EuroSurg-1:

Obesity in major gastrointestinal surgery

An international, student-driven study of obesity and post-operative complications

Study protocol v3.0

6 December 2015

The EuroSurg-1 project is supported by:

Email: info@eurosurg.org
Facebook: www.facebook.com/EuroSurg
Twitter: https://twitter.com/EuroSurg

<table>
<thead>
<tr>
<th>Key Study Dates:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Study registration period:</td>
<td>Mon 7th December 2015 onwards</td>
</tr>
<tr>
<td>Data collection periods:</td>
<td>Mon 1st February – Mon 18th April 2016</td>
</tr>
<tr>
<td>Follow-up period ends:</td>
<td>Wed 18th May 2016</td>
</tr>
<tr>
<td>ESCP Annual meeting:</td>
<td>Wed 28th – Fri 30th September 2016</td>
</tr>
</tbody>
</table>
Study co-ordination

Study management group

<table>
<thead>
<tr>
<th>Name</th>
<th>Location</th>
<th>Name</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Merle Stellingwerf</td>
<td>Amsterdam, Netherlands</td>
<td>Stephen Chapman</td>
<td>Leeds, UK</td>
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<td>Mike Bath</td>
<td>Leicester, UK</td>
</tr>
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<td>Ruth Blanco Colino</td>
<td>Barcelona, Spain</td>
<td>Sara Kuiper</td>
<td>Maastricht, Netherlands</td>
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<td>Dmitri Nepogodiev</td>
<td>Birmingham, UK</td>
<td>Gianluca Pellino</td>
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<td>Millie Ngaage</td>
<td>Cambridge, UK</td>
<td>Rutger Stijns</td>
<td>Nijmegen, Netherlands</td>
</tr>
<tr>
<td>James Glasbey</td>
<td>Cardiff, UK</td>
<td>Sandro Pasquali</td>
<td>Padova, Italy</td>
</tr>
<tr>
<td>David Golding</td>
<td>Cardiff, UK</td>
<td>Bahar Busra Ozkan</td>
<td>Samsun, Turkey</td>
</tr>
<tr>
<td>Laura Gavagna</td>
<td>Ferrara, Italy</td>
<td>Tom Drake</td>
<td>Sheffield, UK</td>
</tr>
<tr>
<td>Samuel Lee</td>
<td>Galway, Ireland</td>
<td>Francesco Pata</td>
<td>Varese, Italy</td>
</tr>
</tbody>
</table>

National network committees

In each of the following participating countries a national network committee is responsible for disseminating and running the study:

- Italy
- Netherlands
- Spain – enquiries to eurosurgspain@gmail.com.
- Turkey
- STARSurgUK – United Kingdom and Republic of Ireland. EuroSurg enquiries to David Golding (GoldingD@cardiff.ac.uk)

Students from other ESCP member countries are also welcome to participate in EuroSurg (please contact us at info@eurosurg.org).

Link consultants

Each of the following consultant surgeons acts as a link between participating students in their country and their national colorectal surgery association.

- Mr Simon Bach – United Kingdom

Key contacts:
For matters relating to mini-team setup and audit registration, please contact your local lead (details at www.eurosurg.org). For general enquiries concerning the protocol, please contact the study management group by email (info@eurosurg.org) or on Twitter (@EuroSurg).
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Project timeline

2015

Dec 7  ▪ Protocol released to collaborators.

Dec 7 onwards ▪ Collaborators can register EuroSurg-1 at their centres.

2016

Feb 1 – April 18 ▪ Patient inclusion window.
▪ Each mini-team will collect data on patients over a continuous 2-week period within this window.

May 18 ▪ End of follow-up window.
▪ Each patient should be followed-up for 30 days following their index operation.

June 12 ▪ Deadline for data upload to REDCap online database.

Sept 28 – 30 ▪ European Society of Coloproctology Meeting in Istanbul.
▪ EuroSurg-1 results presented.
About EuroSurg

The EuroSurg collaborative is an international, research and audit collaborative in surgery that is driven by medical students. It was founded following the inaugural European Society of Coloproctology (ESCP) student meeting held in Dublin, September 2015. EuroSurg has evolved quickly with active members in Italy, the Netherlands, Spain, Turkey, the Republic of Ireland and the UK.

The ‘collaborative’ trainee-led model for ‘snapshot’ audit was pioneered in the United Kingdom (UK) by local networks of surgeons in training. These networks were successful in developing and then delivering a number of major surgical research initiatives that included both multicentre cohort studies and multicentre randomised controlled trials. The trainee-led research philosophy has been promoted in a recent *Lancet* publication.

The feasibility of medical students conducting large, multicentre, surgical projects was demonstrated by the Student Audit and Research in Surgery group (STARSurgUK). In 2013, 250 students across 109 UK hospitals evaluated surgical outcomes data from 1500 patients undergoing major gastrointestinal surgery. STARSurg has continued to grow and 180 hospitals participated in our most recent study.

EuroSurg will encourage medical students to form networks that are able to sustain high quality surgical research studies. Students will also acquire new skills in surgical audit and research methodology. This initiative will develop research-active clinicians of the future. EuroSurg will replicate STARSurg’s successful authorship policy, which designates PubMed-citable co-authorship to all collaborators. An example of this can be seen here: [ncbi.nlm.nih.gov/pubmed/25091299](https://ncbi.nlm.nih.gov/pubmed/25091299).

About this study

Obesity has reached ‘epidemic’ levels, challenging health care systems and economies in both developed and developing countries. In Western Europe up to a third of patients undergoing major gastrointestinal surgery are obese.

Obesity is a recognised risk factor for several medical morbidities, including cardiovascular disease and diabetes. It has also been associated with an increased risk of several malignancies including cancer of the colon and oesophagus. Conflicting evidence exists on the impact of obesity on post-operative complications following gastrointestinal surgery. A Swiss study of over 6,000 patients demonstrated no difference in mortality and post-operative morbidity between obese and non-obese patients. An obesity paradox has been proposed with moderate obesity offering protection from adverse events, whereas underweight patients are at greater risk.

The prospective, multicentre Determining Surgical Complications in the Overweight (DISCOVER) study in the UK included 9,300 patients across 163 UK and Irish centres. It found that obesity is associated with an increased risk of post-operative complications in obese patients undergoing surgery for malignancy but not for benign disease. This study will validate these novel findings in an international European cohort whether.
Methods

01

Obesity

Body mass index (BMI) is a readily measured and widely recorded measure of obesity. Throughout this protocol obesity is defined as BMI >30kg/m².

02

Summary

A mini-team of the collaborators (medical students and/or doctors) will participate at each centre, prospectively collecting data over a continuous 14-day period on consecutive patients undergoing major gastrointestinal surgery.

03

Study Aims

(i) To determine whether obesity is associated with excess risk of major post-operative (Clavien-Dindo grade III-V) complications in a European cohort.

(ii) To determine the feasibility of a future, dedicated study on patients undergoing surgery for inflammatory bowel disease.

04

Project Timeline

The overall data collection period will be Monday 1st February to Monday 18th April 2016. Each mini-team will collect data over a 14-day continuous period.

Patients should be included if their operation started ('knife to skin' time when first incision made) within the time period during which you are collecting data.

▲ Multiple teams of students can participate at each centre, collecting data during distinct two-week periods.

05

Centres

- Any hospital in the member nations of the European Society of Coloproctology that performs gastrointestinal surgery may participate.

- All participating centres are required to register the study according to local regulations. Evidence of successful registration should be sent to your national network committee prior to commencement of data collection.

- Following conclusion of the study, it is a requirement of participation that mini-teams at each centre should present the study findings to their hospital’s surgery and audit departments.

Feeding back the study’s findings to your department’s clinicians is essential. Presenting local results will help collaborators develop analytical and presentation skills and will boost their CVs.

EuroSurg-1: protocol version 3.0
06

Inclusion & exclusion criteria

You should collect data on consecutive patients operated at your centre during the data collection period. This means that all eligible patients should be included.

Strategies to identify consecutive patients could include:

- Daily review of elective theatre lists.
- Daily review of handover sheets/ emergency admission and ward lists.
- Daily review of theatre logbooks (both elective and emergency).

Inclusion criteria

Summary: All consecutive adult patients undergoing formation of stoma, gastrointestinal resection or reversal of stoma should be included.

Age: Age 18 years or above.

Timing: Elective or emergency procedures.

Technique: Open, robotic, laparoscopic, laparoscopically-assisted, or laparoscopic converted to open.

Returns to theatre: Each individual patient should only be included in the EuroSurg-1 once. Patients returning to theatre due to complications following earlier surgery may be included, so long as their index procedure has not already been included in EuroSurg-1.

Included procedures:

- Any gastrointestinal resection.
  
  GI resection is defined as complete transection and removal of a segment of the oesophagus, stomach, small bowel, colon or rectum. Wedge resections and appendicectomies are not included. Resection following trauma is included.

- Reversal of ileostomy or colostomy.

- Formation of defunctioning stoma (ileostomy or colostomy), when this is performed as the main procedure.

Exclusion criteria

- Appendicectomy.
- Cholecystectomy.
- Hernia repair - Simple hernia repairs should not be included, but hernia repair with bowel resection should be included.
- Transanal surgery - e.g. TEMS, TAMIS, Altemeier’s procedure.
- Bariatric surgery - e.g. gastric bypass, sleeve gastrectomy, gastric banding.
- Primarily hepatobiliary procedure - e.g. Whipple’s procedure for pancreatic disease (pancreatoduodenectomy).
- Primarily urological procedure - e.g. ileal conduit.
- Primarily gynaecological procedure - e.g. Hartmann’s during surgery for ovarian cancer.
- Primarily vascular procedure - e.g. bowel resection during AAA repair. Emergency laparotomy with bowel resection for mesenteric ischaemia should be included.

07 Covariates
Data will be collected on confounding factors to permit accurate risk adjustment of outcomes. This will include data using the following pre-operative indices:
- The American Society of Anesthesiologists (ASA) score.
- The Revised Cardiac Risk Index (RCRI)\(^9\).
- Smoking history.

08 Outcome Measures
Primary outcome measure
The primary outcome measure is the overall 30-day major adverse event rate, defined as Clavien-Dindo grade III-V complications.

The Clavien-Dindo scale\(^10\) has been selected as the primary outcome measure as it is clinically relevant. It is based on the interventions required to treat complications, taking a holistic account of clinically significant events.

Secondary outcome measures
Anastomotic leak, re-operation and length of stay.

09 Follow-up
The primary and secondary outcome measures will be recorded if they occurred at any point from post-operative Day 1 (day of surgery) to Day 30.

Strategies for follow-up include:
- Regularly reviewing patient notes to identify in-hospital complications.
- 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.

10 Dataset
Data domains that relate to the patient, operation, operative method and postoperative period will be collected. In order to maximise completion of data recording, the dataset includes only those variables that are needed to
accurately risk adjust outcomes relating to the primary study question. Without
adjusting for pre-operative risk, it is likely that any findings would be biased.
Data will **not** be analysed at a surgeon-level, centre-level or country-level.

11 **Data Collation and Governance**

Data will be collected and stored online through a secure server running the
Research Electronic Data Capture (REDCap) web application\(^\text{19}\). REDCap
allows collaborators to enter and store data in a secure system. Collaborators
will be given secure REDCap project server login details, allowing secure data
storage on the REDCap system. **No** patient identifiable information will be
uploaded or stored on the REDCap database without explicit permission from
the hospital. Collaborators may wish to first record data on a paper version of
the data collection pro-forma. Paper copies of any data should be destroyed as
confidential waste within the centre once uploaded to REDCap.

12 **Local Project Registration & Data Governance**

If the option is available, this project should be registered as clinical audit.
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.

If registering this study as a clinical audit, the gold standard should be based
on NICE (National Institute for Health and Care Excellence, UK) guidance that
**all patients should have body mass index (BMI) calculated on admission to
hospital** (NICE CG 32, 1.2.2 & 1.2.6)\(^\text{11}\). In addition, emphasise that:

- 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 seek their NHS trust’s Caldicott Guardian’s approval
to submit data to the REDCap system. Collaborators should explicitly ask for
permission to upload local hospital or NHS numbers, if they wish to do this.

You **must** have confirmation of successful study registration prior to
commencing data collection. REDCap accounts will **not** be issued until

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**A guide to using REDCap can be found at the EuroSurg-1 online hub**

**Printable data pro formas can be found at the EuroSurg-1 online hub**

**You can find an explanation of clinical audit on our website, eurosurg.org, as well as country-specific advice regarding study registration**

**Detailed advice on running the study in your centre can be found in Appendix F**

**For your local leads’ contact details see the eurosurg.org**

**When you apply to register the study, you can include in your application examples of successful ethical approval from around Europe. These will be available form the online study hub**

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

**A guide to using REDCap can be found at the EuroSurg-1 online hub**

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**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.

13

Quality assurance

- **Mini-teams**
  Although many collaborators participating in the study will be medical students, each local team must include at least one qualified doctor to closely supervise the students. The study will additionally be registered with an appropriate sponsoring consultant surgeon at each site.

- **Data completeness**
  Following data collection, only data sets with >95% data completeness will be accepted for pooled national 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 five centres in each participating country. Data validators be a final year student or a qualified doctor who were not involved in initial data collection.

  The validator will select a 2-week study 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.

  **Case ascertainment**
  The validator will independently identify all patients eligible for inclusion over one 2-week study period. The target for data ascertainment is >95%.

  **Data collection**
  The validator will independently collect data for 10 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%.

14

Project team structure

Medical students will take the lead in disseminating and delivering this study, which is supported by a collaboration of medical students, surgical trainees/residents and consultant/attending surgeons (Figure 1).
Figure 1: EuroSurg mini-team structure

- **Study management group**: a core group of medical students and surgical trainees responsible for protocol design, data handling, analysis and drafting of the paper. This group is responsible for use of data resulting from the project.

- **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 students across participating universities.
  - Responsible for co-coordinating mini-teams at local hospitals.
  - Act as a link between mini-teams and the national network committees. First point of contact for local collaborators.
  - Ensure audit outcomes are reported back to clinical teams.

- **Mini-teams**: a team of three people responsible for data collection over a specific 2-week period at a particular centre.
  - A mini-team is formed by a medical student collaborating with a qualified doctor. An additional student or doctor makes the mini-team up to three people.
- 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.
- Each mini-team will work with their local lead to ensure that the audit results are reported back to their audit office/clinical teams.

- **Consultant/attending surgeons**: each mini-team must be supervised by a consultant surgeon. The consultant sponsors registration of the study and ensures collaborators act in accordance with governance guidelines. They should also facilitate presentation of local results.

### 15 Authorship

Mini-team collaborators, supervising consultants, data validators, local leads and the study management group will be eligible for PubMed-citable co-authorship.

**Mini-teams**

A maximum of three collaborators per 14-day data collection/follow-up period will be listed as ‘PubMed’ citable authors, unless an increase in the mini-team is agreed in advance with the study management group. Validators at each site are also eligible for authorship.

Each mini-team collaborator should participate in registering the audit, identifying patients, collecting data and follow-up, ensuring >95% completeness and >98% accuracy targets are met. Centres with >5% missing data will be excluded from analysis and the contributing mini-team will be removed from the authorship list.

- **Consultants**
  - In line with International Committee of Medical Journal Editors authorship guidelines ([http://www.icmje.org/](http://www.icmje.org/)), one consultant per centre is eligible for collaborative PubMed citable co-authorship if they meet the following criteria:
    - (i) Supports local study registration.
    - (ii) Circulates information about the study to consultant colleagues.
    - (iii) Facilitates presentation of local results at a departmental meeting.

- **Local leads**
  - To qualify for authorship, local leads must recruit at least one mini-team at each centre where students from their medical school have surgical placements.
Appendix A: Required data fields

Asterisks indicate data fields included in data accuracy validation.

### General data points – to be collected for all patients

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Patient age</td>
<td>Years</td>
</tr>
<tr>
<td>2</td>
<td>Patient gender</td>
<td>Male, Female</td>
</tr>
<tr>
<td>3</td>
<td>ASA grade</td>
<td>I, II, III, IV, V</td>
</tr>
<tr>
<td>4</td>
<td>History of previous abdominal surgery</td>
<td>Yes, No</td>
</tr>
<tr>
<td>5</td>
<td>* History of ischaemic heart disease</td>
<td>Yes, No</td>
</tr>
<tr>
<td>6</td>
<td>* History of congestive heart failure</td>
<td>Yes, No</td>
</tr>
<tr>
<td>7</td>
<td>* History of cerebrovascular disease</td>
<td>Yes, No</td>
</tr>
<tr>
<td>8</td>
<td>* History of insulin dependent diabetes</td>
<td>Yes, No</td>
</tr>
<tr>
<td>9</td>
<td>* Chronic kidney disease</td>
<td>Yes, No</td>
</tr>
<tr>
<td>10</td>
<td>Last pre-operative serum albumin</td>
<td>Enter number (g/L)</td>
</tr>
<tr>
<td>11</td>
<td>Smoking status&lt;br&gt;(if relevant record pack year history)</td>
<td>Never, Current, Ex-smoker (&lt;6 weeks), Ex-smoker (≥6 weeks), Unknown&lt;br&gt;&lt;em&gt;If smoker/ ex-smoker, calculate pack year history&lt;/em&gt;</td>
</tr>
<tr>
<td>12</td>
<td>Immunosuppressant drug use&lt;br&gt;(multiple selection possible)</td>
<td>Steroids – high dose, Steroids – low dose, 6-mercaptopurine, Methotrexate, Azathioprine</td>
</tr>
<tr>
<td>13</td>
<td>* Was body mass index calculated within 24 hours of admission?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>14</td>
<td>* Body mass index</td>
<td>Enter number&lt;br&gt;&lt;em&gt;If not available, record weight and height&lt;/em&gt;</td>
</tr>
<tr>
<td>15</td>
<td>* Urgency of operation</td>
<td>Elective, Emergency</td>
</tr>
<tr>
<td>16</td>
<td>Operative approach</td>
<td>Open, Laparoscopic, Laparoscopic assisted, Laparoscopic converted to open, Robotic</td>
</tr>
<tr>
<td>17</td>
<td>Primary operation performed</td>
<td>See Annex C</td>
</tr>
<tr>
<td>18</td>
<td>Underlying pathology/ indication</td>
<td>See Annex D</td>
</tr>
<tr>
<td>19</td>
<td>* Anastomotic leak</td>
<td>Yes, No, Not applicable (no anastomosis)</td>
</tr>
<tr>
<td>20</td>
<td>* 30-day major adverse event</td>
<td>Yes, No.&lt;br&gt;&lt;em&gt;If yes: record whether the patient was reoperated&lt;/em&gt;</td>
</tr>
<tr>
<td>21</td>
<td>Post-operative length of stay</td>
<td>Enter days</td>
</tr>
</tbody>
</table>

### Cancer data points – only to be collected for patients undergoing cancer surgery

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>1</td>
<td>Pre-operative nutritional support&lt;br&gt;(multiple selection possible)</td>
<td>Oral, Nasogastric feed, Parenteral feed, None</td>
</tr>
<tr>
<td>2</td>
<td>Known metastatic disease</td>
<td>Yes, No</td>
</tr>
<tr>
<td>3</td>
<td>Neo-adjuvant therapy</td>
<td>Yes, No</td>
</tr>
</tbody>
</table>

### IBD data points – only to be collected for patients undergoing IBD surgery

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Disease distribution&lt;br&gt;(multiple selection possible)</td>
<td>Upper gastrointestinal, Small bowel, Large bowel, Rectum</td>
</tr>
<tr>
<td>2</td>
<td>Pre-operative biologic use&lt;br&gt;(multiple selection possible)</td>
<td>Up to 1 week, 1-6 weeks, 6-12 weeks, 12 weeks - 1 year prior to surgery</td>
</tr>
<tr>
<td>3</td>
<td>Pre-operative nutritional support&lt;br&gt;(multiple selection possible)</td>
<td>Oral, Nasogastric feed, Parenteral feed, None</td>
</tr>
<tr>
<td>4</td>
<td>Last pre-operative haemoglobin</td>
<td>Enter number (g/L)</td>
</tr>
</tbody>
</table>

A printable, user-friendly one-page summary of required data fields will be made available on the EuroSurg-1 online project hub: [http://www.eurosurg.org](http://www.eurosurg.org)
### Appendix B: Data dictionary

The best place to find the necessary information for each data field is indicated.

The first post-operative day is defined as the day of surgery.

<table>
<thead>
<tr>
<th>Data field</th>
<th>Data options/ required data</th>
<th>Data dictionary</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General data points – to be collected for all patients</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Patient age</td>
<td>Years</td>
<td><em>(Clinical notes)</em> Age in whole years</td>
</tr>
<tr>
<td>2 Patient gender</td>
<td>• Male</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Female</td>
<td></td>
</tr>
<tr>
<td>3 ASA score</td>
<td>• Grade I</td>
<td><em>(Anaesthetic chart)</em></td>
</tr>
<tr>
<td></td>
<td>• Grade II</td>
<td>See the American Society of Anaesthesiologists website for definitions and</td>
</tr>
<tr>
<td></td>
<td>• Grade III</td>
<td>examples:</td>
</tr>
<tr>
<td></td>
<td>• Grade IV</td>
<td>[<a href="https://www.asahq.org/resources/clinical-information/asa-physical-status-">https://www.asahq.org/resources/clinical-information/asa-physical-status-</a></td>
</tr>
<tr>
<td></td>
<td>• Grade V</td>
<td>classification-system](<a href="https://www.asahq.org/resources/clinical-information/asa-physical-status-classification-system">https://www.asahq.org/resources/clinical-information/asa-physical-status-classification-system</a>)</td>
</tr>
<tr>
<td>4 History of previous abdominal surgery</td>
<td>• Yes</td>
<td><em>(Admission clerking, clinical notes, clinic letters)</em>. Include any abdominal</td>
</tr>
<tr>
<td></td>
<td>• No</td>
<td>surgery for any indication – e.g. include appendicectomy, cholecystectomy,</td>
</tr>
<tr>
<td>5 History of ischaemic heart disease</td>
<td>• Yes</td>
<td>nephrectomy, caesarian section, etc.</td>
</tr>
<tr>
<td></td>
<td>• No</td>
<td><em>(Admission clerking, clinical notes, clinic letters)</em>. Required to calculate</td>
</tr>
<tr>
<td>6 History of congestive heart failure</td>
<td>• Yes</td>
<td>RCRI.</td>
</tr>
<tr>
<td></td>
<td>• No</td>
<td><em>(Admission clerking, clinical notes, clinic letters)</em>. Required to calculate</td>
</tr>
<tr>
<td>7 History of cerebrovascular disease</td>
<td>• Yes</td>
<td>RCRI.</td>
</tr>
<tr>
<td></td>
<td>• No</td>
<td><em>(Admission clerking, clinical notes, clinic letters)</em>. Required to calculate</td>
</tr>
<tr>
<td>8 History of insulin dependent diabetes</td>
<td>• Yes</td>
<td>RCRI.</td>
</tr>
<tr>
<td></td>
<td>• No</td>
<td><em>(Admission clerking, clinical notes, clinic letters)</em>. Required to calculate</td>
</tr>
<tr>
<td>9 History of chronic kidney disease</td>
<td>• Yes</td>
<td>RCRI.</td>
</tr>
<tr>
<td></td>
<td>• No</td>
<td><em>(Admission clerking, clinical notes, clinic letters)</em>. Required to calculate</td>
</tr>
<tr>
<td>10 Last pre-operative serum albumin</td>
<td>• Enter number</td>
<td><em>(Clinical notes, pathology results system)</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Enter value in grams per litre (g/L).</td>
</tr>
</tbody>
</table>
11 Smoking history
- Never smoked
- Current smoker
- Ex-smoker (<6 weeks)
- Ex-smoker (≥6 weeks)
- Unknown

Record smoking status as at time of admission.

**For ex-smokers:** record when they stopped smoking: <6 or ≥6 weeks ago.

**For current and ex-smokers:** Record their total pack year history. Pack year history can be calculated online at: [http://smokingpackyears.com](http://smokingpackyears.com)

12 Immunosuppressant drugs
**Select multiple options if appropriate**
- Steroids – low dose
- Steroids – high dose
- 6-mercaptopurine
- Methotrexate
- Azathioprine

(Admission clerking, clinical notes, drug chart)

**Steroids:** Low dose <20mg, high dose ≥20mg prednisolone or equivalent. Only include patients who were on steroids within a week of operation.

**Other drugs:** Only include patients who were on 6-MP, MTX or azathioprine within one month of operation.

13 Was body mass index (BMI) calculated within 24hr of admission?
- Yes
- No

(Admission clerking, clinical notes, observation chart, drug chart)

If BMI was calculated in a pre-operative assessment clinic, select 'yes'.

If BMI not recorded: Enter closest weight (in kilograms, kg) recorded to date of admission and any height recorded since age 18 years (in centimetres, cm).

14 Body mass index (BMI)

Enter number

(Admission clerking, clinical notes, observation chart, drug chart)

If BMI not recorded: Enter closest weight (in kilograms, kg) recorded to date of admission and any height recorded since age 18 years (in centimetres, cm).

15 Urgency of surgery
- Elective
- Emergency

(Effective note, clinical notes)

**Elective surgery:** any planned admission for surgery.

**Emergency surgery:** any surgery on the same admission as diagnosis.

16 Operative approach
- Open
- Laparoscopic
- Laparoscopic, assisted
- Laparoscopic, converted
- Robotic

(Effective note)

**Laparoscopic:** Surgery performed exclusively using instruments inserted in to the abdomen through small ports.

**Laparoscopic, assisted:** Laparoscopic surgery in which an incision is enlarged to deliver a specimen or to insert a gloved hand into the abdomen.

**Laparoscopic converted (to open):** Surgery initially started laparoscopically but for unforeseen reasons decision made to change to an open approach.

17 Primary operation performed

See Appendix C for a full list of procedures.

(Effective note, clinical notes)

For each procedure indicate whether:
1) There was a gastrointestinal anastomosis made.
2) There was a stoma made.

18 Underlying pathology/ indication

See Appendix D for a full list of pathologies.

(Effective note, clinical notes)

19 Anastomotic leak
- Yes
- No
- N/A (no anastomosis)

(Clinical notes, discharge letter, clinic letters)

Include anastomotic leaks detected clinically, radiologically or intra-operative.

Include all leaks regardless of how they were managed.
### 20  30-day major adverse event
(Chavien-Dindo grades III – V)
- No major adverse events
- Grade III
- Grade IV
- Grade V

30-day major adverse events are defined as Clavien-Dindo grade III – V complications. Select highest grade complication experienced by the patient. See Appendix E for full definitions.

If yes: record whether the patient returned to theatre for unplanned re-operation.

### 21  Post-operative length of stay
- Enter days

This should be calculated from the first post-operative day to day of discharge. If the patient remains admitted in hospital at the end of 30-day follow-up, enter ‘30’

---

### Cancer data points – only to be collected for patients undergoing cancer surgery

<table>
<thead>
<tr>
<th>1</th>
<th>Pre-operative nutritional support</th>
<th>Oral</th>
<th>Nasogastric feed</th>
<th>Parenteral feed</th>
<th>None</th>
<th>(Admission clerking, clinical notes, clinic letters, drug chart)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Select multiple options if appropriate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### IBD data points – only to be collected for patients undergoing IBD surgery

<table>
<thead>
<tr>
<th>1</th>
<th>Disease distribution</th>
<th>Upper gastrointestinal</th>
<th>Small bowel</th>
<th>Large bowel</th>
<th>Rectum</th>
<th>(Admission clerking, clinical notes, clinic letters, imaging/ endoscopy reports)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Select multiple options if appropriate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2</th>
<th>Pre-operative biologic use</th>
<th>1 week prior to surgery</th>
<th>1-6 weeks prior to surgery</th>
<th>6-12 weeks prior to surgery</th>
<th>12 weeks to 1 year prior to surgery</th>
<th>(Admission clerking, clinical notes, clinic letters, drug chart)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Select multiple options if appropriate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3</th>
<th>Pre-operative nutritional support</th>
<th>Oral</th>
<th>Nasogastric feed</th>
<th>Parenteral feed</th>
<th>None</th>
<th>(Admission clerking, clinical notes, clinic letters, drug chart)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Select multiple options if appropriate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4</th>
<th>Last pre-operative haemoglobin</th>
<th>Enter number</th>
<th>(Clinical notes, pathology results system)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Enter value in grams per litre (g/L) – i.e. normal range for men 135-180 g/L.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix C: Procedure list

Included procedures

For each procedure indicate whether:
1) There was a gastrointestinal anastomosis made.
2) There was a stoma made.

Oesophagogastrectomy
Total oesophagectomy
Partial oesophagectomy
Total gastrectomy
Partial gastrectomy
Gastroduodenectomy
Total excision of duodenum
Partial excision of duodenum
Total jejunectomy
Partial jejunectomy
Ileectomy (resection of ileum)
Right hemicolecctiony
Transverse colectomy
Left hemicolecctiony

Sigmoid colectomy
Rectosigmoidectomy
Subtotal colectomy
Total colectomy
Abdominoperineal excision
Proctectomy
Anterior resection
Panproctocolectomy
Completion proctocolectomy & IPAA
Formation of colostomy
Formation of ileostomy
Closure of colostomy
Closure of ileostomy
Other unlisted procedure (enter free text)

Excluded procedures

These are examples of excluded procedures, not an exhaustive list.

Appendicectomy
Cholecystectomy
Diagnostic laparoscopy only
Diagnostic laparotomy only
Examination under anaesthetic of retum
Femoral hernia repair*
Gastric banding
Gastric bypass
Haemorrhoidectomy
Ileal conduit
Incisional hernia repair*
Inguinal hernia repair*

Nissen fundoplication
Pancreatoduodenectomy
Peritoneal lavage/ washout only
Refashioning of stoma*
Repair of parastomal hernia*
Repair of perforated duodenal ulcer
Resiting of stoma*
Sleeve gastrectomy
Stricturoplasty
Umbilical hernia repair*
Wedge resection of stomach/ bowel
Whipple’s procedure

*These procedures should be included if a gastrointestinal resection was performed as part of the operation.
Appendix D: Diagnoses list

Other unlisted diagnosis *(please enter free text)*
Adhesional bowel obstruction
Anorectal Prolapse
Bleeding: peptic ulcer
Bleeding: small bowel / colon (no malignancy / diverticular disease)
Bleeding: upper GI variceal haemorrhage
Bleeding: lower GI, unspecified
Colitis: Crohn's disease
Colitis: indeterminate
Colitis: infectious (e.g. *C. Difficile*)
Colitis: Ischaemic
Colitis: ulcerative colitis
Complication of previous surgical operation / procedure
Diverticular disease: non-perforated
Diverticular disease: with perforation
Fistula: Colovaginal
Fistula: Colovesical
Fistula: Enterocutaneous
Fistula: Gastrocolic
Foreign Body
Intestinal intussusception
Perforation of oesophagus
Stercoral perforation of colon
Trauma: non-penetrating (blunt)
Trauma: penetrating
Tumour: any benign tumour or polyp
Tumour: metastatic cancer (operation on a metastasis)
Tumour: primary cancer (operation on any primary tumour)
Volvulus: caecal
Volvulus: sigmoid
Appendix E: 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. 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, is a **complication**.

In the Clavien-Dindo classification\(^\text{10}\), 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 IIIb).

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 IIIa complication. Since **negative exploratory laparotomies** are considered to be diagnostic procedures, they should not be recorded as complications.

**PLEASE NOTE:** in EuroSurg-1 we are only collecting major (grade 3-5) complications. If a patient had no complications, or only grade 1-2 complications, entered “no major complications”. If they experienced major complication(s), enter the most severe complication grade they suffered.
<table>
<thead>
<tr>
<th>Grade</th>
<th>Definition (examples listed in italics)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>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 <strong>not</strong> treated with antibiotics. <strong>Examples:</strong> Ileus (deviation from the norm); hypokalaemia treated with K; nausea treated with cyclizine; acute kidney injury treated with intravenous fluids.</td>
</tr>
<tr>
<td>II</td>
<td>Requiring pharmacological treatment with drugs beyond those allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included. <strong>Examples:</strong> 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.</td>
</tr>
<tr>
<td>IIia</td>
<td>Requiring surgical, endoscopic or radiological intervention, <strong>not under</strong> general anaesthetic. <strong>Examples:</strong> Therapeutic endoscopic therapy (do not include diagnostic procedures); interventional radiology procedures.</td>
</tr>
<tr>
<td>IIib</td>
<td>Requiring surgical, endoscopic or radiological intervention, <strong>under</strong> general anaesthetic. <strong>Examples:</strong> Return to theatre for any reason.</td>
</tr>
<tr>
<td>IVa</td>
<td>Life-threatening complications requiring critical care management – <strong>single organ</strong> dysfunction, or neurological complications including brain haemorrhage and ischemic stroke (excluding TIA). <strong>Examples:</strong> Single organ dysfunction requiring critical care management, e.g. pneumonia with ventilator support, renal failure with filtration; SAH; stroke.</td>
</tr>
<tr>
<td>IVb</td>
<td>Life-threatening complications requiring critical care management – <strong>multi-organ</strong> dysfunction.</td>
</tr>
<tr>
<td>V</td>
<td>Death of a patient</td>
</tr>
</tbody>
</table>
Appendix F: Key steps for successful inclusion of your centre

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 co-ordinate 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 continuous data period within the data collection period to suit your availability. The data collection period will be Monday 1st February to Monday 18th April 2016. Multiple teams of students can participate at each centre, collecting data during distinct two-week periods.

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.

   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 all patients meeting inclusion criteria within your two week window.

8. Regularly follow-up for information on complications over the 30-day post-operative period. This study is prospective, 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.

10. It is a condition of participation in EuroSurg-1 that following completion of the audit at your centre you must ensure that your local results are presented to your hospital’s surgical department.
Appendix G: References