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How do we define and identify high-risk surgical patients

Submission date 10/07/2025	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 24/07/2025	**Overall study status** Ongoing	
Last Edited 24/07/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The current definition of 'high-risk' general surgical patients is based on a 5 in 100 chance of dying. This definition does not accurately reflect the differences between planned and emergency surgeries or variations across specialities. Emergency surgery patients generally have different characteristics that make them more high-risk compared to those undergoing planned surgery. The actual risk of dying from planned surgery is lower than this definition suggests, but other complications are more likely and impactful, which are not considered. The impact of these complications on patients' lives is also not accounted for in this definition. Labelling a patient as high-risk triggers important care decisions. This study aims to explore and understand patients' and clinicians' perceptions of the label of 'high-risk' and how this impacts their decision-making and discussions around planned care. These findings will be compared with the outcomes that are commonly recorded. The findings from this study will contribute to a definition that is hopefully more representative of what matters most to those involved in this process. This will hopefully help improve the way patients considered to be 'high-risk' are identified and managed.

Who can participate?
Focus Group Study
Adults (people who are 18 years and older) who have had an operation in one of the hospitals in NHS Greater Glasgow and Clyde on their bowel, pancreas or oesophagus in the past year. They must have been discharged from the hospital and consent to take part.

Clinician Survey
Doctors, specialising in general surgery and anaesthetics in the United Kingdom, who are willing to complete a short online survey.

What does the study involve?
Focus Group Study
After reading the patient information sheet and completing the consent form, participants will be invited to complete a questionnaire before 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 majority's decision.

The questionnaires will contain general questions about the understanding of the topic of being 'high risk for surgery' and the 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.

The focus group will last approximately 1-2 hours and will be conducted in a comfortable, non-judgmental setting. Participants will be divided into small groups to discuss their experiences, opinions, and thoughts on 'being high risk for surgery' and how this influenced their decision for surgery. The discussions will be guided by a trained facilitator who will ask open-ended questions to encourage meaningful conversations. 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 participants can choose what to share, ensuring medical confidentiality is maintained. Participants will receive a unique study ID to help anonymise all information. After the study is done, participants will have the opportunity to receive a summary of the results.

Clinician Survey
Participants will be invited to complete a short online survey on their views on the label of 'high-risk' relating to elective general surgery. The survey will be completely anonymous and will not collect any identifiable information. Results of the survey will be made available, ideally through distribution by the professional bodies that circulated the survey. Participants must first consent to the anonymous results being collected, analysed and published/presented before taking part in the survey.

What are the possible benefits and risks of taking part?
Focus group study
Participants will have the opportunity to share their views and experiences with others and contribute towards research. Light refreshments will be available at the focus group, if held in person. As a thank you for participants' valuable contributions and time, travel expenses will be reimbursed (up to a specified amount), and participants will receive a voucher. There is a time commitment and the potential for travel to be involved, if held in person. The questionnaires are likely to take 15 minutes to complete, and the focus group is expected to take 1.5 to 2 hours, excluding travel. If the focus group is held in person, participants will be asked to travel to the location. Some topics discussed might touch on personal or sensitive experiences and could feel emotionally challenging. Participants will be offered the opportunity to bring a support person with them, and resources made available on the participant information sheet for those who may require additional support regarding emotions or topics discussed during the focus group.

Clinician survey
There are minimal risks associated with taking part in the clinician survey. The survey is expected to take a short amount of time to complete, and so there is a small time commitment associated with participation.

Where is the study run from?
This study is part of Dr Anna-Marie Tiah's intended PhD research project with the University of Glasgow and primarily takes place in the West of Scotland. The clinician survey is intended to be national; however will be conducted virtually and coordinated from Glasgow.

When is the study starting and how long is it expected to run for?
January 2025 to May 2026. The Focus Group Study is anticipated to start in August 2025 and will likely run until May 2026. The clinician survey is anticipated to start in August 2025 and will likely run until May 2026.

Who is funding the study?
The study is anticipated to be supported through charitable or endowment funding, subject to final confirmation.

Who is the main contact?
Dr Anna-Marie Tiah, anna-marie.tiah@glasgow.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
355125

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
UGN25SG172

Study information

Scientific Title

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

Acronym
DIALOGUE

Study objectives
1. Understand patients' views of the label of 'high-risk'
2. Undersand clinicians' views of the label of 'high-risk' and their reasoning for referral to the 'high-risk' pre-operative clinics
3. Integrate findings into a definition of 'high-risk' that is more reflective of these views

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 18/06/2025, North of Scotland Research Ethics Committee 2 (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, United Kingdom; +44 (0)1224 558458; gram.nosres@nhs.scot), ref: 25/NS/0064

Study design
Prospective mixed methods study

Primary study design
Observational

Study type(s)
Other, Quality of life, Safety

Health condition(s) or problem(s) studied
Patients' and clinicians' perceptions of label of 'high-risk' in context of elective general surgery.

Interventions
Individuals who have undergone elective pancreatic, oesophagectomy or colorectal surgery will be invited to take part in the focus group component of the study. The aim is to recruit a total of thirty participants. Written consent will be obtained before taking part. Before attending the focus groups, participants will be invited to complete short questionnaires on their perceptions of the term 'high-risk' and health literacy. This will highlight emerging themes, understanding of terminology used during these discussions, to determine topics and the level at which to pitch the discussion. The focus groups will be conducted either entirely in person or online, depending on the majorities' preference, and will consist of likely 3-4 focus groups with 6-10 individuals each. Participants will be encouraged to speak freely and share their opinions, but discouraged from sharing any identifiable information. They will also have a unique study ID, which will be used from enrolment in the study to preserve confidentiality. The focus groups will be recorded, transcribed and analysed. Anonymous results will be made available to all participants, if desired, upon completion of the study.

Clinicians practising in general surgery and anaesthetics in the NHS in the UK will be surveyed for their opinions and practices on identifying and referring patients to preoperative 'high-risk' clinics. This will be in the form of a short virtual survey distributed by anaesthetic and surgical

professional bodies. No personal identifiable information will be collected as part of this survey, and participants will be made aware of this, the scope, and the intended distribution of results of the survey before agreeing to take part. The results will be quantitatively and qualitatively analysed, and a summary of the results will likely be made available through the professional bodies that agreed to circulate the survey.

Intervention Type
Other

Primary outcome(s)
1. Patients' perceptions of the label of 'high-risk', currently defined as 5% mortality, in the context of elective general surgery, will be measured using a thematic analysis of qualitative data gathered from the conduct of focus groups likely to occur in October to November 2025
2. Clinicians' perceptions of the label of 'high-risk', currently defined as mortality > 5%, in the context of elective general surgery and reasoning for referral to the preoperative 'high-risk' clinic, will be measured using quantitative and qualitative analysis of virtual survey results likely to occur in August to September 2025

Key secondary outcome(s))
1. Alternative outcomes to consider in the label/definition of 'high-risk' are measured through emerging themes from the results of the focus groups and survey after both components are completed and analysed
2. Alignment between patients' and clinicians' perceptions of 'high-risk' is measured through emerging themes from the results of the focus groups and survey after both components are completed and analysed
3. Alignment between patients' and clinicians' perceptions of 'high-risk' and current outcomes recorded in databases measured through comparing analysis of the results of focus groups and surveys, and reviewing databases that currently collect outcome data for patients undergoing elective general surgery locally and nationally
4. Influence on perceptions of 'high-risk' and decision making in the context of elective general surgery measured through emerging themes from the results of the focus groups and survey after both components are completed and analysed
5. Suggestions of alternative definitions are likely to be achieved through thematic analysis of survey and focus group responses, with the potential for specific opinions to be stated about this in both arms of the study, after the results of both the survey and focus groups are analysed

Completion date
01/05/2026

Eligibility

Key inclusion criteria
Focus groups:
1. Adults (defined as people over the age of 18)
2. Undergone elective pancreatic, oesophagectomy or colorectal surgery for cancer in the past year
3. The procedure must have been within one of the hospitals in NHS Greater Glasgow and Clyde
4. Have since been discharged from the hospital
5. Able and willing to engage in group discussion
6. Consent to participate in the focus group

Clinician survey:
1. Anaesthetic and Surgical Trainees/speciality grade doctors
2. Anaesthetic and General Surgical Consultants
3. Currently working in the NHS in the United Kingdom
4. Consent to participating in clinician survey (implied by completion of the survey)

Participant type(s)
Healthy volunteer, Patient, Health professional, Employee, Population

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
110 years

Sex
All

Key exclusion criteria
Focus group:
1. Children (defined as people under the age of 18)
2. Not undergone one of the stipulated procedures
3. Emergency procedures
4. Procedure outside of NHS Greater Glasgow and Clyde
5. Still an inpatient
6. Not able and/or willing to engage in group discussion
7. Not able/willing to consent to participation in group discussion

Clinician survey:
1. Do not meet the criteria to be classified as an appropriate trainee/speciality grade doctor
2. Do not meet the criteria to be classified as an appropriate consultant
3. Not currently working in the United Kingdom
4. Not able/ willing to consent to take part in clinician survey

Date of first enrolment
01/08/2025

Date of final enrolment
01/02/2026

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Glasgow Royal Infirmary
84 Castle Street
Glasgow
United Kingdom
G4 0SF

Study participating centre
Royal Alexandra Hospital
Paisley
United Kingdom
PA2 9PN

Study participating centre
Queen Elizabeth University Hospital
1345 Govan Road
Glasgow
United Kingdom
G51 4TF

Study participating centre
Gartnavel General Hospital
1053 Great Western Road
Glasgow
United Kingdom
G12 0YN

Study participating centre
New Victoria Hospital
55 Grange Rd
Glasgow
United Kingdom
G42 9LL

Study participating centre
Stobhill Hospital
133 Balornock Road

Glasgow
United Kingdom
G21 3UW

Study participating centre
Inverclyde Royal Hospital
Larkfield Road
Greenock
United Kingdom
PA16 0XN

Sponsor information

Organisation
University of Glasgow

ROR
https://ror.org/00vtgdb53

Funder(s)

Funder type
Other

Funder Name
Investigator Initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The data resulting from the anonymous analysed findings are likely to be stored in a non-publicly available repository and may be made available upon request by first contacting Dr Anna-Marie Tiah (anna-marie.tiah@glasgow.ac.uk) for the duration of her PhD research project and thereafter by contacting the University of Glasgow.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	Participant information sheet version 0.7	11/11/2025	11/11/2025	No	Yes
Protocol file		23/07/2025	24/07/2025	No	No