be isolated and then interrogated. The NERCI database is likely to be accessed in a similar format. The areas of interest include, but are not limited to demographics, procedure, pre-operative morbidity, level of care post-operatively, duration at level of care, complications, repeated procedures, days in hospital, admission and discharge dates, new post-operative morbidity, repeat surgical procedures, functional capacity pre and post-operatively.

DATA ANALYSIS

Literature review

Study selection: All retrieved studies will be imported into Covidence (literature review software supported by the University of Glasgow) be screened for eligibility base on predefined inclusion and exclusion criteria. Abstracts and titles will be screened initially by two independent reviewers with conflicts resolved via discussion and by a third reviewer. Full text review will then commence in a similar manner.

Data extraction: Data from eligible studies will be extracted using the PRISMA and PICO framework. This will be assisted using Covidence software.

Bias assessment: A bias assessment tool will be used to determine the risk of bias.

Data synthesis: Descriptive statistics will be used to summarise the characteristics of the various studies. It will be determined if the studies are homogenous enough to conduct full quantitative analysis. If not, narrative analysis will be performed to summarise key themes. Qualitative analysis will be assisted using NVivo (qualitative and thematic analysis software supported by the University of Glasgow). Statistical analysis will be assisted using R Studio, an open-access statistical program that is freely available to use.

Focus group work

Content analysis

Recordings will be transcribed verbatim both manually and with the assistance of auto transcription software supported by the University of Glasgow (i.e. Echo360). The transcriptions will include verbal interaction. Notes from the facilitators/ observers of the focus group will help record any key non-verbal interactions. The transcriptions will be anonymised and so no patient identifiable information will be included in the analysis.

The transcriptions will be initially reviewed and key emerging concepts noted manually and with the assistance of thematic analysis software supported by the University of Glasgow (i.e. NVivo). Based on these key concepts a list codes (akin to categories) will be created (28). Codes similar in nature will form the basis of emerging themes (28). We will seek the assistance of a qualitative research expert to support the analysis.

Immediate debrief with moderators following the sessions will allow for recording of initial thoughts on the group interaction and their perception on how they facilitated the discussion. To enable transparency the debrief conversations / reports will be facilitated by another member of the research team. This will be bolstered by a manual review of the recordings to identify key elements of group dynamics, such as interaction types, engagement levels, group hierarchies, the role of the moderator, and non-verbal cues exhibited by participants.

By combining analysis from the four focus groups comprised of different people at different times we will increase the validity of results. As previously stated, we will seek the assistance of a qualitative research expert to assist in assessing the data thereby reducing individual bias for interpretation.

The identified themes will be connected to the initial research question, with key findings and their implications clearly outlined.

Reporting

The findings will be reported in line with an approved and structured reporting tool such as the ‘consolidated criteria for reporting qualitative research’ (COREQ) (29).

The Principal Investigator, Dr Anna-Marie Tiah, will be responsible for transcription, de-identification and storage of the data.

Questionnaire

Responses for the health literacy questionnaires will be scored based on standardised scoring guidelines as stipulated by the questionnaires’ developers. Descriptive and comparative analysis will

be carried out on the interpretation of surgical risk questionnaire to determine patterns and enhance analysis of focus group responses.

Clinician survey

Content analysis

No confidential information will be collected. A preliminary analysis will be performed in Excel to enable descriptive analysis and familiarisation with the data. Correlation analysis will be performed using R Studio. Content analysis will be performed for the questions that enable free text responses, which are anticipated to support possible trends seen in the quantitative data.

Reporting

Results of survey will be documented systematically as per the requirements for any research study and in line with the guidance for any future peer reviewed publications. This will include information on the methodology, time frame for data collection, number of respondents, descriptive and quantitative analysis, results, discussion and conclusion.

Database review

Data extraction: Data within the Perioperative database is already anonymised and coded. This is likely to be applicable to the NERCI database also, however once access is granted this can be confirmed and the necessary steps followed to ensure anonymity. The data within the Perioperative database is presented in excel files. The data will be filtered to only include patients who have undergone elective general surgical procedures and then the various outcomes established and recorded. Once collated this can then be extracted to R Studio to facilitate statistical analysis. Once access to the NERCI database is obtained, it will be possible to assess whether this approach is applicable to it as well.

Content analysis: Descriptive analysis will be performed on the collated data in Excel. This will allow for an understanding of emerging themes and help form the basis for further correlation analysis using R Studio. Further subgroup analysis, including but not limited to regression analysis, will be performed using R Studio.

DATA MANAGEMENT

Literature review

Data collection

Data will be collected using appropriate databases, such as PubMed, Web of Science, Embase and potentially CINAHL. CSV files of search results will be imported into Covidence where screening and review can occur. Data will be collated and analysed in excel spreadsheets and R Studio.

Storage
Data will be stored and archived securely on Dr Anna-Marie Tiah's hard drive and backed up on a separate private USB drive.

Versions and Access
Files for data extraction will be labelled in standardized naming convention, including details such as the file type, version number, initials and date (e.g., "DataExtractionSheet_v1_AMBT_2025-03-20.xlsx"). Updates to documents will increment the version number (e.g., v2, v3) and initials of last person to make changes to reflect changes.

Sharing
Any data that requires to be shared between the principal investigator and supervisors or other members of research team will be sent via secure University of Glasgow or NHS email addresses.

Focus group work and questionnaires

De-identification/ coding aka anonymisation
The intended number of information packs will be printed and collated. Information packs will be coded by Dr Anna-Marie Tiah in the following fashion P01, P02, P03 etc, this will be henceforth referred to as the participant code. A template with a column of the codes and section for inputting corresponding patient details will be created. Participants details will be recorded next to the corresponding pack number on the participant log when a pack is sent out. Henceforth the code will be used to refer to the participants.

There will be detailed explanation in the information pack for the reasoning for the code system, i.e. to ensure the anonymity of participants. There will also be instructions to use this code to identify themselves when attending the focus group.

Once the recruitment phase is completed the participant logs used by the cancer nurse specialists will be collected by Dr Anna-Marie Tiah. It will be kept securely on an NHS computer, accessed through secure single user log in. To prevent the loss of this record, a physical copy will be securely stored within the research department at the Lister building, Glasgow Royal Infirmary, Glasgow. Dr Anna-Marie Tiah will be responsible for the coding and safekeeping of the participant log. On completion of the study the participant log will be destroyed.

Transcription
If the focus group is held in person – upon arrival the participants names will be checked off against the participant log. They will be given a badge with their corresponding number which they will be asked to wear for identification purposes. They will not be requested to disclose any confidential information at any point. It will be their choice if they choose to disclose this information. This will be made clear in the patient information sheet issued beforehand and reiterated on the day.

If the focus group is held virtually – the participants will be asked to log in 5 minutes before the start, using their participant code as the screen name. Before being admitted to the focus group they will be reminded that they will not be requested to disclose personal information at any point, it is therefore their choice if decide to do so.

The above will allow for the coded responses from the questionnaires to be matched to focus group transcription. Transcription will be done manually and with the assistance of ECHO 360 software. Participants will be referred to by their participant code in transcriptions. Dr Anna-Marie Tiah will be responsible for transcribing and coding the transcriptions.

Storage/ Archive

The original recordings will be retained for duration of the study after which they will be destroyed. During the study the files of the recordings will be encrypted and stored securely. The anonymised transcriptions and collated questionnaire data will be kept for a duration of 10 years in line with the University of Glasgow data management guidelines. They will be stored in a University of Glasgow approved repository. The chief investigator, Prof Moug, will be the custodian of the research data for 10 years.

Access

Dr Anna-Marie Tiah, her PhD supervisors Professor Moug and Professor Quasim, and certified qualitative research expert will have access to the recordings to aid in transcription. De-identification will be done simultaneously during transcription. During the study the anonymised transcripts will be accessed by Dr Anna-Marie Tiah, her supervisors and other members of the research team to enable data analysis.

Clinician Surveys

De-identification/ coding aka anonymisation

No individual identifiable information will be collected therefore not applicable.

Storage/archive

The collated results will be kept for a duration of 10 years in line with the University of Glasgow data management guidelines. They will be stored in a University of Glasgow approved repository. Dr Anna-Marie Tiah will be responsible for the storage and archiving.

Access

Results of the survey will be accessed via private, NHS, and University of Glasgow computers all requiring secure log ins. Dr Anna-Marie Tiah, her supervisors and other members of the research team will have access to the collated results to enable data analysis.

Database review

De-identification/ coding aka anonymisation

Data in the perioperative database is already anonymised and coded. Viewing of the database and analysis is accessed via a secure server that is password protected and controlled by Safehaven.

The rules applicable to accessing the NERCI database will be adhered to. It is likely the data will be anonymised but a similar process to the perioperative database will need to be followed.

Storage/archive

During the project data will be stored in accordance with database hosts' rules and regulations. Only anonymised analysis will be exported to be viewed outside of the secure database.

TIMESCALE

Literature review

Planning and refining search methodology took 6 months. Study extraction and screening is expected to take 3 months. Data analysis and write up is expected to take 3 to 6 months.

Focus group

Recruitment and collection of questionnaires is anticipated to take 2 months with a view to potential extension depending on uptake. Focus group is anticipated to last 1 day with the session lasting no more than 2 hours. Transcription of audio recordings from focus group and questionnaire responses is anticipated to take 3 weeks. Analysis of questionnaire is anticipated to take 1 week. Initial coding of audio recordings from focus group is anticipated to take 3 weeks. Theme development from focus groups is anticipated to take 3 weeks. Refinement and reporting of focus group analysis is anticipated to take 4 weeks.

Clinician survey

Creation and refinement, allowing for specialist input is required to take 2 months. Recruitment and data collection is expected to take 1 month. Data analysis is expected to take 2 months.

Database review

Familiarisation and collation of data is anticipated to take 3 to 6 months. Analysis of data is expected to take 6 to 12 months.

6 STUDY SETTING

Literature review

Data in the form of published studies will be collected remotely via an appropriate computer from appropriate databases such as PubMed, Web of Science, Embase and/ or CINAHL. The database and University of Glasgow regulations will be adhered to for collection, data synthesis and subsequent publication.

Focus group

The participants recruited will be from multiple hospitals within the same health board, NHS Greater Glasgow and Clyde. The hospitals within this health board include Glasgow Royal Infirmary, Royal Alexandra Hospital, Queen Elizabeth University Hospital, Inverclyde Royal Hospital, Gartnavel

General Hospital, New Victoria Hospital and New Stobhill Hospital. The participants will be accessed via the cancer nurse specialists for the specialties included. Pancreatic and oesophagectomy surgeries are centralised procedures, exclusively conducted at Glasgow Royal Infirmary within the West of Scotland. Colorectal surgeries are also performed at Glasgow Royal Infirmary alongside those carried out at the other included sites.

Clinician Surveys
Our goal is to recruit participants nationally who fit the criteria. This will ensure a diverse distribution limiting bias in practice. We will ask professional bodies (such as the Anaesthetic Association of Great Britain and Ireland) to advertise the survey.

Database review
Perioperative database is Glasgow based database encompassing a variety anonymised perioperative datasets for patients in Glasgow.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

Literature review
See Appendix 2: Literature review Inclusion and Exclusion Criteria

Focus group work
Adult patients within NHS Greater Glasgow and Clyde who have undergone either elective pancreatic, oesophagectomy or colorectal surgery for cancer or suspected cancer in the past year. See below for full inclusion and exclusion criteria.

Clinician surveys
Anaesthetic and general surgery trainees and consultants currently working in the United Kingdom. See below for full inclusion and exclusion criteria.

Database review
Adult patients who have undergone elective general surgical procedures.

7.1.1 Inclusion criteria

Literature review

- See Appendix 2: Inclusion and Exclusion Criteria

Focus group work

- Adults (defined as people over the age of 18)
- Undergone elective pancreatic, oesophagectomy or colorectal surgery for cancer in past year

- Procedure must have been within one of the hospitals in NHS Greater Glasgow and Clyde as stipulated in section 6
- Since been discharged from hospital
- Able and willing to engage in group discussion
- Consent to participating in the focus group

Clinician surveys

- Anaesthetic and Surgical Trainees/ specialty grade doctors – defined as those who are currently enrolled in a recognised training programme, either anaesthetics or surgery, and/or are a member of the Royal College of Anaesthetists or the Royal College of Surgeons respectively
- Anaesthetic and General Surgical Consultants – defined as those who have achieved certificate of completion of training (CCT) in either anaesthetics or general surgery
- Currently working in the United Kingdom
- Consent to participating in clinician survey (implied by completion of the survey)

Database review

- Adults (defined as people over the age of 18)
- Undergone elective general surgical procedure

7.1.2 Exclusion criteria

Literature review

- See Appendix 2: Inclusion and Exclusion Criteria

Focus group work

- Children (defined as people under the age of 18)
- Not undergone one of the stipulated procedures
- Emergency procedures
- Procedure outside of NHS Greater Glasgow and Clyde
- Still an inpatient
- Not able and/or willing to engage in group discussion
- Not able / willing to consent to participation in group discussion

Clinician surveys

- Do not meet criteria to be classified as appropriate trainee/ specialty grade doctor
- Do not meet criteria to be classified as appropriate consultant
- Not currently working in the United Kingdom
- Not able/ willing to consent to take part in clinician survey

Database review

- Children (defined as people under the age of 18)
- Have not undergone elective general surgical procedure

7.2 Sampling

Literature review
The number of studies is unspecified as it is dependent on studies retrieved.

Focus group work
Plan for 30 patients in total, 10 from each group (Pancreatic, Colorectal, Oesophagectomy)

Clinician Survey
Survey invitations will be distributed through carefully selected channels, in the form or professional bodies such as the Anaesthetic Association of Great Britain and Ireland (AAGBI) and Association of Surgeons of Great Britain (ASGBI). Participation will rely on individuals self-assessing their eligibility against the inclusion criteria and completing the survey accordingly. The number of participants required for the survey is currently unspecified and will be determined based on participant uptake and statistical calculations.

Database review
The number of cases is unspecified as it is dependent on data recorded.

7.2.1 Size of sample

Literature review
Not applicable

Focus group work
The sample size determination adheres to current guidelines regarding the group size and the number of groups required to achieve 80–90% information saturation during analysis. Further details are provided in the 'METHODS' section (Section 5).

Clinician surveys
The sample size will be determined by statistical calculations and subsequent participant uptake.

Database review
The sample size is unspecified as it is dependent on data recorded.

7.2.2 Sampling technique

Literature review
A carefully compiled search strategy will be applied to appropriate databases. The studies retrieved will be screened in Covidence and the ones that meet the inclusion criteria analysed as part of the literature review.

Focus group work
The identification of participants meeting the inclusion criteria will be facilitated by the cancer nurse specialists for each surgical group. Their expertise will be utilised to ensure appropriate selection of eligible individuals who are in routine contact with them post operatively.

Clinician surveys
Survey invitations will be distributed through carefully selected channels, in the form or professional bodies such as the Anaesthetic Association of Great Britain and Ireland (AAGBI) and Association of Surgeons of Great Britain (ASGBI). Participation will rely on individuals self-assessing their eligibility against the inclusion criteria and completing the survey accordingly.

Database review
Relevant entries will be selected based on predefined inclusion criteria applied to the database and stipulated data extracted and collated accordingly.

7.3 Recruitment

Literature review
Not applicable

Focus group work
Recruitment will be facilitated by the cancer nurse specialists for each surgical group within previously stipulated hospitals in NHS Greater Glasgow and Clyde. Their expertise and rapport with eligible individuals will be utilised to ensure appropriate selection. The identification and initial contact phase is expected to be over the phone or in person during routine follow up. This will be done via routine contact and so no additional travel provisions are expected. They will either be given an information pack on the day or it can be sent out later date by a member of the research team/ cancer nurse specialist. The pack will contain secretaries' contact number so patients can phone in to state agree to partake and preference for in person or virtual. Once they have agreed to partake, Dr Anna-Marie Tiah will make contact to notify them of the date and location for the focus group and help answer any questions. Given that each information pack will contain a unique identifier, all cancer nurse specialists and members of the research team sending out the packs will keep a note of the pack number. Dr Anna-Marie Tiah will keep a secure log of the pack number that corresponds with the patient details.

This phase is expected to last 2 months, allowing for eligible individuals to have sufficient time to review the patient information pack and complete questionnaires.

Clinician survey
Survey invitations will be distributed through carefully selected channels, in the form of professional bodies such as the Anaesthetic Association of Great Britain and Ireland (AAGBI) and Association of Surgeons of Great Britain (ASGBI).

Database review
Not applicable

7.3.1 Sample identification

Literature review
A carefully compiled search strategy will be applied to chosen databases. The studies retrieved will be screened in Covidence and the ones that meet the inclusion criteria analysed as part of the literature review. This process will be carried out by Dr Anna-Marie Tiah.

Focus group work
Eligible individuals will be identified by the cancer nurse specialists for each surgical group. Dr Anna-Marie Tiah will be overseeing this process with the assistance of supervisors Professor Moug and Professor Quasim.

Clinician surveys
A list of eligible surgical and anaesthetic departments will be created using readily available online resources, combined with existing knowledge and consultations with individuals familiar with other departments. Dr Anna-Marie Tiah will be overseeing this process with the assistance of supervisors Professor Moug and Professor Quasim. Invitations will be extended to all surgical and anaesthetic departments that facilitate general surgery for adults.

Database review
Eligible cases will be identified by Dr Anna-Marie Tiah based on predefined inclusion criteria.

7.3.2 Consent

Literature review
Not applicable

Focus group work
Eligible individuals will be identified by the cancer nurse specialists for each surgical group during routine clinical contact. If this is in person, the patient will be given a patient information pack containing the patient information sheet, consent form, questionnaire, and privacy notice. If over the phone, consent will be obtained verbally to post or email, depending on patient preference, the patient information pack. The recruitment process is expected to take last a month allowing for adequate time for questions from eligible individuals regarding the study to be addressed prior to consent being obtained. Written consent will be obtained before the focus group if virtual and/ or on the day if in person. This will be obtained through completion of the consent form and can be taken by any member of the research team involved in the process. Capacity will be assessed at the time of obtaining written consent. The research team will not be responsible for reassessing capacity after consent has been provided.

Clinician surveys
No identifiable information will be recorded on the survey. There will be a written statement highlighting this in the explanation for the survey, consent and capacity will be implied by completion.

Database review
Not applicable

8 ETHICAL AND REGULATORY COMPLIANCE

Literature review
not applicable

Focus group work
The study will be conducted in compliance with all applicable ethical guidelines and regulatory requirements as stipulated by the University of Glasgow, NHS Greater Glasgow and Clyde and the Health Research Authority (HRA). This includes adherence to Good Clinical Practice (GCP), NHS Greater Glasgow and Clyde and University of Glasgow policies. Ethical approval for the study will be obtained via completion of Integrated Research Application System (IRAS) overseen by the HRA. Participants will be provided with clear, comprehensive information about the study and will give written informed consent before participation. Data confidentiality and participant anonymity will be safeguarded in accordance with data protection regulations as stipulated by the HRA, university of Glasgow, and NHS Greater Glasgow and Clyde. Protocol amendments deemed significant or meeting the specified criteria will be submitted for additional ethical review, with the study carefully monitored to maintain compliance with all ethical and regulatory standard.

Clinicians survey
The study will be conducted in compliance with all applicable ethical guidelines and regulatory requirements as stipulated by the University of Glasgow and the NHS. This includes adherence to Good Clinical Practice (GCP), NHS and University of Glasgow policies. We will seek appropriate ethical and NHS management approval.

Database review
Ethical approval has been granted for access to the Perioperative database. The necessary approval will be sought for access to the NERCI database, and all stipulations adhered to during conduct of the project.

8.1 Assessment and management of risk

Literature review
Not applicable

Focus group work

Risk to participants

- **Time commitment:** The questionnaire and pre focus group tasks are expected to take 15 minutes to complete. The focus group is expected to take approximately 1.5 to 2 hours. This does not include potential travel involved (if the focus group is held in person).

- **Travel:** If the focus group is held in person participants will need to make their own way to and from the venue. Help with and reimbursement for travel arrangements can be arranged for participants upon request.

- **Emotional Discomfort:** Some topics discussed might touch on personal or sensitive experiences and could feel emotionally challenging. The moderators of the groups will be experienced and pay close attention for anyone who may find the discussion challenging, offering emotional support if required. There will be an optional participant debrief session at the end of the focus group (Appendix 10 'Participant debrief session template' attached), during which participants will be invited to share any feelings or thoughts that have arisen because of the focus group. Information on this and other resources available has been provided in the Participant Information Sheet.

- **Confidentiality Concerns:** Although every effort will be made to maintain participants' privacy, there is a small risk that information shared during the session could be unintentionally disclosed by other participants. Participants will receive a patient information sheet stating the importance of respecting other participants'' confidentiality and wellbeing. Moderators will reiterate this message at the beginning of the focus group session.

Risk to researchers

- **Workload and exhaustion:** The process of organising and running a study can be challenging. There is a network of people including supervisors and colleagues who can offer guidance and support if required.

- **Managing Group Dynamics:** Managing a group with a dominant or disruptive individual can be challenging. To limit the potential impact of this scenario, there will be several co-moderators to assist in facilitating the discussion, ground rules have been set in the participant information sheet and will be reiterated before the session begins, group size will be kept to a manageable size (ideally no more than 8 participants to one moderator), and there will be a debrief session (Appendix 11 – 'Facilitator's debrief sheet' attached) at the end with the research team involved.

- **Technical difficulties:** if the focus group is conducted virtually there is the potential for connectivity or software issues to occur. To mitigate for this, we will ensure familiarisation with the software, use a secure NHS email to log in to Microsoft teams and both record and

transcribe the session simultaneously. This will allow for transcription at a further date if the initial transcription is not suitable.

Clinician survey

The survey is expected to pose minimal risk; however, there is a possibility it may evoke negative emotions. Clinicians have access to internal departmental support, including colleagues, college tutors, clinical directors, and educational supervisors, who are well-equipped to address such concerns.

Database review

Not applicable

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Literature review

Not applicable

Focus group work

Prior to starting the focus group work, ethical approval in the form of IRAS granted by the NHS research ethics committee will be obtained. The principal investigator, Dr Anna-Marie Tiah, will be responsible for ensuring this occurs and will ensure that the University of Glasgow and NHS REC are informed upon completion of the study. If the study were to end prematurely, Dr Anna-Marie Tiah will be responsible for informing the necessary governing bodies. Upon completion Dr Anna-Marie Tiah will submit a report to the necessary governing bodies.

Clinician survey

Prior to starting the survey Dr Anna-Marie Tiah will ensure that the necessary approval is in place. The HRA 'Do I need NHS REC review?' toolkit confirmed that NHS REC review is not required. For studies involving NHS staff, the standard procedure is to obtain ethical approval through the University of Glasgow. Since IRAS approval is already being pursued for the focus group component, the application will also encompass the clinician survey.

Database review

The necessary approval has been obtained for accessing the Perioperative database. The necessary approval has will be obtained for accessing the NERCI database. Dr Anna-Marie Tiah will be responsible to ensuring adherence to stipulations.

Regulatory Review & Compliance

Literature review
Not applicable

Focus group work
NHS GGC R&D approval will be sought prior to commencing the focus group work and stipulations adhered to during the study. It has been reviewed and approved by the University of Glasgow research regulation and compliance team.

Clinician survey
Appropriate NHS management approval will be sought prior to commencing the clinician survey and stipulations adhered to during the study. It has been reviewed and approved by the University of Glasgow research regulation and compliance team. University of Glasgow research guidelines will be adhered to for the conduct of the survey.

Database review
The Perioperative database is overseen by Safehaven. Stipulations provided by Safehaven will be adhered to for the database review.

Amendments

In line with the University of Glasgow and NHS GGC R&D policy any significant changes to the approved study likely require an amendment. Any proposed amendments will be initiated by the PI and authorised by the sponsor before being submitted for approval. Before the amendment can be implemented, favourable approval must be sought from HRA REC and GGC R&I offices, as applicable.

8.3 Peer review

The study undergoes regular review by the principal investigator's supervisors, who possess expert knowledge in the field. This process is further strengthened through the input and guidance of additional subject matter experts.

8.4 Patient & Public Involvement

Patient and public involvement will be included by potentially engaging an individual with expertise in patient experience and public engagement to attend and assist in facilitating the focus group

8.5 Protocol compliance

We acknowledge that accidental deviations may occur at any time and will ensure they are promptly documented and addressed by the Principal Investigator.

8.6 Data protection and patient confidentiality

Literature review
No confidential information is included. Data will be stored and protected in a safe manner aligned to guidance by the University of Glasgow.

Focus group
'DATA MANAGEMENT' (Section 5) outlines how the data will be managed, processed and stored. Details on data management will be outlined in the participant information packs, in line with the Data Protection Act 1998. The data will be pseudonymised and backed up on a secure network wherever possible. No identifiable participant data will be stored on University of Glasgow computers.

Clinician Survey
'DATA MANAGEMENT' (Section 5) outlines how the data will be managed, processed and stored. Details on data management will be outlined in description of the survey distributed, in line with the Data Protection Act 1998. The data will be pseudonymised and backed up on a secure network wherever possible. No identifiable participant data will be stored on University of Glasgow computers.

Database review
'DATA MANAGEMENT' (Section 5) outlines how the data will be managed, processed and stored. The databases hold anonymized data, removing the obligation to notify individuals.

The principal investigator will be the data custodian and ensure all data management rules are adhered to stringently.

8.7 Indemnity

Literature review
Not applicable

Focus group work
Indemnity will be provided in accordance with the University of Glasgow, acting as the sponsor for this study, and NHS GGC, as the participating site.

Clinician survey
Not applicable

Database review
Not applicable

8.8 Access to the final study dataset

Literature review
Dr Anna-Marie Tiah, her supervisors, and experts in the fields whose help is enlisted to assist with analysis will have access to the final dataset.

Focus group work
Dr Anna-Marie Tiah, her supervisors, and experts in the fields whose help is enlisted to assist with analysis will have access to the final dataset.

Clinician survey
Dr Anna-Marie Tiah, her supervisors, and experts in the fields whose help is enlisted to assist with analysis will have access to the final dataset.

Database review
Dr Anna-Marie Tiah, her supervisors, and experts in the fields whose help is enlisted to assist with

analysis will have access to the final dataset.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

Literature review
The results of the literature review are intended to be published in a peer reviewed journal and as part of Dr Anna-Marie Tiah's post-doctoral thesis. Any funding utilised to pay for application to peer reviewed journal will be acknowledged in accordance with the funders and journal's policies.

Focus group work
Anonymised results will be made available to participants and members of the research team. The results of the focus group work are intended to be published in a peer reviewed journal and as part of Dr Anna-Marie Tiah's post-doctoral thesis. Any funding utilised to pay for application to peer reviewed journal will be acknowledged in accordance with the funders and journal's policies.

Clinician survey
Anonymised results will be made available to participants and members of the research team. The results of the clinician survey are intended to be published in a peer reviewed journal and as part of Dr Anna-Marie Tiah's post-doctoral thesis. Any funding utilised to pay for application to peer reviewed journal will be acknowledged in accordance with the funders' and journal's policies.

Database review
Anonymised results will be made available to members of the research team. The results of the database review are intended to be published in a peer reviewed journal and as part of Dr Anna-Marie Tiah's post-doctoral thesis. Any funding utilised to pay for application to peer reviewed journal will be acknowledged in accordance with the funders and journal's policies.

9.2 Authorship eligibility guidelines and any intended use of professional writers

Dr Anna-Marie Tiah will be designated as the primary author, with supervisors and contributors (acknowledged for their input to the study design and analysis) included as co-authors. Discussions on authorship will be carried out openly and finalised collaboratively to ensure all contributors' input is properly credited.

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11. APPENDICIES

11.1 Appendix 1- Literature review search criteria

PubMed search criteria
POSSUM OR "Physiological and Operative Severity Score for the Enumeration of Mortality and Morbidity" OR P-POSSUM OR P - POSSUM OR "Portsmouth Physiological and Operative Severity Score for the Enumeration of Mortality and Morbidity" OR “Portsmouth-Physiology and Operative Severity Score for the enUmeration of Mortality” OR “Portsmouth Physiology and Operative Severity Score for the enUmeration of Mortality” OR “Portsmouth physiology and operative severity score for the enumeration of mortality and morbidity” OR “Portsmouth-physiology and operative severity score for the enumeration of mortality and morbidity” OR “Physiology and Operative Severity Score for the enUmeration of Mortality” OR “Portsmouth-physiology” OR “Portsmouth physiology” OR ACS NSQIP OR NSQIP OR "NSQIP OR ACS NSQIP score" OR "ACS NSQIP calculator" OR "NSQIP calculator" OR "NSQIP score" OR "American College of Surgeons NSQIP" OR "American College of Surgeons national surgical quality improvement program" OR “American college of surgeons national surgical quality improvement program database” OR "American College of Surgeons national surgical quality

improvement program surgical risk calculator" OR "American College of Surgeons national surgical quality improvement program surgical risk score" OR "American College of Surgeons NSQIP surgical risk calculator" OR "American College of Surgeons NSQIP surgical risk score" OR E-PASS OR EPASS OR "E-PASS model" OR "EPASS model" OR "EPASS score" OR "E-PASS score" OR "The Estimation of Physiologic Ability and Surgical Stress" OR "The Estimation of Physiologic Ability and Surgical Stress score" OR "The Estimation of Physiologic Ability and Surgical Stress model" OR "identification of risk in surgical patients score" OR "identification of risk in surgical patients score (IRIS)" OR "IRIS Score" OR "MALE risk score" OR "MALE score" OR "Male, Anemic, Low albumin, Eighty-five years or over score" OR "Male, Anemic, Low albumin, Eighty-five years or over risk score" OR BHOM score OR "biochemistry and haematology outcomes models" OR "biochemistry and haematology outcomes models score" OR "otago surgical audit score" OR "fried's 5 point frailty score" OR “frieds 5 point frailty score” OR “fried phenotype of frailty” OR “fried frailty scale” OR “fried frailty phenotype” OR "clinical frailty scale" OR "rockwood clinical frailty scale" OR "clinical frailty scale rockwood" OR "rockwood frailty scale" OR "edmonton frail scale" OR "electronic frailty index" OR SURPAS OR “Surgical Risk Preoperative Assessment System”OR ASA OR “American Society of Anesthesiologists (ASA)” OR “American Society of Anesthesiologists Classification” OR “ASA Physical status” OR “American Society of Anesthesiologists Physical status” OR “ASA Physical status classification system” OR “American Society of Anesthesiologists Physical status classification system” OR “American Society of Anesthesiologists Physical Status Grading”

AND (title/abstract)

Surgery OR surgical OR “general surgery” OR operation OR operative OR operate

AND (title/abstract)

"high risk" OR "high-risk" OR "higher risk" OR risky OR risk

AND (title/abstract)

morbidity OR co-morbidity OR co-morbidities OR "adverse operative outcome" OR "adverse operative result" OR "adverse operative outcomes" OR "adverse operative results" OR complication OR complications OR "operative complications" OR “operative complication” OR "post operative complications" OR "postop complications" OR "post-op complications" OR “adverse post operative outcomes” OR “adverse post-op outcomes” OR “adverse postop outcomes” OR “surgical complication” OR “surgical complications” OR “post surgical complication” OR “post surgical complications” OR “postop surgical complication” OR “post operative surgical complication” OR “postop surgical complications” OR “post operative surgical complications”

AND (all fields)
elective* OR routine* OR planned* OR scheduled* OR voluntary* OR optional* OR prearranged* OR non-urgent* OR nonurgent* OR nonemergency* OR non-emergency*

NOT (all fields)
Paediatric(s) OR pediatric(s) OR neuro* OR cardi*

Filters: full text, English
Results: 1020
Covidence – 1019 (deduplicated)

11.2 Appendix 2 – Literature review inclusion/ exclusion criteria

Categories	Include	Exclude
Population	• Adults (>18 years) • Patients undergoing general surgical procedures within the abdominal/pelvic/ thoracic cavity (includes patients undergoing general surgical procedures in conjunction with another case/specialty involved for e.g. urological/gynae/ thoracic (see details of procedures this includes)) • Elective cases (see details of definition)	• Paediatrics (<18 years) • General surgical procedures that are not intra- cavity i.e. not intra-abdominal/ intra-thoracic/ intra-pelvic (e.g. breast, thyroid, parathyroid surgery) • Solely non-general surgical procedures (i.e. if it's not specified as general surgical patient or not undergoing one of the procedures on the list specified) • Emergency cases (see details of definition)

Intervention/ Exposure	• Risk of **morbidity** assessed with one of the following risk scores
	  ○ Physiological and Operative Severity Score for the Enumeration of Mortality and Morbidity (POSSUM)
	  ○ Portsmouth Physiological and Operative Severity Score for the Enumeration of Mortality and
		• Only risk of **mortality** assessed
		• None of specified risk scoring systems used (i.e. using another risk scoring system or one that is specific to one particular outcome as opposed to generalised morbidity e.g. cardiac complication specific risk scoring systems)

	Morbidity (P-POSSUM) ○ American College of Surgeons national surgical quality improvement program surgical risk calculator (ACS NSQIP) ○ The Estimation of Physiologic Ability and Surgical Stress score / model (E-PASS) ○ identification of risk in surgical patients score (IRIS) ○ Male, Anaemic, Low albumin, Eighty-five years or over risk score (MALE score) ○ biochemistry and haematology outcomes models score (BHOM score) ○ otago surgical audit score ○ fried's 5 point frailty score (*or analogous name – see list of variations*) ○ Rockwood Clinical Frailty Scale ○ Edmonton Frail Scale ○ Electronic frailty index ○ Modified frailty index (mFI-5/ mFI-11)	

	○ Surgical Risk Preoperative Assessment System (SURPAS) ○ American Society of Anaesthesiologists Physical status classification system (ASA) ○ Risk analysis index ○ Multidimensional frailty score ○ revised-Risk Analysis Index (RAI-rev) ○ Multidimensional Prognostic Index (MPI) score ○ Groningen Frailty Indicator (GFI)	

Comparator/ Context	• Other form of assessing high risk patients
	  • Clinical acumen
	  • Anyone who was determined to have predicted mortality >5%
	  • Patients admitted to level 2 or 3 (HDU or ICU) care post op
		• No mention of alternative form of assessing high risk patients

Outcome	• Reporting some form of morbidity (can include other patient centred measures that can be viewed as surrogate for morbidity e.g. increased length of stay, discharge location if discharged to increased level of care i.e. increased package of care or assisted living,	• No mention of risk of morbidity

	unexpected ICU/HDU admission etc.) *And/ or* • Reporting definition of 'high-risk' patient because of using morbidity risk scoring tool	
Study Characteristics	• RCT • Observational • Cohort • Cross-sectional • Qualitative • Quantitative • Case control • Single or multi-centre • Must specify statistical methods and/ or qualitative analysis techniques used to analyse the data [*this is more for when assessing full article as details of ethical approval unlikely to be mentioned in abstract*] • Must specify relevant ethical and consent approvals sought and followed if applicable (i.e. if a trial or study of some description NOT necessarily database projects or literature reviews) [*this is more for when assessing full article as details of ethical approval unlikely to be mentioned in abstract*]	
Other	List of general surgical procedures (if specific procedure and not specialty specified): • Closure of bypass of oesophagus	

	• Injection sclerotherapy for oesophageal varices • Bypass of oesophagus • Total oesophagectomy and interposition of intestine • Revision of anti-reflux procedures • Sub-total oesophagectomy with anastomosis in neck • Thorascopic oesophagogastric myotomy • Transoral incisionless fundoplication • Transabdominal anti-reflux operation • Transabdominal repair of diaphragmatic hernia • Transabdominal repair of hiatus hernia • Transthoracic repair of paraesophageal hiatus hernia • Open excision of lesion of oesophagus • Repair of congenital oesophageal atresia • Transthoracic fundoplication and gastroplasty • Transthoracic repair of diaphragmatic hernia • Thoracic fundoplication • Lap repair of hiatus hernia or anti-reflux procedures • Vagotomy/ seromyotomy • Oesophagectomy / oseophagogestrectomy with anastomosis in chest • Bypass of duodenum	

	• Endoscopic submucosal dissection of duodenal lesions • Open excision of congenital lesion of duodenum including malrotation • Open excision of lesion of duodenum • Closer of perforated ulcers of duodenum • Bypass of ileum • Redo operation of ileum/ colon • Bypass of jejunum • Open operations of ileum • Opern resection of small intestine tumour • Lap assisted resection of small intestine • Revision of ileostomy • Surgery of correction of congenital intestinal atresia • Intubation of jejunum for decompression of intestine • Open formation of ileostomy • Open formation of jejunostomy • Ileoanal anastomosis and creation of pouch • Lap ileostomy • Appendectomy (lap/open) • Excision of transverse colon • Extended excision of right hemi colon • Intra-abdominal manipulation of colon for intussusception • Open formation of colostomy	

	• Lap colostomy and stoma formation m • Lap assisted left colon resection • hemicolectomy • sigmoidectomy • total excision of and ileorectal anastomosis • drainage of appendix or intra-abdominal abscess • bypass of colon • closure of colostomy • anterior resection • dilation of structure of rectum • haemorrhoidectomy • anorectal stretch • anterior resection • proctocolectomy • Abdo perineal pull through • colectomy and colostomy • destruction/ excision of lesion of anus • haemorrhoid artery ligation • resection of rectum and anus • rectal biopsy • injection of bulking agents for faecal incontinence • ileoanal anastomosis and creation of pouch • excision of pilonidal abscess • fixation of rectum for prolapse • sigmoidoscopy • perianal/anal operation of any kind • rectopexy • sphincterotomy • Abdo perineal resection • adrenalectomy	

	• bile duct – excision or anastomosis or exploration
	• Cholecystectomy
	• pancreatic operation of any kind
	• splenectomy
	• hepatectomy / operation of liver of any kind
	• pancreatic transplant
	• liver transplant
	• kidney transplant
	• bowel transplant
	• Mult visceral transplant
	• repair of inguinal hernia
	• repair of femoral hernia
	• repair of incisional hernia
	• repair of ventral hernia
	  ○ epigastric
	  ○ umbilical
	• repair of perianal hernia
	• repair of diaphragmatic hernia
	• laparoscopic adhesiolysis
	• open drainage of subphrenic abscess
	• laparotomy
	• excision of presacral tumour
	• excision of retroperitoneal tumour/ abscess
	• cytoreductive surgery
	• suprapubic drainage of pelvic abscess
	• wedge excision or removal of omentum
	• vagotomy
	• gastro-jejunostomy
	• pyloroplasty
	• lap biliary gastric bypass
	• gastropexy
	• gastrostomy / closure of gastrostomy	

	• gastric bypass / Roux-en-Y • gastro-jejunostomy • gastrectomy • gastroelectrical mechanical stimulation • closure of peptic ulcer • gastric banding • endoscopic mucosal resection • endoscopic removal of percutaneous endoscopic gastrostomy • endoscopic submucosal dissection of gastric lesions • other open operations of stomach • pyloromyotomy • capsule endoscopy • oesophageal pH monitoring (e.g. Bravo) • enteroscopy • oesophago-gastro-duodenoscopy (OGD) • oesophageal manometry • colonoscopy (including fibreoptic) • endoscopic upper gastrointestinal ultrasound • proctoscopy • ileoscopy • double balloon enteroscopy • endoscopic mucosal resection • endoscopic ultrasound • insertion of percutaneous gastrostomy/ jejunostomy • surgical ERCP • sigmoidoscopy	

	• anoscopy / high resolution anoscopy (HRA) • creation of peritovenous shunt (Levine/Denver) Definition of elective 'operation planned in advance' Fried's 5 point frailty score a.k.a • Fried frailty scale • Fried frailty criteria • Fried frailty phenotype • Fried frailty index • Frailty index • Frailty classification • Physical frailty assessment • Frailty severity score • Geriatric frailty score • Age-related frailty measure • Functional decline score • Vulnerability index	

13.3 Appendix 3 – Patient Information Sheet

University of Glasgow | College of Medical, Veterinary & Life Sciences

FOCUS GROUP PARTICIPANT INFORMATION SHEET

1. Study title

How do we define and identify the 'high-risk' general surgical patient?

2. Invitation paragraph

Thank you for reading this information sheet. You are being invited to take part in this study to understand what 'high risk' means for surgery. Our goal is to create a better definition to improve identifying, managing, and consenting high-risk patients. It is important that you understand the purpose of this project and what it will involve before you decide to take part. Please read the following information carefully and discuss with others if you like. Please ask us if there is anything that you would like more information on. A copy of this participant information sheet and signed consent form will be given to you to keep, if you decide to take part.

3. What is the purpose of the study?

Background:

The label of 'high risk' for surgery impacts care. The current definition considers the risk of death and does not include other important outcomes for patients. While the risk of death from planned surgery is low, the likelihood of other complications is higher.

Aim:

This study aims to understand what 'high risk' means to patients and incorporate these perspectives, along with actual surgical outcomes, into the definition. This will ensure consistent management and improve the consent process.

4. Why have I been invited to participate?

You have been invited to take part in this study because you had a significant operation in the past year. This does not necessarily mean that you were considered to be a high-risk patient.

You can only be in this study if:

- You are an adult (over the age of eighteen)
- You have had an operation on your bowel or pancreas or oesophagus in the past year
- Your operation was in a hospital within Greater Glasgow and Clyde (this includes Glasgow Royal Infirmary, Queen Elizabeth University Hospital, Royal Alexandra Hospital, Inverclyde Royal Hospital, Gartnavel General Hospital, New Victoria Hospital, New Stobhill Hospital)
- You have since been discharged from hospital
- You consent to take part

5. Do I have to take part?

No, it is your choice whether to take part. If you decide to take part, you will be given this information sheet and be asked to sign a consent form. You are free to withdraw at any time without giving a reason by contacting the study team. The decision to partake in this study will not affect your care in any way.

6. What will happen to me if I take part?

Introduction: After reading the patient information sheet and completing the consent form, you will be invited to complete a questionnaire prior to attending a focus group session. All potential participants will be asked about their preference for an in person or online (via a Teams call) format for the focus group work. A single format will be chosen based on the majorities' decision.

Questionnaire: The questionnaire will contain general questions your understanding of the topic of being 'high risk for surgery' and your understanding of some of the terms that are mentioned in the consent process before surgery. Many people find medical terms difficult to understand, and healthcare professionals may sometimes use jargon. There will also be a short questionnaire that aims to assess any gap between what doctors communicate and what patients understand about what is being said.

Focus Group Session: The focus group will last approximately 1-2 hours and will be conducted in a comfortable, non-judgmental setting. You will join a small group of other participants to discuss your experiences, opinions, and thoughts on 'being high risk for surgery' and how this influences your decision for surgery. The discussions will be guided by a trained facilitator who will ask open-ended questions to encourage meaningful conversations.

Access to Health Records: As part of the study the researcher will access your health records to confirm the details of the surgery you underwent. This information will be used solely for research purposes and will remain confidential. All data will be handled in accordance with data protection regulations, ensuring your privacy and security. If you have any concerns or questions about this, please feel free to discuss them with the research team.

Confidentiality and Privacy: All information shared on the questionnaire and during the focus group will be treated with the utmost confidentiality. The focus group session will be audio-recorded to accurately capture the discussion, but no personally identifiable information will be included in the final research report. The focus group discussion will not address specific patients, and you can choose what to share, ensuring medical confidentiality is maintained. To uphold rigorous standards,

you'll receive a unique identifier, and your questionnaire responses and focus group transcription will be anonymised.

Follow-Up: If more information is needed, we might have follow-up questions or sessions. Your participation in follow-up activities is entirely voluntary.

Feedback and Results: After the study is done, you will have the opportunity to receive a summary of the results. This will help you understand how your input has made a difference to the overall study.

7. What do I have to do?

General information and pre session tasks: If you would like to take part in the study, please read the information sheet and complete the consent form along with your preference for a virtual or in person focus group and the best contact details to inform you of the details for the focus group.

You will have the opportunity to bring someone along with you to the focus group, please indicate on the form sent out to you if you would like to do so.

Complete the questionnaire: You will need to complete the questionnaire and return it via post in the prepaid envelope.

Attend the Focus Group Session: You will need to attend a scheduled focus group session, which will last approximately 1-2 hours. The session will be held at a convenient location or virtually, depending on most of the participants' preference. If the focus group is held in person, you will need to make your way to and from the venue. Help with and reimbursement for travel arrangements can be arranged upon request.

Participate in Discussions: During the focus group, you will be asked to share your thoughts, experiences, and opinions on your understanding of the term 'high risk' and how it impacts decisions around surgery. Feel free to speak openly, there are no right or wrong answers, your opinions matter.

Respect Confidentiality: While participating in the focus group, please respect the confidentiality of other group members. You will not be asked to disclose any personal information. Please do not share any personal information or comments made by others

Provide Feedback: If requested, please provide feedback on the focus group process or any follow-up questions after the session.

8. What are the possible disadvantages and risks of taking part?

Time commitment: The questionnaire and pre focus group tasks are expected to take 15 minutes to complete. The focus group is expected to take approximately 1.5 to 2 hours. This does not include potential travel involved (if the focus group is held in person).

Travel: If the focus group is held in person you will need to make your way to and from the venue. Help with and reimbursement for travel arrangements can be arranged upon request.

Emotional Discomfort: Some topics discussed might touch on personal or sensitive experiences and could feel emotionally challenging. There will be a debrief session at the end of the focus group where you are invited to share any feelings or thoughts that have arisen because of the focus group.

Should you feel the need for additional support, you can reach out to the following services:

- Lifelink, an organisation that provides resources and counselling for residents in Glasgow City. Further details are available on their website: https://www.lifelink.org.uk/
- Breathing Space, a free and confidential phone service offering assistance for anyone experiencing anxiety or low mood. Further details are available on their website: https://www.breathingspace.scot/.
- You may also consider contacting your GP for further support.

Confidentiality Concerns: Although every effort will be made to maintain your privacy, there is a small risk that information shared during the session could be unintentionally disclosed by other participants.

9. What are the possible benefits of taking part?

Share your opinions and influence change: This an opportunity to share your opinion on a very important topic. Your input will help by contributing to informing a new definition for the 'high risk' surgical patient which is likely to benefit the management of patients and improve care.

Contribute to Research: Your input will provide valuable insight into the implications of the label of being 'high risk' for surgery and allow for further work in this area.

Share you experiences and connect with others: You will have the opportunity to share your experiences and connect with others who may have gone through a similar experience.

Incentives: To thank you for your valuable input and time in study we offer:

- **Monetary compensation:** You will receive a gift voucher (to be confirmed) for attending the focus group
- **Travel Reimbursement:** If you incur any travel expenses to attend the session, we will reimburse your costs up to £10
- **Refreshments**: Light snacks and beverages will be provided during the focus group session (if in person) to ensure your comfort.

10. Will my taking part in this study be kept confidential?

- All information collected about you, including audio recordings, their transcriptions, and any questionnaires you return, will be kept strictly confidential. You will be identified by an ID number, and any information about you, including your name and address on the questionnaires, will be removed so that you cannot be recognized from it. Please note that assurances on confidentiality will be strictly adhered to unless evidence of serious harm, or risk of serious harm, is uncovered. In such cases, the University of Glasgow and Greater Glasgow and Clyde may be obliged to contact relevant statutory bodies/agencies.

- Any data in paper form, including returned questionnaires, will be stored in locked cabinets in rooms with restricted access at the University of Glasgow/ Glasgow Royal Infirmary. All data in electronic format, including transcriptions of audio recordings, will be stored on secure password-protected computers. No one outside of the research team or appropriate governance staff will be able to find out your name, or any other information which could identify you

11. What will happen to my data?

- We will only collect names and contact details at the beginning of the study to enable us to contact you to send the questionnaire out and arrange attendance to the focus group. Your responses to the questionnaire and transcription of the audio recording will be anonymised and kept in accordance with University of Glasgow data regulations. This means that the University of Glasgow is responsible for looking after your information and using it properly. We may keep non-identifiable information about you for 10 years after the study has finished and will not pass this information to a third party without your express permission.
- Your rights to access, change or move the information we store may be limited, as we need to manage your information in specific ways for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible. You can find out more about how we use your information from Dr Anna-Marie Tiah.

- Researchers from the University of Glasgow collect, store and process all personal information in accordance with the General Data Protection Regulation (2018).
- All study data will be held in accordance with The General Data Protection Regulation (2018)
- The data will be stored in archiving facilities in line with the University of Glasgow retention policy of up to 10 years. After this period, further retention may be agreed, or your data will be securely destroyed in accordance with the relevant standard procedures.
- Your identifiable information might be shared with people who check that the study is done properly and, if you agree, in coded form with other organisations or universities to carry out research to improve scientific understanding. Your data will form part of the study result that will be published in expert journals, presentations, student dissertations/theses (if applicable) and on the internet for other researchers to use. Your name will not appear in any publication.

12. What will happen to the results of the research study?

Once the research study is completed, the results will be analysed and compiled into a final report. The key findings and insights from the study will be:

Shared with Participants: Participants who are interested will receive a summary of the research findings, showing how their input impacted the study.

Published in Academic Journals: The results may be published in scientific journals, presented at conferences, and shared with the broader research community to contribute to the advancement of knowledge in this area.

Potential Impact on Practice and Policy: The findings could contribute to shaping healthcare practices and policies, with the aim of enhancing patient care and services.

Confidentiality Maintained: All results will be reported in a way that maintains your confidentiality. There will be no individual participant identifiable information published in any publications or reports resulting from the study.

13. Who is organising and funding the research?

Dr Anna-Marie Tiah is organising the study as part of her post-doctoral degree with the University of Glasgow. The study will likely be funded by the University of Glasgow MVLS fund and additional funding from a charity/organisation (in the process of being arranged).

14. Who has reviewed the study?

The project has been reviewed by the University of Glasgow research regulation and compliance team, the North of Scotland (2) Research Ethics Committee, and NHS GGC R&I Management.

15. Contact for Further Information

In the first instance please contact:
Dr Anna-Marie Tiah
University of Glasgow

For any complaints or in the second instance please contact:
University of Glasgow Research Regulation and Compliance Team at RRC@glasgow.ac.uk

Thank you for taking part in this study. Your input is invaluable and will help improve patient care. We appreciate your time and effort in sharing your experiences and insights.

13.3 Appendix 4 – Consent form

University of Glasgow | College of Medical, Veterinary & Life Sciences

Centre Number:

Project Number:

Participant Identification Number for this trial:

Title of Project: How do we define and identify the 'high-risk' general surgical patient?

Name of Researcher(s): Dr Anna-Marie Tiah, Prof Susan Moug, Prof Tara Quasim

FOCUS GROUP CONSENT FORM

Please initial box

How do we define and identify high-risk surgical patients

I confirm that I have read and understood the Participant Information Sheet version v4 dated June 2025.	☐
I confirm that I have read and understood the Privacy Notice version v1.1 dated 27.02.2025.	☐
I have had the opportunity to think about the information and ask questions and understand the answers I have been given.	☐
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.	☐
I confirm that I agree to the way my data will be collected and processed, and that data will be stored for up to 10 years in University of Glasgow archiving facilities in accordance with relevant Data Protection policies and regulations.	☐
I understand that all data and information I provide will be kept confidential and will be seen only by study researchers and regulators whose job it is to check the work of researchers.	☐
I agree that my name, contact details and data described in the information sheet will be kept for the purposes of this research project.	☐
I understand that if I withdraw from the study, my data collected up to that point will be retained and used for the remainder of the study.	☐
I agree to take part in the study.	☐

I agree to my medical records being accessed and reviewed to determine details of my surgical procedure.	☐
I agree to my interview/focus group being audio-recorded.	☐
I understand that the answers from questionnaire will be anonymised and stored for up to 10 years in University of Glasgow archiving facilities in accordance with Data Protection policies and regulations.	☐
I understand that the recorded focus group will be transcribed word by word and the transcription stored for up to 10 years in University of Glasgow archiving facilities in accordance with Data Protection policies and regulations.	☐

How do we define and identify high-risk surgical patients

I understand that my information and things that I say in the focus group may be quoted in reports and articles that are published about the study, but my name or anything else that could tell people who I am will not be revealed. ☐

I agree for the anonymised research data, such as anonymised transcriptions and analysis from the focus group to be archived in the UK data archive or other approved archiving facilities, and that other researchers can have access to this data only if they have scientific and ethical approval and agree to preserve the confidentiality of this information as set out in this form. ☐

I agree that should significant concerns regarding my mental or physical health arise during my participation in the study that a member of an appropriate clinical team will be immediately informed. ☐

Name of participant	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Researcher	Date	Signature

(1 copy for participant; 1 copy for researcher)

13.3 Appendix 5 – Pre Focus Group Questionnaire

Pre Focus Group Questionnaire

Thank you for taking the time to complete this questionnaire. Your responses are invaluable and will add to the discussion during the focus group. There are no wrong answers, please feel free to state your opinions for each of the questions. Maintaining your confidentiality is very important to us, please do not include any personally identifiable information.

How do we define and identify high-risk surgical patients

The following explanations are included to assist with completion of the survey.

1. **'High-risk'** - the medical team use this definition to help make decisions about surgery. Someone is considered 'high-risk' if they have a 5% chance of dying from the operation (in other words, 5 out of a 100 people who have the operation, may not survive).
2. Other things come into consideration but do not form part of the definition, such as being older, having other medical issues or illnesses, and not being able to do activities that others of a similar age and stage can do.

Questions

1. Do you think a 5 out of 100 chance of dying is too high or too low to define 'high-risk'?

   Yes ☐ ☐

   If yes, what number (out of a 100) do you think should be considered 'high-risk'?

   _____

2. What do you understand by the term 'high-risk'?

   _____

   _____

   _____

   _____

   _____

3. What do you think makes someone 'high-risk' for surgery?

4. What do you understand by the term '**mortality**'?

5. What do you understand by the term '**morbidity**'?

6. Do you think complications after your operation (such as post-operative infection, bleeding, organ failure etc) are linked to needing critical care, staying in hospital longer, being put on a ventilator, going back into hospital, or developing a new condition like breathing or heart problems?

Yes ☐ No ☐

Please feel free to explain your thoughts if you want to.

_____

_____

_____

_____

_____

7. Do the complications themselves, or the way they affected your life, matter to you more, less, or about the same? Please choose one of the following.

More ☐ Less ☐ About the same ☐

8. Did you discuss the risks of the operation before your surgery?

Yes ☐ No ☐

9. Did you discuss how the risks may impact your life?

Yes ☐ No ☐

10. Did the risks discussed influence your decision to have surgery?

Yes ☐ No ☐

How did they influence your decision?

_____

_____

_____

_____

_____

11. Were there other options, apart from an operation, mentioned?

Yes ☐ No ☐

Please feel free to explain the other options mentioned if you want to.

_____

_____

_____

_____

_____

13.3 Appendix 6 – METER Health literacy form

The form was developed by Katherine A Rawson et al (30)

The following list contains some real medical words. For example, some of the words have to do with body parts or functions, kinds of diseases, or things that can make your health better or worse. The list also contains some items that may look or sound like medical words but that are not actually real words. As you read through the list, put an “X” next to the items that you know are real words. You should not guess. Only put an “X” next to an item if you’re sure it’s a real word.

_____ Irrity _____ Arthritis _____ Obesity _____ Flu _____ Behaviose _____ Syphilis _____ Potassium _____ Hormones _____ Nerves _____ Pilk _____ Rection _____ Blout _____ Boweling _____ Exercise _____ Pustule _____ Cerpes _____ Kidney _____ Emergency _____ Potient _____ Menopause _____ Diagnosis _____ Depretion _____ Jaundice _____ Gallbladder _____ Miscarriage _____ Hepatitis _____ Astiringe _____ Nutral _____ Asthma _____ Inflammatory _____ Anemia _____ Allagren _____ Prognincy _____ Stress _____ Ellargic _____ Inlest _____ Pollent _____ Malories _____ Cancer _____ Alcoheliose _____ Antibiotics _____ Antiregressant _____ Colitis _____ Diabetes _____ Occipitent _____ Nausion _____ Impetigo _____ Menstrual _____ Abghorral _____ Seizure _____ Appendix _____ Fam _____ Infarth _____ Dose _____ Hemorrhoids _____ Testicle _____ Eye _____ Midlocation _____ Insomniate _____ Bloodgatten _____ Sexually _____ Pelvince _____ Vaccilly _____ Prescription _____ Germs _____ Gonorrhea _____ Tumic _____ Fatigue _____ Osteoporosis _____ Constipation

13.3 Appendix 7 – Privacy Notice

PRIVACY NOTICE

Privacy Notice for Participation in Research Project: 'How do we define and identify the 'high-risk' general surgical patient?' Conducted by Dr Anna-Marie Tiah

Your Personal Data

The University of Glasgow will be what's known as the 'Data Controller' of your personal data processed in relation to your participation in the research project 'How do we define and identify the 'high-risk' general surgical patient?' This privacy notice will explain how NHS Greater Glasgow and Clyde and The University of Glasgow will process your personal data.

Why we need it

We are collecting basic personal data such as your name and contact details to conduct our research. We need your name and contact details to send you out a questionnaire and arrange the focus group.
We only collect data that we need for the research project. We will only collect names and contact details at the beginning of the study to enable us to contact you to send the questionnaire out and arrange attendance to the focus group. Your responses to the questionnaire and transcription of the audio recording will be anonymised and kept in accordance with NHS Greater Glasgow and Clyde and University of Glasgow data regulations. This means we will de-identify your personal data from the research data by assigning each participant a unique identifier.
Although every effort will be made to maintain your privacy, there is a small risk that information shared during the session could be unintentionally disclosed. Please see accompanying **Participant Information Sheet**.

Legal basis for processing your data

We must have a legal basis for processing all personal data. As this processing is for Academic Research, we will be relying upon **Task in the Public Interest** to process the basic personal data that you provide. For any special categories data collected we will be processing this on the basis that it is **necessary for archiving purposes, scientific or historical research purposes or statistical purposes**
Alongside this, to fulfil our ethical obligations, we will ask for your **Consent** to take part in the study. Please see accompanying **Consent Form**.

What we do with it and who we share it with

All the personal data you submit is processed by members of the research team based in NHS Greater Glasgow and Clyde and at the University of Glasgow in the United Kingdom. In addition, security measures are in place to ensure that your personal data remains safe: results from questionnaires and transcription from the audio recording of the PPI group will undergo pseudonymisation and be stored securely on the NHS Greater Glasgow and Clyde and University of Glasgow's premises/ computers.
Please consult the **Consent form** and **Participant Information Sheet** which accompanies this notice.
Due to the nature of this research, it is very likely that other researchers may find the data collected to be useful in answering future research questions. We will ask for your explicit consent for your data to be shared in this way.
We will provide you with a summary of the research findings, showing how your input has impacted the study upon request.

What are your rights? *

GDPR provides that individuals have certain rights including: to request access to, copies of and rectification or erasure of personal data and to object to processing. In addition, data subjects may also have the right to restrict the processing of the personal data and to data portability. You can request access to the information we process about you at any time.

If at any point you believe that the information we process relating to you is incorrect, you can request to see this information and may in some instances request to have it restricted, corrected, or erased. You may also have the right to object to the processing of data and the right to data portability.

Please note that as we are processing your personal data for research purposes, the ability to exercise these rights may vary as there are potentially applicable research exemptions under the GDPR and the Data Protection Act 2018. For more information on these exemptions, please see UofG Research with personal and special categories of data.

If you wish to exercise any of these rights, please submit your request via the webform or contact dp@gla.ac.uk

Complaints

If you wish to raise a complaint on how we have handled your personal data, you can contact the University Data Protection Officer who will investigate the matter.
Our Data Protection Officer can be contacted at dataprotectionofficer@glasgow.ac.uk

If you are not satisfied with our response or believe we are not processing your personal data in accordance with the law, you can complain to the Information Commissioner's Office (ICO) https://ico.org.uk/

Who has ethically reviewed the project?

This project has been ethically approved via Health Research Authority Integrated Research Application System (IRAS), University of Glasgow and NHS Greater Glasgow and Clyde.

How long do we keep it for?

Your **personal** data will be retained by the University of Glasgow only for as long as it is necessary for recruitment to the study and analysis of results. After this time, personal data will be securely deleted.
Your **research** data will be retained for a period of ten years in line with the University of Glasgow Guidelines. Specific details in relation to research data storage are provided on the Participant Information Sheet and Consent Form which accompany this notice.

13.3 Appendix 8 – Focus group discussion points

Building on pre-questionnaire

1. Ideally better understand as a group if they think existing comorbidities, age, surgery type makes someone high risk
2. What is it a high risk for? Is it for dying, or complications or both, or patient related outcomes?
3. When they've heard the term do they think it relates to all of the above?
4. What should it relate to?
5. Which of those are important to discuss?
6. Have they as a group had that discussion?
7. Is management discussed in this context?
8. Do patients' decisions depend on the risk of dying or complications or impact of complications?
9. Would knowing you are considered high risk:
    a. Prompt asking for an explanation as to why?
    b. Help contextualise the conversation around management?
    c. Help with the decision-making process?

13.3 Appendix 9 – Clinician survey

Clinician Survey

Suggested questions for clinicians to determine practice of identifying and referring patients to the high-risk clinic. This questionnaire is intended for virtual circulation, and the format below reflects the planned drop-down menus and question flow.

How do we define and identify high-risk surgical patients

Prelude:

The definition of 'high-risk' general surgical patients, based on a 5% mortality rate, fails to account for differences between elective and emergency surgeries or variations across specialties. Elective procedures typically have lower mortality rates, but other significant complications and their impact on patients' lives are overlooked. Designating a patient as high-risk impacts critical care decisions. This survey is part of Dr Anna-Marie Tiah's PhD that seeks to understand patients' and clinicians' perceptions of 'high-risk' in elective general surgery to help create a more accurate definition and ultimately improve outcomes. No personally identifiable information is collected as part of this survey. Thank you for taking the time to complete this survey, your input is invaluable. By completing this survey, you consent to results being published as part of Dr Anna-Marie Tiah's thesis, in any peer reviewed journals, and presentations to learned societies.

Screening question before showing survey (to ensure it reaches intended recipients).

1. Are you currently a consultant or trainee specialising in anaesthesia or general surgery?
   - Yes
     - Proceed to next section
   - No
     - Thank you for taking the time to complete this survey, unfortunately it is only intended for doctors practicing in anaesthesia or general surgery.

Demographic data:

1. What country do you work in?
   - Scotland
   - Northern Ireland
   - England
   - Wales
2. What type of hospital is it?
   - District general hospital
   - Tertiary hospital
   - Teaching hospital
   - Specialist hospital
   - Community or cottage hospital
   - Other (please specify)
3. What specialty do you work in?
   - Anaesthetics
   - Surgery
4. Are you a consultant?
   - Yes
     - Proceed to next section

- No
    - Proceed to question 5

5. Are you currently in an approved training program?
    - Yes
    - No
6. What grade of training are you (if currently out of program please tick the most appropriate box before pausing training)?
    - CT1
    - CT2
    - CT3
    - CT4
    - ST3
    - ST4
    - ST5
    - ST6
    - ST7
    - ST8
7. Have you completed or started an approved training program in surgery or anaesthesia?
    - Yes
        - Proceed to question 8
    - No
        - Thank you for taking the time to complete this survey, unfortunately it is only intended for doctors practicing in anaesthesia or general surgery.
8. Are you a specialty grade doctor?
    - Yes
        - Proceed to next section
    - No
        - Proceed to question 9
9. Are you a clinical fellow?
    - Yes
        - Proceed to question
    - No
        - Thank you for taking the time to complete this survey, unfortunately it is only intended for doctors practicing in anaesthesia or general surgery.

Identification of high-risk patients:

Please answer the following questions in relation to identifying high-risk patients for elective general surgery.

How do we define and identify high-risk surgical patients

1. Which of the following sources of information do you review when determining if someone is high-risk for surgery *(tick all that apply)*?
    - Patient history
    - Lab results
    - Imaging
    - Functional capacity assessments
    - Previous operation notes
    - Previous anaesthetic charts
    - MDT documentation
    - Other (please specify)
2. Which of the following patient characteristics, if any, would you consider to be important in determining a patient to be high risk for surgery *(tick all that apply)*?
    - Age over 65
    - Multiple Co-morbidities
    - Functional status
    - Lifestyle factors
    - Poor previous surgical outcomes
3. Do you prioritise patient characteristics over procedure type when determining if someone is high risk for surgery?
    - Always
    - Often
    - Sometimes
    - Rarely
4. To what extent do pre-existing conditions, like heart disease or diabetes, impact risk evaluation?
    - A bit
    - A lot
    - Depends on other factors
    - Not a lot
5. To what extent does age influence risk evaluation?
    - A bit
    - A lot
    - Depends on other factors
    - Not a lot
6. Is frailty an independent factor that influences you decision-making process?
    - Yes
    - No
7. To what extent previous surgical outcomes impact risk evaluation?
    - A bit
    - A lot

- Depends on other factors
- Not a lot

8. Do you rely on input from other healthcare providers (e.g. specialty nurses, intensivists, cardiologists etc.) to help identify high-risk patients?

    - Always
    - Often
    - Sometimes
    - Rarely

9. Do you utilise any of the following risk tools/ scores to identify and classify high-risk patients for surgery (choose all that apply)?

- Physiological and Operative Severity Score for the Enumeration of Mortality and Morbidity (POSSUM)
- Portsmouth Physiological and Operative Severity Score for the Enumeration of Mortality and Morbidity (P-POSSUM)
- American College of Surgeons national surgical quality improvement program surgical risk calculator (ACS NSQIP)
- The Estimation of Physiologic Ability and Surgical Stress score / model (E-PASS)
- Identification of risk in surgical patients score (IRIS)
- Male, Anaemic, Low albumin, Eighty-five years or over risk score (MALE score)
- biochemistry and haematology outcomes models score (BHOM score)
- Otago surgical audit score
- Fried's 5 point frailty score
- Rockwood Clinical Frailty Scale
- Edmonton Frail Scale
- Electronic frailty index
- Modified frailty index (mFI-5/ mFI-11)
- Surgical Risk Preoperative Assessment System (SURPAS)
- American Society of Anaesthesiologists Physical status classification system (ASA)
- Risk analysis index
- Multidimensional frailty score
- revised-Risk Analysis Index (RAI-rev)
- Multidimensional Prognostic Index (MPI) score
- Groningen Frailty Indicator (GFI)
- Other (please specify)

Barriers and pitfalls to identification

Please answer the below questions in relation to being 'high-risk' for surgery.

1. Do you believe that defining high-risk as a mortality rate of 5% or higher is appropriate?
   - Yes
   - No
2. What do you think about this threshold?
   - About right
   - Too low
   - Too high
3. Do you think current risk tools/ scores reliably identify high-risk patients?
   - Yes
   - No
   - Unsure
4. Does variability in defining and identifying high-risk surgical patients across different specialties or settings create challenges in maintaining consistent practices within your role?
   - Yes
   - No
   - Unsure
5. What are the challenges to identifying high-risk patients?
   - Time pressure
   - Incomplete records
   - Lack of pertinent investigations
   - Variation in identification practice
   - Other (please specify)

Referral practice to high-risk clinic

Please answer the below questions in relation to referral to a pre-operative high-risk clinic.

1. Do you or have you worked at a hospital with access to a high-risk pre-operative clinic?
   - Yes
     - Proceed to question 2
   - No
     - Thank you for contributing to this survey. Your input is invaluable for understanding how high-risk surgical patients are identified.
2. What factors prompt referral to a high-risk clinic (tick all that apply)?
   - Age >65
   - Significant co-morbidities
   - Frailty
   - Poor functional status
   - Increased surgical complexity
   - High-risk determined by risk tool/ score
   - Other (please specify)

3. Do collaborative discussion with colleagues (including allied healthcare professionals) influence referral decisions?
   - Always
   - Often
   - Sometimes
   - Rarely

13.3 Appendix 10 - Participant debrief session template

Objective: To ensure participants leave the session feeling informed, supported and aware of our gratitude for their contribution to the study.

Expected duration: 10 – 15 minutes

Suggested script

1. Welcome and Gratitude:

- 'Thank you for participating in the focus group session today. Your input is invaluable to the study!'

2. Purpose of the Study:

- 'As mentioned in the Participant Information Sheet the purpose of the study is to create a better definition to improve identifying, managing, and consenting high-risk patients...'

3. Emotional Check-In:

- 'We appreciate that some of the topics discussed today may have been sensitive and can be emotionally challenging. How are you feeling after the session? Please feel free to share any feelings, thoughts or concerns...'

4. Confidentiality Reminder:

- 'Your confidentiality is of utmost importance to us, please respect other participants' confidentiality and do not share any personal information discussed today…'

5. Support Resources:

- 'If you feel you need additional support, there are additional resources mentioned in the participant information sheet.'

6. Opportunity for Questions:

- 'Do you have any questions about today, the study or anything else you would like to discuss?'

13.3 Appendix 11 – Facilitator's debrief sheet

Facilitator's Debrief Sheet

Focus Group Title: [Insert Title]

Date: [Insert Date]

Facilitator: [Insert Name(s)]

Note-Taker: [Insert Name]

1. Content review
    a. Summarise the main ideas and key points from discussion, highlighting any initial themes
    b. Reflect on whether discussion was aligned with research questions
    c. Flag any potential gaps in discussion
    d. Note order of speakers, key non-verbal interactions that may have occurred (please use the participants' study IDs when recording)
2. Group dynamics
    a. Were all participants actively involved?
    b. Were there particularly dominating participants?
    c. Any issues with the interaction between participants?
    d. Did any of the group dynamics highlighted influence the conversation?
3. Views on moderation
    a. Did the questions elicit appropriate discussion?
    b. Were there any issues guiding conversation?
    c. Were there any difficulties facilitating the discussion?
    d. Was there sufficient time to achieve appropriate discussion?
4. Logistics feedback
    a. Was the number of participants enough to facilitate discussion?
    b. Was the setting appropriate for the session?
    c. Were there any technical issues? (recording, note taking, accommodating comfort breaks etc.)
5. Feedback – please provide any feedback not captured with the above questions