

The 2017 European Society of Coloproctology (ESCP) international snapshot audit of left colon, sigmoid and rectal resections – study protocol

ESCP Cohort Studies and Audits Committee

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Trial Protocol

**The 2017 European Society of Coloproctology (ESCP) international snapshot audit of
left colon, sigmoid and rectal resections – study protocol**

ESCP Cohort Studies and Audits Committee*

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Abstract

Background: Left hemicolectomy, sigmoid, and rectal resections are commonly performed colorectal operations. There is significant variability exists in the techniques utilised to undertake these operations, ~~as well as~~ at patient, surgeon and unit level.

Aim: To explore differences in patients, techniques and outcomes across anthe 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.

Methods: A two-month prospective audit to be performed across Europe in early 2017, co-ordinated by the European Society of Coloproctology. The main audit 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. 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 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 (2015) 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 (2016) 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 their frequency, there remains uncertainty about the optimal method of undertaking these operations, 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:~~ may identify include:

- Method of access (laparoscopic/open/robotic/trans-anal) versus outcome
- Method of anastomosis (handsewn/stapled) versus outcome
- Patient and disease factors versus outcome
- Hospital and surgeon factors versus outcome
- Inflammatory bowel diseases (IBD): factors and perioperative interventions versus outcome.
- Neoadjuvant therapy practices versus outcome

2 - Methods

A) Summary

International prospective audit of all consecutive patients undergoing left hemicolectomy, sigmoid and rectal resections over an eight week period. ~~As this is an audit, no change to normal patient management is required.~~

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

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

Follow-up: All patients will be followed for 30 days post-operation. All data collection should therefore be completed by 9th June 2017.

B) 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.

C) Inclusion Criteria

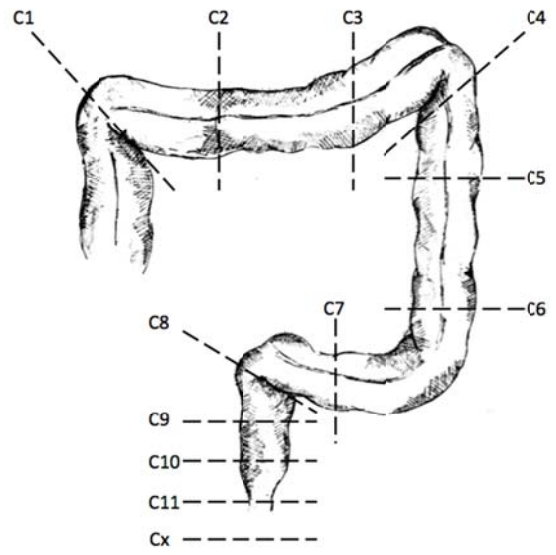
Adult patients undergoing:

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

All eligible procedures should be entered, including:

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

Figure 1 – Schematic of operation resection margins for recording in the audit



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)

D) Exclusion Criteria

1. Colostomy reversal/closure/take down
2. More than one anastomosis
3. Total colectomy, subtotal colectomy and panproctocolectomy
4. Proximal colonic resection margin sitting 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

E) 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

F) Centre eligibility

All hospitals/units performing gastrointestinal surgery are eligible to join this audit. No unit size or case throughput stipulations are made. Countries both within and outside Europe are invited to 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.

G) 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.

H) Data completion and organisation

Complete CRFs are shown in Figure 2

This study is an audit 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 ~~usual 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 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 of data.

I) 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.

J) 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). 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.

K) 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.

L) 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 “The 2017 European Society of Coloproctology (ESCP) collaborating 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**” – published in Colorectal Disease in 2017: <https://onlinelibrary.wiley.com/doi/abs/10.1111/codi.13646>

M) 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.

N) 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.

O) 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 ESCP 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).

P) 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.

Authorship list

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FIGURE 2 - Study flowsheet showing patient pathway and CRF completion times

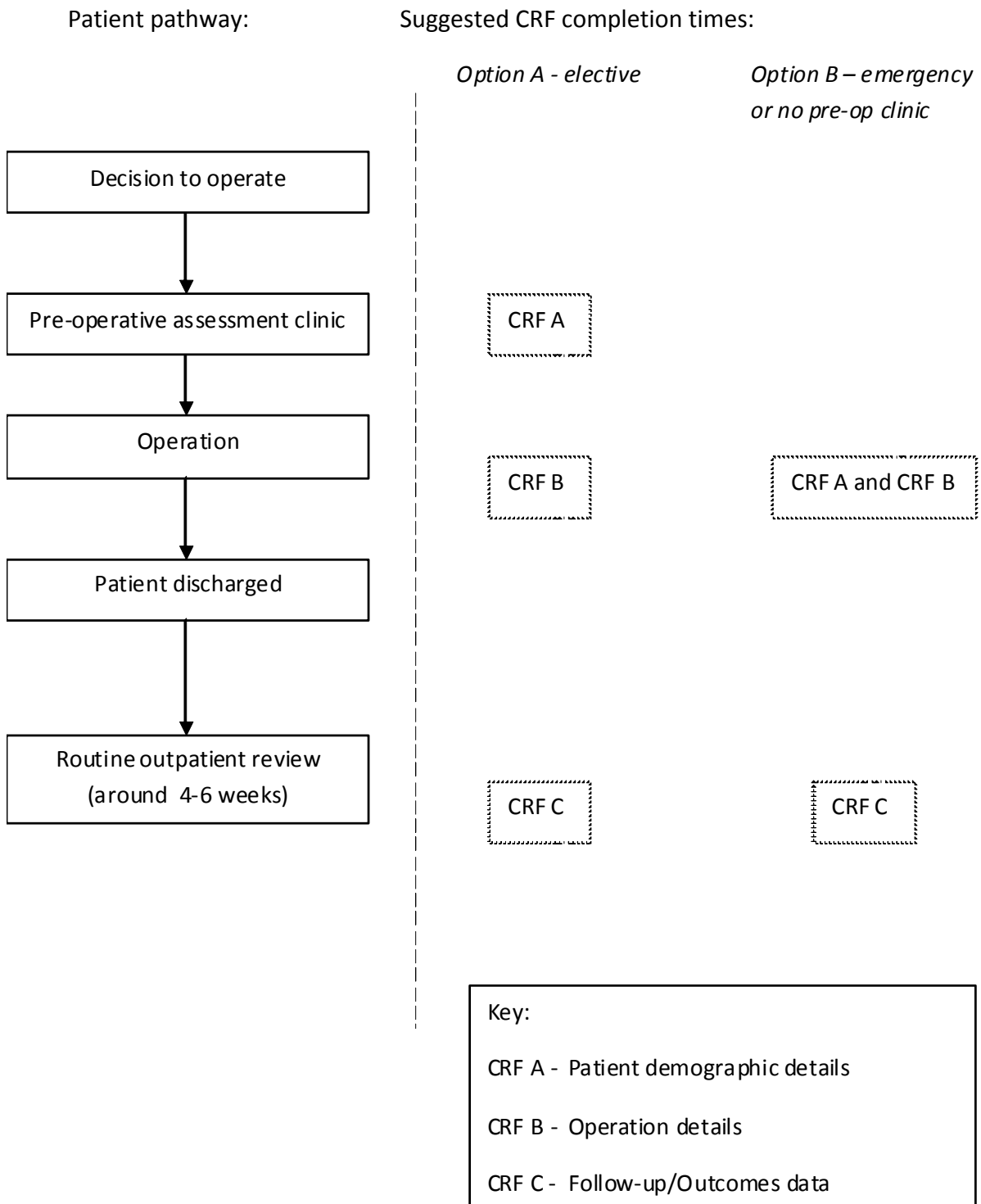


FIGURE 3 - CASE REPORT FORMS

CASE REPORT FORM A – patient demographics

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

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

Crohn's disease extension data points				
Pre-operative immunosuppressant drugs <i>select multiple drugs, if appropriate</i>	<input type="checkbox"/> Steroids, low dose <input type="checkbox"/> 6-mercaptopurine	<input type="checkbox"/> Steroids, high dose (≥20mg prednisolone or equivalent) <input type="checkbox"/> Methotrexate	<input type="checkbox"/> Azathioprine	Low dose: <20mg prednisolone or equivalent Include systemic steroids given within a <u>week</u> of surgery. Include 6MP, MTX, azathioprine given within a <u>month</u> of surgery.
Pre-operative biologic use	<input type="checkbox"/> None <input type="checkbox"/> 6-12w prior to surgery	<input type="checkbox"/> 1w prior to surgery <input type="checkbox"/> 12w to 1 year prior to surgery	<input type="checkbox"/> 1-6w prior to surgery	w = weeks <i>select multiple options, if appropriate</i>
Steroid stress dose	<input type="checkbox"/> Yes	<input type="checkbox"/> No	A single high dose of steroids at induction to reduce surgical stress response in patients already on steroids	
Cancer extension data points				
<u>Initial pre-treatment staging (no neoadjuvant therapy given, or prior to neoadjuvant therapy if it was given):</u>				
T stage	<input type="checkbox"/> T1 <input type="checkbox"/> T4	<input type="checkbox"/> T2	<input type="checkbox"/> T3	
N stage	<input type="checkbox"/> N0	<input type="checkbox"/> N1	<input type="checkbox"/> N2	
M stage	<input type="checkbox"/> M0	<input type="checkbox"/> M1		
EMVI detected on MRI	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
Threatened (<2mm) CRM on MRI	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
<u>Neoadjuvant therapy:</u>				
What neoadjuvant (pre-operative) therapy was administered, if any	<input type="checkbox"/> None <input type="checkbox"/> Long-course chemoradiotherapy	<input type="checkbox"/> Chemotherapy only	<input type="checkbox"/> SCRT: short-course radiotherapy	
<u>Post-treatment staging (for patients who underwent neoadjuvant therapy, repeat staging prior to surgery):</u>				
Was the patient re-staged following neoadjuvant treatment	<input type="checkbox"/> Yes <i>(complete details below)</i>	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable (no neoadjuvant treatment)	
T stage	<input type="checkbox"/> T1 <input type="checkbox"/> T4	<input type="checkbox"/> T2	<input type="checkbox"/> T3	
N stage	<input type="checkbox"/> N0	<input type="checkbox"/> N1	<input type="checkbox"/> N2	
M stage	<input type="checkbox"/> M0	<input type="checkbox"/> M1		
EMVI detected on MRI	<input type="checkbox"/> Yes	<input type="checkbox"/> No		EMVI = extramural venous invasion -
Threatened (<2mm) CRM on MRI	<input type="checkbox"/> Yes	<input type="checkbox"/> 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	<input type="checkbox"/> None	<input type="checkbox"/> MBP only	<input type="checkbox"/> MBP + preop oral antibiotics	MBP = Mechanical bowel preparation
Surgeon in charge	<input type="checkbox"/> Colorectal trainee <input type="checkbox"/> General surgery trainee	<input type="checkbox"/> Colorectal consultant surgeon <input type="checkbox"/> General consultant surgeon		Consultant = attending/ specialist 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	<input type="checkbox"/> Enteric fistula <input type="checkbox"/> Bowel obstruction	<input type="checkbox"/> Acute colitis/ proctitis <input type="checkbox"/> Intra-abdominal / pelvic abscess	<input type="checkbox"/> Bowel perforation	You may select multiple findings
Initial operative approach	<input type="checkbox"/> Open If robotic/ laparoscopic: Was this converted to open	<input type="checkbox"/> Robotic <input type="checkbox"/> Yes	<input type="checkbox"/> Laparoscopic <input type="checkbox"/> No	Conversion to open: wound made or extended to allow access to vascular pedicle or to complete safe dissection
Was a part of the operation undertaken with a transanal approach?	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
Operation duration (mins)	_____ minutes			Time from incision to skin closure
Skin closure	<input type="checkbox"/> Suturing	<input type="checkbox"/> Stapling		
Intra-operative blood transfusion	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
Intra-operative complications	<input type="checkbox"/> None <input type="checkbox"/> Injury to adjacent organs or structures (e.g. ureter)	<input type="checkbox"/> Vascular injury	<input type="checkbox"/> Bowel injury (e.g. duodenum)	
Anastomosis	<input type="checkbox"/> Handsewn	<input type="checkbox"/> Staples	<input type="checkbox"/> None	
If no anastomosis:	<input type="checkbox"/> Standard APR <input type="checkbox"/> Hartmann type-operation (rectal stump left)	<input type="checkbox"/> Inter-sphincteric APR	<input type="checkbox"/> Extra-levator APR	
If handsewn or stapled anastomosis				
Anastomotic configuration	<input type="checkbox"/> Side to side	<input type="checkbox"/> Side to end	<input type="checkbox"/> End to end	
Anastomosis distance from anus	_____ cm			Only required for rectal resections
Intra-operative leak test performed?	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
De-functioning stoma	<input type="checkbox"/> Loop ileostomy <input type="checkbox"/> None	<input type="checkbox"/> End ileostomy	<input type="checkbox"/> Loop colostomy	

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

Handsewn anastomosis extension data points			
Technique for primary anastomosis	<input type="checkbox"/> Continuous sutured	<input type="checkbox"/> Interrupted sutured	
Suture material for primary anastomosis	<input type="checkbox"/> Biosyn	<input type="checkbox"/> Capron (Nurolon)	<input type="checkbox"/> Catgut
	<input type="checkbox"/> Dexon	<input type="checkbox"/> Ethibond (TiCron)	<input type="checkbox"/> Maxon
	<input type="checkbox"/> Monocryl	<input type="checkbox"/> Monomax	<input type="checkbox"/> Monosyn
	<input type="checkbox"/> Nylon (Ethilon)	<input type="checkbox"/> PDS (Monoplus)	<input type="checkbox"/> Polysorb
	<input type="checkbox"/> Prolene (SurgiPro)	<input type="checkbox"/> Safil	<input type="checkbox"/> Silk
	<input type="checkbox"/> Vicryl (Novosyn)	<input type="checkbox"/> 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	<input type="checkbox"/> Full thickness bowel	<input type="checkbox"/> Sero-muscular only	
Number of layers	<input type="checkbox"/> Single layer	<input type="checkbox"/> 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	<input type="checkbox"/> Linear	<input type="checkbox"/> Circular	
If circular stapler used			
Device for primary anastomosis	<input type="checkbox"/> CDH (Ethicon)	<input type="checkbox"/> CEEA (Covidien)	<input type="checkbox"/> ECS (Ethicon)
	<input type="checkbox"/> EEA (Covidien)	<input type="checkbox"/> SDH (Ethicon)	<input type="checkbox"/> Other: _____
Stapler diameter size	_____ mm		Circular stapler diameters vary 21-33mm
If linear stapler used			
Device for primary anastomosis	<input type="checkbox"/> Endopath (Ethicon)	<input type="checkbox"/> GIA (Covidien)	<input type="checkbox"/> NTLC (Ethicon)
	<input type="checkbox"/> TA (Covidien)	<input type="checkbox"/> TCT (Ethicon)	<input type="checkbox"/> TL (Covidien)
	<input type="checkbox"/> TLC (Ethicon)	<input type="checkbox"/> TX (Ethicon)	<input type="checkbox"/> Other: _____
Was apex of anastomosis stapled?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
<u>if apex stapled, device used:</u>	<input type="checkbox"/> Endopath (Ethicon)	<input type="checkbox"/> GIA (Covidien)	<input type="checkbox"/> NTLC (Ethicon)
	<input type="checkbox"/> TA (Covidien)	<input type="checkbox"/> TCT (Ethicon)	<input type="checkbox"/> TL (Covidien)
	<input type="checkbox"/> TLC (Ethicon)	<input type="checkbox"/> TX (Ethicon)	<input type="checkbox"/> Other: _____
<u>if apex stapled, was it oversewn:</u>	<input type="checkbox"/> No	<input type="checkbox"/> Yes – continuous	<input type="checkbox"/> Yes – interrupted

CASE REPORT FORM C – follow up details

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

TABLE 1 – Audit timelines

Key dates:	
22 December 2016	Draft protocol published
1 February 2017 to 15 March 2017	Patient inclusion window starts <i>Sites should start collecting at least 8 weeks of consecutive patient operations within this window.</i> <i>Sites should follow up each patient for 30 days.</i>
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 <i>This is the deadline for data submission</i>
22 September 2017	Preliminary data at ESCP 2017 Berlin

TABLE 2- Unit questionnaire

To be completed at site registration stage

Provision of surgical services	
Is your centre a:	University hospital/ tertiary centre; 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)