PROTECT-AEGIS Standard operating procedure

Data Definitions

SOP No. 3 | Version 1.0

Effective: 23/05/2025 | Review: 23/05/2026

Authors: S. Begum, P. Dias, T. Abbott

Authorisation: Caroline Thomas (Lead Investigator)

1. Purpose

1.1 To provide further guidance on the eligibility criteria, follow-ups and time lines.

2. Surgical procedures

2.1 Examples of typical procedures include but are not limited to

- Abdominoperineal (AP) resection with anastomosis
- Abdominoperineal pull-though resection with colo-anal anastomosis
- Anterior resection
- Colectomy (total and ileorectal anastomosis)
- Gynaecological procedures which also include bowel resection and anastomosis
- Ileoanal anastomosis and creation of pouch
- Ileo-caecal resection (with anastomosis or ileostomy formation)
- Left hemicolectomy (with anastomosis /colostomy)
- Pancreatectomy (partial/distal/total)
- Pancreaticoduodenectomy (Whipple procedure)
- Panproctocolectomy and ileostomy
- Resection of duodenal tumour
- Resection of lesion(s) of the liver which also include bowel resection and anastomosis
- Resection of small bowel (+/- tumour)
- Right hemicolectomy (with anastomosis /colostomy)
- Sigmoid colectomy

2.2 Definitions

- *Severe organ dysfunction (ASA 4)*
  American Society of Anaesthesiologists physical status classification system 4. This is a patient with severe systemic disease that is a constant threat to life. The ASA grade for a patient is as per anaesthetist assessment.
- *Estimated glomerular filtration rate (eGFR) less than 45 ml/min*
  Renal impairment is defined as estimated glomerular filtration (eGFR) less than 45ml/min. Please use lowest eGFR value available in the 30 days prior to surgery according to the value recorded on the results system. A patient who's lowest eGFR in this time period is less than 45 ml/minute is excluded from AEGIS.
- *Peptic ulcer disease*
  Patients who have experienced two or more episodes of proven ulceration or bleeding, or upper gastrointestinal perforation are excluded from PROTECT-AEGIS. This does not include patients with mild gastritis or peptic ulcer disease, which is easily tolerated and treatable. This will be decided by the doctor who assesses eligibility. This will be documented in the medical notes and/or information from the patient.
- *Solid organ or bone marrow transplant*
  Solid organ or bone marrow transplant includes transplantation of kidney, liver, heart, lungs. Bone marrow transplant may be reported as stem cell transplant.
- *Chronic pain*
  Chronic pain is pain that continues for longer than three months, either as part of another health condition, or despite investigations and treatment
- *Use of analgesic medications in the past three months*
  Include any painkillers the patient uses, however infrequently. Include painkillers taken via any route, including by mouth, skin patches etc.

3. Pain management

3.1 Immediate post-operative pain management (from end of surgery until 23:59 on the day of surgery)

- This section asks for details of pain relief administered in the immediate post-operative care period, e.g. in a PACU or recovery area.

3.2 Other pain management medication:

- The drugs given as examples below are not an exhaustive list and the British National Formulary should be used to confirm which drugs have been administered.
    - Examples of morphine immediate release preparations: Oramorph and Sevredol.
    - Examples of morphine modified release (MR) preparations: MST and Zomorph.
    - Examples of Oxycodone immediate release preparations: OxyNorm, OxyFast, OxyIR, Shortec.
    - Examples of Oxycodone modified release (MR) preparations: OxyContin, Oxycodone MR, Longtec.
- If a patient receives a drug which is a combination of analgesics, e.g. co-codamol, please record these separately. In this example, paracetamol and codeine would be recorded separately.
- Opioid and other drug infusions and intermittent boluses including patient controlled intravenous analgesia
- If the patient has, for example, a non-standard PCAS, please document the opioid component in the table and use the 'other, please state' option to add in any adjuncts used, e.g. ketamine.

3.3 Local anaesthetic infusion and intermittent boluses

- If a patient receives an infusion which is a combination of more than one drug, please record these separately, e.g. an epidural infusion which contains levobupivacaine and fentanyl should be recorded as a local anaesthetic infusion and as a fentanyl infusion.

4. Pain score

4.1 Overall Benefit of Analgesia (OBAS) score

- Please record all individual components of the Overall Benefit of Analgesia (OBAS) score.
- Please complete this score with the patient using the following script. If this data cannot be collected on the day, please collect this retrospectively and indicate this on the CRF.
    - 'Please rate your current pain at rest on a scale of 0 to 4, where 0 is no pain, and 4 is the maximum pain imaginable. (0 = none, 1=slight, 2=moderate, 3=severe, and 4= very severe/ worst imaginable)
    - Please rate any distress or bother caused by vomiting in the past 24 hours from 0, none at all, to 4 very severe. (0= none, 1= a little/slight/ rarely, 2= somewhat/

moderate/occasionally, 3= quite a bit/ severe/frequently and 4= very much/ very severe/ almost constantly)

- Please grade any distress and bother from itching in the past 24 hours from 0, none at all to 4, very severe. (0= none, 1= a little/slight/ rarely, 2= somewhat/ moderate/occasionally, 3= quite a bit/ severe/frequently and 4= very much/ very severe/ almost constantly)
- Please grade any distress and bother from sweating in the past 24 hours from 0, none at all, to 4 very severe. (0= none, 1= a little/slight/ rarely, 2= somewhat/ moderate/occasionally, 3= quite a bit/ severe/frequently and 4= very much/ very severe/ almost constantly)
- Please grade any distress and bother from feeling cold or shivery in the past 24 hours from 0, none at all, to 4 very severe. (0= none, 1= a little/slight/ rarely, 2= somewhat/ moderate/occasionally, 3= quite a bit/ severe/frequently and 4= very much/ very severe/ almost constantly)
- Please grade any distress and bother from feeling dizzy in the past 24 hours, from 0, none at all, to 4 very severe. (0= none, 1= a little/slight/ rarely, 2= somewhat/ moderate/occasionally, 3= quite a bit/ severe/frequently and 4= very much/ very severe/ almost constantly)
- Overall, how satisfied are you with your pain treatment during the past 24 hours (0 not satisfied at all to 4 very satisfied. (0= not at all, 1= a little, 2= somewhat, 3= mostly and 4= very satisfied).'

4.2 Numeric Rating Scale

- Please record the pain reported by the patient using the 0-10 Numeric Rating Scale. Please use the Numeric Rating Scale supplied for use in the study.

4.3 Additional points

- Mental capacity - Medically-induced loss of consciousness to deliver routine medical care is not considered loss of capacity. If the patient subsequently requires unanticipated intubation and ventilation, and if doses of ibuprofen are omitted, this will be recorded.