1. Population Needs

1.1 National/local context and evidence base

Rectal cancer is relatively common, with an incidence of 179 cases per million. In approx 20% of cases, however, the cancer involves structures outside the bowel wall and can be classified as advanced. A small proportion of these advanced cases have tumours involving the presacral and bony structures such that in order to remove the tumour it is necessary to take part of the bony pelvis and other pelvic organs en bloc to clear the tumour.

Locally recurrent rectal cancer often involves the pelvic floor and necessitates removal of the lower sacrum to clear the tumour. To date, the true incidence of these cases is unknown as many patients have not had access to specialist units that offer this level of surgery. Referral arrangements have historically been unstructured and not comprehensive.

Surgery for recurrent and advanced rectal cancers is challenging and should only be undertaken by experienced surgical teams based within specialised units. En bloc removal of the tumour and the bone that it is attached to requires skill that is not routine in colorectal surgery. In the majority of cases it is necessary to remove all the pelvic organs (a pelvic exenteration or total pelvic clearance) this requires joint working with colorectal, urological, gynaecological and orthopaedic and/or neurosurgeons followed by reconstruction by plastic surgeons. The operation takes in the order of 10-12 hours. Because of the extensive nature of the surgery there are significant complications that can occur but are kept to a minimum in the hands of an experienced team.
The national caseload of referrals for consideration for Distal Sacrectomy surgery in England is estimated to be 450 cases per year referred with one-third of these considered appropriate for surgery (150 cases per year).

At present, there is no national reference or guidance regarding the management of this subset of patients with rectal cancer. A group of clinicians have recently drawn up guidance for the management of rectal cancer extending beyond the anatomical boundaries of standard surgical resection (yet to be published).

2. Scope

2.1 Aims and objectives of service

The aim of this service is to optimise outcomes and improve life expectancy for patients with T4 primary rectal cancer and recurrent rectal cancer that required en bloc excision of the pelvic floor, pelvic organs and distal sacrum (below S2) in an attempt to achieve a clear resection margin.

The service will achieve this aim by:
- Providing a timely assessment of referred candidate patients with a view to ascertaining suitability for resection.
- Developing a management plan for patients and either accepting them for surgery or providing an onward referral.
- Undertaking surgery on suitable patients in a timely way.
- Appropriate liaison with relevant Cancer Networks and MDTs.
- Undertaking detailed audit relating to the delivery of this service

2.2 Service description/care pathway

The specialised service offers multidisciplinary team (MDT) discussion and treatment for patients with locally advanced or locally recurrent rectal cancer that cannot be offered potentially curative treatment without distal sacrectomy.

Timely referral is required from a colorectal MDT to the specialist advanced pelvic cancer MDT.

This service pathway for this service is as follows:
- Referral from Colorectal Cancer MDT
- MDT assessment of suitability for pelvic resection & sacrectomy
- Elective Admission for Surgery
- Surgical Procedure
- Recovery
- In-patient Discharge
- Follow-up
- Discharge to local MDT

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The service will be delivered as follows:

- The service will be delivered via a ‘specialist advanced pelvic cancer MDT’ will, as a minimum comprise the MDT specified below.
- Patients who are potential candidates for distal sacrectomy surgical procedures will be discussed at the MDT.

The specialist advanced pelvic cancer MDT shall:

- Meet regularly and be quorate
- Review all clinical and pathological data
- Assign a surgeon and key worker to the patient who will see the patient and discuss the role of excision with that patient
- If suitable, perform the surgery by appropriate techniques
- Deliver a properly oriented specimen to histopathology
- Ensure that the final histology is discussed at the MDT
- Ensure that appropriate plans are made for further follow-up
- A detailed and prescriptive follow-up pathway including dates for surveillance endoscopies computerised tomography (CT) and magnetic resonance imaging (MRI) scans is communicated to the referring MDT so that these can be performed closer to the patient’s home
- If Distal Sacrectomy surgery is thought to be inappropriate, refer the patient back to the referring MDT
- The nurse specialist (key worker) from the specialist advanced pelvic cancer MDT and primary MDTs should ensure accurate and timely communication about the patient’s progress through the pathway.

The MDT may decide that an examination under anaesthetic is necessary as part of the planning prior to surgery. If so the patient would be admitted the evening before surgery (particularly if there is a long distance to travel)

Definitive excisional surgery will be undertaken as an inpatient procedure with an anticipated length of stay of 16 days.

**MDT Review**

Patients will be referred to the specialised service having been discussed by the local colorectal cancer MDT. The specialist advanced pelvic cancer MDT will review the imaging undertaken by the local centre (e.g. magnetic resonance imaging (MRI); computerised tomography (CT); and positron emission tomography (PET)) and identify a treatment plan.

Patients will then be reviewed in clinic and a treatment plan finalised. At this outpatient appointment the patient have an opportunity to discuss the pros and cons of surgery. The patient will be given written information regarding the procedure, the hospital stay and immediate postoperative information regarding recovery. They will be introduced to the principle surgeon and nurse specialist as the link worker with a telephone contact for the team. A summary of the discussions and
management plan will be provided to the GP and be offered to the patient if they wish to have a copy. If there has been no up-to-date haematology, biochemistry and tumour markers these will be done at the outpatient attendance. Methycillin resistant staphylococcus aureus (MRSA) screening will also be undertaken.

If a patient has co-morbidities it may be considered useful to recommend investigations at the referring centre to assess pulmonary and cardiac function. If these cannot be co-ordinated locally the patient may need to attend the specialist centre for pre-op workup.

Appropriate patients will be listed for surgery, and patients considered not appropriate for surgery will be referred back to the originating MDT.

Post-surgically, histology results will be discussed at the MDT to confirm completeness of excision and guide any further treatment required. The MDT will also agree a follow-up plan for each patient.

**Surgery**

The patient will be admitted the afternoon or evening before the date for definitive surgery. Blood cross matching for six units would be standard. The patient will be seen by the surgical and anaesthetic team and consent obtained. The patient will be seen by the stoma team and the abdominal wall marked appropriately for double stomas. The patient should receive full anti deep vein thrombosis (DVT) prophylaxis.

The operating schedule will be staffed as a three session day (8.00am -8.00pm) The colorectal and urological teams need to be available for all three sessions. The neuro/ortho and plastic teams need to be available for two later sessions.

Postoperative care should be at critical care level 2 or 3 depending on the condition of the patient during and at the end of the procedure.

Length of stay in critical care unit (CCU) will vary from an average of 48 hours but can be considerably longer particularly if there have been large transfusion requirements.

Nutritional requirements will be determined by the dietetic department and total parenteral nutrition (TPN) is started on the evening of surgery or the next day and is likely to be required for 7 postoperative days. If there is urinary leakage and an ileus TPN may be required for longer ~ 10 days until the anastomoses are sealed and normal gut peristalsis resumes.

Continued stoma nurse input is required from day 3 post op to assist the patient in managing both urostomy and colostomy.

Daily haematology and biochemistry are required for 10 days.
Postoperative transfusion may be required in 20% of patients.

On discharge the patient should receive advice regarding continuing anti-DVT prophylaxis for 28 days.

The patient and their carers will be given written information regarding how to contact the specialist team after discharge in case of concerns or complications.

**Follow up Review**

The patient will attend out-patient follow-up six to eight weeks following surgery to check recovery from surgery, wounds and discuss the histology. Prior to the appointment, the histology will be discussed at an MDT and a management plan devised if additional treatment is advised. Usually this would be in the form of adjuvant chemotherapy which could be administered by a cancer service close to the patient’s home.

**Minimum Staffing Requirement**

- Two Colorectal Surgeons experienced in undertaking Distal Sacrectomy procedures
- Urological Neuro/Orthopaedic, and plastic surgical input
- Lead Radiologist
- Lead Pathologist
- Clinical / Medical Oncologist
- Clinical Nurse specialist (including Macmillan Link Nurse)
- Clinical Pharmacist
- Theatre Support Staff
- Two Anaesthetists
- Stoma Therapy Service
- NICE compliant Nutrition Support Team (with total parenteral nutrition (TPN) capability minimum of Dietician; Pharmacist; Nutrition Nurse Specialist; consultant medic)
- Data Manager – particular focus on Audit and Outcomes.

**Minimum Infrastructure Requirements**

- Suitable outpatient facilities
- Inpatient facilities
- Access to Operating Theatre (with dedicated elective theatre allocation)
- Critical care facilities

**Entry / Exit Point to Specialised Service**

The Specialised Service commences at the point where a referral is received by a suitably qualified referrer from a colorectal MDT. Criteria are adult patients with T4 primary rectal cancers and recurrent rectal cancer involving the pelvic floor, presacral fascia and sacrum. Access is for patients who have undergone MDT
assessment at the local secondary care service with imaging for staging local and extra-pelvic disease. Patients should be considered fit for complex major surgical intervention

Patients will remain under the care of the specialised service until:
- They are assessed as being unsuitable for surgery and are discharged back to the referrer or are referred on to another service.
- They complete the pathway and following surgery are determined ready and it is safe to discharge back to local services. This will ordinarily be at the first outpatient attendance following discharge from the inpatient surgical spell. Occasionally “tidy up” surgery may be necessary and may involve plastic reconstructive perineal surgery. This will be performed by the specialised unit if clinically indicated. If not the patient will be returned to the referring unit.
- They become ineligible for NHS funded care or they die whilst undergoing treatment.
- They elect to discontinue receiving care provided by this service.

2.3 Population covered

The service outlined in this specification is for patients ordinarily resident in England*; or otherwise the commissioning responsibility of the NHS in England (as defined in Who Pays?: Establishing the responsible commissioner and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_127393

(*Note: for the purposes of commissioning health services, this EXCLUDES patients who, whilst resident in England, are registered with a GP Practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP Practice in England)

Specifically, this service is for adults with T4 primary rectal cancer and recurrent rectal cancer who are considered likely to benefit from an en bloc excision of the pelvic floor, pelvic organs and distal sacrum (below S2) in an attempt to achieve a clear resection margin.

2.4 Any acceptance and exclusion criteria

Commissioning for Distal Sacrectomy surgery shall be restricted to:
- Patients who have an advanced rectal cancer with a tumour involving the presacral and bony structures
- Patients with a locally recurrent rectal tumour involving the pelvic floor.

The criteria for referral shall be:
- The rectal cancer is T4 involving the presacral fascia and/or sacral bone
The lesion is recurrent rectal cancer involving the presacral fascia and/or sacral bone
The patient has been seen by a colorectal surgeon and has been fully discussed at the referring MDT
The patient is fit for the procedure
All necessary details are on a referral proforma signed by the chair of the referring MDT or consultant colleague on his behalf.

All patients referred would have been investigated, staged, discussed and at the primary MDT. Referrals should be on an agreed proforma with the minimum dataset. This should be signed off by the chair of the primary MDT.

Exclusions
The following groups of patients are considered unsuitable for Distal Sacrectomy surgery:

- Patients with unstable cardiac disease
- Patients with debilitating pulmonary function
- Patients with irreversible renal failure.

### 2.5 Interdependencies with other services

#### Co-located services

Services which must be provided from the same healthcare setting (i.e. the same hospital site) as the specified service are as follows

Services:

- Critical Care service
- General medical services
- CT and MRI scanning (for post op management)
- Nutrition service including parenteral nutrition
- Stoma Therapy services
- Tissue Viability service
- Interventional radiology service

#### Interdependent services

Services which the specified service will require access to routinely, for care provided during the period of the pathway described in this specification, but for which there is no absolute requirement for these services to be physically co-located on the same healthcare delivery site are:

Services which provide:

- Surgical specialties: urology, gynaecology, orthopaedic, neurological, plastic surgery
- Blood transfusion service
- Renal medicine
- PET-CT Scanning facilities
- Histopathology

Related services

The service forms part of a pathway of care provided in a number of settings by different providers. The service will need to maintain excellent communication with other agencies and services providing care to the patient including their General Practitioner and secondary care Cancer Centre who will be responsible for the longer-term follow-up of patients treated by this service.

This service is MDT based and relies on many specialities working together both in the primary (referring) colorectal MDT and the specialist advanced pelvic cancer MDT. It involves travel and possible treatment away from home which may need input from social services.

3. Applicable Service Standards

3.1 Applicable national standards e.g. NICE, Royal College

These are:
- Maximum two week wait for suspected cancers
- 31 day maximum wait from diagnosis to first definitive treatment
- 31 day maximum wait for subsequent treatment
- 62 day maximum wait from urgent GP referral or screening referral or consultant upgrade to first definitive treatment.

This is the reason for the recommendation that the patient is discussed at the local colorectal MDT before treatment. The participating specialist advanced pelvic cancer MDTs should contribute to the National Bowel Cancer Audit (NBOCAP) as well as maintaining a detailed database of outcomes including local and systemic recurrence and need for salvage radical resections and their outcomes.

The specialist advanced pelvic cancer MDT should have an annual audit meeting dedicated to discussing outcomes. Referring MDTs will be circulated with the minutes of these meetings. Operational meetings should be held regularly to ensure smooth patient journey through the pathway.

Any centre undertaking this procedure should, as a minimum, have two colorectal surgeons skilled in this procedure who each undertake a minimum of 20 surgical cases per year. They need the support of specialist urological, orthopaedic, neurosurgical, and plastic surgical teams.

Centres should, once published, consider the deliberations of the consensus group.
‘BeyondTME’ and reflect on the implications for clinical practice. As a minimum, the recommendations outlined in this paper should be considered at the annual business meeting of the Distal Sacrectomy service.

### 4. Key Service Outcomes

Providers will develop and maintain a database that, as a minimum, collects performance indicators:
- R0 resection rates
- Length of Stay in Critical Care Unit
- Length of Stay per episode
- Blood transfusion volume
- Return to theatre
- Post op complications Grade 1-4 (Int ref)
- 30 d mortality
- 1,3,5y survival
- Local recurrence
END.