COMPASS study - Management of COMPlicAted intra-abdominal collectionS after colorectal Surgery

An international, observational, multicentre study

Study protocol v1.0

30th November 2019

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Key Study Dates:

Study registration opens:	November 2019
Data collection periods:	3rd February to 26th April 2020
Last follow-up period ends:	26th May 2020
ESCP Annual meeting:	23rd - 25th September 2020, Vilnius

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Study coordination

Study Management Group

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*Medical students joining the study management group as new members will be listed on the EuroSurg website and in the revised versions of the protocol

Study Advisory Group

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National management groups

In each participating country, EuroSurg will liaise with a national management group to disseminate and coordinate the study at a local level. Please refer to below for the list of the national surgical research collaboratives partners of EuroSurg.

Key contacts:
For matters relating to mini-team setup and audit registration, please contact your local lead or national committee. If unsure who your local lead/national committee is, or for general enquiries concerning the protocol, please contact us by email (eurosurgstudents@gmail.com) or on Twitter (@EuroSurg).

Collaborative Partners

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Study timeline

Sep 2019	Provisional summary protocol released at the EuroSurg session, ESCP 2019, Vienna
November 2019	Final protocol released
Oct - Dec 2019	National committees established Collaborators can register COMPASS at their hospitals
Nov - Jan 2019	Application for ethical approval at local centres Application for REDCap Logins
3rd Feb to 26th April	**Study inclusion periods** ● Period 1: 3 Feb 2020 - 16 Feb 2020 ● Period 2: 24 Feb 2020 - 8 Mar 2020 ● Period 3: 16 Mar 2020 – 29 Mar 2020 ● Period 4: 13 Apr 2020 - 26 Apr 2020
26th May	End of last 30-day follow-up period
March - June 2020	Data validation
30th June 2020	Deadline for uploading data on REDCap
30th July 2020	Deadline for data validation
Aug - Nov 2020	Data analysis
Sep 2020	Initial results presented at ESCP 2020, Vilnius

About EuroSurg

The EuroSurg collaborative is an international research group led by students and surgical trainees (1). 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 and the United Kingdom. In our most recent study, IMAGINE (2), which explored post-operative ileus in colorectal surgery, centres from South Africa, Australia and New Zealand took part as well.

The model for trainee-led research collaboratives was pioneered in the UK by local networks of trainee surgeons (3). 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 (4,5).

Collaboration across international surgical communities produces transferable results which may inform the design of future RCTs and changes in clinical practice. Through participating in the EuroSurg project, students will acquire essential skills in surgical audit and research methodology (6). EuroSurg will replicate previous groups' successful authorship policy, which designates all student and trainee collaborators as PubMed-citable "Collaborators". An example of this authorship model can be seen here: EuroSurg Collaborative. *Safety and efficacy of non-steroidal anti-inflammatory drugs to reduce ileus after colorectal surgery.* Br J Surg. 2019 Oct 9. doi: 10.1002/bjs.11326.

Study Background

Surgical drains have historically been part of the postoperative management of intra-abdominal collections. Their primary aim is to evacuate established or potential collections originating from abscesses, bleedings and/or leaks (7).

Recent guidelines and systematic reviews recommend against the routine use of prophylactic drains after colorectal surgery procedures (8-10). A Cochrane meta-analysis carried out in 2004 concluded that there was insufficient evidence for the use of prophylactic drains after elective colorectal anastomoses (11). In 2017, a randomised controlled trial, GRECCAR 5, included 494 patients undergoing oncological rectal excision and showed no benefit of pelvic drains (12). A recent meta-analysis by Podda *et al* (13) concluded that prophylactic drains do not have beneficial or harmful effects after a colorectal anastomosis and, therefore, they should not be routinely used.

On the basis of existing evidence, ERAS guidelines (14) strongly recommend against the routine use of pelvic and peritoneal drains as they have shown no effect on clinical outcome.

However, currently, the routine use of prophylactic drains after colorectal surgery is still widespread (15). As part of our last EuroSurg study, IMAGINE (16), centres filled out a survey regarding their adherence to ERAS guidelines. Preliminary data has shown that 35% of participating centres routinely leave drains after colorectal surgery for most of their patients.

Reasons to justify drainage after colorectal surgery include: prevention of complicated intra-abdominal collections; early detection of haemorrhage, anastomotic leakage, or other complications, and reduction of the incidence of anastomotic leak and pelvic sepsis (17,18). On the other hand, the routine placement of prophylactic drains is also associated with adverse events. Drains have been shown to be associated with an increased production of serous fluid, which could lead to wound infections, promote adhesions and could even result in a higher risk of anastomotic leak (19,20). In addition, they could cause irritation and offer an inward track for contamination.

It is common opinion that early detection of intra-abdominal collections might prevent additional surgical or percutaneous procedures necessary during the postoperative period (21). However, there is no consensus on which type of drain should be used and for how long it should be left in situ.

The aim of this international multi-centre cohort study is to define the incidence of drain placement after colorectal surgery and to describe drain management practices.

Methods

1. Definition for intra-abdominal collections

Postoperative collection altering the normal postoperative course management and requiring antibiotics or radiological/endoscopic/surgical intervention.

2. Summary

"Mini-teams" of up to three collaborators (medical students and/or doctors) per data collection period will prospectively collect data over a continuous 14-day period at each participating centre. This will be on consecutive patients undergoing elective or emergency colorectal surgery, with follow-up to 30 postoperative days. All mini-teams should be supervised by one surgical consultant of reference per centre. Each participating centre will be required to fill out a survey regarding their local drain management practices.

3. Study Aims

- **Primary Aim:** To audit compliance to Enhanced Recovery After Surgery (ERAS) guidelines on avoiding routine placement of prophylactic drains in colorectal surgery.
- **Secondary Aims**:
    - To assess whether placement of a postoperative drain is associated with earlier detection of collections and anastomotic leak.
    - To examine when drains can be safely removed.
    - To explore the clinical decision-making process for drain placement after colorectal surgery.
    - To characterise the incidence of complicated postoperative collections and their clinical management in colorectal surgery in an international cohort.

4. Project Timeline

Data collection will take place between 3rd February 2020 and 26th April 2020 during the following four predefined 14-day data collection periods.

- **Period 1:** 08:00 AM 3 Feb 2020 to 08:00 AM 17 Feb 2020 (+ 30 Day Follow-up)
- **Period 2:** 08:00 AM 24 Feb 2020 to 08:00 AM 09 Mar 2020 (+ 30 Day Follow-up)
- **Period 3:** 08:00 AM 16 Mar 2020 to 08:00 AM 30 Mar 2020 (+ 30 Day Follow-up)
- **Period 4:** 08:00 AM 13 Apr 2020 to 08:00 AM 27 Apr 2020 (+ 30 Day Follow-up)

An extra period may be opened at the discretion of the steering committee to allow for the participation of centres that encountered difficulties in obtaining the necessary ethical approvals:

- **Period 5:** 08:00 AM 27 Apr 2020 to 08:00 AM 11 May 2020 (+ 30 Day Follow-up)

At each hospital, one mini-team per period will collect data on eligible patients admitted over a 14-day period. Data on 30-day outcomes after the day of surgery will also be collected. The deadline for uploading collected data onto REDCap is 30th June 2020.

Patients should be included if their operation started (defined as 'knife-to-skin' time) within the time period during the data collection periods as specified above.

▲ One mini-team of up to three collaborators can take part in each 14-day period. Multiple mini-teams can participate at each centre, but no more than one team per period at the same centre. To be listed as PubMed-citable collaborators, centres are required to participate in at least one data collection period. ▲

5. Centres

- COMPASS is open to any hospital in the member countries of the European Society of Coloproctology (ESCP), the Royal Australasian College of Surgeons (RACS) and South African centres, which routinely perform elective or emergency colorectal surgery. Participation of centres from other countries will be considered on a case-by-case basis.
- All participating centres are required to register the study according to local regulations. Evidence of successful registration must be uploaded onto REDCap prior to commencement of data collection. Centres will not be allowed to upload patients' data onto REDCap without evidence of successful registration of the study.
- In the UK, COMPASS has been designated an audit of practice. Internationally, individual study investigators are responsible for ensuring the correct audit, ethical or departmental approval has been achieved prior to commencing data collection (this can be registered as an audit or service evaluation, if appropriate).
- Following the conclusion of the study, it is a recommended that mini-teams at each centre present the study findings to their hospital's surgery departments as part of the audit process.

▲ Providing feedback on the project's findings to your department's clinicians is an essential step for improving care. Presenting local results will help you to develop your presentation skills & CV. ▲

6. Eligibility criteria

Summary: Consecutive adult patients (≥18 years of age) undergoing emergency or elective colorectal surgery through any operative approach should be included.

- **Inclusion criteria**

Age	Age 18 years or above.
Procedure	Any formation of colostomy/ileostomy, resection of large bowel, or reversal of stoma (See **Appendix B** for full list).
Urgency	Emergency and elective procedures.
Technique	Open, laparoscopic, laparoscopic converted, robotic, robotic converted procedures are all eligible.

- **Exclusion criteria**

Procedures	• Appendicectomy (unless procedure involves a right hemicolectomy) • Transanal surgery - *e.g. TaTME, TEMS, TAMIS, Altemeier's procedure.* • Primarily urological procedure - *e.g. ileal conduit.* • Primarily gynaecological procedure - *e.g. Hartmann's during ovarian cancer surgery* • Primarily vascular procedure - *e.g. bowel resection during AAA repair.* • Diagnostic laparoscopy or laparotomy without resection of colon or rectum • Inguinal, incisional or femoral hernia, without resection of colon or rectum • Surgery involving major multi-visceral surgery – *e.g. pelvic exenteration*
Re-operation	Each individual patient should only be included in the COMPASS study once. Return to theatre during the same admission or follow up is regarded as a complication.

▲ If an in-hospital patient recovering from another primary procedure NOT previously included undergoes emergency surgery, this MUST be included in the study as emergency case. ▲

i.e. Patient A is recovering from an AAA repair and undergoes large bowel resection due to bowel ischaemia one day later the previous surgery. He was correctly not included after the AAA repair, as that is a primarily vascular procedure and it did not involve any large bowel resection, but should be included after the bowel resection.

You should collect data on consecutive elective patients operated at your hospital during the data collection period. **All eligible patients** must be included. Strategies to identify consecutive patients could include:

- Daily review of elective theatre lists.
- Daily review of handover sheets and ward lists.
- Daily review of theatre logbooks
- Daily on call review of patients undergoing emergency surgery

7. Outcome Measures

I. **Primary outcome measure**:

- Adherence to selected Enhanced Recovery After Surgery (ERAS) guidelines regarding rate of routine prophylactic drain insertion in colorectal surgery (22).

II. **Secondary outcome measures**:

- Rate of intra-abdominal postoperative collections, defined as collections which alter the normal postoperative course (e.g. requiring either medical, radiological, endoscopic or surgical intervention) (23).
- Time-to-diagnosis (days) of intra-abdominal postoperative collections defined as collections which alter the normal postoperative course (e.g. requiring either medical, radiological, endoscopic or surgical intervention) (23).
- Rate of drain-related complications defined as:
  - Surgical site infection (Centers for Disease Control and Prevention – CDC – definition: A surgical site infection is an infection that occurs after surgery in the part of the body where the surgery took place);
  - Cutaneous irritation at the drain insertion site (defined as reversible damage of the skin associated with rash, dry skin, itchiness, red discolouration and/or hives);
  - Small bowel evisceration and herniation of omentum (defined as prolapse of small bowel and/or omentum through the drain site after the removal of the drain);
  - Bowel injury (defined as intraoperative identification of or CT-proven drain-related iatrogenic bowel perforation) (7,24).
- Time (measured in whole days) until drain removal and drain output (quantity and contents) on day of removal. Daily output will be calculated adding up the volumes drained in the 24 hours prior to the morning ward round. Contents are defined as serous fluids (with or without blood staining), frank blood, purulent and faecal.
- Overall 30-day adverse event rate as defined by the Clavien-Dindo scale of postoperative complications (25) and length of stay (days).

Day of surgery is defined as Post-operative Day (POD) 0. The day after surgery is therefore defined as POD 1 and day 10 after surgery as POD 10.

8. Measuring drain output

Drain output (volume and contents) should be assessed daily until removal or for the first ten days after surgery (Day 0: day of surgery – Day 10).

▲ Strategies to record drain output and day of drain removal ▲

- Speaking to ward staff, including doctors and nurses
- Reviewing patient notes daily, particularly drain charts
- Participating in daily ward rounds and doctor reviews

Remember: recordings of drain output must correspond to the entire day (8am to 8am). It is advised that you collect data one day in retrospect to capture all relevant data.

9. Covariates

Data will be collected on audit standards, and confounding factors for risk of intra-abdominal postoperative complications to permit accurate risk adjustment of outcomes. Without appropriately adjusting for risk factors, it is likely that any findings would be biased and unable to be appropriately analysed on a national scale. Data will **not** be analysed at a surgeon-level or centre-level. A full list of required data fields is available in Appendix A, and on the REDCap database.

10. Follow-up

Patients will be followed for 30 days after surgery. All secondary outcome measures will be recorded if they occurred at any point from postoperative Day 0 (day of surgery) to Day 30.

No change to 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.

11. Data Analysis & Sample Size

Based on the previous EuroSurg IMAGINE audit, COMPASS is anticipated to include 150 centres in the UK and 150 centres in Europe and Australasia. With consideration to recent figures provided by the UK National Bowel Cancer Audit 2016 (26) and previous EuroSurg studies, it has been estimated that, on average, three patients will undergo colorectal resection per week at each participating centre. Therefore, a sample of approximately 5000 patients is anticipated. No surgeon-, hospital- or country-specific comparisons will be performed.

Further secondary analyses may be performed at the Study Management Group's discretion.

12. Data Collection and Governance

Data will be collected and stored online through a secure server running the Research Electronic Data Capture (REDCap) web application (27, 28). 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 service is managed by the Birmingham Surgical Trials Consortium (BiSTC) REDCap system hosted at the University of Birmingham, United Kingdom. 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.

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

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

13. Local Project Registration

If the option is available, this project may be registered as clinical audit or service evaluation. Alternatively, it may be necessary to obtain formal ethical approval. It is the responsibility of the local mini-team at each site ensure that the study is registered appropriately, according to local regulations. This process should be supervised by a local consultant/attending surgeon at each centre.

▲ Check with your supervising consultant how the study should be registered at your hospital. You can also **seek advice** from your local lead and National Committee/collaborative ▲

In the UK, the study may be registered as a clinical audit or "service evaluation". The gold standard is based on ERAS® Guidelines for Colorectal Surgery (14):

Pelvic and peritoneal drains show no effect on clinical outcome and should not be used routinely.
Evidence level: High
Recommendation grade: Strong

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.

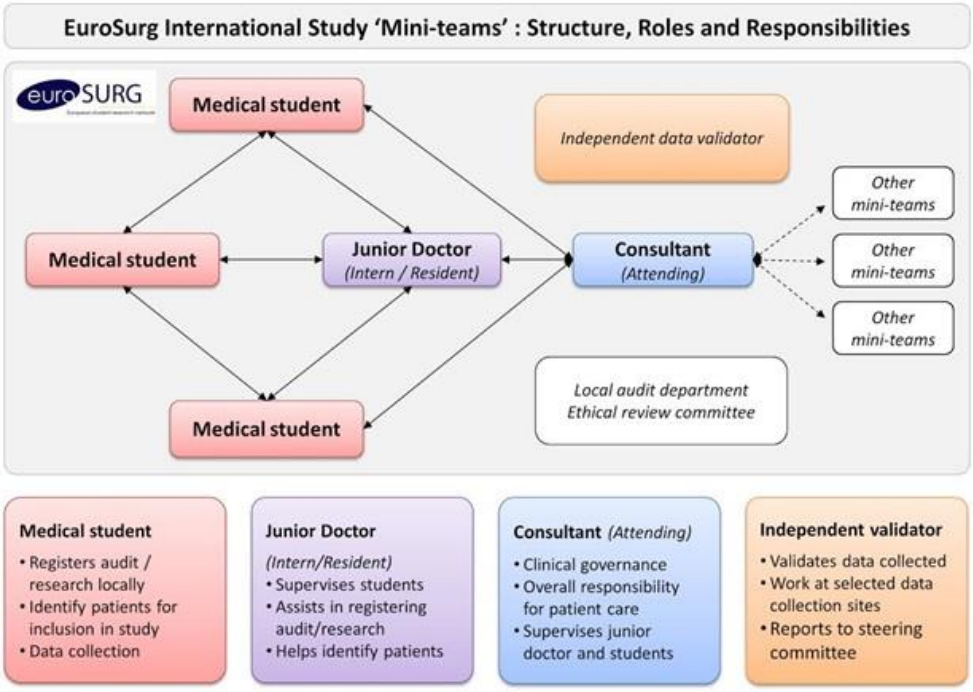
▲ Collaborators should complete the mandatory data governance e-learning module which will be made available on the online project hub: http://www.eurosurg.org ▲

You **must** have confirmation of successful study registration prior to commencing data collection. REDCap accounts will **not** be issued until evidence is sent to your national network committee that you have successfully registered the study at your centre.

14. Quality assurance

Design: This protocol was written with guidance from an international expert cross-speciality advisory group and with the contribution of patient representatives, similarly to previous studies conducted by EuroSurg and ESCP cohort study group (2, 29). A **data dictionary** will be developed to help collaborators in collecting data and patient inclusion. E-learning materials will be available on the website (eurosurg.org).

Project team structure: Medical students will take the lead in disseminating and delivering this study alongside junior doctors. These 'mini-teams' should be supervised by a consultant surgeon at each site (Figure 1). Each team should include at least one qualified doctor to provide additional local support for participating medical students.



Training: The protocol was formally launched at the European Society of Coloproctology (ESCP) meeting on 26th September 2019. Investigators will be trained in the study background, design, and methodology. COMPASS regional and local leads are encouraged to hold local meetings with collaborating teams at their medical school to brief them on the protocol, and to feedback any local issues or questions raised. To ensure collaborators understand the study topic, drain follow-up, inclusion criteria, application of the Clavien-Dindo classification and the principles of data governance, they will all be asked to complete a series of online e-learning modules (pass mark is 100%) prior to starting data collection.

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.

Validation: Data validation will be performed at a minimum of five centres in each participating country. 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 assigned a random 2-week data collection period at a 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. There are two components of validation:

I. **Case ascertainment:**
   - The validator will independently identify all patients eligible for inclusion over the one 2-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%.

15. Authorship

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 (30), all research outputs from COMPASS 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):

- **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.

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

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

- **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.

- **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.

- **Local leads**: a network of medical students and surgical trainees across participating hospitals. The local lead could be a junior doctor/resident in those centres without medical students able to participate. They act as a single lead point of contact for data collection at each site who has overall responsibility for site governance registration and co-ordinating handover between local collaborator teams. Only one person can fulfil this role. Minimum requirements for authorship on COMPASS outputs include:
    - Primary person responsible in obtaining local approvals for conduct of the COMPASS audit (e.g. registration of the study and gaining permission to upload data to REDCap).
    - Active involvement **one** mini-team during a data collection period at the centre which meets the criteria for inclusion within the COMPASS dataset.
    - Co-ordination of handover between all local collaborator teams at the centre, and involvement in local dissemination of COMPASS and other EuroSurg activities.
    - Presentation of local results at their centre from the COMPASS audit (or otherwise arranges another collaborator to present on their behalf).
    - Recruitment of an independent data validator for their centre.
    - Acts as a link between mini-teams and the national network committees, including being the first point of contact for local collaborators.
    - Ensure audit outcomes are reported back to clinical teams.
    - Active involvement in a mini-team during a data collection period at the centre which meets the criteria for inclusion within the COMPASS dataset.

▲ In the UK/ROI, STARSurg regional leads will co-ordinate mini-teams across multiple hospitals associated with their university. These will be credited separately, with the local lead role being optional. **Its role will be adapted to other participating countries with coexisting National networks and Collaboratives** ▲

- **Local collaborators (data collectors)**: A team of up to 3 people responsible for data collection per specialty group over a specific 2-week period at a particular centre. This should ideally be formed by 1-2 medical students collaborating with a resident (FY1/first year resident to senior registrar grade). Minimum requirements for authorship on COMPASS outputs 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 COMPASS dataset (minimum of 1 eligible patient contributed per mini-team).
    - Collaboration with the regional / local lead to ensure that the audit results are reported back to the audit office / clinical teams.

In exceptional circumstances where local teams anticipate a very high volume of patients being eligible for inclusion, they may contact the study management group for permission to add an additional person to their mini-team. Any increase in the mini-team **must be agreed in advance** with the study management group.

- **Local validators (data validators)**: A person (either a final year student or a qualified doctor) not involved in the primary data collection at the centre. They will be assigned a random 2-week study period performed at the centre to determine the case ascertainment and data accuracy of data collected by the mini-team. Data validation will occur following completion of data collection (including follow-up). Minimum requirements for authorship on COMPASS outputs include:
  - Successful completion of data validation for their assigned eligible data collection period at their centre.
  - Submission of the complete data validation report to the relevant national committee or EuroSurg management group by the specified deadline.

- **Supervising Consultant / attending surgeons**: Each mini-team must be supervised by a consultant surgeon. Minimum requirements for authorship on COMPASS outputs include:
  - Sponsorship of local audit registration, and responsible to ensure local collaborators act in accordance with local governance guidelines. Inclusion of at least one data collection period at their centre which meets the criteria for inclusion within the COMPASS dataset.
  - Facilitation of local audit results presentation and support of appropriate post-audit interventions.
  - Completion of workplace-based assessments for students or trainees (ePortfolio/ISCP), if requested.

To be credited with authorship, everyone involved will be required to supply an ORCID to their local / regional lead (https://orcid.org/register).

- This is a free / easy to obtain digital identifier which is widely used in research / often required by journals to submit papers (structured as a 16 digit number e.g. 1234-1234-1234-1234).
- Eurosurg will be using ORCIDs to create the authorship list by downloading the name of the collaborator using the ORCID (and so this is mandatory to be able to be credited with authorship).
- The only mandatory information you are required to provide on your ORCID profile is your name (as you wish it to be displayed on the COMPASS authorship list), with visibility settings set to "Everyone".

Criteria for centre inclusion within COMPASS:

- Successful completion of **at least one data collection period** at the centre (with a minimum of one eligible patient per period included).
- Obtain all appropriate **local approvals** for conduct of the COMPASS audit.
- Individual data collection periods will only be included when:
  I. >95% data completeness has been achieved.
  II. Validation targets have been achieved (if performed).
  III. All data for the period has been uploaded within the specified deadlines.

Please note if these criteria are not met, then the contributing mini-team and/or the centre may be removed from the dataset and authorship list (get in contact asap with potential issues arise so we can support your centre to be included). See Appendix D for advice to help ensure successful inclusion of your centre in the COMPASS audit.

16. Patient and Public Involvement

To better understand the role of drains in colorectal surgery and their impact on the post-operative period, we asked the opinion of patients, aiming to clarify what matters to them most in the post-operative period. Patients were invited to fill out an anonymous survey through social media. The main questions concerned their experience with drains in the post-operative period, with an emphasis on to which extent, in their opinion, the drain(s) facilitated / slowed down their recovery. Patients were also asked whether anyone discussed with them the possibility of placing a drain during surgery and to give their opinion regarding which are the most important outcomes a study focussed on surgical drains should explore.

Patients were concerned about possible post-operative complications and felt that their doctors placed a drain to prevent them. However, at the same time, they feared the drain might have slowed down their recovery as it caused severe pain and it significantly reduced their mobility and, therefore, independence. In light of their replies, we structured our study to capture the drain management practices of an international cohort of colorectal surgeons. We used the patients' insight to formulate a centre survey and case report form that will help us explore whether most surgeons adhere with the Enhanced Recovery After Surgery (ERAS) guidelines and, if not, understand their reasons for not being compliant.

Patient and public involvement in this study is 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).

We thank all the patients that generously dedicated their time to answer our questionnaire.

Acknowledgements

We thank the **Birmingham Surgical Trials Consortium (BiSTC)** for kindly hosting COMPASS 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/

We thank the **Società Italiana di Chirurgia Colo-Rettale (SICCR and Young SICCR)** for their kind support.

Appendix A: Data Dictionary

Please use the case report form together with this Data Dictionary to facilitate data collection

Preoperative data points	Required data (definition / comment)
Patient age	**Years** (whole years at the time of operation)
Patient gender	**Male / Female**
Patient ASA grade	**Grade I-V** (Full ASA classification available at: https://www.asahq.org/resources/clinical-information/asa-physical-status-classification-system).
Smoking status	**Current** (includes those who stopped smoking within 6 weeks), **Previous**, **Never**.
Patient height	**Meters** (record to two decimal places)
Patient weight	**Kilograms** (record to one decimal places)
Body Mass Index *(if either weight or height unknown)*	**Underweight** (<18.5), **Normal range** (18.5-24.9), **Overweight** (25-30), **Obese** (>30).
History of abdominal surgery	**Yes** / **No**
Pre-existing abdominal stoma	**Yes – colostomy** / **Yes – jejunostomy or ileostomy** / **No stoma**
History of ischaemic heart disease	**Yes** (Myocardial infarction or Angina) / **No**
History of congestive heart failure	**Yes** / **No**

History of cerebrovascular disease	**Yes** (transient ischemic attack or stroke) / **No**
History of diabetes mellitus	**Yes (Type 1) / Yes (Type 2)** / **No**
Control of diabetes mellitus	**IF** diabetes mellitus present **Yes, insulin controlled** / **Yes, tablet controlled** / **Yes, diet controlled** / **No**
Last pre-operative blood test values	**Haemoglobin** (grams / litre) **/ White Cell Count** ($x10^9$ / litre) **/ estimated Glomerular Filtration Rate** (ml / min) / **C Reactive Protein** (milligrams / litre).
History of immunosuppression	**HIV** (antiretroviral therapy, no/unknown), **Steroids** (yes: oral, intravenous or topical e.g. prednisolone, fludrocortisone, dexamethasone, no), **Other immunosuppressive drug** (yes, e.g. azathioprine, methotrexate, biologic agents, no), **Chemotherapy** (yes, current chemotherapy or if the last cycle was within 12 weeks of operation, no).
Operative data points	**Required data (definition / comment)**
Underlying pathology/indication	**Malignancy** / **Inflammatory bowel disease** / **Diverticular disease** / **Bowel ischaemia** / **Small bowel obstruction** / **Large bowel obstruction** / **Other benign**
Perforated bowel	**Yes** / **No**
Operative urgency (NCEPOD Classification of Intervention, available at https://www.ncepod.org.uk/classification.html)	**Immediate** (Immediate life, limb or organ-saving intervention – resuscitation simultaneous with intervention. Normally within minutes of decision to operate). **Urgent** (Intervention for acute onset or clinical deterioration of potentially life-threatening conditions, for those conditions that may threaten the survival of limb or organ, for fixation of many fractures and for relief of pain or other distressing symptoms. Normally within hours of decision to operate) **Expedited** (requiring early treatment where the condition is not an immediate threat to life, limb or organ survival. Normally within days of decision to operate). **Elective** (Intervention planned in advance of routine admission to hospital)
Operative 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).
Operative approach	**Open** (performed exclusively using instruments inserted in to the abdomen through a surgical incision). **Laparoscopic** (performed exclusively using instruments inserted in to the abdomen through small ports) or **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).
Primary operation performed	**Select main procedure** from Appendix B (closest option from the drop-down list or enter as free text by selecting "other").
Anastomosis creation	**Yes – intraperitoneal** / **Yes – extra peritoneal** / **No**
Stoma formation	**Yes – colostomy** / **Yes – jejunostomy or ileostomy** / **No stoma**
Documented air leak	**Recorded** (positive) / **Recorded** (Negative) / **Not recorded**
Duration procedure	**Minutes** (from knife-to-skin to closure of skin).
Intraoperative blood transfusion	**Yes** / **No**
Intraoperative complications	**None** / **Vascular injury** / **Bowel injury** (e.g. duodenum) / **Injury to other organs or structures** (e.g. ureter)
Abdominal drain(s) inserted at time of surgery	**Yes** / **No**
Reason for drain identified	**Not identified** **Excessive intraoperative blood loss** (or concern regarding this). **Excessive intraoperative fluid (not blood) collections** (or concern regarding this). **Contaminated or dirty surgery**

	Positive air leak test (the intra-operative air leak test is a common intraoperative test used to identify mechanically insufficient anastomosis) **Poor vascularisation of the anastomosis** (determined visually or by ICG fluorescence) (or concern regarding this). **Other reason identified (please specify)**
Number of drains	**Number**
Type of drain(s) used	**Open** (open drains drain fluid on to a gauze pad or into a stoma bag e.g. Penrose) / **Close** (tubes draining into a bag or bottle, e.g. Jackson-pratt). **Active** (drains maintained under suction) / **Passive** (drains that have no suction and work according to the differential pressure between body cavities and the exterior). *(see REDCap for pictures)*
Drain location	**Subcutaneous drain** **Intraabdominal drain – pelvis** **Intraabdominal drain – peritoneal cavity** **Intraabdominal drain – posterior to the anastomosis** **Intraabdominal drain – anterior to the anastomosis** **Intraabdominal drain – near the anastomosis (not in contact)**
Daily postoperative data points (*to be completed for each inserted drain)*	**Required data (definition / comment)**
Day of surgery is defined as Post-operative Day (POD) 0. The day after surgery is therefore defined as POD 1 and day 10 after surgery as POD 10.	
Volume drained **(Daily POD 1-10)**	**Millilitres** (recordings of drain output must correspond to the entire day, i.e. 8am to 8am). *It is recommended that you collect data one day in retrospect*.
Contents of drain output **(Daily POD 1-10)**	**Serous fluid** (with or without blood staining) / **Frank blood** / **Purulent** / **Faecal** *(see REDCap for pictures)*
Drain-related data points	**Required data (definition / comment)**

Day of drain removal	**Post-operative Day (POD)**
Surgical site infection	**Yes – Site of Drain(s) / Yes – Other incision / No** As defined by US Centers for Disease Control and Prevention (CDC)
Surgical site infection type	**Yes - Superficial** (skin or subcutaneous tissue) / **Yes - Deep** (fascial and muscle layers) / **Yes - Organ/Space SSI** (intrabdominal) / **No**.
Small bowel evisceration/herniation of omentum	**Yes – Site of Drain(s) / Yes – Other incision / No** Prolapse of small bowel and/or omentum through an incision.
Drain-related iatrogenic bowel perforation	**Yes - Intraoperative** / **Yes – Postoperative (not during removal)** / **Yes – Postoperative (during removal)** / **No**.
Drain-related skin irritation	**Yes** (reversible damage of the skin at the drain insertion site associated with rash, dry skin, itchiness, red discolouration and/or hives) / **No**
Other Drain-related complication	**Please specify**
Reason(s) for drain removal	1. **Clinical rationale**: a). Drain output satisfactory (Yes, No) - if yes: low volume, (haemo)serous fluid, other (please specify). b). Drain-related complications. c). Inadvertent/premature drain withdrawal. d). Other (please specify) 2. **Radiological confirmation of no significant ongoing collection** (Yes - pre removal, Yes - post removal, No).
Post-operative blood transfusion	**Yes** / **No**
Day of blood transfusion	**Post-operative Day (POD)**
History of collection(s) requiring treatment within 30 days (either medical, surgical, endoscopic, radiological)	**Yes** / **No**
Day of collection(s) identification	**Post-operative Day (POD)**

Collection(s) identification method	1. **Clinical only** a). Symptoms. b). Change in drain output (if inserted at time of surgery). 2. **Radiological** a). Imaging due to clinical suspicion b). Routine imaging as per hospital policy c). Incidental finding (imaging for other indication).
Collection(s) treatment	**Conservative management** (none or antibiotic therapy) **Percutaneous drainage** **Surgery**
Total postoperative antibiotic duration	**Number of days** (Total antibiotic duration including both intravenous and oral antimicrobial therapy for the treatment of the collection(s). Post-operative antimicrobial therapy started before the identification of the collection(s) should not be included.)
Outcome data points	**Required data (definition / comment)**
Anastomotic leak within 30 days	**Yes - Radiological diagnosis** / **Yes - Surgical diagnosis** / **No**
Day of anastomotic leak diagnosis	**Post-operative Day (POD)**
Length of hospital stay (days)	**Days**
30 day readmission	**Yes** / **No**
Highest 30-day complication grade	**None / Clavien-Dindo Grade I-V** (see Appendix C for the full Clavien-Dindo scale). *For Grade V please collect:* Death during primary admission? Yes/No Postoperative day of death: _____ day

Appendix B: Included procedures

- Ileocolic resection
- Right hemicolectomy
- Extended right hemicolectomy
- Transverse colectomy
- Left hemicolectomy
- Sigmoid colectomy (including Hartmann's Procedure)
- Anterior resection
- Sub-total colectomy
- Total colectomy
- Pan-proctocolectomy
- Completion proctectomy
- Closure/reversal of stoma (ileostomy or colostomy)
- Formation of stoma (ileostomy or colostomy)

Appendix C: Clavien-Dindo classification system

Adverse post-operative 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 post-operative course that has an adverse effect on the patient and is not either a treatment failure or sequel.

In the Clavien-Dindo classification (13), 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 **intra-operative death**; this is classified as grade V.

All post-operative 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 (examples listed in italics)
I	Any deviation from the normal postoperative course without the need for pharmacological (other than the "allowed therapeutic regimens"), surgical, endoscopic or radiological intervention. Allowed therapeutic regimens are: selected drugs (antiemetics, antipyretics, analgesics, diuretics and electrolyte replacement), physiotherapy and wound infections opened at the bedside but **not** treated with antibiotics. *Examples: Ileus (deviation from the norm); hypokalaemia treated with K; nausea treated with cyclizine; acute kidney injury treated with intravenous fluids.*
II	Requiring pharmacological treatment with drugs beyond those allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included. *Examples: Surgical site infection treated with antibiotics; myocardial infarction treated medically; deep venous thrombosis treated with enoxaparin; pneumonia or urinary tract infection treated with antibiotics; blood transfusion for anaemia.*
III	Requiring surgical, endoscopic or radiological intervention *Examples: Therapeutic endoscopic therapy (do not include diagnostic procedures); interventional radiology procedure, return to theatre*
IV	Life-threatening complications requiring critical care management, neurological complications including brain haemorrhage and ischemic stroke (excluding TIA). *Examples: Single or multiple organ dysfunction requiring critical care management, e.g. pneumonia with ventilator support, renal failure with filtration; SAH; stroke.*
V	Death of a patient

Appendix D: Key steps successful centre inclusion

1. Contact your **local lead** about participation in the study at the centre of your choice. They will connect you to any other interested medical students and doctors at your centre.

2. Form a **mini-team** of **up to three collaborators**. If possible a **medical student** should coordinate the team and lead audit registration/data collection. They must be supported by at least one motivated doctor. This can be a doctor of any grade, but should preferably a junior doctor/ resident.

3. Choose a **14-day data collection period** within the data collection period to suit your availability. Multiple teams of students can participate at each centre, collecting data during distinct one-week periods. A single mini-team is permitted to collect data for more than one period if they have capacity.

4. Ensure that you secure **formal study approval** from your hospital according to local regulations.

   - This must be done prior to commencing data collection. UK collaborators should seek their NHS Trust's Caldicott Guardian's approval to upload data to REDCap. Non-UK collaborators should seek guidance from your national committee on your country's specific approval processes.
   - Ensure that your centre is aware that this is study is **international** and data will be uploaded to **REDCap**. For more details on REDCap & data security see Section 12 of the study protocol. **No changes** to normal follow-up should be made.

It is essential that you begin this process immediately; approval can take up to 2-3 month. If you have any difficulties or are unsure what is required contact your local lead, your supervising surgeon, or your national network committee.

5. Once the audit is registered, please forward evidence of this to your national network committee**.** REDCap accounts will not be issued until proof of audit registration is received.

6. Arrange to **meet** with the other members of your mini-team, including the junior doctor/resident and, if possible, supervising consultant. If possible meet up with the **preceding mini-team** at your centre also. They will have a lot of helpful advice regarding what worked well. In you mini-team agree in advance who will be responsible for each stage of the project, e.g. identifying patients, collecting baseline data, completing follow-up, data entry to REDCap. Talk through how you will identify patients and collect required

data, it will be particularly helpful if the consultant is present to offer guidance regarding this.

7. **Identify** <u>all</u> patients meeting **inclusion criteria** within your 14-day period.

8. Regularly **follow-up** for information on complications over the **30-day post-operative period.** This study is a prospective study**,** so you should not wait until the end of the post-operative period to follow-up patients. Discuss the best way to follow up patients with the consultant supervising your audit, as this will vary from centre to centre.

9. Ensure all data has been uploaded to the **REDCap** system and you have completed all fields, avoiding **missing data points**. If more than 5% of patients at your centre are missing data, your centre cannot be included and your name will be withdrawn from the author list.

It is a **condition** of participation in the COMPASS study that following completion of the audit at your centre you **<u>must</u>** ensure that your **local results are presented** to your hospital's surgical department.

Appendix E: References

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