Acute PresentatiOn of CoLorectaL Cancer: an internatiOnal snapshot

An international, multi-centre study of emergency presentations of colorectal cancer

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Version 2.0

EuroSurg
Website: eurosurg.org
General email: apollo.eurosurg@gmail.com
REDCap queries: apollo.eurosurg@gmail.com
Twitter: @EuroSurg

Key Study Dates
Study registration opens: 2nd November 2022
Data collection periods: 16th January 2023
Last follow-up period ends: 11th September 2023
ESCP Annual meeting: 20th-23rd September 2023

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Study Management Group

Name	Training stage	Twitter
Niall Brindl	Resident Surgeon, Heidelberg	@BrindlNiall
Daoud Chaudhry	Foundation Doctor (FY1), Stoke-On-Trent	@da_chaudhry
Kassandra Gressmann	4th year medical student, Dublin	
Amie Hilder	3rd year medical student, Melbourne	@amie_hilder
Esther Matey	Foundation Doctor (FY1), Scotland	
Irène Santos	6th year medical student, Porto	@IreneSantos_P
Adam Turňa	4th year medical student, London	@AdamTurna2
Laura Kehoe	5th year medical student, Dublin	
Mustafa Ege Seker	5th year medical student, Istanbul	@MEgeSeker
Noor Essa	5th year medical student, Dublin	
Mafalda Sampaio Alves	5th year medical student, Porto	@sampalvmaf
Muhammed Elhadi	Medical doctor, Tripoli	@ElhadiMuhammed
Chris Varghese	Trainee intern, University of Auckland	@chrisvarghese98
William Xu	Trainee intern, University of Auckland	@williamxu_98

Scientific Advisory Group

Name	Position	Twitter
Ian Bissett	Professor and consultant colorectal surgeon	@ian_bissett
Sue Blackwell	PPI representative at ESCP	@littlemissileo
Stephen Chapman	Research fellow and surgical trainee	@SJ_Chapman
Ruth Blanco Colino	Surgical trainee	@ruthbc93
Eloy Espin	Professor and consultant colorectal surgeon	@eloiespin
James Glasbey	NIHR Doctoral Research Fellow, Birmingham, UK	@DrJamesGlasbey
Susan Moug	Professor and consultant colorectal surgeon	@susanmoug
Dion Morton	Professor and consultant colorectal surgeon	
Dmitri Nepogodiev	Public Health Registrar	@dnepo
Francesco Pata	Consultant colorectal surgeon	@drfrancescopata
Gianluca Pellino	Consultant colorectal surgeon	@GianlucaPellino
Peter Pockney	A/professor and consultant colorectal surgeon	@PPockney
Alessandro Sgrò	Surgical trainee	@AlessandroSgr1
Wal Baraza	Consultant colorectal surgeon	

Collaborative Partners

STARSurg Collaborative
https://starsurg.org/
starsurguk@gmail.com
Twitter: @STARSurgUK

itSURG Collaborative
www.itsurg.org
itsurg.group@gmail.com
Twitter: @it_surg

PTSurg Collaborative
www.ptsurg.org
info@ptsurg.org
Twitter: @pt_surg

SIGMA Collaborative
www.SIGMA-studies.org
team@SIGMA-studies.org
Twitter: @sigmastudies

TASMAN Collaborative
https://anzsurgsocs.org/tasman/
tasmananz@gmail.com
Twitter: @TASMANCollab

Study Delivery Timeline

Dates	Description
Study set up	
Sep 2022	Provisional proposal released at EuroSurg session, ESCP 2022, Dublin
1 Nov 2022	Final protocol release
Oct - Dec 2022	National committees established Patient involvement to prioritise outcomes
Nov - Jan 2022	Application for ethical approval at local centres Application for REDCap Logins
16 Jan 2023	First Collaborator REDCap Accounts Generated (then on a rolling twice weekly basis for all new collaborators – Tuesdays and Fridays)
Data collection	
16 January 2023 - 13 June 2023	Any period of 6 weeks within this 5 month period for patient recruitment. Additional periods can be completed for a total of 12/18 weeks
11 September 2023	Last day of 90-day follow-up
Data validation and analysis	
30 September 2023	Data validation
15 October 2023	REDCap Database Locked, Final Data Submission Deadline
30 October 2023	Deadline for data validation
November 2023	Data analysis and write up
Sep 2023	Preliminary results presented at ESCP 2023 (first half of cohort)

Executive summary

Primary aim: Describe the variation in the operative and non-operative management of emergency presentations of colon and rectal cancer in an international cohort.

Secondary aims:

- Identify risk factors for mortality (intraoperatively, at 30-days and at 90-days) and ostomy rates (at 30- and 90-days) in patients deemed for active management (i.e., not for palliative management) to develop a risk prediction model
- Validate risk criteria of large bowel obstruction in patients with previously known colorectal cancer undergoing neoadjuvant chemotherapy or awaiting elective surgery

Who?

- Patients aged 18 years and above presenting to the hospital acutely with colorectal cancer (CRC) for malignant large bowel obstruction (LBO), perforation, CRC-related haemorrhage or other reasons within the data collection periods. Both those managed with and without surgery will be included
- Patients with localised and metastatic disease will be included
- Patients with known colorectal cancer diagnoses will be included if they present acutely (e.g., with disease progression)

- Patients presenting acutely for the side effects of chemotherapy/radiotherapy of known cancers will be excluded

What?

Data will be collected on patients' presenting status and symptoms, patient management strategies, and intraoperative and postoperative outcomes.

When?

Prospectively over 2023 in consecutive 6-week data collection blocks between January and June with 90-day follow-up till September.

About EuroSurg

The EuroSurg collaborative is an international research group led by students and surgical trainees. Founded at the European Society of Coloproctology (ESCP) 2015 meeting, it has since expanded rapidly with active members in Czech Republic, France, Germany, Italy, Netherlands, Spain, Turkey, Portugal, Ireland, the United Kingdom, Sweden, Norway, Greece, Hungary, Latvia, South Africa, New Zealand and Australia.[1] In our most recent study COMPASS[2,3] which explored the use of peritoneal drains after elective and emergency colorectal surgery, over 20 different countries were involved. Previous EuroSurg projects can be found at http://eurosurg.org/ and include EuroSurg-1, [4] IMAGINE, [5–7] COMPASS, [3] and CASCADE.[8]

The model for trainee-led research collaboratives was pioneered in the UK by local networks of trainee surgeons. These networks have been successful in delivering major surgical research initiatives, including multicentre cohort studies and randomised controlled trials (RCTs). The feasibility of students conducting similar projects was first demonstrated by the Student Audit & Research in Surgery (STARSurg) collaborative, which has delivered several national cohort studies in the UK.[9,10]

Collaboration across international surgical communities produces transferable results which may inform the design of future RCTs and changes in clinical practice. Through participating in a EuroSurg project, students will acquire essential skills in surgical audit and research methodology. EuroSurg's authorship policy designates all student and trainee collaborators as PubMed-citable "Collaborators". An example of this authorship model can be seen here.[3,5]

Introduction

Colorectal cancer (CRC) presents as an emergency in as many as a third of patients,[11,12] 80% of the time with obstruction and, less commonly, perforation and haemorrhage.[13] Emergency surgery for CRC is associated with mortality in 15-34%, morbidity in 32-64%,[14] higher ostomy rates, and poorer health related quality of life,[14] Patients presenting emergently with CRC also tend towards more deranged physiology and advanced tumour biology.[13,15]

Existing guidelines on the optimal management of such cases are based on predominantly low grade evidence,[16] and current series remain small. Global practices in the management of emergency CRC remain unquantified. There are various options for patients presenting acutely with colorectal cancer, such as primary resection with anastomosis, colonic stenting as a bridge to elective surgery, primary resection with an end colostomy, or defunctioning stomas. Furthermore, with the rising use of neoadjuvant chemotherapy for colonic cancer,[17] management pathways have become increasingly complex. Accurate operative and anastomosis risk prediction in acutely presenting colorectal cancer may help guide clinical decision making.

A significant number of patients presenting with malignant large bowel obstruction also have disseminated disease.[18] For these patients, self-expandable metal stents may offer a lower risk of permanent stoma compared to traditional surgical options, but also may result in perforations.[19,20] The use of stents worldwide remains unquantified.

There is impetus for an international snapshot audit of emergency presentations of CRC to capture prospective outcome data and describe the variation in management worldwide. These data would be useful to externally validate ongoing trials, and identify new research gaps to power new trials.

APOLLO (Acute PresentatiOn of CoLorectaL Cancer: an internatiOnal snapshot) is an international, multi-centre, prospective observational study which will address this need and aims to describe the operative and non-operative management of emergency presentations of colon and rectal cancer in an international cohort.

Methods

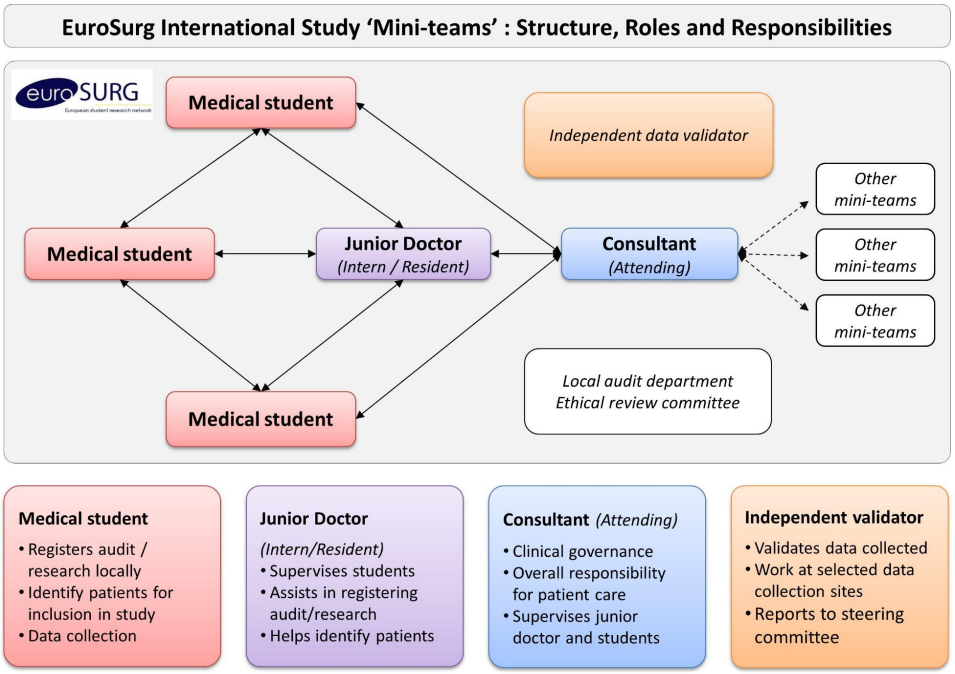
1. Study aims

The primary aim of the **APOLLO** (Acute PresentatiOn of CoLorectaL Cancer: an internatiOnal snapshot) study is to describe the operative and non-operative management of emergency presentations of colon and rectal cancer in an international cohort. Secondary aims will be to describe 30-day and 90-day management outcomes, identify the risk factors for intraoperative, 30-day, and 90-day mortality and ostomy rates in patients deemed for active management (i.e., not for palliative management), and develop a mortality and ostomy risk prediction model for patients undergoing active management for colorectal cancer. This study will also aim to validate risk criteria of large bowel obstruction in patients with previously known colorectal cancer undergoing neoadjuvant chemotherapy or awaiting elective surgery

2. Study design

APOLLO is an international, multi-centre, prospective observational study of acutely (i.e. unplanned and non-elective presentation to hospital for urgent or emergency reasons) presenting colorectal cancer. This study will adapt the student- and trainee-led collaborative research model. 'Mini-teams' of collaborators will participate at each hospital, with a range of members including medical students, junior doctors, trainees, registrars, and supervising consultants (**Figure 1**). It is compulsory to have a consultant supervisor who is able to guide and advise how you may register the study at your hospital, and what approvals will be required. **It will also be compulsory to have 1 general surgical trainee as a member of your mini-team.**

Figure 1: Mini-team structure



At each hospital, one mini-team per period will collect data on eligible patients admitted over a consecutive 6-week period. Patients should be included if their hospital admission started (defined as 'date of hospital admission') within the time period during the data collection periods as specified above.

3. Setting

APOLLO is open to any secondary or tertiary hospitals across the world with a general or colorectal surgery department performing major colorectal cancer surgery. All participating centres will be required to register the study according to local regulations, evidence of which must be uploaded onto REDCap prior to the commencement of data collection from each respective site. As this is an audit of practice, no change to normal patient management is required.

In the UK, **APOLLO** has been designated an audit of practice. Internationally, individual study investigators are responsible for ensuring the correct approvals have been achieved prior to commencing data collection. At each hospital, one mini-team per period will collect data on eligible patients admitted over a consecutive 6-week period. Following the conclusion of the study, it is recommended that mini-teams at each centre present the study findings to their hospital's surgery departments in order to close the audit loop.

4. Project timeline

Collaborators at each participating centre will prospectively collect data for all eligible patients over minimum 6-week periods from January to June 2023. Sites can contribute in multiple 6-week periods, providing they are **not** overlapping.

There will be a rolling start date from 16 January, 2023 to 1 May, 2023. The last date a patient can be recruited is the 13 June. All 90-day follow-up should be completed by 11 September, 2023. Recruitment dates may be extended at the discretion of the steering committee, allowing for extensions if there are delays in site initiation.

5. Patient eligibility

Summary: Consecutive adult patients (≥18 years of age) presenting acutely (i.e. unplanned and non-elective presentation to hospital for urgent or emergency reasons) for symptoms of known or unknown colorectal cancer assessed by hospital surgical teams. Patients should be included regardless of operative or non-operative management, and curative or palliative intent.

Inclusion criteria	
Age	18 years and above
Patient pathology	Patients admitted to the hospital acutely with **primary colon AND/OR rectal adenocarcinoma** and referred to general/colorectal surgical departments This includes: ● Patients who are operated on for curative/palliative treatment of colorectal cancer ● Patients who are referred to general surgery for assessment (irrespective of if they proceed to surgery) ● New diagnoses of colorectal cancer
Extent of cancer	All patients including extra-abdominal metastatic, intra-abdominal metastatic and non-metastatic disease
Known cancer	Patients presenting for the first time with colorectal cancer **AND/OR** Known colorectal cancer diagnosis with progression of disease. i.e. obstruction of known colorectal cancer
Patient presentation	Symptomatic presentation of colorectal cancer i.e. large bowel obstruction, haemorrhage, perforation
Exclusion criteria	
Presenting for side effects of cancer treatment	Patients presenting acutely for the side effects of chemotherapy/radiotherapy of known cancers are excluded
Patients with non-colorectal primary cancers	Non-primary colorectal cancers that have metastasised to the colon and rectum (e.g., melanoma or lymphoma). Primary neuroendocrine tumours, gastrointestinal lymphomas, gastrointestinal stromal tumours, and primary colorectal squamous cell carcinomas should also be excluded.
Previously included in dataset	Patients should only be included once in APOLLO

All eligible patients must be included to avoid selection bias.

6. Patient identification

Teams should collect data on consecutive eligible patients at their hospital during the data collection period. Strategies to identify consecutive patients could include:

- Daily review of theatre lists
- Daily review of handover meetings/sheets and ward lists
- Daily review of theatre logbooks
- Daily review of new inpatient referrals to surgical team
- Daily on call review of patients undergoing emergency surgery
- Colorectal cancer multidisciplinary team meetings

7. Outcomes and variables

Primary outcome: 90-day mortality since day of presentation

Secondary outcomes include:

- Inpatient mortality, 30-day mortality since day of presentation
- Operative 30- and 90-day mortality rates
- Rates of primary anastomosis
- 30- and 90-day stoma formation and reversal rates
- Rate and grade of surgical complications
- Rates of stenting in those with left-sided LBO, rates of stenting in those treated with palliative intent [21,22], rate of colonic stenting complications
- Rate of representation for patients managed nonoperatively
- Rates of radiological assessment on admission
- Proportion of patients presenting acutely with large bowel obstruction with known colorectal cancer who had high risk criteria for obstruction (as defined by the FOXTroT obstruction criteria) at index assessment

Audit standard outcomes:

- All patients with suspected LBO should have a contrast-enhanced CT [23]
- <20% 90-day mortality after emergency colorectal cancer surgery (grade b) (consistent with NBOCA recommendations)

Variables

- Covariates are detailed in **Appendix B**

8. Follow up

Patients will be followed up for 90-days after presentation. No change in routine follow up should take place. Collaborators should be proactive in identifying follow-up data, but this should be done within the limits of routine follow up.

Strategies for follow-up include:

- Regularly reviewing patient notes to identify in-hospital complications
- Participating in daily ward rounds and doctor reviews
- Reviewing clinic notes and clinic letters, if seen in clinic by 30 days
- Checking electronic systems and handover lists for re-admissions
- Checking for emergency department re-attendances

9. Data collection and storage

Data will be collected and stored online via the Research Electronic Data Capture (REDCap) web application,[24,25] hosted and managed by the Birmingham Surgical Trials Consortium (BiSTC) REDCap system hosted at the University of Birmingham, United Kingdom.

REDCap allows collaborators to enter and store data in a secure system. It is widely used by academic institutions throughout Europe and all storage of web-based information by this system is encrypted and compliant with HIPAA-Security Guidelines in the United States.

The security of the study database system is governed by the policies of the University of Birmingham. Data management and data security within the BiSTC REDCap will abide by the requirements of the General Data Protection Regulations (GDPR) and any subsequent amendments. Collaborators will be given secure REDCap project server login details, allowing secure data storage on the REDCap system.

No patient data will be uploaded or stored on the REDCap database without prior local permissions.

All data should be handled in accordance with local data governance policies, and all paper copies of any data should be destroyed as confidential waste within the centre once uploaded to REDCap.

It will not be possible to store patient identification numbers (hospital numbers) on REDCap. A unique ‘REDCap ID’ will be generated by the system for each patient. If needed, you may keep a local cross-reference of hospital numbers and REDCap IDs. This should be kept in a secure, encrypted spreadsheet on a hospital, password-protected computer. No patient identifiable data will be uploaded or stored on the REDCap database.

One REDCap login will be issued per collaborator and **only** that person may use the login. If you experience problems, please email apollo.eurosurg@gmail.com.

Data collected during the **APOLLO** study can be used for future analyses at the Study Management Group's discretion.

10. Statistical analysis plan

The primary descriptive analysis will be investigating emergency CRC presentation and their respective management.

- Presenting symptoms — rates of obstruction, perforation and bleeding
- Management approaches — resection, primary anastomosis, end-stoma formation, stents, palliation
- Outcomes — rates of mortality, ostomy rates

Planned secondary analyses include:

- A risk prediction tool in emergency CRC surgery with curative intent for 30- and 90-day mortality will be created per the TRIPOD statement to guide management in emergency colorectal cancer surgery if the recruitment numbers allow (LBO ± perforation/others). This will allow colorectal surgeons to preoperatively predict short term morbidity and mortality and determine which patients may instead benefit from a lower-risk bridging stent before elective surgery.
- A risk prediction tool for whether to anastomosis or not (preoperative) to aid decision making

For model development, a mixed effects logistic regression model will be built with candidate variables selected based on clinical plausibility. Relative model fits will be assessed using Akaike information criterion (AIC) to obtain the most parsimonious model. Area under the receiver operating characteristic curve (AUROC) will be used to assess discrimination. The linearity assumption for logistic regression will be assessed by plotting. Validation of the model will be performed as the methods of Bonsdorff et al [26]. Statistical analysis will be completed using R (R Foundation Statistical Program).

11. Local governance and ethical approval

It is compulsory to have a consultant supervisor who is able to guide and advise how you may register the study at your hospital, and what approvals will be required. These must be added to the REDCap database as evidence of approvals. You may also seek advice from your local audit department, or get in touch with the apollo.eurosurg@gmail.com for further advice. **It will also be compulsory to have a minimum of 1 general surgical registrar as members of your mini-team when possible (*2 recommended if possible*).** If there is only one or no general surgical registrar available, team structures will be approved on a case-by-case basis.

In the UK, the study may be registered as a clinical audit or “service evaluation” to assess mortality after emergency colorectal cancer surgery:

> *<20% 90-day mortality after emergency colorectal cancer surgery (grade b) (consistent with NBOCA recommendations)*

When registering the study, the following points should be made clear:

- All data collected will measure current practice

- No changes to normal patient pathways/ treatment will be made
- This is an international audit

UK collaborators should also seek their NHS trust's Caldicott Guardian's approval to submit data to the REDCap system.

Collaborators should complete the mandatory data governance e-learning module which will be made available on the online project hub: http://www.eurosurg.org

12. Quality assurance

Design: This protocol was written with guidance from an international expert cross-speciality advisory group and with the contribution of patient representatives. A data dictionary will be developed to help collaborators in collecting data and patient inclusion. E-learning materials will be available on our website (eurosurg.org).

Data completeness: Following data collection, only data sets with >95% data completeness will be accepted for pooled analysis. To emphasise the importance of data completeness to collaborators, centres with >5% missing data points will be excluded from the study and collaborators from those centres withdrawn from the published list of citable collaborators. See further details under 'Authorship and miniteams'.

Validation: Data validation will be performed to ensure all consecutive cases were recruited. Data validators may be either a final year student or a qualified doctor who were not involved in the initial data collection.

The validator will be required to validate a minimum of 1x 6-week period for the centre for which they are acting as the data validator. The validator will require to review every case to confirm case ascertainment and subsequently check a random 20% of collected data points to ensure accurate data collection.

After completing validation, the validator will send a summary of how many records were reviewed and error rates to the study management group. There are two components of validation:

I. Case ascertainment:

The validator will independently identify all patients eligible for inclusion over the one 6-week study period. The target for data ascertainment is >95%.

II. Data collection

The validator will independently collect data for the key data fields relating to risk-adjustment and outcome measures (see **Appendix A**).

Any conflicts with the data originally submitted by the relevant mini-team will be resolved by discussion between the validator and the mini-team. The target for accuracy of collected data is >98%.

13. Authorship and mini-teams

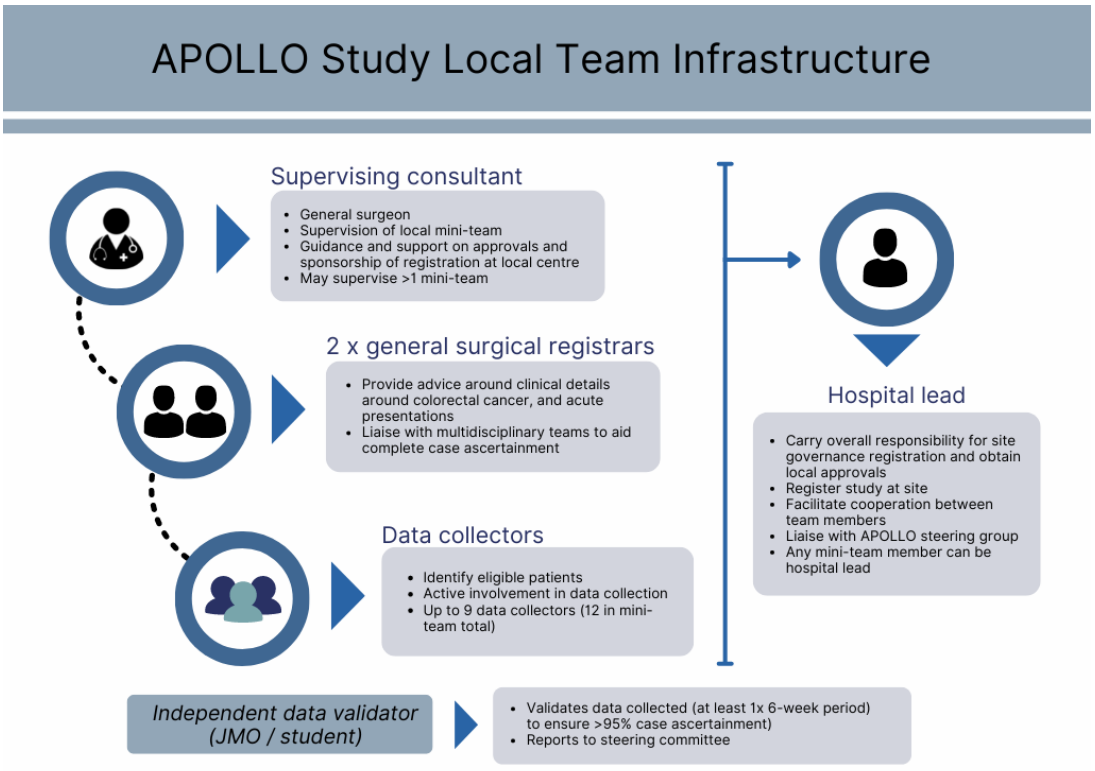
Medical students will take the lead in disseminating and delivering this study, which is supported by national committees of medical students, trainees and consultant/attending surgeons.

In accordance with National Research Collaborative (NRC) authorship guidelines [27], all research outputs from **APOLLO** will be listed under a single corporate authorship ("EuroSurg Collaborative"). All collaborators will be listed as PubMed-citable collaborators within the EuroSurg Collaborative in accordance with the roles defined below (so long as the minimum requirements for authorship are achieved):

To be credited with authorship, all collaborators must provide a valid ORCID identifier (https://orcid.org/register). Authorship lists for all papers will be made from these.

Mini-teams for the **APOLLO** study can consist of up to 12 members, including a minimum of 1 supervising consultant, and 1 general surgical registrar (*for small centres with no trainees, this requirement will be waived*). Any of the 12 mini-team members can be the **Hospital Lead** and will be responsible for maintaining communication with the EuroSurg Steering Committee.

Tip: We recommend that 6 of the 9 other members are allocated to data collection over a 6-week consecutive period, and 3 of the 9 other members are allocated to collecting 30- and 90-day follow-up data.



Collaborator role descriptions are as follows:

1. **Local supervising consultant/attending:** provide guidance for approval processes, facilitate communication within the hospital, and mentor and facilitate medical students, junior doctors and registrars in conducting the study at your local site. They have overall responsibility for the site governance registration and should support data collection. Only one person can fulfil this role. Minimum requirements for authorship include:
    - Sponsorship of local study registration, and responsibility to ensure local collaborators act in accordance with local governance guidelines.
    - Successful completion of data collection at a centre which meets the criteria for inclusion within the **APOLLO** dataset.
    - Facilitation of local result presentation and support of appropriate local interventions.

    Sponsorship through the audit approval / project registration process by a consultant does not constitute authorship, nor does inclusion of a consultants' patients alone in the audit serve sufficient for authorship.

2. **Hospital lead:** this role can be fulfilled by a medical student, junior doctor, trainee or the consultant supervisor/PI (as above). Prior experience in collaborative research is recommended but not essential. Additional support can be sought from EuroSurg. They will be the single lead point of contact for data collection at each site and will liaise with the local PI and EuroSurg. You must be responsive to communication from the PI, governance bodies, and EuroSurg.
    - Primary person responsible in obtaining local approvals for conduct of the **APOLLO** Study (e.g. registration of the audit, seeking permission to upload data to REDCap).
    - Successful completion of data collection at a centre which meets the criteria for inclusion within the **APOLLO** dataset.
    - A hospital lead guide can be found in **Appendix D**.

3. **General Surgical Registrar/Resident/Trainee**: a minimum of 1 member of the mini-team is required to be general surgical registrar. It is recommended 2 general surgical registrars/trainees are included in your team if possible. Their role will be:
    - Providing advice around clinical details around colorectal cancer, and acute presentations
    - Liaising with multidisciplinary teams to aid complete case ascertainment

4. **Local collaborators**: a team of up to 9 data collectors per specialty, per centre). Minimum requirements for authorship on **APOLLO** publications include:
    - Compliance with local audit approval processes and data governance policies.
    - Active involvement in data collection over at least one data collection period at a centre which meets the criteria for inclusion within the **APOLLO** dataset.
    - Collaboration with the hospital leads to ensure that the audit results are reported back to the audit office / clinical teams.

5. **Local validators:** A final year medical student or junior doctor not involved with data collection whose role is to ensure adequate **data ascertainment** and **data collection accuracy** (see 12. Quality assurance)
    - The validator will be a 6-week data collection period at their local centre to validate. Data validation will occur following completion of data collection (including follow-up).
    - After completing validation, the validator will send a summary of how many records were reviewed and error rates to the study management group.

6. **National network committees**: A core group of medical students and surgical trainees in each participating country responsible for study dissemination, protocol translation and supporting students to correctly register and run the study at each participating centre.

7. **Writing Group:** A group of medical students, junior doctors and external advisory board members responsible for the overall scientific content, data analysis, and preparation of individual research manuscripts.

8. **Study management group:** A core group of medical students and junior doctors who have overall responsibility for protocol design, project coordination, and data handling

9. **Data Management and Statistical Analysis group:** A sub team who take overall responsibility for the quality assurance of data analysis and statistical analysis plans.

10. **External Advisory Group:** A panel of cross-disciplinary field experts who are able to ensure contextual and scientific relevance of the protocol design, data fields and data interpretation.

Criteria for site inclusion within APOLLO

- Successful in obtaining all relevant local approvals for conduct of the **APOLLO** Study
- Have completed the site survey
- Successful data collection of at least one eligible patient per period for each site
- Individual sites must also ensure
    1. They obtain **>95% data completeness** for all required fields
    2. All data has been uploaded by the specified database closure deadline

Should these criteria not be met, the contributing mini-team and any data they contribute may not be included in the final study, and they may be removed from any authorship lists. You are advised to get in touch with us as soon as possible so we may support you with ensuring your site is able to successfully collect data towards the **APOLLO** Study.

For guidance relating to mini-team setup and audit registration, please contact your local supervising consultant or local lead. If you would be interested in signing up as a PI for a new centre not currently involved, or for any general enquiries regarding the protocol, please contact us via email (apollo.eurosurg@gmail.com) or Twitter (@EuroSurg)

14. Patient and public involvement

To better understand the outcomes important to patients living with colorectal cancer we asked the opinion of patients, aiming to clarify what matters to them most in the acute period. Patients were invited to fill out an anonymous survey through social media.

The main questions concerned their experience with presenting to the hospital in an emergency with colorectal cancer, with an emphasis on which outcomes after surgery were most important to them. Furthermore, an emphasis was placed on understanding what information was presented to them regarding treatment options in the acute setting.

Patient and public involvement in this study will be reported according to the short form of the Guidance for Reporting Involvement of Patients and the Public (GRIPP2) reporting checklist (https://www.bmj.com/content/358/bmj.j3453).

15. Expected outputs

Unit level data for comparison will be fed back to collaborators to support local service improvement (upon request). This project will be submitted for presentation at national and international conferences. Manuscript(s) will be prepared following close of the project.

Acknowledgements

We thank the **Birmingham Surgical Trials Consortium (BiSTC)** for kindly hosting **APOLLO** on their REDCap servers.
Website: https://www.birmingham.ac.uk/research/activity/mds/trials/BiSTC/index.aspx

We thank the **European Society of Coloproctology (ESCP)** for their kind support.
Website: https://www.escp.eu.com/

Appendix A: APOLLO Study Case Report Form

APOLLO Case Report Form (CRF)

Use with Appendix (Data Dictionary) to help data collection.

REDCap unique ID	
Data collection date range	

Section 1: Baseline data fields — Date of presentation

Age		Sex	◻ M ◻ F	ASA Grade	◻ I ◻ II ◻ III ◻ IV ◻ V	Weight (kg)		Height (cm)		BMI	

Clinical frailty score	◻ 1. Very fit ◻ 2. Well ◻ 3. Managing well ◻ 4. Vulnerable ◻ 5. Mildly frail ◻ 6. Moderately frail ◻ 7. Severely frail ◻ 8. Very severely frail ◻ 9. Terminally ill	Charlson comorbidity index	◻ MI ◻ CHF ◻ PVD ◻ CVA/ TIA ◻ Dementia ◻ COPD ◻ Peptic Ulcer Disease ◻ Hemiplegia ◻ Leukaemia ◻ Lymphoma ◻ AIDS
		Diabetes mellitus	◻ Diet controlled ◻ Uncomplicated ◻ End-organ damage
		Liver disease	◻ Mild ◻ Moderate ◻ Severe
		CKD	◻ eGFR < 60 ◻ Dialysis ◻ Post kidney transplant ◻ uraemia
		Solid tumour	◻ Localised ◻ Metastatic
			◻ None of the Above

Smoking Status	◻ Current ◻ Stopped smoking <6 weeks ◻ Stopped smoking 6 weeks – 1 year ◻ Stopped smoking >1 year ◻ Never smoked ◻ Unknown	History of abdominal surgery	◻ Yes ◻ No	Including this operation, number of operations in the 30-days prior to procedure	◻ 1 operation ◻ 2 operations ◻ >2 operations

Section 2: Disease details

Known cancer	◻ Yes – date of diagnosis dd/mm/YYYY ◻ No	If known cancer, status of known cancer	◻ Awaiting elective surgery ◻ Undergoing neoadjuvant chemotherapy/radiotherapy before surgery ◻ Non-surgical management (including palliative) ◻ Other (specify) _____	Reason for acute presentation	◻ Bowel obstruction ◻ Haemorrhage ◻ Anaemia ◻ Perforation ◻ Other (specify)

Location of tumour	◻ Caecum ◻ Ascending colon ◻ Hepatic Flexure ◻ Transverse colon ◻ Splenic flexure ◻ Descending colon ◻ Sigmoid or rectosigmoid ◻ Rectum ◻ Synchronous → branching		
FIT status in past year	◻ Positive ◻ Negative ◻ Unknown	Colonic investigation in past year	◻ Colonoscopy ◻ CT colonography ◻ CT colonoscopy minimal preparation
		If yes:	◻ Malignancy diagnosed ◻ Polyp resected ◻ Polyp not resected ◻ Nil findings

Section 3: Radiological and endoscopic investigations

Radiological assessment	Yes : ◻ Non-contrast CT, ◻ Contrast CT, ◻ MRI rectum, ◻ Abdominal XR, ◻ Other (specify) _____	◻ No	Radiological features	◻ Circumferential tumour ◻ Stricturing tumour ◻ Obstructing tumour	
Endoscopic assessment	◻ Yes	◻ No	Endoscopic findings	◻ Unable to pass scope ◻ Circumferential tumour ◻ Stricturing tumour ◻ Ulcerating tumour ◻ Polypoid tumour. ◻ Obstructing tumour	

T-stage	◻ T1 - Invades submucosa ◻ T2 - Invades muscularis propria ◻ T3 - Beyond muscularis propria ◻ T4 - Adjacent organs/peritoneum	N-stage	◻ NX (cannot be assessed) ◻ N0. ◻ N1 (1-3 nodes) ◻ N2 (4+ nodes)	M-stage	◻ MX (cannot be assessed) ◻ M0 (no distant metastases) ◻ M1 (distant metastases)
Mismatch repair gene status		◻ Proficient ◻ Deficient ◻ Unknown			

If ***known cancer***, were CT/PET assessments done at the *previous* time of diagnosis	◻ Yes ◻ No	Tick all radiological features that apply for the across:	◻ Circumferential tumour on radiology; ◻ Stricturing tumour on radiology	
If ***known cancer***, was endoscopy done at the *previous* time of diagnosis?	◻ Yes ◻ No	Tick all endoscopic features that apply for the across:	◻ Unable to pass endoscope beyond tumour ◻ Stricturing disease on endoscopy	

Section 4: Management

Intent of treatment	◻ Curative (treat the cancer) ◻ Palliative (symptomatic treatment i.e. relief of obstruction without intention to attempt cure of cancer)
Immediate management at this presentation (tick all that apply)	◻ Surgical ◻ Procedural ◻ Non-operative ◻ Other (specify)
	◻ Resection: ◻ Right ◻ Left ◻ Subtotal ◻ Total colectomy ◻ Hartmann's procedure ◻ Stoma: ◻Loop ◻End ◻ Primary anastomosis ◻ Colonic metallic stent ◻ Transanal drainage tube _____

Section 5: Surgical variables *if undertaken*

Operative urgency	◻ Immediate ◻ Urgent ◻ Expedited ◻ Elective	Intra-operative contamination	◻ Clean-contaminated ◻ Contaminated ◻ Dirty	Operative approach	◻ Open ◻ Laparoscopic ◻ Laparoscopic-assisted ◻ Laparoscopic converted to open ◻ Robotic ◻ Robotic converted to open

Intraoperative complications	◻ None ◻ Vascular injury ◻ Bowel injury ◻ Injury other organs or structures	Surgeon skill level	◻ Consultant colorectal surgeon ◻ Emergency general surgeon/non-colorectal surgeon ◻ Surgical resident/registrar ◻ Other _____	Critical care unit admission	◻ Yes - planned ◻ Yes - unplanned ◻ No

Section 6: Endoscopic procedure variables if stenting undertaken for obstructing tumour

Endoscopic urgency	◻ Immediate ◻ Urgent ◻ Expedited ◻ Elective	Endoscopic complications	◻ None ◻ Technical failure and inadequate decompression ◻ Bowel perforation ◻ Procedure abandoned	Proceduralist skill level	◻ Consultant colorectal surgeon ◻ Consultant gastroenterologist ◻ Surgical/gastroenterology resident/registrar ◻ Other _____

<table>
<tr><th colspan="10">Section 7: 30-day follow up</th></tr>
<tr><td>Location</td><td colspan="3">□ Inpatient
□ Discharged from index admission dd/mm/yy
□ Dead dd/mm/yy</td><td colspan="3">Highest 30-day Clavien-Dindo complication grade (if surgery)</td><td colspan="3">□ None □ I □ II □ IIIa/IIIb □ IVa/IVb □V</td></tr>
<tr><th colspan="10">Section 8: 90-day follow up</th></tr>
<tr><td>Location</td><td colspan="2">□ Inpatient
□ Discharged from index admission dd/mm/yy
□ Dead dd/mm/yy</td><td>Highest 90-day Clavien-Dindo (if surgery)</td><td>□ None □ I □ II
□ IIIa/IIIb
□ IVa/IVb □V</td><td>Pathological results</td><td>□ pR0
□ pR1
□ pR2</td><td>Started neoadjuvant chemotherapy</td><td>□ Yes dd/mm/yy
□ No</td></tr>
<tr><td>Late complications of colonic stents?</td><td>□ Yes dd/mm/yy
Specify:
□ Migration
□ Obstruction
□ Other
_____</td><td>□ No
□ NA</td><td>Stoma reversed within 90 days</td><td>□ Yes dd/mm/yy
□ No
□ NA</td><td>Elective colorectal resection completed if no primary surgery</td><td>□ Yes dd/mm/yy
□ No
□ NA</td><td>Anastomotic leak (if surgery)</td><td>□ Yes dd/mm/yy
□ No</td></tr>
<tr><td>Readmission within 90 days</td><td>□ Yes dd/mm/yy
□ No</td><td>Reason for readmission:</td><td colspan="2">□ Bowel obstruction
□ Haemorrhage
□ Anaemia
□ Perforation
□ Other
_____</td><td>Discharge date of readmission</td><td>dd/mm/yy
□ NA</td><td>Reoperation within 90 days</td><td>□ Yes dd/mm/yy
□ No</td></tr>
</table>

Appendix B: Data Dictionary

Baseline data fields	Required data (definition/comment)
Data collection period	Start date - end date
Age	Years (at time of presentation)
Sex	Male/Female
American Society of Anesthesiologists (ASA) physical status	I, II, III, IV, V
Body Mass Index	(BMI) Height, weight, BMI (calculator)
Smoking	Current - cigarette Current - vaping Previous (stopped smoking <6 weeks) - cigarette Previous (stopped smoking <6 weeks) - vaping Previous (stopped smoking 6 weeks – 1 year) - cigarette Previous (stopped smoking 6 weeks – 1 year) - vaping Previous (stopped smoking>1 year) - cigarette Previous (stopped smoking>1 year) - vaping Never smoked
Charlson comorbidity index	Myocardial Infarction (MI) Congestive Heart Failure (CHF) Peripheral Vascular Disease (PVD) Cerebrovascular Accident (CVA) or Transient Ischaemic Attack (TIA) Dementia Chronic Obstructive Pulmonary Disease (COPD) Peptic Ulcer Disease Liver Disease (mild - chronic hepatitis or cirrhosis w/o portal hypertension, moderate - cirrhosis with portal hypertension but no variceal bleeding hx, severe - cirrhosis with portal hypertension with variceal bleeding hx) Diabetes Mellitus (none or diet controlled, uncomplicated, end-organ damage) Chronic Kidney Disease (CKD) Estimated Glomerular Filtration Rate (eGFR) <60/ml/min/1.73m2 , dialysis or post kidney transplant, or uraemia. Hemiplegia Solid tumour (localised, metastatic) Leukaemia Lymphoma AIDS None of the Above
Clinical Frailty Score [28]	1. **Very fit.** Robust, active, energetic, well-motivated, and fit; these people commonly exercise regularly and are in the most fit group for their age.

	2. **Well.** People who have no active disease symptoms but are less fit than people in category 1. Often, they exercise or are very active occasionally, e.g., seasonally. 3. **Managing well.** People whose medical problems are well controlled but are not regularly active beyond routine walking. 4. **Vulnerable.** While not dependent on others for daily help, often symptoms limit activities. A common complaint is being “slowed up”, and/or being tired during the day. 5. **Mildly frail.** These people often have more evident slowing and need help in high order instrumental activities of daily living (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework. 6. **Moderately frail.** People need help with all outside activities and with keeping house. Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (cuing, standby) with dressing. 7. **Severely frail.** Completely dependent for personal care, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months). 8. **Very severely frail.** Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness. 9. **Terminally ill.** Approaching the end of life. This category applies to people with a life expectancy <6 months, who are not otherwise evidently frail.
History of abdominal surgery	Yes/no
Including this operation, number of operations this patient has had in the 30 day period prior to this procedure	1 operation 2 operations >2 operations
Disease details	
Date of acute presentation	dd/mm/YYYY
Known cancer	Yes - known cancer (date of diagnosis) No - first presentation of colorectal cancer

Reason for acute presentation (tick all that apply)	Bowel obstruction Haemorrhage/anaemia Perforation Other (specify)
If known cancer Status of known cancer	Awaiting elective surgery Undergoing neoadjuvant chemotherapy/radiotherapy before surgery Non-surgical management (including palliative) Other (specify)
Location of tumour	Caecum Ascending colon Hepatic Flexure Transverse colon Splenic flexure Descending colon Sigmoid or rectosigmoid Rectum Synchronous → fill second checkbox
FOBT (faecal occult blood test) status in past year	Positive Negative Unknown
FIT (faecal immunochemical test) status in past year	Positive Negative Unknown
Colonic investigation in past year	Colonoscopy/CT colonography/CT colonoscopy minimal preparation If yes: Yes - malignancy diagnosed Yes - polyp resected Yes - polyp not resected Nil findings
Radiological and endoscopic investigations	
Radiological assessment completed on *this* presentation (tick all that apply)	Yes - non-contrast CT Yes - contrast CT Yes - MRI rectum Yes - abdominal X-ray Yes - other (specify) No
T-stage (preferably on contrast staging CT)	T1 - Invades submucosa T2 - Invades muscularis propria T3 - Beyond muscularis propria T4 - Adjacent organs or peritoneum
N-stage	NX (cannot be assessed)

	N0 N1 (1-3 nodes) N2 (4+ nodes)
M-stage	MX (cannot be assessed) M0 (no distant metastases) M1 (distant metastases)
Radiological features (tick all that apply)	Circumferential tumour Stricturing tumour Obstructing tumour
Mismatch repair gene status	Deficient Proficient Unknown
Endoscopic assessment completed at *this* assessment	Yes No
Endoscopic findings (tick all that apply)	Unable to pass scope Circumferential tumour Stricturing tumour Ulcerating tumour Polypoid tumour Obstructing tumour
*If **known cancer**,* were CT/PET assessments done at the *previous* time of diagnosis?	Yes/No
Tick all radiological features that apply for the above	Circumferential tumour on radiology; Stricturing tumour on radiology
*If **known cancer**,* was endoscopy done at the *previous* time of diagnosis?	Yes/No
Tick all endoscopic features that apply for the above	Unable to pass endoscope beyond tumour; Stricturing disease on endoscopy
Management	
Is the intent of treatment curative or palliative?	Curative (treat the cancer) Palliative (symptomatic treatment i.e. relief of obstruction without intention to attempt cure of cancer)
Immediate management at *this* presentation of colorectal cancer	Surgical ● Resection - Yes/no ○ Right/left/subtotal/total colectomy/Hartmann's procedure ● Stoma - yes (loop)/ yes (end)/no ● Primary anastomosis - yes/no Procedural ● Colonic metallic stent ● Transanal drainage tube

	Non-operative management Other (specify)
Surgical variables *If surgery undertaken*	
If surgical management What is the urgency of surgical intervention - NCEPOD classification	Immediate Urgent Expedited Elective
Intraoperative contamination	**Clean-Contaminated**: (Gastrointestinal (GI) and genitourinary (GU) tracts entered but no gross contamination). **Contaminated**: (GI or GU tracts entered with gross spillage or major break in sterile technique). **Dirty**: (There is already contamination prior to operation, e.g. faeces or bile).
If surgical management What was the operative approach	**Open** (performed exclusively using instruments inserted into the abdomen through a surgical incision). **Laparoscopic** (performed exclusively using instruments inserted in to the abdomen through small ports) **Laparoscopic-assisted** (laparoscopic surgery in which an incision is enlarged to deliver a specimen or to insert a gloved hand into the abdomen). **Laparoscopic converted to open** (surgery planned to be performed laparoscopically but for unforeseen reasons the decision was made to change to an open approach) **Robotic** (robot-assisted surgery with no conversion to either laparoscopic or open approaches). **Robotic converted to open** (surgery planned to be performed robotically but for unforeseen reasons the decision was made to change to an open approach).
Intraoperative complications	None / Vascular injury / Bowel injury (e.g. duodenum) / Injury to other organs or structures (e.g. ureter) / Intraoperative mortality
Surgeon skill level	Consultant colorectal surgeon Emergency general surgeon/non-colorectal surgeon Surgical resident/registrar Other
Critical care unit admission	Yes - planned Yes - unplanned No
Endoscopic procedure variables *If stenting undertaken for obstructing tumour*	
If endoscopic management What is the urgency of surgical intervention	Immediate Urgent Expedited

NCEPOD classification	Elective
Endoscopic complications	None / Technical failure and inadequate decompression / Bowel perforation / / procedure abandoned
Proceduralist skill level	Consultant colorectal surgeon Consultant gastroenterologist Surgical/gastroenterology resident/registrar Other (specify)
30-day follow up	
Outcome	Inpatient Dead *(specify days from index admission that death occurred)* Discharged (date of discharge from index admission)
Highest 30-day Clavien-Dindo complication grade *(if surgery)*	None I II IIIa/IIIb IVa/IVb V
90-day follow up	
Outcome	Inpatient Dead *(specify days from index admission that death occurred)* Discharged (date of discharge from index admission)
Highest 90-day Clavien-Dindo complication grade *(if surgery)*	None I II IIIa/IIIb IVa/IVb V
Pathological results	pR0, pR1, pR2
Started neoadjuvant chemotherapy	Yes (specify date) No
If colonic stent was placed, were there late complications within 90 days?	Yes (specify date) Stent migration / Stent obstruction / Other (specify) No
If a stoma was formed, was the stoma reversed within 90 days?	Yes (specify date) No
If primary resection did not occur at index admission, was elective surgery for resection completed within 90 days?	Yes (specify date) No

Did the patient readmission within 90 days for reasons other than surgery?	Yes (specify date) No
Reason for representation	Bowel obstruction Haemorrhage/anaemia Perforation Other (specify)
Date of discharge from readmission	Specify date - to calculate *days alive and out of hospital*
If the patient had surgery at any point within 90 days, did an anastomotic leak occur?	Yes (specify date) No
LOS of index admission	Days
Reoperation within 90 days	Yes (specify date) No

Appendix C: National Lead Survey

Data field	Required data
Is there a national colorectal cancer screening programme in place in your country?	Yes/No
If yes, what is the method of screening	Faecal immunochemical test (FIT), sigmoidoscopy, colonoscopy, CT colonography, other stool test, other test
If yes, what is the inclusion criteria for screening?	Age [...] to [...] Other criteria *Please provide reference*
If FIT is used, what was the cut-off threshold for a positive test?	In screening: µg Hb/g In symptomatics: µg Hb/g
Centre volume	Number of colorectal resections/year
Hospital beds	Number of beds
Number of colorectal surgical consultants	
Is there a colorectal multidisciplinary team meeting (MDT)?	Yes (if yes - number of colorectal cancer diagnoses passed through MDT over the entre 6-week period) No
Is your centre offering neoadjuvant chemotherapy for colon cancer	Yes

Appendix D: Clavien-Dindo Grading of Surgical Complications

Adverse postoperative events may be divided up into treatment failures, sequelae and complications.

- **Failure of treatment** occurs when the original surgery fails to achieve its intended benefits; for example, persistent pain following laparoscopic cholecystectomy or tumour recurrence following cancer surgery.
- **Sequelae** are the recognised consequences of a given procedure; for example, gut malabsorption following a large small bowel resection or immune deficiency following splenectomy.
- **Complication**: Any deviation from the normal postoperative course that has an adverse effect on the patient and is not either a treatment failure or sequel.

In the Clavien-Dindo classification,[29] the factor determining the severity of a complication is the treatment required. Consequently, a given complication may be graded differently depending on how it has been managed. For example, an anastomotic leak may be managed just with antibiotics if it is contained (grade II) or it may require re-operation under anaesthetic (grade III).

Some other considerations:

- Intra-operative complications are not considered unless they have an adverse effect on the patient post-operatively. The only exception to this is i**ntra-operative death**; this is classified as grade V.
- **All postoperative adverse events** are included, even when there is no direct relationship to the surgery.
- **All adverse events within the follow-up** period (30 days) are included, even if they occur following discharge.
- **Diagnostic procedures** are not included. For example, a diagnostic oesophagoduodenoscopy (OGD) to look for a source of bleeding without any intervention would not be considered a complication, but a therapeutic OGD with clipping of a bleeding vessel would be considered a grade III complication. Since negative exploratory laparotomies are considered to be diagnostic procedures, they should not be recorded as complications.

Grade	Definition
Grade I	Any deviation from the normal postoperative course not requiring surgical, endoscopic, or radiological intervention. This includes the need for certain drugs (e.g. antiemetics, antipyretics, analgesics, diuretics, and electrolytes), treatment with physiotherapy, and wound infections that are opened at the bedside

Grade II	Complications requiring drug treatments other than those allowed for Grade I complications; this includes blood transfusion and total parenteral nutrition (TPN)
Grade III	Complications requiring surgical, endoscopic or radiological intervention ● Grade IIIa - intervention not under general anaesthetic ● Grade IIIb - intervention under general anaesthetic
Grade IV	Life-threatening complications; this includes CNS complications (e.g. brain haemorrhage, ischaemic stroke, subarachnoid haemorrhage) which require intensive care, but excludes transient ischaemic attacks (TIAs) ● Grade IVa - single-organ dysfunction (including dialysis) ● Grade IVb - multi-organ dysfunction
Grade V	Death of the patient

Appendix E: American Society of Anaesthesiologists (ASA) Classification

ASA Class	Definition
I	A normally healthy patient
II	A patient with mild systemic disease
III	A patient with severe systemic disease
IV	A patient with severe systemic disease that is a constant threat to life
V	A moribund patient who is not expected to survive without the operation
VI	A declared brain-dead patient whose organs are being removed for donor purposes

Appendix F: How to make your centre a success

Further details can be found at the **APOLLO study hub** and on the **APOLLO local lead guide**

As a hospital lead, you are responsible for coordinating the APOLLO study at your hospital. This document will guide you through some of the steps you can take to make the project a success at your centre. For further information, please contact your national committee.

1. Publicise the project

At your local medical school and hospital site, aim to advertise the APOLLO study as widely as possible. This may include the following approaches:

- Promotional posters
- Public announcements in lectures and hospital/university meetings
- Social media, including creating a Facebook group or Twitter page
- Emails to local surgical departments, societies, and associations
- Emails to individuals who may be interested in the project

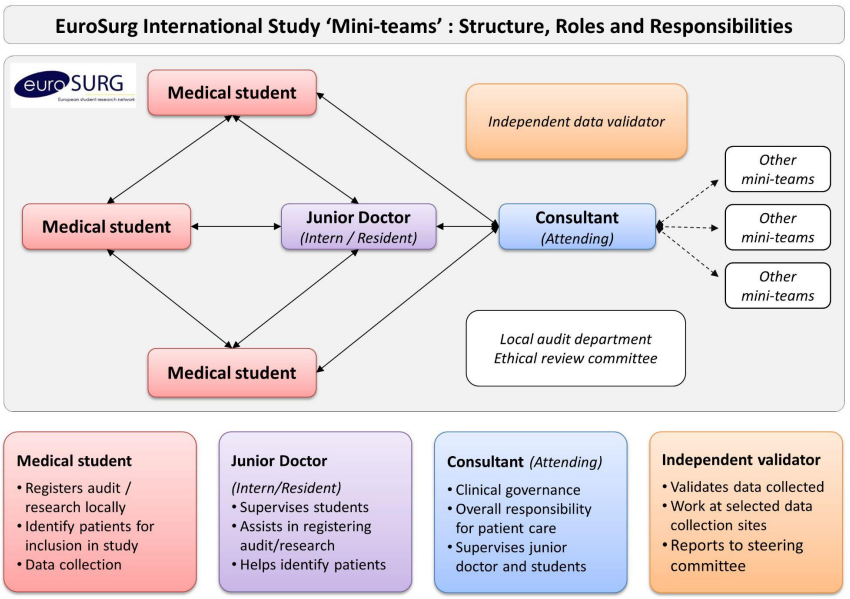
Gaining early interest/momentum in the local project delivery will ensure maximum participation from students and trainees/residents. It is also essential to gain the support of a local surgical consultant/attending at each hospital. Strategies to achieve this may include:

- Presenting the APOLLO protocol at local hospital/university meetings
- Arranging a meeting with the head of department to discuss the protocol

2. Recruit collaborators to 'mini-teams'

As a hospital lead, you are responsible for creating and managing "mini-teams" of students and trainees/residents at each hospital. Mini-teams for the **APOLLO** study can consist of up to 12 members, including a minimum of 1 supervising consultant, and a minimum of 1 general surgical registrars (2 recommended).
Tip: We recommend that 6 of the 9 other members are allocated to data collection over a 6-week consecutive period, and 3 of the 9 other members are allocated to collecting 30- and 90-day follow-up data.

Collaborators at each participating centre will prospectively collect data for all eligible patients over minimum 6-week periods from January to June 2023. Sites can contribute in multiple 6-week periods, providing they are not overlapping.



The same mini-team may collect data across multiple different data collection periods, if they so wish. However, each mini-team must collect data across different data collection periods, i.e. no patients may be included more than once in the REDCap database.

3. Get audit or ethical approval early

All countries involved in the APOLLO study will have different requirements for study or research approval. Speak to your national committee for further advice on the requirements in your country, or to seek advice about local guidelines. They may be able to provide details required for registration and help you to facilitate local approvals. This process can take a long time so it is important to start this as early as possible!

4. Prepare for the Study Launch

Once you have created mini-teams at your local hospitals and gained study approval, you are almost ready to start collecting data for the APOLLO study. There are some final important steps to ensure all collaborators are ready to begin data collection. This includes:

- Arrange a local meeting will all collaborators to discuss the study and answer questions
- Ensure that all mini-teams are complete and know where/when they are due to collect data
- Ensure all collaborators have a copy of the full protocol
- Ensure that all collaborators are registered with the REDCap system

Appendix G: Australian APOLLO Local Data Management Plan

1. Access to Patient Records

Members of the local research mini-team who will be involved in accessing patient health records for data collection purposes should be named on the relevant local site specific approval. The local mini-team Principle Investigator (PI) will be responsible for overseeing data collection at their site. This will include ensuring that data collectors adhere to local protocols and ensuring that all data uploaded to the central REDCap database is de-identified.

2. Data Collection and Storage

Data will be collected and stored online via the Research Electronic Data Capture (REDCap) web application, hosted and managed by the Birmingham Surgical Trials Consortium (BiSTC) REDCap system hosted at the University of Birmingham, United Kingdom. Each collaborator will have their own unique REDCap database login which will only give them access to the participant data for which they are responsible. No participant identifiable data will be entered into the REDCap database. Data will be stored for 15 years and then destroyed using approved file deletion techniques.

3. Local Site Cross Reference

Each site will maintain records of which participant is recruited into the study and their unique REDCap identifier through the use of a local cross-reference of hospital numbers and REDCap IDs. This will be kept in a secure, encrypted spreadsheet on a hospital, password-protected computer. Any local site cross-reference of hospital numbers and REDCap IDs created to facilitate data collection will be destroyed after the end of the data collection and data validation period (i.e. the nominated data-lock date).

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