

# **COHORT STUDY PROTOCOL**

An international non-randomized time-bound prospective observational cohort study addressing the epidemiology and management of Small Bowel Obstruction

Study period: November 01st 2023 - May 31st 2024

ClinicalTrials.gov Registration: NCTxxxxxxx

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# **ESTES SnapSBO Study Steering Committee**

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### Introduction

Multi-center, '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 randomized controlled trials<sup>1</sup>.

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

## Scope

Small bowel obstruction (SBO) and its complications are frequently seen in patients admitted through the Emergency Departments of all acute care hospitals<sup>2</sup>.

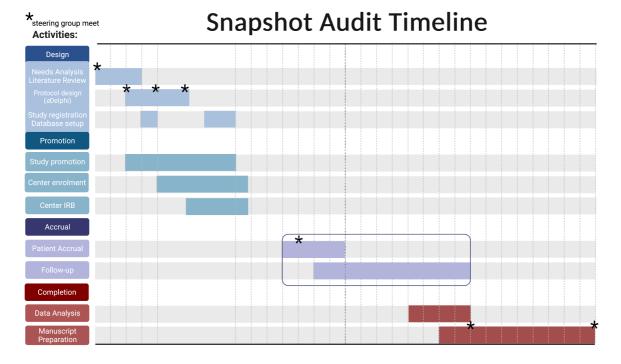
There is variation in the optimal use of imaging, the appropriate timing and duration of non-operative management attempts, anti-microbial therapies and the criteria for surgical management, which results in heterogeneity in approaches and outcomes across international clinical centers. The expected number of SBO cases in most clinical centers is predictable, enabling a suitable sized cohort of patients to be gathered in the snapshot audit.

This 'ESTES snapshot audit' -a prospective observational cohort study- has a dual purpose. Firstly, as an epidemiological study, it aims to uncover the burden of disease. Secondly, it aims to demonstrate current strategies employed to diagnose and treat these patients. These twin aims will serve to provide a 'snapshot' of what we are doing now, but will also be hypothesis-generating while providing a rich source of patient-level data to allow further analysis of particular clinical question.

# **Key Study Dates**

06 may 2023	Snapshot Launch at ECTES 2023, Ljubljana. Center enrolment and local IRB submission
01 november 2023 - 01 may 2024	Patient enrolment. Ninety (90) consecutive day enrollment within this six (6) month window
01 may 2024	Final day for new patient enrolment
31 July 2024	Final day of patient follow-up (60 days from admission on 01 may 2024)
01 August 2024 - 01 September 2024	Local data validation, completion, and final upload
01 september 2024	REDCap® database locked; this is the deadline for data submission and center inclusion.





### **Definitions**

**Mechanical small bowel obstruction (SBO):** An intrinsic, extrinsic or endoluminal process which narrows or occludes the bowel lumen and delays the passage of luminal contents.

**Ileus:** Functional motility disorder characterized by adynamic paralytic bowel, leading to many of the same symptoms of mechanical obstruction, but without a single site of obstruction demonstrable on imaging. Common causes include recent abdominal surgery, medications such as opiates, and electrolyte disturbances<sup>2</sup>.

**Complete SBO:** Obstruction with no passage of luminal contents beyond the point of obstruction<sup>3</sup> (Appendix A).

**Partial SBO:** Incomplete obstruction with luminal narrowing but some contents continue to pass through the intestine. This is distinguished from complete obstruction by the continued passage of bowel movements and flatus, and a non-peritonitic abdominal exam<sup>3</sup>.

**Small bowel dilatation:** Luminal diameter of >3 cm.

**Transition zone:** Short segment area between dilated proximal bowel and decompressed distal bowel. Sometimes called a transition point and is radiographic evidence of SBO.

**Bowel compromise:** when there is ischemia or injury that has led to necrosis and/or perforation of the bowel wall<sup>4</sup>.

**Adhesions:** Fibrous tissue that connects surfaces or organs within the peritoneal cavity that are normally separated. Such adhesions are the results of an adaptive healing response of the peritoneum upon tissue handling or contact with blood or purulence, but also caused by other conditions like radiotherapy, endometriosis, inflammation or local response to tumors<sup>5</sup>.

**Virgin abdomen:** abdomen of a patient without prior surgery. Although there is no consensus in the literature about radiotherapy, known peritoneal inflammatory disease or primary abdominal wall hernias, in our study we will consider only those non-operated inside the definition<sup>6</sup>.

Water Soluble Oral Contrast (WSOC) challenge: a combined diagnostic study and therapeutic intervention utilized in the evaluation and management of small bowel obstruction.

### **Methods**

#### Summary

Prospective audit of consecutive patients admitted in Emergency Department for mechanical small bowel obstruction over a 3 month period. The audit shall include unscheduled patient admissions from November 2023 until May 2024 as outlined in 'Key Study Dates'.

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

#### **Primary Objective**

To explore differences in patients, management and outcomes across the entire cohort to identify areas of practice variability resulting in apparent differences in outcome warranting further study. The outcomes that the study will examine are:

- Incidence of small bowel obstruction by etiology.
- Differences in clinical presentation.
- Diagnostic work-up.
- Non-operative management strategies.
- Time to surgery and outcomes.
- Complications related to disease and/or therapies within 60 post-operative days.
- Length of Emergency Department and Hospital stay.
- Re-admission within 6 months for related conditions.

#### Methods for identifying patients

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

- 1. Daily review of emergency department (non-operative) and operating room lists.
- 2. Daily review of team handover sheets / emergency admission lists / ward lists.
- 3. Review of operating room logbooks.
- 4. Use of electronic systems to flag any readmissions of patients identified and treated.

#### Research Questions

#### **Primary Research Questions**

- What is the global incidence of SBO?
- What are the treatment algorithms currently employed in the management of these patients?
- Proportion of non-operatively managed patients?
- Proportion of surgical patients approached laparoscopically?
- Recurrence rate within 6 months?

### **Secondary Research Questions**

- What is the incidence and etiology of virgin abdomen SBO?
- What is the incidence of early postoperative SBO?
- What is the success rate for non-operative management?
- What is the prevalence of complications and treatment failure in the nonoperative management of SBO?
- Proportion of patients that underwent WSOC challenge, and under what indications?
- What are the Patient Related Outcomes results?

#### Inclusion and Exclusion Criteria

#### **Inclusion Criteria:**

Adult patients (≥16 years of age) admitted for mechanical small bowel obstruction. Example etiologies which should be included:

Adhesions.

Hernias with bowel compromise (incisional/parastomal, ventral, inguinal, femoral, obturator, internal).

Malignancy (primary: lymphoma, carcinoid, GIST, adenocarcinoma/metastatic disease: colon, ovarian, gastric, pancreatic, melanoma and others).

Enteroliths/gallstones/bezoars/foreign bodies

Radiation.

Inflammation (Crohn's disease, mesenteric adenitis, appendicitis, diverticulitis, tuberculosis, actinomycosis, ascariasis).

Congenital (malrotation, duplication cysts).

Trauma (hematomas, ischemic strictures).

#### Exclusion criteria:

Functional small bowel obstruction (dysmotility or adynamic ileus secondary to abdominal operations, peritonitis, trauma or medications).

#### Center eligibility

All hospitals/units performing general surgery are eligible to join this audit. No unit size or case throughput stipulations are made. Any clinical center is welcome to participate so long as the protocol is adhered to. Countries outside Europe are eparticipate in this audit.

All participating centers will be required to register their details with the ESTES cohort study office and will be responsible for their own local approvals process prior to the start of the data collection period. Inclusion of data sets will be subject to local approval from participating clinical Centers.

Centers 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 the study REDCap® database on the November 1st 2024.

#### Patient follow-up

The audit is designed so normal patient follow-up pathways can be used to obtain outcome data. No additional visits or changes to normal follow-up should be made. However, local investigators should be proactive in identifying post-diagnosis 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 reattendances or re-admissions, and reviewing post-operative radiology reports.

#### Data completion

This research is an observational and non-interventional audit that collects data along the usual course patient pathway. The Data Collection Instrument (DCI) has been designed to reflect common parameters. We envisage that participating clinical Centers will identify a team of 4-5 members; one Consultant (clinical 'lead' of the study), trainee surgeons or data administrators who will undertake the logistical roles as well as co-ordinate data entry.

DCI 2 (patient demographics), DCI 3, 4, 5 (past medical and surgical history) and DCI 8 and 10 (follow-up information) can be completed by any suitably qualified member of the local team. DCI 6 (Current episode emergency details) and F7 (Initial complementary exams) must be completed by or in direct conjunction with an admitting staff surgeon who was present, as DCI 9 (operation details) by a staff surgeon also present itself. It should ideally be completed as close to the end of surgery as feasible, to ensure data accuracy and completeness.

#### Missing data and retrospective patient entry

The online database has been designed to allow sites to securely access an individual patient's data 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 maximize data completion and emphasize its importance to collaborators, participating Centers 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 <u>eligible</u> patients that were missed primarily and for whom contemporaneous patient and operation data was not entered.

#### Data collection system and information governance

Data will be recorded on a dedicated, secure server running on the REDCap® web application. REDCap® allows for secure upload and storage of data, in compliance with European Union General Data Protection Regulation 2018 (GDPR) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) legislation.

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 individual investigators; other sites' data will not be accessible. It is the responsibility of each participating Center to ensure their own records comply with local data governance legislation, GDPR or HIPAA, as applicable.

#### 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 Center. It is the responsibility of the local team at each site to ensure that local audit approval (or equivalent) is completed for their Center. Participating Centers will be asked to confirm that they have gained formal approval at their site.

#### **Authorship**

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 by the steering group on behalf of a single corporate authorship – e.g "ESTES SnapSBO Group."

#### Publication of data

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 studies8, (appendix C) 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 patient, 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 can be made available after the end of the study; however, it will not be possible or permissible to de-anonymise patient data stored in REDCap®, in strict compliance with GDPR and HIPAA.

#### Data governance

The ESTES Cohort Studies Committee welcomes the use of the data for further research that benefits patients. Requests can be submitted to the ESTES Cohort Studies Committee. Data sharing is subject to ESTES approval and the appropriate safeguarding as determined by the ESTES. Any future sub-projects should also comply with our policy of a single corporate authorship e.g. "ESTES SnapSBO 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.

#### Financial arrangements

This study is undertaken voluntarily by participating institutions under the coordination of the Emergency Surgery Cohort Study Steering Committee. It is not anticipated that participating Centers would bear any costs. Similarly, no financial reimbursement will be made to units or investigators.

### Reference list

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- 6. Amara Y, Leppaniemi A, Catena F, Ansaloni L, Sugrue M, Fraga GP, et al. Diagnosis and management of small bowel obstruction in virgin abdomen: a WSES position paper. *World J Emerg Surg.* 2021;16(1):36.
- 7. Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Annals of Surgery. 2004 Aug 1;240(2):205–13*.
- 8. Vandenbroucke JP, Elm E von, Altman DG, Gøtzsche PC, Mulrow CD, Pocock SJ, et al. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): Explanation and elaboration. *Int J Surg. 2014; 12(12): 1500–24*.
- 9. Mellor K, Hind D, Lee MJ. A systematic review of outcomes reported in small bowel obstruction research. *J Surg Res. 2018; 229: 41–50*.

# **REDCap® Data Collection Instruments**

## Data Collection Instrument 1 - Patient and Centre Demographics

Hospital Details*	Data	Values
Primary, Secondary or Tertiary Hospital	List	List
Number of Beds	Integer	0 – 3000
Number or UCI beds	Integer	0 – 3000
Emergency Theatre	List	Tick Applicable
Acute Surgical Assessment Unit	Binary	Yes/No
Number of General Surgery Consultants	Integer	1-20
Split on call (Upper + Lower GI available)	Binary	Yes/No
Acute Care Surgery	Binary	Yes/No
Is ERAS practiced in General Surgery?	Binary	Yes/No

<sup>\*</sup>will be filled once for each center

### Data Collection Instrument 2 - Patient demographics

Demographics	Key Name	Data Type	Values
Country Code	СС	List	List of included countries (chain, number)
Center ID	CID	List	List of study centers (chain, number)
Patient ID	PID	Chain	Country code-Centre ID-patient number (chain, number)
Age (years)	AGE	Integer	Number
Sex	SEX	List	Male, Female
Body Mass Index	ВМІ	Integer	Weight (Kg) Height (Cm) BMI (integer)
Date of Admission	DOA	Date; time	Date of index admission dd/mm/yy hh:mm
Date of Discharge	DOD	Date	Date of discharge from hospital
Length of Stay	LOS	Integer	Number of Days (Integer; calculated from the admission and discharge date)
Cathegory	CAT	List	Ethiology (Adhesions, Bezoar, Gallstone ileus, Hernia (primary/internal/incisional/parastomal), Stenosis (anastomotic, inflammatory/endometriosis), Tumor (primary/carcinomatosis/Radiotherapy), congenital (malrotation)

## Data Collection Instrument 3 - Patient past medical history

Past Medical history	Key Name	Data Type	Values
Morbid Obesity (BMI>35)	МО	Binary	Yes/No. MO if BMI > 35
Diabetes Mellitus	DM	Binary	Yes/No
Cerebro-Vascular Disease	CVD	Binary	Yes/No
Chronic Obstructive Pulmonary Disease	COPD	Binary	Yes/No
Anticogulant/aggregant Medications	ACAM	Binary	Yes/No
Ischemic Heart Disease	IHD	Binary	Yes/No
Hypertension	НВР	Binary	Yes/No. HBP if sBP>140 or dBP >90
Liver Disease	LD	Binary	Yes/No
Chronic Kidney Disease	CKD	Binary	Yes/No. eGFR ≤59
Inmunosupression/Oral Corticosteroids/ Chemotherapy	CIS	Binary	Yes/No (on admission)
Radiotherapy	RTP	Binary	Yes/No
Endometriosis	END	Binary	Yes/No
Crohn's disease	CHRD	Binary	Yes/No
Abdominal malignancy	AM	Binary	Yes/No. Including Gynecologic origin
Abdominal malignancy origin	AMO	List	Colorectal/Gynecologic/Gastroesophageal/Hepatobiliary/Splenic/ Pancreatic/Urologic/Haematologic

## Data Collection Instrument 4 - Patient past surgical history

Past Surgical history	Key Name	Data Type	Values
Previous abdominal surgery	PAS	Binary	Yes/No (excludes abdominoplasty and cesarean section)
Number of previous abdominal surgeries	NPS	Integer	Number (includes gyne and hernia surgeries)
Appendectomy	APP	Binary	Yes/No
Hernia surgery	HES	Binary	Yes/No
SBO surgery	SBOS	Binary	Yes/No
Previous peritonitis	PP	Binary	Yes/No
Date First Surgery (if one also the last)	DFS	Date	dd/mm/yy
First Surgery Technique	FST	Chain	Surgical technique
First Surgery Category	FSC	List	Predefined: CRS, GIS, HBPS, AWS, GIN, URO, VAS, AA (appendectomy)
First Surgery Laparoscopy	FSL	Binary	Yes/No (including conversion)
First Surgery Emergency	FSE	Binary	Yes/No
Date Last Surgery	DLS	Date	dd/mm/yy, Only in case >1 abdominal surgery
Last Surgery Technique	LST	Chain	Surgical Technique
Last Surgery Emergency	LSE	Binary	Yes/No
Last Surgery Laparoscopy	LSL	Binary	Yes/No (including conversion)
Time Last Surgery to Episode	TLSE	Calc	DOA (dd/mm/aa) - DLS (dd/mm/aa) = in Years

# Data Collection Instrument 5 - Patient past SBO history

Past SBO history	Key Name	Data Type	Values
Previous SBO	PSBO	Binary	Yes/No
Number SBO Previous Episodes	NOE	Integer	Number
Date Last Episode	DLE	Date	dd/mm/yy
Previous WSOC challenge	PG	Binary	Yes/No
Previous Success Non-operative Treatment	PSCT	Binary	Yes/No
Previous Single Band Addesion	PSBA	Binary	Yes/No
Previous Small Bowel Resection	PSBR	Binary	Yes/No
Previous SBO Etiology	PSBOE	Chain	Previous SBO cause (Adhesions/Primary Hernia/Incisional Hernia/Parastomal Hernia/Bezoar/Radiation enteritis/Primary tumor

## Data Collection Instrument 6 - Current episode Symptoms and signs

Current Episode Clinical Symptoms	Key Name	Data Type	Values
Date Symptoms Start	DSS	Date; time	dd/mm/yy hh:mm
Abdominal Pain	SAP	Binary	Yes/No
Nausea	NAU	Binary	Yes/No
Vomiting	SV	Binary	Yes/No
Decreased Appetite	DAP	Binary	Yes/No
Constipation	SNPS	Binary	Yes/No (No pass stools)
Obstipation	SNPG	Binary	Yes/No (No pass gas)
Diarrhea	DIAR	Binary	Yes/No
Abdominal Distension	ADI	List	No/Mild/Severe
Peristalsis	SPE	List	Absent; Normal; Increased
Temperature	ST	Decimal	Number (ºC) i.e 36.5
Heart rate	SHR	Integer	Number
O2 Saturation	SO2	Integer	Number
Systolic Blood Pressure	SBP	Integer	Number
Respiratory rate	SRR	Integer	Number
SIRS Score	SIRS	Integer	Number (1-4) (temperature >38°C or <35°C, heart rate >90 beats/min, respiratory rate >20 breaths/min or PCO $_2$ < 32 mmHg, and WBC > 12000 cells/mm3 or <4000 cells/mm
SBO Type	SBOT	Binary	Complete/Incomplete (if SNPS or SNPG are Yes)

## Data Collection Instrument 7 - Initial Complementary Exams

Current Episode Initial Complementary Exams	Key Name	Data Type	Values
White Blood Cell Count	WBC	Integer	Number x10³
Hemoglobin	НВ	Decimal	Number (g/dL)
Potassium	К	Decimal	Number (mEq/L)
Creatinine	CRE	Decimal	Number (mg/dL)
CRP	CRP	Decimal	Number (mg/L)
INR	INR	Decimal	Number (mg/L)
Lactate	LAC	Decimal	Number (mg/dL)
Date First Plain Abdominal X ray	DFXR	Date; time	dd/mm/yy hh:mm
First AXr Stand up	FXRS	Binary	Yes/No
First AXr Air-Fluid Levels	FXRAF	Binary	Yes/No
First AXr Gastric Distension	FXRGD	Binary	Yes/No
First AXr Colonic Gas	FXRCG	Binary	Yes/No
Date Computed Tomography	DCT	Date; time	dd/mm/yy hh:mm
Computed Tomography Type	CTT	List	None; Without Contrast; IV Contrast; Oral Contrast; Double Contrast
CT Report Free Fluid	CTFF	Binary	Yes/No
CT Report Disminished Bowel Enhancement	CTDBE	Binary	Yes/No
CT Report Pneumatosis	СТР	Binary	Yes/No
CT Report Portal Gas	CTPG	Binary	Yes/No
CT Report Pneumoperitoneum	CTN	Binary	Yes/No
CT Report Small Bowel Wall Thickness	CTBWT	Decimal	Number (milimeters)
CT Report Small Bowel Diameter	CTSBD	Decimal	Number (Centimeters)
CT Report Feces Sign	CTFS	Binary	Yes/No (breadcrumb sign)
CT Report Peak Sign	CTPS	Binary	Yes/No (visible caliber change)
CT Report Whirl Sign	CTWS	Binary	Yes/No
CT Report Etiological Diagnosis	CTED	Binary	Yes/No (reported)
CT Report Diagnosis	CTE	Chain	Diagnosis (ie: single adhesion, matted adhesions, Hernia, Tumor)
AAST SBO	AAST	List	I, II, III, IV, V

## Data Collection Instrument 8 - Current episode, course evolution

Current Episode Course Evolution	Key Name	Data Type	Values
Severity Signs	CESS	Binary	Yes/No (if one is present: Unstable hemodynamics, peritonitis, sepsis (SIRS>2), acidosis, high lactate)
Ischemia Radiologic Signs	IRS	Binary	Yes/No (if one is YES: CTFF, CTDBE, CTP, CTPG, CTN, CTBWD>3mm, mesenteric edema)
Nasogastric/nasojejunal tube Insertion	NGTI	Binary	Yes/No
Initial NGT debit	INGTD	Integer	Number (mL)
Antibiotic Prophylaxis	PXATB	Binary	Yes/No
Antibiotic Treatment (if > 1 day)	TTATB	Binary	Yes/No
Treatment Fluids (ml/first 24h)	TTFL	Decimal	Number (ºC)
Treatmet Steroids	TTST	Binary	Yes/No
Total Urinary Output	TUO	Decimal	Number
WSOC Challenge	GGF	Binary	Yes/No
Exclusion Criteria for WSOC	GGFEC	List	No/Pregnancy/Inflamatory Bowel disease/Incarcerated hernia/Previous Radiotherapy/Mechanic inflammatory ileus/Tumor or carcinomatosis/Early postoperative period<1month/allergy to GGF)
Date WSOC	GGFD	Date; time	dd/mm/yy hh:mm
Post WSOC Vomiting	GGFPV	Binary	Yes/No
Post WSOC NGT debit	GGFNG	Decimal	Number (ºC)
Total Number of simple Abdominal X Ray	NXR	Integer	Number
Date Last Simple Abdominal X Ray	DLXR	Date; time	dd/mm/yy hh:mm
Last AX Ray WSOC in Stomach	LXR GGFS	Binary	Yes/No
Last AX Ray Deterioration	LXRD	Binary	Yes/No
Last AX Ray Colonic Air	LXRCA	Binary	Yes/No
Last AX Ray Colonic WSOC	LXRGGFC	Binary	Yes/No
Gas Pass	GP	Binary	Yes/No
Date Gas Pass	DGP	Date; time	dd/mm/yy hh:mm
Stools Pass	SP	Binary	Yes/No
Date Pass Stools	DSP	Date; time	dd/mm/yy hh:mm
Date Start Oral Feeding	DSOF	Date; time	dd/mm/yy hh:mm
Date Discharge from Emergency	DDE	Date; time	dd/mm/yy hh:mm
Emergency Department Lenght of Stay	EDLOS	Integer	Hours (calculation DDE-DOA)
Non-operative Treatment Success	COTS	Binary	Yes/No

## Data Collection Instrument 9 - Current episode Surgery

Current Episode Surgery	Key Name	Data Type	Values
Surgery Indicated Without Non-operative Attempt	SIWA	Binary	Yes/No
Date of Surgery	DSU	Date; time	dd/mm/yy hh:mm
Time to Surgery	TTSU	Integer	Hours (calculation DSU-DOA)
Laparoscopy	LAP	Binary	Yes/No (initiated)
Conversion	LAPC	Binary	Yes/No
Operative Time	ОТ	Integer	Number (Minutes)
Single Band Adhesilysis	SBA	Binary	Yes/No
Peritoneal Adhesion Index	PAI	Integer	Number
Ischemic Bowel	IB	Binary	Yes/No
Perforated Bowel	РВ	Binary	Yes/No
Serosal Tear	SUST	Binary	Yes/No (if one at least)
Unintended Bowel Perforation	UBP	Binary	Yes/No (if handmade)
Bowel Resection	SUBR	Binary	Yes/No
Anastomosis	SUBA	Binary	Yes/No
Stoma	SUST	Binary	Yes/No
Damage control (Open Abdomen)	SUDC	Binary	Yes/No
Hernia Repair	SUHR	Binary	Yes/No

## Data Collection Instrument 10 - Current episode, Final outcome

Current Episode Outcome	Key Name	Data Type	Values
Postoperative Complication	РОСО	Binary	Yes/No (if one at least)
Broncoaspirative pneumonia	BAP	Binary	Yes/No
New Acute Kidney Insufficiency	NAKI	Binary	Yes/No
New Onset Cardiac Arrhythmia	NOCA	Binary	Yes/No
Deep Vein Thrombosis/Pulmonary Embolism	DVT	Binary	Yes/No
Superficial Surgical Site Infection	SSSI	Binary	Yes/No
Deep Surgical Site Infection	DSSI	Binary	Yes/No
Organ Space Surgical Site Infection	OSSSI	Binary	Yes/No
Anastomotic leak	AL	Binary	Yes/No
Reoperation	RELAP	Binary	Yes/No
Most Severe Complication	MSCO	Chain	Named
Clavien Dindo	CLDI	List	I, II, IIIa, IIIb, IVa, IVb, V
ICU	ICU	Binary	Yes/No
ICU Date of Admission	ICUDOA	Date; time	Date of ICU admission dd/mm/yy hh:mm
ICU Date of Discharge	ICUDOD	Date; time	Date of discharge from ICU dd/mm/yy h:mm
ICU Lenght of Stay	ICULOS	Integer	${\it Number of Days (Integer; calculated from the admission and discharge date)}$
Death	RIP	Binary	Yes/No
Readmission during study period	READ	Binary	Yes/No (if after episode)