Title
IMAGINE: Ileus **MA**na**G**ement **IN**t**E**rnational
An international, observational study of postoperative ileus and provision of management after colorectal surgery

Division
General/colorectal surgery

Background/rationale
Key points
- Ileus is slowing of gastrointestinal transit that is not associated with mechanical obstruction
- It most commonly presents following surgery and usually lasts 2 to 4 days.
- Prolonged postoperative ileus contributes significantly to longer hospitalisation and increased healthcare costs
- Treatment of ileus includes bowel rest, supportive care, and treatment of any underlying exacerbating factors.

Impact of ileus
In the US, Ileus adds to healthcare costs by approximately $750 million to $1 billion annually. About 22 million inpatient surgical procedures are performed each year in the US, and about 2.7 million of these patients develop postoperative ileus lasting more than 1 day. Approximately 10% of patients are re-admitted to hospital after undergoing major abdominal surgery, and approximately half of these re-admissions are due to delayed onset of postoperative ileus. This condition also increases hospital costs due to necessary testing, such as CT scans, when the patients are re-admitted. Because of this need for diagnostic testing, postoperative ileus results in costs comparable to those for other more serious postoperative complications.

Importance of this audit
Prevention of ileus requires a multi-modal approach, including the substitution of postoperative opioid analgesia with non-steroidal anti-inflammatory drugs and thoracic epidural analgesia, early enteral feeding, early ambulation, and the use of laparoscopy rather than laparotomy whenever possible. These components are recommended as part of a BMJ Best Practice Guideline. An international audit of compliance with ileus reduction guidelines will identify pathways for improvement of patient care, and generate hypotheses for future research studies.

References
- Senagore AJ. Pathogenesis and clinical and economic consequences of postoperative ileus. Am J Health Syst Pharm. 2007;64:S3-S7.
- Luckey A, Livingston E, Taché Y. Mechanisms and treatment of postoperative ileus. Arch Surg. 2003;138:206-214.
- Story SK, Chamberlain RS. A comprehensive review of evidence-based strategies to prevent and treat postoperative ileus. Dig Surg. 2009;26:265-275.
- Doorly MG, Senagore AJ. Pathogenesis and clinical and economic consequences of postoperative ileus. Surg Clin North Am. 2012;92:259-272. Abstract

Aims/objectives

This international study aims to audit adherence to BMJ Best Practice Guidelines for prevention of ileus following elective colorectal surgery

Audit standards
BMJ Best Practice Guidelines: Jul 08. 2016

1. Observation for return of gastrointestinal function should be undertaken in the postoperative period (considering risk factors, nausea and vomiting, abdominal distension, and the absence of features of mechanical obstruction)

2. A multi-modal strategy should be taken to diminish the effects of postoperative ileus, including:
   - Use of a laparoscopic approach where possible
   - Remove orogastric or nasogastric tubes at the completion of surgery
   - Facilitate early enteral feeding
   - Use non-steroidal anti-inflammatory drugs (NSAIDs) for early analgesia
   - Use opiate-sparing strategies including patient-controlled analgesia and epidural analgesia
   - Use alvimopan where available
   - Promote the postoperative use of chewing gum

3. Tests indicating in suspected ileus should include
   - Daily serum electrolytes, including magnesium
   - Full blood count and C-reactive protein

4. Underlying conditions as potential causes for ileus such as sepsis, intra-abdominal infections, or other acute/systemic illnesses should be recognised and treated

Study design
International prospective clinical audit against a Best Practice Guideline, led by the EuroSurg collaborative (www.eurosurg.org)

Sample size
In an average colorectal surgical Unit it is expected that between 10 and 20 eligible surgeries will per performed during a two week study period. It is anticipated that the audit will be conducted in at least 150 centres across 8 countries, including a minimum of 1500 patients overall.

Data extraction: Prospective (clinical notes will not be required)

Data governance:
Data will be collected and stored online through a secure server running the Research Electronic Data Capture (REDCap) web application. REDCap allows collaborators to enter and store data in a secure system. It is widely used by academic institutions throughout Europe and all storage of web-based information by this system is encrypted and compliant with HIPAA-Security Guidelines in the United States. The service is managed by the University of Birmingham, UK. Collaborators will be given secure REDCap server login details, allowing secure data storage on the REDCap system. No patient identifiable information will be uploaded or stored on the REDCap database. All anonymous data will be held for a total of three years, after which it will

be permanently removed from the server space. Paper copies of data should be destroyed as confidential waste within the centre once uploaded to REDCap.

Timeline:
Sept 2017: IMAGINE protocol released
Oct-Dec 2017: Governance/audit approvals in place
Study Inclusion Period 1: 0800AM 22 Jan 2018 – 0800AM 5 Feb 2018
Study Inclusion Period 2: 0800AM 12 Feb 2018 – 0800AM 26 Feb 2018
Study Inclusion Period 3: 0800AM 5 Mar 2018 – 0800AM 19 Mar 2018
Completion of 30-day follow up by 17th April 2018
May 2018: Deadline for REDCap data uploads: 31 May 2018
Jul 2018: Manuscript writing
Sep 2018: Dissemination via local, national and international meetings and peer reviewed publication

Proposed presentation/feedback details
The IMAGINE audit will be fed back by presentation to hospital level governance meetings including local, national and international adherence figures. A formal written report will also be submitted for peer-review.

Please attach the IMAGINE study protocol including the case record forms to this audit approval form