European Society of COLOPROCTOLOGY

ESCP

# 2017 ESCP snapshot audit

# STUDY PROTOCOL

## *Left colon, sigmoid and rectal resections*

**Study period: 1 February – 09 June 2017**

**Protocol version 2.5 (15 March 2017)**

| **Key dates:** | |
|---|---|
| **22 December 2016** | **Draft protocol published** |
| **1 February 2017**<br>**to 15 March 2017** | **Patient inclusion window starts**<br>***Sites should start collecting at least 8 weeks of consecutive patient operations within this window.***<br>***Sites should follow up each patient for 30 days.*** |
| **10 May 2017** | **Last day of operation to include in data collection** |
| **9 June 2017** | **Last day of patient follow up (8 weeks from patients operated on 10 May 2017).** |
| **30 June 2017** | **REDCap database locked**<br>***This is the deadline for data submission*** |
| **22 September 2017** | **Preliminary data at ESCP 2017 Berlin** |

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## Abstract

**Background:** Left hemicolectomy, sigmoid, and rectal resection are commonly performed colorectal resections. Variability exists in the techniques utilised to undertake these operations, as well as at patient, surgeon and unit level. This high quality pan-European prospective audit will establish current practices and correlate them against outcomes.

**Aim:** To explore differences in patients, techniques and outcomes across the international cohort to identify areas of practice variability resulting in apparent differences in outcome warranting further study.

**Endpoints:** A three-stage data collection strategy collecting patient demographics, operative details and outcome markers. Several outcomes measures will be used including mortality, surgical morbidity (including anastomotic leak) and length of hospital stay.

**Primary research question:** Does anastomotic technique impact upon post-operative outcomes?

**Methods:** This two-month prospective audit will be performed across Europe in early 2017, and co-ordinated by the European Society of Coloproctology. This will be preceded by a one-week, five centre pilot. Sites will be asked to pre-register for the audit and obtain appropriate regional or national approvals. The ESCP cohort studies sub-committee shall assist sites to register where possible. During the study period all eligible operations will be recorded contemporaneously and followed-up through to 30 days. The audit will be performed using a standardised pre-determined protocol and a secure online database. In the first ESCP conducted audit in 2015, 38 countries registered 3208 patients undergoing right hemi-colectomy, while in the second audit 2441 patients undergoing stoma closure were recruited from 48 countries. It is expected that equivalent numbers will be obtained in this audit. The report of this audit will be prepared in accordance with guidelines set by the STROBE (strengthening the reporting of observational studies in epidemiology) statement for observational studies.

**Discussion:** This multicentre, pan-European audit will be delivered by colorectal surgeons and trainees in an organised and homogenous manner. The data obtained about areas of variability in provision or practice, and how this may impact upon outcomes, will serve to improve overall patient care as well as being hypothesis generating and inform areas needing future prospective study.

## 1 - Introduction

Multicentre, snapshot cohort studies or audits have the ability to gather large patient numbers in short time periods from many hospitals. They allow exploration of differences in patients, techniques and management across the cohort to identify areas of practice variability that may result in apparent differences in outcome. As such, whilst not providing true evidence of efficacy or the impact of a particular variable, they can be hypothesis-generating and can identify areas warranting further study in future randomised controlled trials.

The European Society of Coloproctology has recognised the strengths of this form of research, as well as its power in bringing together surgeons and colorectal units across multiple regions or countries for a common research goal, thus strengthening an active network of research participation across Europe.

The first pan-European snapshot audit promoted by the ESCP focused on right hemicolectomy and ileocecal resection surgery succeeded in recruiting 3208 patients from 38 countries, five of them were outside Europe. This success continued with the second audit on stoma closure, which recruited 2527 patients from 312 centres in 48 countries.

Scope

Left colon, sigmoid and rectal resections are frequent colorectal operations performed in almost all hospitals where gastrointestinal surgery are performed. We anticipate that any hospital undertaking general surgery will undertake these procedures on a routine basis.

Despite the frequency of the operation, there remains uncertainty about the optimal method of undertaking it, which results in a range of methods currently utilised to access, mobilise and anastomose the bowel. In addition, patient demographics and disease characteristics vary between units and countries, as do unit policies and throughput levels.

Examples of the areas of variability that this snapshot audit will provide contemporaneous international data upon:

- Method of access (laparoscopic/open/conversions) versus outcome
- Method of anastomosis (handsewn/stapled) versus outcome
- Method of stapling technique versus outcome
- Patient factors versus outcome
- Hospital and surgeon factors versus outcome
- Inflammatory bowel diseases (IBD): factors and perioperative interventions versus outcome.

# 2 - Methods

## A) Summary

Pan-European, prospective audit of consecutive patients undergoing any left hemicolectomy, sigmoid and rectal resections over a minimum 2-month period. The audit shall include operations from 1 February 2017 to 15 March 2017. The sites must include operations for at least 8 consecutive weeks. In order to meet this minimum 8 weeks criterion, sites must start enrolling operations by 15 March 2017.

*Commencement timeframe:* The sites will start within a time window from 1 February to 15 March 2017. Following commencement, the sites will be required to include patients for at least 8 consecutive weeks.

*Final date for operation inclusion:* The sites can include operations that occur up to 10 May 2017.

All patients will be followed for 30 days post-operation. Data collection should therefore be completed by 9 June 2017.

As this is an audit, no change to normal patient management is required.

## B) Primary Objective

To explore differences in patients, techniques and outcomes across the entire cohort to identify areas of practice variability resulting in apparent differences in outcome warranting further study.

Examples of the postoperative outcomes that the study will examine are:

- Complications (type, grade and rate) within 30 post-operative days
- Length of post-operative stay in the hospital
- Readmission within 30 postoperative days
- Histopathological results

## C) Primary Research Question

(should this be required for local approvals process)
Does anastomotic technique impact upon post-operative outcomes?

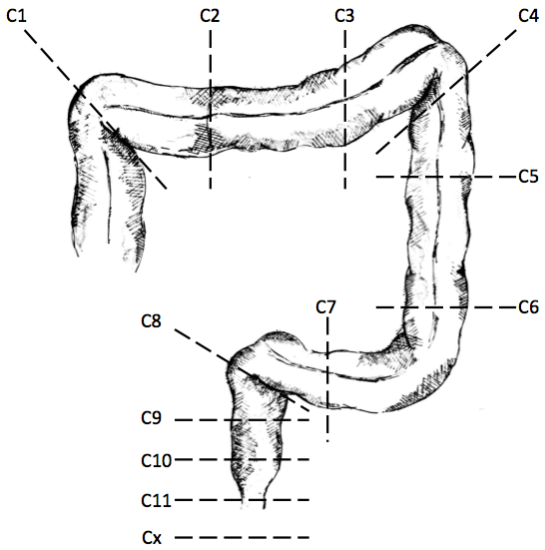
## D) Inclusion Criteria

Adult patients undergoing:

- Left hemicolectomy
- Sigmoid resections
- Rectal resections
- Abdominoperineal resection (APR)
- Completion proctectomy

Procedures should be included:

1. Any approach (open, laparoscopic or robot assisted)
2. Benign and malignant indications
3. Resection with or without anastomosis
4. Emergency, expedited and elective setting




The proximal level of bowel transection may be at C1 to C9.

The distal level of bowel transection may be at C4 to Cx.

C1 - hepatic flexure
C2 - proximal third transverse
C3 - distal third transverse
C4 - splenic flexure
C5 - proximal descending
C6 - distal descending
C7 - mid sigmoid
C8 - rectosigmoid junction
C9 - upper third rectum
C10 - mid third rectum
C11 - lower third rectum
Cx - no distal resection margin: complete excision of rectum and anal canal (eg APR)

## E) Exclusion Criteria

1. Colostomy reversal/closre/take down
2. More than one anastomosis
3. Total, subtotal and panproctocolectomies
4. Proximal resection above the hepatic flexure
5. Patients with Crohn's disease who undergo upstream stricturoplasty at the same time as left colon resection.
6. Pelvic exenteration

## F) Methods for identifying patients

Multiple methods may be used according to local circumstances/staffing:

1. At the pre-operative assessment clinic (for elective operations)
2. Daily review of elective theatre lists
3. Daily review of team handover sheets / emergency admission lists / ward lists
4. Review of theatre logbooks

## G) Centre eligibility

All hospitals/units performing gastrointestinal surgery are eligible to join this audit. No unit size or case throughput stipulations are made. Countries outside Europe can also participate in this audit.

All participating centres will be required to register their details with the ESCP cohort study office and will be responsible for their own local approvals process prior to the start of the data collection period.

Centres should ensure that they have appropriate pathways and manpower to include all consecutive eligible patients during the study period and provide >95% completeness of data entry before locking of REDCap database on the 30 June 2017.

## H) Patient follow-up

The audit is designed so normal patient follow-up pathways can be utilised to obtain outcomes data. No additional visits or changes to normal follow-up should be made.

However, local investigators should be proactive in identifying post-operative events (or lack thereof), within the limits of normal follow-up. These may include reviewing the patient notes (paper and electronic) during admission and before discharge to note in-hospital complications, reviewing hospital systems to check for re-attendances or re-admissions, and reviewing post-operative radiology reports, as well as the notes from the in-person outpatient review which we anticipate will occur between 4 and 6 weeks post-operation in most circumstances.

## I) Data completion and organisation

CRFs are shown in section 4.

This research takes the form of an audit study and no changes to the normal patient pathway need to be instigated for it to be run. Case report forms (CRFs) have been designed to reflect the normal practice and be completed with minimal extra work from the clinical team. We envisage that most hospitals opening for the study will identify a team of 4-5 members, including one or more Consultant-level members (which most centres require to

be the official local 'lead' of the study), and trainee surgeons, junior doctors or data administrators who will undertake the organisational and logistical roles as well as co-ordinate data entry.

CRF A (patient demographics) and CRF C (follow-up information) can be completed by any suitably qualified member of the local team.

We do stipulate the CRF B (operative details) must be completed by, or in direct conjunction with, a surgeon who was present during the operation itself. It should ideally be completed immediately after surgery, at the same time as the operation notes are written, to ensure data accuracy and completeness.

## J) Missing data and retrospective patient entry

The online database has been designed to allow sites to securely access an individual patient's data for all CRFs throughout the study period. This means that any missing or erroneous data can be altered by the local investigators whilst the data collection period is ongoing. In order to maximise data completion and emphasise its importance to collaborators, participating centres with >5% missing data in **mandatory fields** (i.e. less than 95% data completeness) will be excluded from the study.

The study design means that sites may retrospectively identify eligible patients that were missed primarily and for whom contemporaneous patient and operation data was not entered. We are happy for these patients to be entered during the study period providing that CRF B (operative details) is completed by, or in direct conjunction with, a surgeon who was present during the operation itself.

## K) Data collection system and information governance

Data will be recorded contemporaneously on a dedicated, secure server running the Research Electronic Data Capture (REDCap) web application. REDCap allows collaborators to enter and store data in a secure system. No patient identifiable data (name, date of birth, address, etc) will be recorded on REDCap.

Registered local investigators will have individual password-protected access to their unit's data entered on to REDCap. During the running of the audit, only local data will be visible to investigators; other sites' data will not be accessible.

In order to facilitate entry of follow-up data, investigators will need a way to link REDCap records to patient records. This can be achieved by keeping a password protected spreadsheet containing a look-up table. This should cross-reference the automatically generated REDCap ID number for each patient against their local identifier number.

The Birmingham Surgical Trials Consortium (BiSTC) will provide administrative support for the project and the REDCap system. The REDCap system used is hosted by the University of Birmingham (UK). This system was used in the 2016 ESCP audit on stoma closure. Many hospitals already use these data collection tools to measure clinical practice and drive improvements in healthcare in multiple disease settings.

Data will be stored securely on encrypted and certified servers for a minimum of five years under the governorship of the European Society of Coloproctology (ESCP). The data may be used for future research although it should be noted that the anonymised nature of the database means individual patients will not be reverse-identifiable in the future.

## L) Local approvals

All data collected will measure current practice, with no changes made to normal treatment. As such, this study should be registered as an audit of current practice at each participating centre. It is the responsibility of the local team at each site to ensure that local audit approval (or equivalent) is completed for their centre. Participating centres will be asked to confirm that they have gained formal approval at their site.

## M) Authorship

A maximum of 5 investigators from each individual site will be included as formal co-investigators in this research, and will be Pubmed searchable and citable. The output from this research will be published under a single corporate authorship – e.g "Pan-European Cohort Studies Group" or similar.

An identical process of multicentre audit and publication/authorship has been used recently in the publication of main study from the first audit: "**The relationship between method of anastomosis and anastomotic failure: an international snapshot audit**" – submitted to Colorectal Disease journal in 2016.

## N) Pilot

A one-week pilot across five hospitals across Europe will be performed to test the data collection tool. Adjustments based on these experiences may be made before rolling out the main audit.

## O) Publication of data

Data will be published as a pool from all participating units. Subgroup analyses by disease, technique or outcome variables may be presented, but no hospital-level or surgeon-level data will be published whereby an individual unit or surgeon could be identified. If local

investigators would like a breakdown of their own unit's data for benchmarking purposes and local presentation/discussion, this will be available after the end of the study.

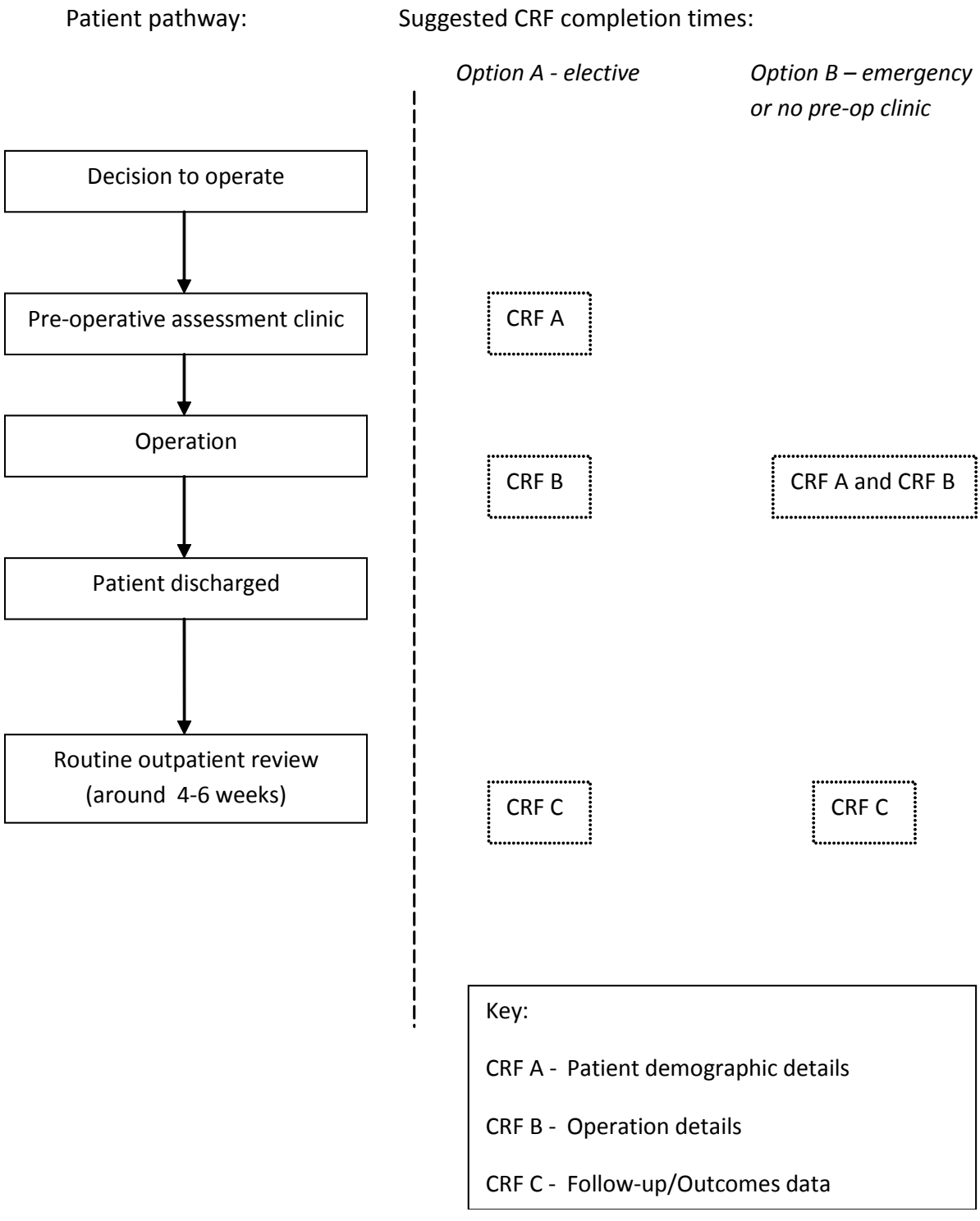
## P) Data governance

The ESCP Cohort Studies Committee welcomes the use of the data for further research that benefits patients. Requests can be submitted to the ESCP Cohort Studies Committee. Data sharing is subject to ESCP approval and the appropriate safeguarding as determined by the ESCP. Any future subprojects should also comply with our policy of a single corporate authorship e.g. "Pan-European Cohort Studies Group" or similar. However, authors' contributions will be highlighted in accordance with the recommendations for the conduct, reporting, editing, and publication of scholarly work in medical journals (commonly referred to as the Vancouver Convention) by the International Committee of Medical Journal Editors (ICMJE).

## Q) Financial arrangements

This study is supported by the European Society of Coloproctology. Participating centres will not bear any costs. Similarly, no financial reimbursement will be made to units or investigators for their involvement in the project.

## 3 - Study flowsheet showing patient pathway and CRF completion times



# 4 - CASE REPORT FORMS

## CASE REPORT FORM A – *patient demographics*

| | | | | | |
|---|---|---|---|---|---|
| Date of surgery | _____ / _____ / _____ | | | | This is an optional field to help you identify and follow up patients |
| Gender | ☐ Male | ☐ Female | | | |
| Age | _____ | | | | Age on day of operation |
| ASA grade | ☐ Grade I: healthy person | ☐ Grade II: mild systemic disease | ☐ Grade III: severe systemic disease | | . |
| | ☐ Grade IV: systemic disease that is a constant threat to life | | ☐ Grade V: moribund | | |
| History of IHD/ stroke | ☐ Yes | ☐ No | | | IHD = ischaemic heart disease |
| History of anticoagulant treatment | ☐ Yes | ☐ No | | | Anti-coagulant use (e.g. warfarin, coumadin) prior to admission to hospital |
| History of diabetes mellitus | ☐ Yes | ☐ No | | | Include diet, tablet and insulin controlled DM |
| Smoking history | ☐ Never | ☐ Ex-smoker: stopped **more** than 6 weeks ago | ☐ Ex-smoker: stopped **less** than 6 weeks ago | | |
| | ☐ Current smoker | | | | |
| Body Mass Index | _____ | **If BMI unknown:** | Weight: _____ kg | Height: _____ cm | Height/weight only required if BMI unavailable |
| Preoperative nutritional support | ☐ None | ☐ Oral supplement | ☐ Parenteral nutrition | | |
| | ☐ Enteral nutrition (NG tube, PEG) | | | | |
| Urgency of surgery | ☐ Elective (planned) | ☐ Expedited | ☐ Emergency | | Expedited: within 2 weeks of decision<br>Emergency: within 24 hours of decision |
| Indication | ☐ Benign polyp | ☐ Crohn's disease | ☐ Diverticular disease | | |
| | ☐ Malignancy (cancer) | ☐ Trauma | ☐ Ulcerative colitis | | |
| | ☐ Other: _____ | | | | |
| Location of disease | ☐ Splenic flexure | ☐ Left colon | ☐ Sigmoid colon | | For synchronous tumours you may select multiple sites |
| | ☐ High rectum (11-15cm) | ☐ Middle rectum (7-10cm) | ☐ Low rectum (0-6cm) | | |
| Pre-operative albumin | _____ g/L **or** mmol/L | | | | Enter most recent pre-operative value |
| Pre-operative haemoglobin | _____ g/L **or** mmol/L | | | | Enter most recent pre-operative value |
| Pre-operative enteric fistula | ☐ Yes | ☐ No | | | Fistula between bowel and other organ/ skin |
| Pre-operative abscess | ☐ Yes | ☐ No | | | Intra-abdominal or pelvic abscess, within 3 months of surgery |
| **If yes:** | US or CT guided percutaneous abscess drainage | ☐ Yes | ☐ No | | Include US/ CT drainage procedures completed within 3 months of surgery |
| **If yes:** | Interval from abscess drainage to operation | | _____ days | | |

## CASE REPORT FORM A – *Crohn's disease / cancer extension data points*

| **Crohn's disease extension data points** | | | | |
|---|---|---|---|---|
| Pre-operative immunosuppressant drugs<br>*select multiple drugs, if appropriate* | ☐ Steroids, low dose | ☐ Steroids, high dose (≥20mg prednisolone or equivalent) | | Low dose: <20mg prednisolone or equivalent |
| | ☐ 6-mercaptopurine | ☐ Methotrexate | ☐ Azathioprine | Include systemic steroids given within a week of surgery. Include 6MP, MTX, azathioprine given within a month of surgery. |
| Pre-operative biologic use | ☐ None | ☐ 1w prior to surgery | ☐ 1-6w prior to surgery | w = weeks |
| | ☐ 6-12w prior to surgery | ☐ 12w to 1 year prior to surgery | | *select multiple options, if appropriate* |
| Steroid stress dose | ☐ Yes | ☐ No | | A single high dose of steroids at induction to reduce surgical stress response in patients already on steroids |
| **Cancer extension data points** | | | | |
| Initial pre-treatment staging (**no** neoadjuvant therapy given, or **prior** to neoadjuvant therapy if it was given): | | | | |
| T stage | ☐ T1 | ☐ T2 | ☐ T3 | |
| | ☐ T4 | | | |
| N stage | ☐ N0 | ☐ N1 | ☐ N2 | |
| M stage | ☐ M0 | ☐ M1 | | |
| EMVI detected on MRI | ☐ Yes | ☐ No | | |
| Threatened (<2mm) CRM on MRI | ☐ Yes | ☐ No | | |
| Neoadjuvant therapy: | | | | |
| What **neo**adjuvant (pre-operative) therapy was administered, if any | ☐ None | ☐ Chemotherapy only | ☐ SCRT: short-course radiotherapy | |
| | ☐ Long-course chemoradiotherapy | | | |
| Post-treatment staging (for patients who underwent neoadjuvant therapy, repeat staging prior to surgery): | | | | |
| Was the patient re-staged following neoadjuvant treatment | ☐ Yes *(complete details below)* | ☐ No | ☐ Not applicable (no neoadjuvant treatment) | |
| T stage | ☐ T1 | ☐ T2 | ☐ T3 | |
| | ☐ T4 | | | |
| N stage | ☐ N0 | ☐ N1 | ☐ N2 | |
| M stage | ☐ M0 | ☐ M1 | | |
| EMVI detected on MRI | ☐ Yes | ☐ No | | EMVI = extramural venous invasion - |
| Threatened (<2mm) CRM on MRI | ☐ Yes | ☐ No | | CRM = circumferential resection margin |

*N.B. if liver metastasis is operated prior to colorectal resection, please record as M0 even if original radiological staging M1*

## CASE REPORT FORM B – *operative details*

| | | | | | | |
|---|---|---|---|---|---|---|
| Pre-operative bowel preparation | ☐ None | ☐ MBP only | ☐ MBP + preop oral antibiotics | | | MBP = Mechanical bowel preparation |
| Surgeon in charge | ☐ Colorectal trainee | ☐ Colorectal consultant surgeon | | | | Consultant = attending/ specialist |
| | ☐ General surgery trainee | ☐ General consultant surgeon | | | | Trainee = registrar/ resident |
| Proximal level of bowel transection | Select C1 – C9: _____ | | | | | Please refer to diagram on page 7 |
| Distal level of bowel transection | Select C4 – Cx: _____ | | | | | Please refer to diagram on page 7 |
| Intra-operative findings | ☐ Enteric fistula | ☐ Acute colitis/ proctitis | ☐ Bowel perforation | | | You may select multiple findings |
| | ☐ Bowel obstruction | ☐ Intra-abdominal / pelvic abscess | | | | |
| Initial operative approach | ☐ Open | ☐ Robotic | ☐ Laparoscopic | | | Conversion to open: wound made or extended to allow access to vascular pedicle or to complete safe dissection |
| **If robotic/ laparoscopic:** | Was this converted to open | ☐ Yes | ☐ No | | | |
| Was a part of the operation undertaken with a transanal approach? | ☐ Yes | ☐ No | | | | |
| Operation duration (mins) | _____ minutes | | | | | Time from incision to skin closure |
| Skin closure | ☐ Suturing | ☐ Stapling | | | | |
| Intra-operative blood transfusion | ☐ Yes | ☐ No | | | | |
| Intra-operative complications | ☐ None | ☐ Vascular injury | ☐ Bowel injury (e.g. duodenum) | | | |
| | ☐ Injury to adjacent organs or structures (e.g. ureter) | | | | | |
| Anatomosis | ☐ Handsewn | ☐ Staples | ☐ None | | | |
| **If no anastomosis:** | ☐ Standard APR | ☐ Inter-sphincteric APR | ☐ Extra-levator APR | | | |
| | ☐ Hartmann type-operation (rectal stump left) | | | | | |
| **If handsewn or stapled anastomosis** | | | | | | |
| Anastomotic configuration | ☐ Side to side | ☐ Side to end | ☐ End to end | | | |
| Anastomosis distance from anus | _____ cm | | | | | Only required for rectal resections |
| Intra-operative leak test performed? | ☐ Yes | ☐ No | | | | |
| De-functioning stoma | ☐ Loop ileostomy | ☐ End ileostomy | ☐ Loop colostomy | | | |
| | ☐ None | | | | | |

## CASE REPORT FORM B – *handsewn/stapled anastomosis extension data points*

| | | | | |
|---|---|---|---|---|
| **Handsewn anastomosis extension data points** | | | | |
| Technique for primary anastomosis | ☐ Continuous sutured | ☐ Interrupted sutured | | |
| Suture material for primary anastomosis | ☐ Biosyn | ☐ Capron (Nurolon) | ☐ Catgut | |
| | ☐ Dexon | ☐ Ethibond (TiCron) | ☐ Maxon | |
| | ☐ Monocryl | ☐ Monomax | ☐ Monosyn | |
| | ☐ Nylon (Ethilon) | ☐ PDS (Monoplus) | ☐ Polysorb | |
| | ☐ Prolene (SurgiPro) | ☐ Safil | ☐ Silk | |
| | ☐ Vicryl (Novosyn) | ☐ Other: _____ | | |
| Suture gauge for primary anastomosis | _____ | | | e.g. 6-0, 5-0, 4-0, 3-0, 2-0, 1-0, 0, 1, 2 etc |
| Bites taken for primary anastomosis | ☐ Full thickness bowel | ☐ Sero-muscular only | | |
| Number of layers | ☐ Single layer | ☐ Two layers | | Two layers = another layer of sutures taken after the primary bowel anastomosis is completed |
| **Stapled anastomosis extension data points** | | | | |
| Device for primary anastomosis | ☐ Linear | ☐ Circular | | |
| If circular stapler used | | | | |
| Device for primary anastomosis | ☐ CDH (Ethicon) | ☐ CEEA (Covidien) | ☐ ECS (Ethicon) | |
| | ☐ EEA (Covidien) | ☐ SDH (Ethicon) | ☐ Other: _____ | |
| Stapler diameter size | _____ mm | | | Circular stapler diameters vary 21-33mm |
| If linear stapler used | | | | |
| Device for primary anastomosis | ☐ Endopath (Ethicon) | ☐ GIA (Covidien) | ☐ NTLC (Ethicon) | |
| | ☐ TA (Covidien) | ☐ TCT (Ethicon) | ☐ TL (Covidien) | |
| | ☐ TLC (Ethicon) | ☐ TX (Ethicon) | ☐ Other: _____ | |
| Was apex of anastomosis stapled? | ☐ Yes | ☐ No | | |
| **If apex stapled, device used:** | ☐ Endopath (Ethicon) | ☐ GIA (Covidien) | ☐ NTLC (Ethicon) | |
| | ☐ TA (Covidien) | ☐ TCT (Ethicon) | ☐ TL (Covidien) | |
| | ☐ TLC (Ethicon) | ☐ TX (Ethicon) | ☐ Other: _____ | |
| **If apex stapled, was it oversewn:** | ☐ No | ☐ Yes – continuous | ☐ Yes – interrupted | |

## CASE REPORT FORM C – *follow up details*

| | | | | |
|---|---|---|---|---|
| Post-operative admission to intensive care unit | ☐ No admission to ICU | ☐ Planned from operating theatre | | Intensive care unit = ICU/ ITU/ Critical care unit |
| | ☐ Unplanned, from ward | ☐ Unplanned, from operating theatre | | |
| Peak CRP level | _____ mg/L | Peak CRP level up to and including on post-operative day three (day of operation is day zero) | | |
| Clavien-Dindo complication grade | ☐ None | ☐ Grade I | ☐ Grade II | ☐ Grade IIIa |
| | ☐ Grade IIIb | ☐ Grade IVa | ☐ Grade IVb | ☐ Grade V |
| Anastomotic leak | ☐ None | ☐ Yes – Grade A | ☐ Yes – Grade B | Grade A = no radiological or surgical intervention |
| | ☐ Yes – Grade C: surgical intervention | | | |
| **If anastomotic leak occured:** | Post operative day anastomotic leak diagnosed: _____ | | | Grade B = radiological intervention (eg drain) |
| Intra-abdominal or pelvic collection | ☐ Yes | ☐ No | | |
| **If collection occured:** | Post operative day anastomotic leak diagnosed: _____ | | | The day of operation is day zero. |
| Surgical site infection | ☐ Yes | ☐ No | | |
| Length of post op stay | _____ days | | | |
| 30 day readmission | ☐ Yes | ☐ No | | |
| **If readmitted, reason for readmission:** | _____ | | | |
| 30 day reoperation | ☐ Yes | ☐ No | | |
| **If reoperated, reason for reoperation:** | ☐ Anastomotic leak | ☐ Bowel obstruction | ☐ Hernia | |
| | ☐ Wound related problem | ☐ Other: _____ | | |
| Postop histology | ☐ Benign polyp | ☐ Crohn's disease | ☐ Diverticular disease | |
| | ☐ Malignancy (cancer) | ☐ Ulcerative colitis | ☐ Other: _____ | |
| **Cancer extension data points:** | | | | |
| Grade of differentiation | ☐ Well differentiated | ☐ Moderate differentiation | ☐ Poorly differentiated | |
| Histological T stage (post-op) | ☐ T0 | ☐ T1 | ☐ T2 | |
| | ☐ T3 | ☐ T4 | | |
| Histological N stage (post-op) | ☐ N0 | ☐ N1 | ☐ N2 | |
| Histological M stage (post-op) | ☐ M0 | ☐ M1 | | |
| Complete pathological response | ☐ Yes | ☐ No | | |
| Number of harvested lymph nodes | _____ | | | |
| Number of lymph nodes with metastases | _____ | | | |
| Histological evidence of EMVI | ☐ Yes | ☐ No | | EMVI = extramural venous invasion |
| Distance to closest resection margin | _____ mm | | | |

## 5- Unit questionnaire

To be completed at site registration stage

| **Provision of surgical services** | |
|---|---|
| Is your centre a: | University hospital/ tertiary centre;<br>District general hospital; |
| How many consultant-level surgeons perform colorectal resection operations at your site? | (number) |
| How many consultant-level specialist colorectal surgeons are at your site | (number) |
| How many beds are in your hospital in total (all specialties)? | (number) |
| How many general surgical beds are in your hospital? | (number) |
| How many high dependency (HDU) and intensive care (ITU) beds are in your hospital? | (number) |