

# **DECISION MAKING IN LOCALLY ADVANCED AND LOCALLY RECURRENT RECTAL CANCER – A PATIENT AND CLINICIAN PERSPECTIVE.**

## **Volume 1**

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## **Summary**

This thesis relates to locally advanced and locally recurrent rectal cancer (LARC and LRRC) and examines the decision-making process in patients contemplating potential surgical cure with pelvic exenteration (PE). It will determine the factors that influence the decision to undergo or to decline surgery for both patients and clinicians.

The aim of this research is to produce a validated Patient Decision Aid (PtDA) for patients with LARC and LRRC to facilitate the shared decision making (SDM) process.

## **Objectives**

1. To undertake a systematic literature review to identify existing validated PtDAs and grey literature including online forums for PE.
2. To explore whether English patient information leaflets (PILs) exist at centres worldwide performing exenterative surgery.
3. To explore through qualitative interviews patient views regarding what factors are important to them when making decisions regarding PE surgery.
4. To explore through qualitative interviews with clinicians their views regarding what they perceive to be important for the patient to consider when making decisions regarding PE surgery.
5. To use the findings from the literature review and qualitative interviews to inform the first stage development of a PtDA that outlines treatment options for patients with LARC or LRRC.
6. To develop the PtDA using key stakeholders.
7. To assess the content and face validity of the PtDA.
8. To assess the reliability and validity of the PtDA.
9. To assess the feasibility and efficacy of the PtDA.

## **Declarations and Statements**

### **Declaration**

This work has not previously been accepted in substance for any degree and is not being concurrently submitted in candidature for any degree.

Signed (candidate)



Date 23rd October 2024.....

### **Statement 1**

This thesis is the result of your own investigations, except where otherwise stated and that other sources are acknowledged by footnotes giving explicit references and that a bibliography is appended.

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### **Statement 2**

I hereby give consent for the thesis, if accepted, to be available for photocopying and for inter-library loan, and for the title and summary to be made available to outside organisations.

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Date 23rd October 2024.....

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## Publications to date

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## Definitions and Abbreviations

|        |                                                               |
|--------|---------------------------------------------------------------|
| ACPGBI | Association of Coloproctologists of Great Britain and Ireland |
| ADLs   | Activities of Daily Living                                    |
| ADM    | Agile Developmental Methodology                               |
| AJCC   | American Joint Committee on Cancer                            |
| ALT    | Anterolateral Thigh Gap                                       |
| ANS    | Autonomic Nervous System                                      |
| APC    | Adenomatous Polyposis Coli                                    |
| APE    | Anterior Pelvic Exenteration                                  |
| APER   | Abdominoperineal Resection                                    |
| AR     | Anterior Resection                                            |
| AV     | Audio-Visual                                                  |
| BSO    | Bilateral Salpingoophrectomy                                  |
| bTME   | Beyond Total Mesorectal Excision                              |
| CAPOX  | Capecitabine combined with Oxaliplatin                        |
| cCR    | Clinical Complete Response                                    |
| CEA    | Carcinoembryonic Antigen                                      |
| CFIR   | Consolidate Framework for Implementation Research             |
| CI     | Chief Investigator                                            |
| CI     | Confidence Interval                                           |
| CMS    | Consensus Molecular Subtypes                                  |
| CNS    | Clinical Nurse Specialist                                     |
| CRC    | Colorectal Cancer                                             |
| CRM    | Circumferential Resection Margin                              |
| CRT    | Chemoradiotherapy                                             |
| CT     | Computerised Tomography                                       |
| DALI   | Decision Aid Library Inventory                                |
| DFS    | Disease-Free Survival                                         |
| EAS    | External Anal Sphincter                                       |
| EBPI   | Evidence Based Patient Information                            |
| ED     | Erectile Dysfunction                                          |
| ELSIE  | Extended Lateral Pelvic Sidewall Excision                     |

|            |                                                                                           |
|------------|-------------------------------------------------------------------------------------------|
| EMVI       | Extramural Vascular Invasion                                                              |
| ENS        | Enteric Nervous System                                                                    |
| EORTC      | European Organisation for Research and Treatment of Cancer                                |
| ESMO       | European Society for Medical Oncology                                                     |
| FAP        | Familial Adenomatous Polyposis                                                            |
| FOLFIRINOX | Leucovorin Calcium [folinic acid], Fluorouracil, Irinotecan Hydrochloride and Oxaliplatin |
| FOLFOX     | Leucovorin, Fluorouracil, Oxaliplatin                                                     |
| Gy         | Gray                                                                                      |
| HCP        | Healthcare Professionals                                                                  |
| HNPCC      | Hereditary Non-Polyposis Colorectal Cancer                                                |
| HR         | Hazard Ratio                                                                              |
| HrQoL      | Health related Quality of Life                                                            |
| HRT        | Hormone Replacement Therapy                                                               |
| IAS        | Internal Anal Sphincter                                                                   |
| IGAP       | Inferior Gluteal Artery Perforator                                                        |
| IMA        | Inferior Mesenteric Artery                                                                |
| IMPACT     | Improving Outcomes For Advanced Colorectal Tumours                                        |
| IMV        | Inferior Mesenteric Vein                                                                  |
| IPAT       | Internal Pudendal Artery Perforator                                                       |
| IPDAS      | International Patient Decision Aid                                                        |
| IQR        | Interquartile Range                                                                       |
| IVF        | In-vitro Fertilisation                                                                    |
| JP         | Juvenile Polyposis                                                                        |
| LAR        | Low Anterior Resection                                                                    |
| LARC       | Locally Advanced Rectal Cancer                                                            |
| LRRC       | Locally Recurrent Rectal Cancer                                                           |
| LVI        | Lymphovascular Invasion                                                                   |
| MDT        | Multidisciplinary Meeting                                                                 |
| MMR        | Mismatch Repair                                                                           |
| MRF        | Mesorectal Fascia                                                                         |
| MRI        | Magnetic Resonance Imaging                                                                |

|         |                                                                      |
|---------|----------------------------------------------------------------------|
| NHS     | National Health Service                                              |
| NICE    | National Institute of Clinical Excellence                            |
| NoMAD   | Normalisation MeASURE Development Questionnaire                      |
| NPT     | Normalization Process Theory                                         |
| OS      | Overall Survival                                                     |
| pCR     | Pathologic Complete Response                                         |
| PE      | Pelvic Exenteration                                                  |
| PI      | Principal Investigator                                               |
| PIL     | Patient Information Leaflet                                          |
| PIP     | Personal Independent Payment                                         |
| PJS     | Peutz-Jeghers Syndrome                                               |
| PNI     | Perineural Invasion                                                  |
| PPE     | Posterior Pelvic Exenteration                                        |
| PPI     | Patient and Public Involvement                                       |
| Prep-DM | Preparation for Decision Making scale                                |
| PRISMA  | Preferred Reporting Items for Systematic Reviews and Meta-analyses   |
| PtDA    | Patient Decision Aid                                                 |
| QoL     | Quality of Life                                                      |
| RCTs    | Randomised Controlled Trials                                         |
| RT      | Radiotherapy                                                         |
| SCPRT   | Short-Course Preoperative Radiotherapy                               |
| SDM     | Shared Decision Making                                               |
| SMA     | Superior Mesenteric Artery                                           |
| SMV     | Superior Mesenteric Vein                                             |
| SRQR    | Standards for Reporting Qualitative Research                         |
| SUNDAE  | Standards for UNiversal reporting of patient Decision Aid Evaluation |
| TAH     | Total Abdominal Hysterectomy                                         |
| TAMIS   | Transanal Minimally Invasive Surgery                                 |
| TEM     | Transanal Endoscopic Microsurgery                                    |
| TME     | Total Mesorectal Excision                                            |
| TNM     | Tumour-Node-Metastasis Classification                                |

|      |                                        |
|------|----------------------------------------|
| TNT  | Total Neoadjuvant Therapy              |
| TPE  | Total Pelvic Exenteration              |
| UC   | Ulcerative Colitis                     |
| VRAM | Vertical Rectus Abdominus Myocutaneous |

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# **Chapter 1. Introduction**

## **1.1 Colon and Rectum**

In order to appreciate locally advanced and locally recurrent rectal cancer (LARC and LRRC) and its subsequent treatment options it is essential to appreciate the anatomy and thus the embryology of the colon and rectum. The large intestine originates at the caecum and terminates at the anus. It can be divided into six parts: ascending colon, transverse colon, descending colon, sigmoid colon, rectum and anus. The colon and rectum are approximately 150cm and 15cm respectively in length.

### **1.1.1 Embryology of the colon and rectum**

The gastrointestinal tract arises by the beginning of the third week of embryonic development. During a process called gastrulation, the three germ layers form. The germ layers include the ectoderm, mesoderm, and endoderm, which together compose the embryonic disc.

The endodermal roof of the yolk sac gives rise to the primitive gut tube. At the beginning of the third week of development, the gut tube is divided into three regions—the midgut, which opens ventrally, positioned between the foregut in the head fold and the hindgut in the tail fold. Progression occurs in three stages. In the first stage, a midgut loop enters the extraembryonic coelom or yolk sac and gradually elongates into a V-shaped loop that projects ventral toward the umbilicus (1). This physiologic herniation of the umbilicus eventually houses a large portion of the digestive tract. The bowel resides in the umbilicus until the third trimester of pregnancy, when it gradually draws back. During this time, the intestines rotate counterclockwise. During the second stage, the primitive intestine returns to the abdominal cavity. While doing so, the intestine and its mesentery rotate an additional 180 degrees counterclockwise for a total of 270 degrees of rotation. The third stage marks the return and fixation of the colon and its mesentery in the abdominal cavity. The ascending colon to proximal transverse colon are derived from the midgut whilst the distal transverse colon to the cranial aspect of the anal canal is derived from the hindgut (1).

Distal rectal development is complex. The cloaca is a specialized area of the primitive distal rectum composed of endoderm- and ectoderm-derived tissues. This area is incorporated into the anal transition zone, which surrounds the dentate line in the adult.

The cloaca exists in a continuum with the hindgut but, at approximately the sixth week, it begins to divide and differentiate into anterior urogenital and posterior anal and sphincter elements (2). Simultaneously, the urogenital and GI tracts are separated by caudal migration of the urogenital septum. During the 10th week of development, the external anal sphincter is formed from the posterior cloaca as the descent of the urogenital septum becomes complete. The internal anal sphincter is formed by the 12th week from enlarged circular muscle layers of the rectum (2).

### **1.1.2 Anatomy of the colon and rectum**

The embryological rotation results in the ascending and descending colon being retroperitoneal whilst the caecum, appendix, transverse colon and sigmoid colon are intraperitoneal structures. The rectum is the last part of the large intestine and connects the sigmoid colon to the anal canal. The rectum begins at the height of S2-S3 and ends at the perineum.

The muscle wall of the colon comprises an inner circular layer and an outer longitudinal layer. The longitudinal layer runs the length of the colon (caecum to rectosigmoid junction) and comprises three flat bands of longitudinal muscle, otherwise known as taenia coli. The typical sacculated appearance of the colon is a consequence of the contracting action of the taenia coli giving rise to multiple haustrations. Another distinguishing feature of the colon are the presence of multiple extraluminal peritoneal tags known as appendices epiploicae.

The rectum is macroscopically distinct from the colon, with an absence of taenia coli, haustra, and omental appendices. It is approximately 15cm in length and begins at the level of the sacral promontory and ends at the anorectal junction. It is divided into three equal segments – the upper, middle and lower third. The upper third of the rectum is covered by peritoneum both anteriorly and laterally. The middle third is covered only anteriorly, with the lower third of the rectum lying deep in the pelvis. In males the peritoneal reflection from the rectum to the posterior bladder wall forms the rectovesical pouch. In females, the peritoneal reflection is posterior to the vagina and cervix, forming the rectouterine pouch (pouch of Douglas). The course of the rectum is marked by two major flexures: sacral flexure – anteroposterior curve with concavity anteriorly (follows the curve of the sacrum and coccyx), and anorectal flexure – anteroposterior curve with convexity anteriorly formed by the puborectalis muscle

(Figure 1). There are additionally three lateral flexures (superior, intermediate and inferior), which are formed by transverse folds of the internal rectal wall.

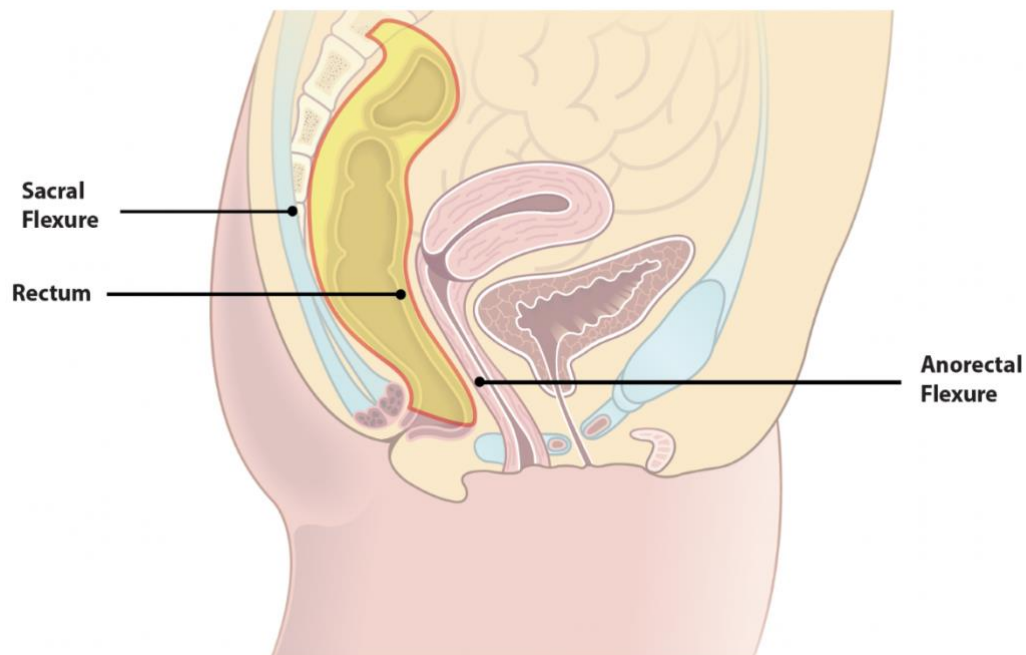


**Figure 1. Anatomical course of the rectum in females**

At the level of the rectosigmoid junction, the taenia coli form a continuous outer longitudinal layer of muscle that surrounds the rectum. The mucosal layer of the large intestine consists of simple columnar epithelial cells, lamina propria and muscularis mucosae. Anatomically the transition from sigmoid colon to rectum occurs with the cessation of the surgical mesocolon with loss of the teniae coli and appendices epiploicae. Conventionally this transition occurs approximately 15 cm above the anal verge, although, rather than being a clear distinction, there is a gradual convergence of the teniae coli (3).

## **1.2 Rectum**

The focus will now be entirely on the rectum.

### **1.2.1 Arterial blood supply**

The rectum receives arterial supply through three main arteries: the superior rectal artery (terminal continuation of the inferior mesenteric artery (IMA)), middle rectal arteries (branches of the internal iliac artery) and the inferior rectal arteries (branches of the internal pudendal artery from the internal iliac artery).



### **1.2.2 Venous and lymphatic drainage**

The venous drainage of the rectum is via the superior, middle and inferior rectal veins. The superior rectal vein drains into the portal venous system via the inferior mesenteric vein (IMV) and directly into the splenic vein, whilst the middle and inferior rectal veins empty into the systemic venous system. Anastomoses between the portal and systemic veins are located in the wall of the anal canal, making it a site for portocaval anastomosis.

The lymphatic drainage of the rectum does not follow the arbitrary subdivision in three levels, i.e., lower (0–5 cm), middle (5–10 cm), and upper (10–15 cm) from the anal verge (4). The rectal lymphatic vessels originate from the intramural lymphatic plexus and drain into the lymph nodes of the mesorectum or the sigmoid mesocolon; these are named mesenteric nodes. The mesenteric lymphatics drain from mesenteric lymph nodes to the retroperitoneal lymph nodes and toward the pelvic sidewall, grossly following the rectal blood vessels that provide the names of each nodal group (5).

### **1.2.3 Nerve supply**

The rectum is innervated by intrinsic and extrinsic nerves. The intrinsic innervation comprises of networks of nerve fibres occupying the space between the longitudinal and circular muscle layers (myenteric plexus of Auerbach), and in the submucosal layer (submucosal plexus of Meissner). There are also additional intrinsic plexuses that collectively form the enteric nervous system (ENS). Extrinsic innervation is from both the parasympathetic and sympathetic divisions of the autonomic nervous system. The parasympathetic supply is from S2-S4 via the pelvic splanchnic nerves and inferior hypogastric plexuses. The sympathetic nervous supply to the rectum is from lumbar splanchnic nerves and superior and inferior hypogastric plexuses.

### **1.2.4 Radiological boundaries of the rectum**

How to define the rectum radiologically has been the source of contention. Various definitions and landmarks have been used throughout the years to determine the upper boundary of the rectum, including the sacral promontory, third sacral vertebra, anterior peritoneal reflection, and distance measurements from the anorectal junction or anal verge (6-8) . An international multidisciplinary expert consensus panel agreed on the “sigmoid take-off” (STO) as the preferred landmark to define the boundary between the rectum and sigmoid colon on imaging (9). The STO marks the junction between

the mesorectum and sigmoid mesocolon and can be recognised on sagittal views as the point from which the sigmoid sweeps horizontally (away from the sacrum) and on axial views as the point from which the sigmoid projects ventrally (10)

### **1.2.5 Physiology of the rectum**

The rectum stores faeces formed in the colon and has an important role in defecation. The rectum is normally empty, but as faeces are propelled into it from the colon, its volume expands. This stimulates pressure sensitive cells in the wall of the rectum and initiates the defaecation reflex. The reflex causes a forceful contraction of the rectum and relaxation of the internal anal sphincter (IAS), controlled by the autonomic nervous system (ANS). This produces the conscious sensation of the need to evacuate, although voluntary contraction of the external anal sphincter (EAS) and puborectalis muscle can prevent incontinence if defecation is not socially acceptable. Contraction of these muscles then reduces the defaecation reflex and reduces the conscious perception of needing to empty the bowel, until another mass movement occurs, and a fresh reflex is created. Once continence has been learned, faeces are expelled through the anal canal when socially acceptable circumstances are found.

## **1.3 Rectal cancer**

### **1.3.1 Epidemiology**

Rectal cancer is one of the leading causes of cancer-related deaths. The latest data from GLOBOCAN 2021 report rectal cancer as 8<sup>th</sup> among all cancers worldwide in terms of both incidence (3.9%) and mortality (3.2%), affecting 732,210 new individuals worldwide each year (11). The cumulative lifetime risk of the disease of 1.2% and 0.65% in males and females respectively (12). In the UK, 14 000 new cases of rectal cancer are diagnosed every year (12).

### **1.3.2 Aetiology**

Most rectal cancers (approximately 90%) are adenocarcinoma in origin with other less common types including squamous cell and lymphoma. It is believed that almost all rectal adenocarcinomas develop through the adenoma-carcinoma sequence, whereby numerous genetic mutations (see below - consensus molecular subtypes (CMS)) through normal rectal epithelium transforming to benign dysplastic adenomatous polyps that then progress to carcinoma (13). The development of carcinoma requires

an accumulation of somatic (acquired) and/or germline (inherited) genetic mutations that are believed to occur over a 10 to 15 years period.

The majority of rectal cancers are sporadic (70%), with an average age diagnosis after 50 years old. A minority of patients (10%) show a true inheritance pattern (which carries a higher risk in patients younger than 50), and the remaining 20% of rectal cancer is seen as familial clustering in the absence of identifiable inherited syndromes.

Somatic mutations occur due to both environmental and lifestyle factors (Table 1).

| Protective factors                                                                                                 | Risk factors                                                 |
|--------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|
| Physical activity                                                                                                  | Red/processed meat consumption                               |
| Diet (fruits and vegetables, fibre, resistant starch, fish)                                                        | Androgen deprivation therapy                                 |
| Vitamin supplements (folate, folic acid, pyridoxine B6, calcium, vitamin D, magnesium),                            | >1 alcoholic drink a day (14) (15)                           |
| Garlic                                                                                                             | High BMI                                                     |
| Coffee                                                                                                             | Smoking, in both current and to a lesser degree, ex-smokers. |
| Drugs (aspirin, non-steroidal anti-inflammatory drugs [NSAIDs], statins, bisphosphonates, angiotensin inhibitors), | Diabetes (16)                                                |
| Hormonal Replacement Therapy in postmenopausal women.                                                              |                                                              |

**Table 1. Risk factors and protective factors for rectal cancer**

Other risk factors for rectal cancer include: personal or family history of colorectal cancer (CRC), adenomatous polyps, and polyps with villous or tubulovillous dysplasia. The risk of CRC is increased with a first degree relative diagnosed with bowel cancer. The risk is increased further with >1 relative diagnosed with bowel cancer or a first degree relative diagnosed < 45 years old. Patients with these risk factors are at high risk for synchronous or metachronous colorectal primary cancer (up to 3% to 5% at five years) and require close screening. Inflammatory bowel disease (more commonly ulcerative colitis (UC) than Crohns disease) with rectal involvement increases rectal cancer risk. For UC, the total lifetime risk of developing CRC either before or after the UC diagnosis has been reported at 2.3% (17). St Mark's surveillance cohort study found a cumulative incidence of 2.9% and 10% in patients with extensive UC at 20-year and 40-year follow-up, respectively (18). However, cumulative incidence of 1% at 10 years, 3% at 20 years and 7% at 30 years have also been reported

(19). Large studies have seen an increased risk of rectal cancer associated with the history of radiation for prostate cancer (HR, 2.06; 95% CI, 1.42 to 2.99) (20).

Approximately 5% of all CRCs are attributed to hereditary colorectal cancer syndromes including familial adenomatous polyposis (FAP) (1%) and Lynch syndrome (hereditary non-polyposis colorectal cancer (HNPCC) (4%). Patients with these conditions have an approximate lifetime risk of developing CRC of 50-80% (21). Almost all patients with FAP will have developed polyps by the age of 35, giving them a 95%-100% risk of developing cancer by the age of 50 (22). FAP can arise secondary to a gene mutation in 25% of cases and therefore does not always require a family history. Other less common hereditary conditions include juvenile polyposis (JP) and Peutz-Jehgers syndrome (PJS) (22).

There are three major molecular pathways linked to the development of CRC. The majority of CRCs develop via the chromosomal instability pathway. 12-15% arise from microsatellite instability (MSI pathway that is a consequence of deficient (d) Deoxyribonucleic acid (DNA) mismatch repair (MMR)(dMMR)). DNA methylation is also thought to be one of the most important epigenetic events that is thought to (23)occur during the early stages of oncogenic transformation (24)

The chromosomal instability (CIN) pathway is an accumulation of mutations unbalancing oncogene and tumour suppressor equilibrium (25). The majority of CRC patients exhibit CIN (65–85%) (26, 27). Patients with FAP developing CRC are commonly associated with the mutation of the tumour suppressor gene adenomatous polyposis coli gene (APC) (28).

Defects in the DNA mismatch repair (MMR) genes commonly MLH1 or MSH2, accumulate errors within the genome at a more rapid rate due to the inability to correct the base mismatch (25). This leads to high levels of microsatellite instability (MSI-H), which are associated with the development of HNPCC (29-31). It is prominently reported in various studies that approximately 15% of all CRCs have high frequency of MSI due to [germline](#) mutations in [mismatch repair](#) (MMR) system or somatic inactivation by promoter hypermethylation of [MLH1](#) gene .A poorer prognosis is associated with the mutation in the KRAS gene (13, 32) and is mutated in about 10% of CRC patients (33). Deficient dMMR (dMMR) can develop from an inherited germline mutation in an MMR gene. dMMR tumours carry somatic mutations in the

BRAF oncogene in approximately half of cases. This has clinical implications which guide treatment regimens. The BEACON regimen (encorafenib [BRAF-inhibitor], binimetinib [MEK-inhibitor], and cetuximab [anti-EGFR]) has been found to be effective for BRAF mutant metastatic CRC. (34, 35). Studies have shown that dMMR tumours have phenotypic features including poor differentiation, and abundant tumour-infiltrating lymphocytes. Furthermore, dMMR tumours have been consistently associated with a better stage-adjusted survival and reduced metastasis compared to proficient MMR (pMMR) tumours (36, 37). High-frequency MSI-H or dMMR has clinical significance as this type of CRC will respond differently to Fluorouracil-based adjuvant therapy (38) and immunotherapy (35). Immunotherapy (pembrolizumab; anti-PD-1) statistically significantly prolongs progression-free survival (PFS) in the first-line setting of patients with microsatellite instable (MSI) tumours (36, 37).

CpG hypermethylation of DNA can activate or silence the expression of certain genes, BRAF and MLH1, respectively. Sporadic oncogenes somatic mutations (RAS, SRC, MYC) have been implicated in CRC, with RAS having the most clinical relevance (25). Tumour suppressor genes require bi-allelic loss (“2-hit model”) and are described in loss of APC 5q21 gene (80% sporadic), TP53 17p gene (50% to 70% sporadic), and DCC/SMAD2-4 18q gene (73% sporadic) (25). Specific MMR gene mutations can occur in MSH2, MLH1, PMS1 and PMS2, MSH6, and MLH3; each can interact with MLH1. This is found in approximately 15% of all sporadic CRC and is universally tested. Consistent data indicate that these tumours have a better stage-adjusted survival compared to proficient MMR or microsatellite stable (MSS) tumours, and may respond differently to chemotherapy (36).

The consensus molecular subtypes (CMSs) of colorectal cancer (CRC) capture tumour heterogeneity at the gene-expression level (39). Molecular subtyping for colorectal cancer was established to resolve inconsistencies among the reported gene expression-based CRC classifications and facilitate clinical translation and subsequent treatment strategies (34). Four consensus molecular subtypes (CMSs) have been identified with distinguishing features:

CMS1 (microsatellite instability immune, 14%), hypermutated, microsatellite unstable and strong immune activation.

CMS2 (canonical, 37%), epithelial, marked WNT and MYC signalling activation.

CMS3 (metabolic, 13%), epithelial and evident metabolic dysregulation; and

CMS4 (mesenchymal, 23%), prominent transforming growth factor- $\beta$  activation, stromal invasion and angiogenesis (34).

Although known as a ‘sequence’, the progression from adenoma to carcinoma is more complicated than a stepwise progression of mutations, and no single mutation is common to all cancers (13).

### **1.3.3 Symptoms**

The most common symptom of rectal cancer is rectal bleeding, often at the end of defecation. Patients may also present with tenesmus (the constant sensation of incomplete evacuation), a change in bowel habit and pain. Weight loss can be non-specific and when present is suggestive of advanced disease (40). A third of recurrences are asymptomatic and are detected during routine post-operative follow up examination, usually within the first 3 years of the primary surgery (41). Pelvic pain, rectal bleeding, discharge, change in bowel habit and non-healing perineal wounds may all be symptoms of recurrent disease. It is estimated up to 50% of patients with local recurrence present with synchronous metastatic disease.

### **1.3.4 Disease spread**

Rectal cancer can spread by any one of four mechanisms: direct extension, lymphatic, haematogenous or transcoelomic spread (40).

Direct, or local spread into adjacent structures can occur in a radial, longitudinal or transverse fashion. Radial spread can be into the prostate, seminal vesicles, sacrum and bladder in male patients, and the uterus or vagina in female patients.

Lymphatic spread typically occurs in an upwards direction along the course of local lymphatic vessels progressing to central (para-aortic) lymph nodes (40). Usually, the most probably involved lymph node is located within a range of 1 cm proximally and distally to the tumour; the tumour subsequently disseminates cranially in >90% of cases (42-45). Tumours located above the peritoneal reflection mainly drain into the mesenteric lymph nodes and are associated with a higher risk of distant metastases (5, 46). Tumours originating, at the level or below the peritoneal reflection have a high likelihood of spreading to the nodal groups of the pelvic sidewall, with a probability of 21% and up to 41.8% respectively (5). The lower is the position of the tumour, the

higher is the probability of spread to the lateral lymph nodes ranging from 11.4% for tumours between 4 and 6 cm from the anal verge to 33.3% of tumours below 4 cm (47, 48). The latest American Joint Committee on Cancer (AJCC) AJCC Tumour-Node-Metastasis classification (TNM 8th edition) defines regional lymph nodes: including mesorectal/pararectal, superior rectal, inferior mesenteric, internal iliac, and inferior rectal lymph nodes. Obturator nodes are not mentioned but usually included within regional lymph nodes (49, 50). Lymph nodes outside these groups are considered non-regional by the AJCC, and therefore as metastatic (M) disease (51).

Haematogenous spread for the majority of rectal cancers will occur via the portal venous system and as a result the liver is the most common organ of metastasis followed by the lungs (40). Other sites of less common distant metastases may include the kidneys, ovaries, and brain.

Transcoelomic spread and peritoneal dissemination is not common, but can result in the spread of cancer to both the peritoneum and omentum (40).

### **1.3.5 Radiological staging**

Accurate pre-treatment staging of rectal cancer is important to facilitate bespoke management tailored to the patients' disease. Computerised Tomography (CT scan) of the chest/abdomen and pelvis is routinely used primarily to search for distant metastatic disease. Magnetic Resonance Imaging (MRI) and/or endo rectal ultrasound are routinely used to provide information about the predicted local stage of the disease, i.e. the predicted T and N stage. After surgical resection of the cancer, pathological staging is derived from examination of the resection specimen. The two most commonly used staging systems for CRC cancer are the Dukes' classification and the Tumour, Nodes, Metastasis (TNM) classification (52, 53). The original Dukes' classification was initially devised solely for rectal cancer, but over the years it has been adopted for use to stage colon cancers. The initial classification comprised of three stages, Dukes' A, B and C and subsequently a further fourth stage, stage D, was added (Table 2) (52). This is also classified as stage I-IV, respectively, by the AJCC (54). The newer AJCC TNM classification (Table 3) is the international standardised format of staging CRC (53). In this system, stages are assigned based on characteristics of the primary tumour (T) and the extent of regional lymph node involvement (N) and distant metastasis (M). In addition, metastasis may be defined clinically or

pathologically, on the basis of preoperative clinical assessment (c) or pathologic (p) evaluation of metastatic tissue (53-55).

|         |                                                                            |
|---------|----------------------------------------------------------------------------|
| Stage A | Invasion into the wall, but not breaching the muscularis propria.          |
| Stage B | Breaching the muscularis propria, but no invasion of regional lymph nodes. |
| Stage C | Invasion into, and involvement of regional lymph nodes.                    |
| Stage D | The presence of widespread metastases                                      |

**Table 2. Dukes staging colorectal cancer 8th edition for CRC**

| TNM clinical classification |                                                                                                                                                           |
|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| T – primary tumour          |                                                                                                                                                           |
| Tx                          | Primary tumour cannot be assessed.                                                                                                                        |
| T0                          | No evidence of primary tumour.                                                                                                                            |
| Tis                         | Carcinoma in situ: invasion of lamina propria.                                                                                                            |
| T1                          | Tumour invades submucosa.                                                                                                                                 |
| T2                          | Tumour invades muscularis propria.                                                                                                                        |
| T3                          | Tumour invades subserosa or into non-peritonealised pericolic or perirectal tissues.                                                                      |
| T4                          | Tumour directly invades other organs or structures and/or perforates visceral peritoneum.                                                                 |
| T4a                         | Tumour perforates visceral peritoneum.                                                                                                                    |
| T4b                         | Tumour directly invades other organs or structures.                                                                                                       |
| N – Regional lymph nodes    |                                                                                                                                                           |
| Nx                          | Regional lymph nodes cannot be assessed.                                                                                                                  |
| N0                          | No regional lymph node metastasis.                                                                                                                        |
| N1                          | Metastasis in 1-3 regional lymph nodes.                                                                                                                   |
| N1a                         | Metastasis in 1 regional lymph node.                                                                                                                      |
| N1b                         | Metastasis in 2-3 regional lymph nodes.                                                                                                                   |
| N1c                         | Tumour deposits(s) i.e. satellites in the subserosa, or in non-peritonealised/pericolic or perirectal soft tissue without regional lymph node metastasis. |
| N2                          | Metastasis in 4 or more regional lymph nodes.                                                                                                             |
| N2a                         | Metastasis in 4-6 regional lymph nodes.                                                                                                                   |
| N2b                         | Metastasis in 7 or more regional lymph nodes.                                                                                                             |
| M- Distant metastasis       |                                                                                                                                                           |
| M0                          | No distant metastasis.                                                                                                                                    |
| M1                          | Distant metastasis.                                                                                                                                       |
| M1a                         | Metastasis confined to one organ (liver, lung, ovary, non regional lymph node(s)), without peritoneal metastases.                                         |
| M1b                         | Metastasis in more than one organ.                                                                                                                        |
| M1c                         | Metastasis to the peritoneum with or without other organ involvement.                                                                                     |

**Table 3. TNM staging colorectal cancer 8th edition for CRC**

The depth of extramural penetration of the tumour has been shown to be an independent prognostic factor in T3 rectal cancer (56), and it is clear that patients with more than 5 mm of extramural spread should be identified because they have a markedly worse prognosis than patients with 5 mm or less of spread (57, 58). High-



quality MRI allows further subclassification of cT3 based on depth of invasion beyond muscularis propria and is utilised within the European Society for Medical Oncology (ESMO) guidelines (59-61) (Table 4). However, subclassification is not validated in any randomized trials and have not been incorporated in any of the TNM versions (62).

| Subclassification of T3 rectal cancer | Depth of invasion beyond the muscularis propria (mm) |
|---------------------------------------|------------------------------------------------------|
| T3a                                   | <1                                                   |
| T3b                                   | 1-5                                                  |
| T3c                                   | 6-15                                                 |
| T3d                                   | >15                                                  |

**Table 4. MRI Subclassification of T3 rectal cancer**

TNM, Dukes and stage can be compared interchangeably (Table 5).

| Stage | T      | N     | M   | Dukes  |
|-------|--------|-------|-----|--------|
| 0     | Tis    | N0    | M0  | -      |
| I     | T1-T2  | N0    | M0  | A or B |
| IIa   | T3     | N0    | M0  | B      |
| IIb   | T4a    | N0    | M0  | B      |
| IIc   | T4b    | N0    | M0  | B      |
| IIIa  | T1-T2  | N1    | M0  | C      |
|       | T1     | N2a   | M0  | C      |
| IIIb  | T3-T4a | N1    | M0  | C      |
|       | T2-T3  | N2a   | M0  | C      |
|       | T1-T2  | N2b   | M0  | C      |
| IIIc  | T4a    | N2a   | M0  | C      |
|       | T3-T4a | N2b   | M0  | C      |
|       | T4b    | N1-N2 | M0  | C      |
| IVa   | Any T  | Any N | M1a | -      |
| IVb   | Any T  | Any N | M1b | -      |

**Table 5. Cross tabulation of TNM and Dukes staging**

### 1.3.6. Histopathological staging

More than 90% of colorectal carcinomas are adenocarcinomas originating from epithelial cells of the colorectal mucosa (63). Other rare types of colorectal carcinomas include neuroendocrine, squamous cell, adenosquamous, spindle cell and undifferentiated carcinomas. Conventional adenocarcinoma is characterized by glandular formation, which is the basis for histologic tumour grading classified by Broder's criteria (64). In well differentiated adenocarcinoma (grade I) >95% of the tumour is gland forming. Moderately differentiated adenocarcinoma (grade II) shows

50-95% gland formation. Poorly differentiated adenocarcinoma (grade III) is mostly solid with <50% gland formation (64). In practice, most colorectal adenocarcinomas (~70%) are diagnosed as moderately differentiated. Well and poorly differentiated carcinomas account for 10% and 20%, respectively.

In World Health Organization (WHO) classification, a number of histologic variants of colorectal carcinomas are listed, such as mucinous, signet ring cell, medullary, micropapillary, serrated, cribriform comedo-type, adenosquamous, spindle cell, and undifferentiated.

Histologic examination of surgically resected specimens serves an irreplaceable role in determining the depth of tumor invasion (T) and the extent of nodal metastasis (N) (Table 3). A standardised synoptic report for colorectal carcinoma following the checklist is recommended by the College of American Pathologists (65). The details that should be included in the report are specimen type, tumour site, tumour size, macroscopic tumour perforation, histologic type, histologic grade, microscopic tumor extension, margins (proximal, distal and radial), treatment effect (for tumors treated with neoadjuvant therapy), lymphovascular invasion, perineural invasion, tumor deposits (discontinuous extramural extension), TNM staging (including the total number of lymph nodes examined and the total number of nodes involved).

### **1.3.7 Treatment**

The treatment options available to a rectal cancer patient are dependent on the stage of disease at presentation results of staging investigation and patient choice. A multimodal approach, including surgery, chemotherapy (both in the neoadjuvant and adjuvant setting), radiotherapy or chemoradiotherapy (CRT) can be incorporated in the management of rectal cancer following multidisciplinary team (MDT) meeting (Figure 2).

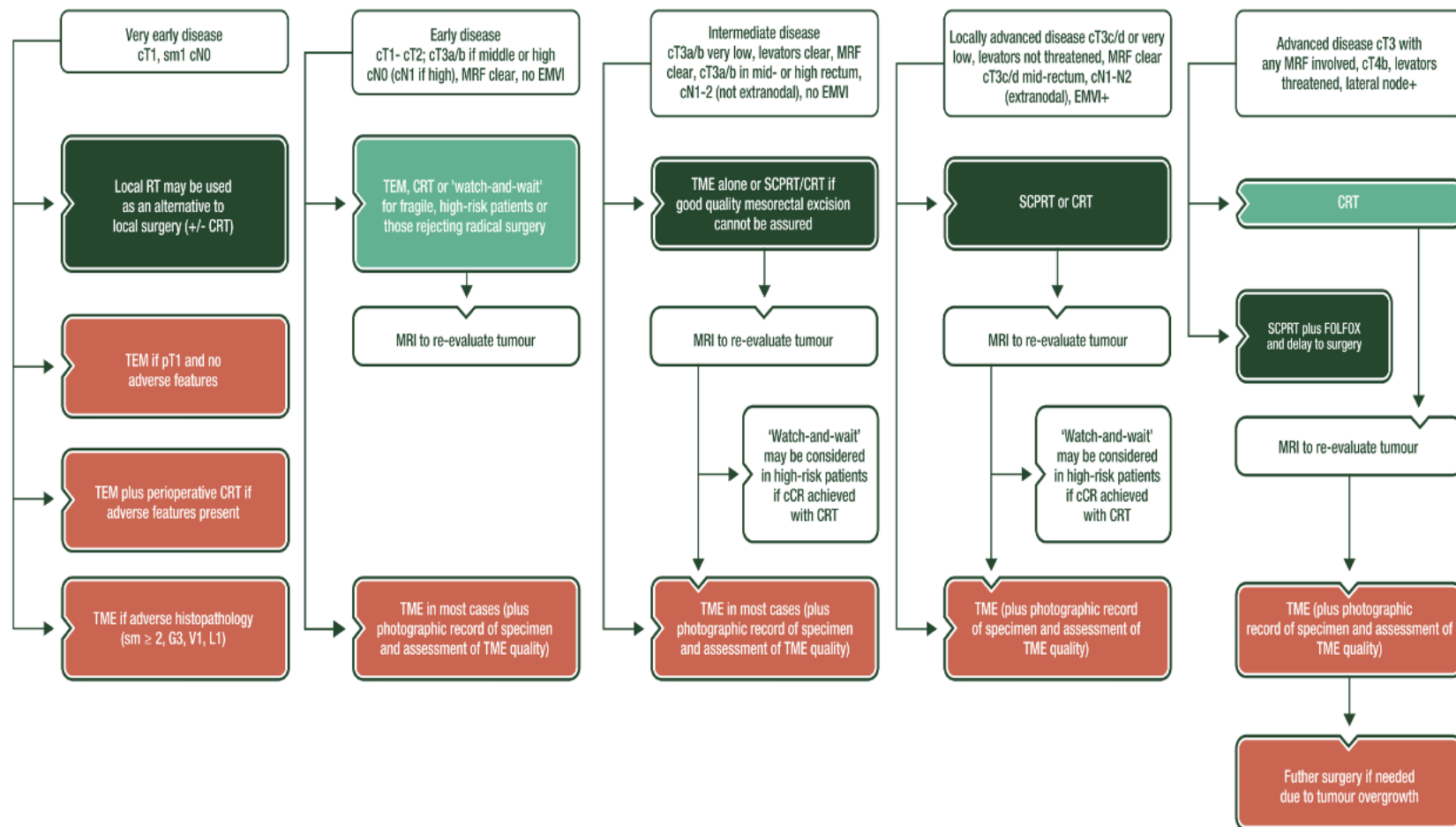


**Figure 2. Rectal cancer treatment algorithm**

(cCR, clinical complete response; CRT, chemoradiotherapy; EMVI, extramural vascular invasion; FOLFOX, leucovorin/fluorouracil/oxaliplatin; MRF, mesorectal fascia; MRI, magnetic resonance image; RT, radiotherapy; SCPRT, short-course preoperative radiotherapy; TEM, transanal endoscopic microsurgery; TME, total mesorectal excision) (66)

### **1.3.7.1 Neoadjuvant treatment**

In the curative setting, some high-risk/advanced tumours may benefit from neoadjuvant (pre-operative) treatment. Patients with stage II-III disease are often treated with neoadjuvant radiotherapy, neoadjuvant chemotherapy/immunotherapy (66, 67) or CRT. The type of treatment used is tailored to the patient's disease. For stage IV disease pre-operative CRT may help to downstage metastatic disease prior to surgical resection (68). There are three schedules of preoperative therapy that are most commonly used:

1. Short course pre-operative radiotherapy (SCPRT) with a 25 Gray (Gy) total dose at 5 Gy/fraction during 1 week, followed by immediate surgery (< 10 days from the first radiation fraction); SCPRT with delayed surgery can also be used alternative to conventional short-course RT, with immediate surgery offering similar oncological out- comes and lower postoperative complications (69).
2. CRT with a recommended dose of 45–50 Gy in 25–28 fractions; a boost with a further 5.4 Gy in 3 fractions can be considered for preoperative radiotherapy if the circumferential resection margin (CRM) is threatened, and for postoperative radiotherapy routinely with 5.4–9.0 Gy in 3–5 fractions according to CRM (66)
3. Total Neoadjuvant therapy (TNT) is a relatively new concept in rectal cancer treatment. TNT is a therapeutic strategy that incorporates chemotherapy with CRT prior to surgery to eradicate occult micro-metastasis uses (as opposed to lower radio-sensitizing chemotherapy doses employed in traditional long-course CRT) in the neoadjuvant setting, before surgery for Locally Advanced Rectal Cancer (LARC) (discussed in 1.3.8). This multimodal treatment has reported promising results in recently reported multi-centre randomized controlled trials (RCTs) that found that TNT may improve disease-free survival (DFS), pathologic complete response (pCR) rates and chemotherapy completion rates (70, 71). Whilst some patients receiving TNT may have a pathological complete response (pCR) to treatment (and thus be initially managed without surgical resection), for the majority of patients definitive curative-intent treatment still depends on complete surgical resection. TNT may change the standard of treatment of LARC with these promising results.

The Rectal Cancer and Preoperative Induction Therapy Followed by Dedicated Operation (RAPIDO) trial used short-course radiation ( $5 \times 5$  Gy over 8 days) followed by FOLFOX (a combination chemotherapy regimen that includes leucovorin calcium [folinic acid], fluorouracil and oxaliplatin; 9 cycles) or CAPOX (capecitabine combined with oxaliplatin; 6 cycles) chemotherapy. Adjuvant chemotherapy was optional (71). It found that TNT had lower disease-related treatment failure rate (hazard ratio [HR] 0.75, 95% confidence interval [CI] 0.60–0.95;  $p = 0.019$ ) and distant metastatic disease (HR 0.69, 95% CI 0.54–0.90;  $p = 0.0048$ ) at 3 years, compared with conventional neoadjuvant treatment. More patients treated with TNT also had a pCR (28.4%; TNT v. 14.3%; standard,  $p < 0.0001$ ), and 85% of patients treated with TNT completed their chemotherapy, compared with 67% of patients in the standard treatment arm (71).

PRODIGE-23 started with FOLFIRINOX chemotherapy (leucovorin calcium [folinic acid], fluorouracil, irinotecan hydrochloride and oxaliplatin; 6 cycles), followed by long-course radiation (50 Gy over 5 weeks) (70). Neoadjuvant Chemotherapy with FOLFIRINOX and Preoperative Chemoradiotherapy for Patients with Locally Advanced Rectal Cancer (UNI-CANCER-PRODIGE-23) trial showed superior 3-year DFS compared with standard neoadjuvant chemoradiation (HR 0.69, 95% CI 0.49–0.97;  $p = 0.034$ ) (70). Three-year metastasis-free survival was also better in the TNT arm (HR 0.69, 95% CI 0.54–0.90;  $p = 0.0048$ ), and there were increased rates of pCR (27.8%; TNT v. 12.1%; standard,  $p < 0.001$ ) (70).

Whilst the trial data have found that the use of pre-operative RT probably affords better local disease control, this has not translated into an overall survival (OS) benefit in longer term follow up, although the results of longer term follow up of several TNT trials are awaited. Whilst the use of RT in the neoadjuvant setting appears to improve local control, it is associated with potential morbidity including worse intestinal and sexual dysfunction after surgery (66).

It is not possible to give a rigid definition of which T and N sub-stages require SCPRT, CRT or TNT. In an otherwise fit patient, if the CRM and/or R0 resection status are

predicted at risk, CRT or TNT are generally advised (72). Otherwise, either SCPRT or CRT can be administered (73, 74).

#### **1.3.7.2 Clinical complete response and a ‘watch-and-wait’ approach.**

Following CRT ,SCPRT or TNT, a clinical complete response (cCR) may be obtained in 10%–40% of patients when assessed after an interval of 12 weeks from the start of treatment (75). cCR is described as absence of tumour according to clinical, radiological and endoscopic investigations; however, the description cannot be as clear as pCR. This was first proposed by Habr-Gama (76) as a non-operative approach also described as ‘organ-sparing treatment’ and ‘rectal preservation’ or the ‘watch and wait’ strategy. The likelihood of achieving a cCR depends partly on initial stage and currently unknown molecular factors. Patients reported to have a cCR may have microscopic disease with a high risk of early recurrence. For patients who appeared to have achieved a cCR the RESEARCH study suggests strict follow up including physical examination including digital rectal exploration, carcinoembryonic antigen (CEA) levels and proctoscopy every 3 months for 2 years and subsequently every 6 months for 3 years. Chest and abdomen CT scans are recommended annually, while MRI of the pelvis is performed every 6 months for 2 years and yearly thereafter. Colonoscopy is performed at 1 year and 4 years following surgery (77)

#### **1.3.7.3 Surgical management**

The type of surgery performed for rectal cancer is dependent on disease stage and patient choice. In low grade (T1) tumours, without the presence of local lymph node involvement, Transanal Minimally Invasive Surgery (TAMIS) can be performed. TAMIS uses specialised laparoscopic surgery in an anal approach rather than an abdominal incision. Once the lesion is removed, the defect in the rectum is usually sutured closed (78, 79) and allows preservation of the anal sphincters.

For more advanced rectal cancers with or without predicted regional lymph node involvement where the mesorectal envelope is not threatened by disease rectal organ excision including total mesorectal excision (TME) is considered the standard of care since it was first described by Professor Bill Heald in 1982 (80). The widespread adoption of mesorectal excision has dramatically reduced the risk of local recurrence, with some contemporary reports showing an incidence of less than 5% (80).

Depending on the height of the tumour, together with patient fitness there are various surgical procedures that can be offered (Figure 3).:

1. Anterior resection (AR): For rectal cancers in the upper two thirds of the rectum, the bowel is divided proximally at the descending colon and below the tumour in the rectum and removed. The anal sphincters are preserved, and the colon is anastomosed (joined) to the remaining portion of the rectum.
2. Low anterior resection (LAR): For rectal tumours in the lower third of rectum, the rectum is excised completely, the colon may be anastomosed directly onto the anal canal.
3. Hartmanns procedure: In situations where it is not safe to anastomose the bowel it may be necessary to form a permanent colostomy and keep the remaining rectum/anus in situ.
4. Abdominoperineal resection (APER); For tumours low in the lower third of the rectum, where sphincter preservation is not possible, the sigmoid colon, rectum and anus, along with regional lymph nodes are excised via two incisions, a midline (laparotomy) incision and a perineal incision. This results in a permanent end colostomy.

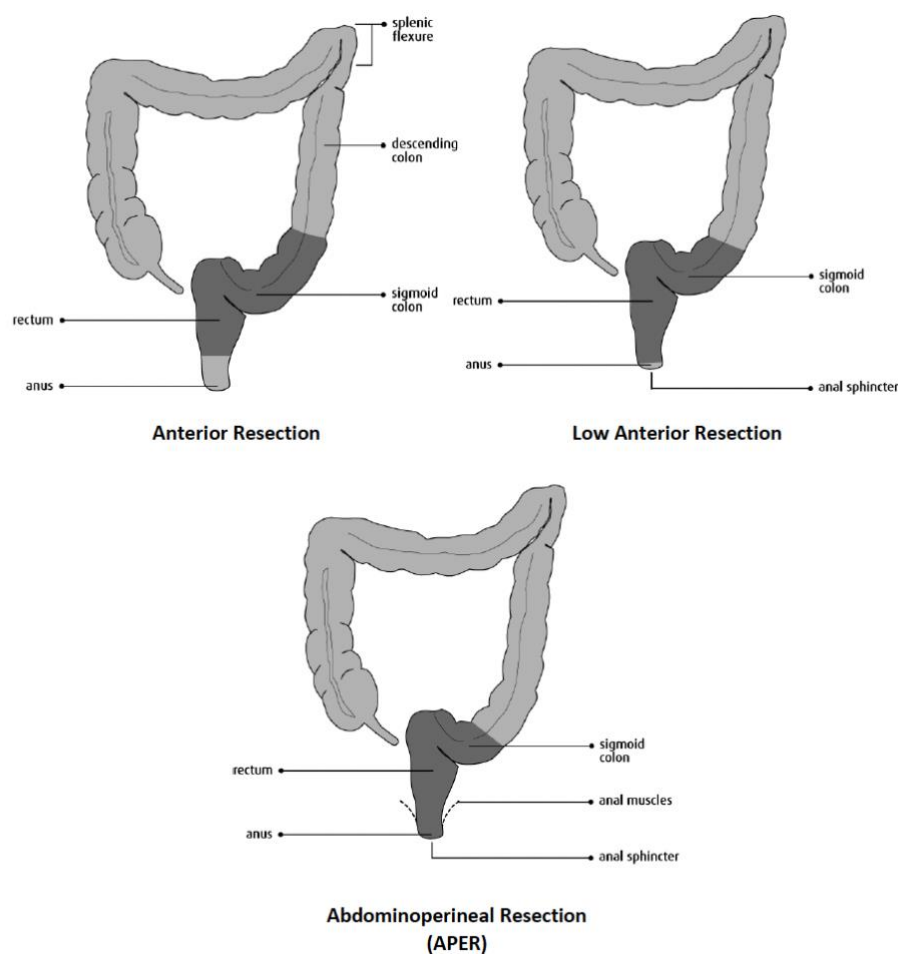


**Figure 3. Rectal cancer surgery**

### **1.3.8 Prognosis**

Since the early nineties, there have been changes in rectal cancer treatment, including better surgery and/or pre-operative RT. Historically, up to 30% of patients who underwent potentially curative surgery subsequently developed local recurrence (80). Contemporary data with a standard TME technique and selective neoadjuvant CRT, has found local recurrence rates of 5–10% (81-86). In addition to improved local control, 5-year OS rates have improved from 48% after conventional surgery was performed in the Swedish Rectal Cancer Trial to >60% after TME surgery (87).

Historically, local invasion into other organs/structures was a contraindication to surgery. Without resection, median survival was <1 year and a 5 year OS of <5% (88). By comparison, the 5-year relative OS rate for patients with rectal cancer is 68%. If the cancer is localised at diagnosis, a survival rate of 90% is expected. Whereas, if the cancer has advanced to regional lymph nodes or surrounding tissues/organs, a 5-year



relative survival rate 74%. Metastatic disease reduces the 5-year relative survival rate to 17% (89).

Historical studies prior to the advent of routine TME surgery found that the following histopathological features impact on the risk of local recurrence: pathological TNM stage, T substage. CRM status (R0 resection), the number/proportion of involved lymph nodes, extracapsular extension, extranodal deposits, tumour differentiation, lymphovascular invasion (LVI), extramural vascular invasion (EMVI) and perineural invasion (PNI) (90).

Lymph node involvement has been associated with a high risk of local recurrence. However, the risk of local recurrence is reduced if the quality of the mesorectal excision is good (i.e. a complete, smooth mesorectum with no defects and no coning), all lymph nodes removed with a negative CRM (91).

Adjuvant (post-operative) chemotherapy has been shown to be effective in patients with stage III rectal cancer and to a lesser extent, in patients with stage II disease (92, 93). Treatment should begin within 8 weeks following surgery and continue for a duration of 6 months (92, 93). The survival benefit of 5 year OS is 80% vs 53% with and without adjuvant therapy (94). Treatment typically consists of a combination of oxaliplatin and a fluoropyrimidine agent. A single randomised, phase II study suggested that adding oxaliplatin to 5-FU/leucovorin in a modified leucovorin/fluorouracil/oxaliplatin regimen (mFOLFOX6) improves relapse-free survival and OS in high-risk rectal cancers without downstaging after pre-operative 5-FU-based CRT (95). Whilst adjuvant chemotherapy is considered the standard of care in stage III rectal cancer patients who were not treated neoadjuvantly with TNT, the morbidity associated with rectal cancer surgery frequently delays or prevents. omission or delay in this scenario is associated with decreased OS (96).

### **1.3.9 Locally advanced rectal cancer**

Rectal cancers invading or extending close to the mesorectal fascia are termed locally advanced rectal cancer (LARC). Of new rectal cancer diagnoses in the UK, about one-third will be locally advanced at the time of diagnosis, accounting for more than 4600 cases of cancer per year (33, 97).

Although the term LARC is often used, an international consensus on the definition is lacking. Definitions vary from tumour growth into the mesorectal fat (clinical tumour

stage 3 (T3)), tumour presence within 1 mm or less of the mesorectal fascia, invasion of adjacent organs or structures (clinical T4 stage), lymph node metastasis (clinical N+-stage), lymph node metastasis lateral to the mesorectal fascia (extramesorectal N+), to extramural vascular invasion (98). In the context of this thesis the term LARC can be defined as primary rectal cancer that involves or extends beyond the mesorectal fascial plane (b-TME) (99, 100).

#### **1.3.10 Locally recurrent rectal cancer**

Locally recurrent rectal cancer (LRRC) following previous potentially curative resection of primary rectal cancer is defined as ‘tumour recurrence in the previous operative field within the pelvis’ (101, 102). Those who receive potentially curative treatment between 19%-40% will be diagnosed with recurrent disease in follow up (103-106), including the risk of local recurrence within the pelvis of 4-8% (107, 108). Local recurrence of rectal cancer mostly occurs within 2 years of the initial surgery with 80% of cases diagnosed within 5 years (109-111), however, some occur after 10 years (112, 113). Fifty percent of patients with LRRC have isolated recurrence without distant metastases (114)

### **1.4 Treatment for LARC and LRRC**

In more advanced cancers with extensive localised disease or locally recurrent cancers, neoadjuvant CRT or TNT is utilised prior to surgery to downstage the tumour (see 1.3.9). If there is contiguous organ involvement a radical procedure called pelvic exenteration (PE) may be necessary to achieve margin negative (R0) status.

#### **1.4.1 Pelvic exenteration**

Pelvic exenteration (PE) was first described in 1948 by Brunschwig when it was considered a palliative operation for advanced cervical cancer with associated peri-operative mortality of 23% (115). PE is now generally performed with curative intent for a variety of advanced or recurrent pelvic malignancies. Improvements in neoadjuvant treatment, operative techniques, and peri and post-operative anaesthetic management have improved mortality and associated morbidity. The 5-year survival has improved to 52% to 60% for patients with LARC and 28% to 40% for patients with LRRC (116, 117). Post-operative mortality is now reported as 0 - 25% (median 2.2%) and morbidity rates of 37%-100% (median 57%) (118). The high rates of morbidity are secondary to the extensive nature of the surgery.

PE is a radical surgical treatment that removes gastrointestinal, gynaecological and urinary organs within the pelvis. It involves the removal of at least two pelvic organs and lymph nodes with the aim of complete resection of the tumour. Similar to an APER, these patients generally undergo two incisions and are left with a permanent end colostomy. A large proportion of patients undergoing PE will also be left with a second stoma (urostomy) for the drainage of urine, as the bladder is occasionally removed during dissection.

The main aim of surgery in LARC and LRRC is to obtain a negative (R0) resection margin as it confers optimal survival benefit in this cohort of patients when compared to a microscopically (R1) or positive margin (119). A curative R0 resection is achieved in 40-50% of patients undergoing surgery (119). It is generally accepted that surgery should not be undertaken if it is believed that surgery will result in an incomplete resection, or the risk of functional impairment or mortality is unacceptable. In very select circumstances operative intervention may be reserved to achieve palliation with treatment aims based on symptom control, prolongation of life and improvement of health-related quality of life (HrQoL) (120).

Historically, relative contra-indications to PE where the benefit of resection was uncertain were encasement of external iliac vasculature, high sacral involvement above S2 sacral segment, extension through the sciatic notch, unresectable extra-pelvic metastasis, and predicted R + resection (121). However, as surgery in this arena has evolved the majority of these are now frequently operated upon in high volume exenteration units where 'higher and wider' resections are now being performed (122). At present, poor performance status, bilateral sciatic nerve involvement, and circumferential bone involvement remain absolute contra-indications.

Exenterative surgery is an umbrella term that incorporates a diverse array of surgical interventions of whom five possible surgical interventions are described in these pages (Figure 4).

1. Anterior pelvic exenteration (APE): an en-bloc resection of the bladder and reproductive organs (prostate and seminal vesicles in males; uterus, vagina and cervix in females). Patients undergoing this procedure are left with a urostomy.

2. Posterior pelvic exenteration (PPE): an en-bloc resection of rectum and reproductive organs, with bladder preservation; these patients are left with an end colostomy.
3. Total pelvic exenteration (TPE): a complete resection of rectum, bladder, reproductive organs and regional lymph nodes; leaving patients with both an end colostomy and urostomy (123).
4. Pelvic exenteration with bone excision: the sacrum, coccyx, pubic bone or ischium is resected together with a combination of PPE or TPE. En-bloc resection of the bony structures typically occurs following completion of the initial multi-visceral resection (Figure 6).
5. Extended lateral pelvic sidewall excision (ELSIE); a lateral compartment excision involving major neurovascular structures including iliac vessels, pelvic autonomic nerves and ureters, which extends through the greater sciatic foramen with or without invading sciatic nerve (124).

However, the techniques for PE surgery have been developed in individual centres with significant heterogeneity in terms of describing individual operations (125). The development of the validated ‘pelvic exenteration lexicon’ now permits standardised reporting of a heterogeneous group of procedures aimed at the complete clearance of LARC and LRRC allowing the description of the individual surgical components of extended pelvic cancer resections and exenterations (126).

In TPE, and to a lesser extent PPE, the radical dissection, leaves a large defect in the perineum, which generally requires surgical reconstruction.

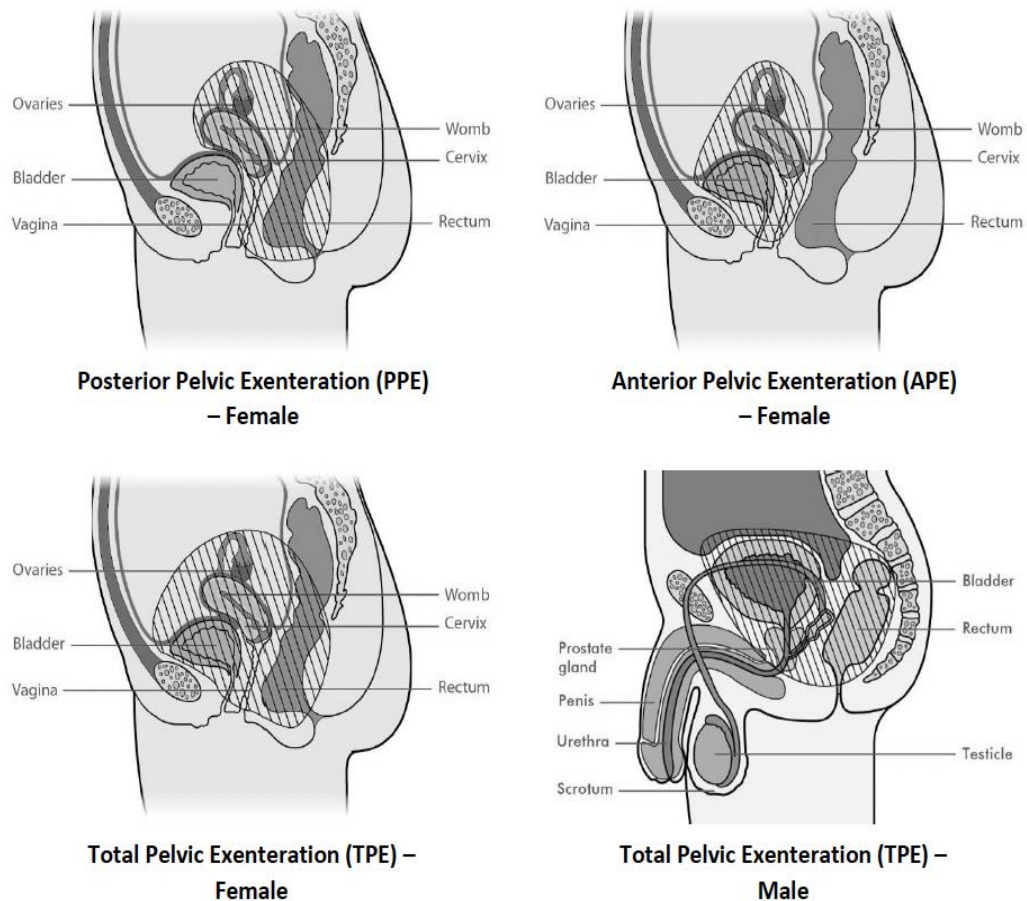


**Figure 4. Various subtypes of pelvic exenteration**

Metastatic disease within the liver and lungs is no longer a contraindication to radical bowel surgery with curative intent, provided the distant disease is potentially resectable with a metastectomy. Patients with single, well localised liver metastases have the highest chance of cure. The treatment aim should be for rapid local control with effective systemic chemotherapy and appropriate sequence/timing of metastectomy.. There are no randomised studies to guide treatment in this scenario, so MDT discussion should guide decision making in this situation (66).

#### **1.4.2 Perineal reconstruction**

Perineal defects are common following PE and may require reconstruction using flaps to close the defect. Reconstructive techniques provide quicker recovery and better quality of life outcomes (127). Options for reconstruction are influenced by the resection required, neoadjuvant treatment, patient comorbidities, prognosis, and surgeon preference (128). There is currently no consensus in the literature on the ideal technique for perineal reconstruction with various techniques being utilised (129-131). Flaps can be classified by their composition, vascularity, movement, and proximity to

the wound (132) Various techniques including myocutaneous (tissue flaps with a solitary vascular supply incorporating skin, subcutaneous tissue, fascia, and the underlying muscle) and fasciocutaneous (tissue flaps that include skin, subcutaneous tissue, and deep fascia) flaps are used. For reconstruction to be successful, it requires well vascularised skin cover, with minimal local contamination and this is often performed with the use of a regional skin flap (133) (Figure 5).

Vertical Rectus Abdominus Myocutaneous (VRAM) Flap: utilises the rectus abdominus muscle with its supplying inferior epigastric vessels. The vertical incision allows the flap to be passed through the pelvis and rotated to fill the defect in the perineum (133) The use of this flap involves a large abdominal incision which needs to be tailored to fit around the stoma site that the patient will require (133).

Gracilis Flap (with or without vastus lateralis); utilises an area of skin between the perineum and thigh (involving the underlying gracilis muscle). This muscle provides the bulk to the defect, with bilateral flaps (from both thighs) often being required for larger defects (133).

Inferior Gluteal Artery Perforator (IGAP) Flap: utilises an area of skin used over the lower buttock that is supplied by the inferior gluteal artery perforator (133).

Anterolateral Thigh Gap (ALT) Flap: utilises the anteromedial thigh skin together with a combination with rectus femoris muscle, tensor fascia lata, anteromedial thigh skin, or the vastus lateralis muscle taking the blood supply from the descending branch of the lateral circumflex femoral artery (a branch from the profunda femoris artery) (134).

Internal Pudendal Artery Perforator (IPAT) Flap: a newer technique which utilises the skin and fascia lateral to the groin crease that is supplied from the perforators of the internal pudendal artery (135).

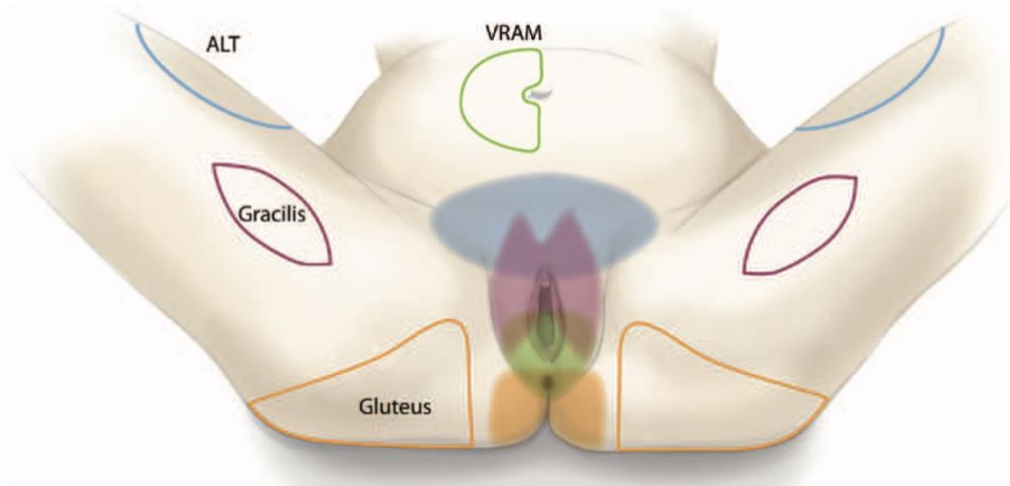


Figure 5. Schematic diagram from donor sites of flaps (116)

### 1.4.3 Multimodal treatments in LRRC

The evidence base for neoadjuvant treatment in LRRC is very limited. A multimodal approach of chemotherapy +/- RT in combination with operative intervention is probably important for the treatment of LRRC with curative intent (125). International consensus recommend LCRT for LRRC who are naive at diagnosis and should be considered for standard-dose, preoperative CRT (45–50 Gy in 5–6 weeks) prior to an attempt at resection (72).

The Association of Coloproctologists of Great Britain and Ireland (ACPGBI) suggest alternative treatment using short course preoperative chemoradiotherapy (SCPRT) followed by a fluoropyrimidine and oxaliplatin-based chemotherapy (136) to this cohort as used in the in the Polish-2 study for LARC (137). Single institution series suggest that SCPRT can be safely combined with triplet chemotherapy (capecitabine, oxaliplatin and bevacizumab) to facilitate the resection of borderline resectable liver metastases and the primary tumour (138) (139).

In patients previously irradiated, re-irradiation to lower doses (with concomitant chemotherapy) is safe and can be used in selected patients to facilitate a curative resection) (140) . Further RT in patients previously treated is contentious due to the concerns of potentially higher rates of morbidity and damage to normal structures with further radiation. As a result, various RT techniques have been developed to circumvent the potential hazards of additional delivery of external beam radiation, including, intraoperative radiotherapy (IORT), brachytherapy and image-guided RT.

However, there is currently very little evidence to support re-irradiation/ neoadjuvant chemotherapy for this cohort of patients and two ongoing phase III trials of these treatments are currently recruiting to determine whether re-irradiation and TNT should be the standard of care. The PelvEx II trial (NCT 04389088) is examining whether induction chemotherapy followed by chemoradiotherapy and surgery is superior to chemoradiotherapy followed by surgery (141). GRECCAR15 (NCT 03879109) compares 6 cycles of FOLFIRINOX chemotherapy followed by surgery with 6 cycles of FOLFIRINOX followed by re-irradiation with 30.6 Gy and then surgery (142).

#### **1.4.4 Prognosis**

The most important prognostic factor influencing OS after surgery is a clear resection margin (R0). Five-year OS benefit in those with clear margins (R0) versus those with microscopic residual disease (R1) vary between 48 and 58% (143-149) whereas those with microscopic residual disease (R1) have a 5-year survival of 10-18% (110, 146, 147, 149-152). Nodal involvement is the second key factor that impacts on survival (153-155). The PelvEx Collaborative Group (PelvEx) published large volume data from 27 centres across the world to establish overall outcomes for PE in LARC and LRRC evaluating 1291 and 1184 patients respectively (156, 157).

PelvEx reported patients with lymph node metastases had a 1.27 times greater hazard of death and a significantly reduced time to local recurrence (12 months vs. 21 months in node negative disease) (116). Those patients with node positivity had a worse median OS compared with those who were node negative (31 months vs 46 months) (116). The median OS of patients with LARC in R0 resection was 43 months with a survival benefit seen in subtypes of neoadjuvant therapy. Adjuvant CRT, RT alone, or chemotherapy alone had a median OS of 37 months, 53 months, and 33 months, respectively (Table 6) (116).

PelvEx also reported a median survival for patients with LRRC with R0 resection of 36 months, compared with 27 months after R1 resection and 16 months following R2 resection. Patients receiving neoadjuvant treatment had a better OS. Median OS for those receiving CRT, RT alone or chemotherapy alone was 32, 36 and 25 months respectively (Table 7) (156).



| LARC                  | Median OS (months) | 3-year OS (%) | 5-year OS (%) |
|-----------------------|--------------------|---------------|---------------|
| Margin status         |                    |               |               |
| R0                    | 43                 | 56.4          | 37.8          |
| R1                    | 21                 | 29.6          | 12.3          |
| R2                    | 10                 | 8.1           | <8.1          |
| Neoadjuvant treatment |                    |               |               |
| Yes                   | 36                 | 49.6          | 31.3          |
| No                    | 26                 | 39.9          | 23.5          |
| Nodal status          |                    |               |               |
| Yes                   | 31                 | 44.3          | 28.9          |
| No                    | 46                 | 58            | 39.7          |

**Table 6. PelvEx overall survival for LARC**

| LRRC                  | Median OS (months) | 3-year OS (%) | 5-year OS (%) |
|-----------------------|--------------------|---------------|---------------|
| Margin status         |                    |               |               |
| R0                    | 36                 | 48.1          | 28.2          |
| R1                    | 27                 | 33.9          | 17.3          |
| R2                    | 16                 | 15            | 3             |
| Neoadjuvant treatment |                    |               |               |
| Yes                   | 32                 | 43.5          | 25.6          |
| No                    | 27                 | 34.1          | 16.4          |
| Nodal status          |                    |               |               |
| Yes                   | 22                 | 21            | 11            |
| No                    | 29                 | 38            | 22.8          |

**Table 7. PelvEx overall survival for LRRC**

### 1.4.5 Outcomes

Irrespective of the intent of surgery, i.e. curative or palliative, surgery in this cohort of patients is associated with high post-operative burden. Morbidity and mortality have decreased significantly over the last 50 years. Post-operative mortality is quoted as less than 5% in recent studies, a considerable decrease on the 23% initially experienced by Brunschwig (115, 158-160), however, morbidity remains high due to the extensive nature of operative intervention. In 2019 the PelvEx collaborative reported a 30-day major complication rate of 37.8% following PE for LARC (116).

Potential morbidity includes bleeding, circulatory events, urinary, gastrointestinal and wound complications, infection and motor dysfunction. Extended pelvic resections are associated with a higher morbidity (161) including significant motor dysfunction, lymphoedema and lower limb ischaemia.

Patients with LRRC will also generally have poorer outcomes in comparison with primary LARC (162, 163). Patients with LRRC experience a lower quality of life (QoL) postoperatively and mixed comparisons with the two groups should be avoided (164). In surgery for LRRC thirty day post-operative morbidity is estimated between 15-68%, with pelvic sepsis and post-operative wound complications being the most common (165). Further intervention, either radiological or surgical is often required to adequately and effectively deal with post-operative complications.

Extensive surgery compromise's function. However, patients with unresected advanced pelvic malignancies also experience pain as a result of bone, nerve or muscle involvement. PE is a major undertaking yet the impact of this procedure on patients has not been widely studied. With 5-year survival as high as 65% in expert centres there are a growing number of PE survivors dealing with the effects of this radical surgery (163, 166, 167). Most of the published data on PE emanate from single centre retrospective case series with a focus on survival and surgical morbidity and mortality, survivorship is an area that has infrequently been addressed in the surgical literature to date. It is a life challenging surgery, leading to major changes that affect patient self-image. A few studies have reported that PE surgery can impact upon physical, psychological and social domains including, regret, trauma, ostomy challenges, body image, sexual function, relationships, social isolation, embarrassment/humiliation, work and finance (166, 168).

## **1.5 Decision making**

Patients with LARC and LRRC have different experiences about the health problem and views on treatment. Choosing the treatment option that is best for the patient means considering how the consequences of each treatment option will affect their life.

### **1.5.1 Informed Decision Making**

Informed decision making occurs when patients understand both the disease or condition under consideration and the implications of the related clinical care, including benefits, harms, limitations, alternatives, and uncertainties (169). Medical decisions have two components: a technical component, which requires knowledge of the risks, benefits, and side effects associated with each treatment option, and a value

component, which requires input from patients about their values and preferences (169).

Patients in the UK report being unprepared for the consequences of PE surgery (170). A qualitative study concluded that information about patient disease, treatment options and morbidity is incomplete at the time of consultation and that this unclear and insufficient communication between patient and physician results in overall poorer quality of life (171).

### **1.5.2 Shared Decision Making**

Shared Decision Making (SDM) between patients and clinicians represents the epitome of patient-centred care. Analysing and understanding evidence-based medicine whilst ensuring that the patient's intentions, values and preferences are considered during the decision-making process are fundamental to SDM. Incorporating patient input is important for all medical decisions and is essential for decisions about preference-sensitive conditions—those for which two or more valid treatment choices are available to most patients, even if one of those choices is to forgo treatment (169). A good decision is one that is informed, consistent with personal values, acted upon and with which patients are satisfied (172). For patients to be able to perform part of the integral decision they need clear, evidence based patient information (EBPI) that is easy to understand, informative and discusses the treatment options that include supportive care (173).

Clinical guidelines recommend that healthcare professionals should involve patients in decisions about treatment in order to make informed choices and inevitably attain informed consent (174). The Kings Fund Shared Decision-Making (SDM) document reports and clarifies the concept and outlines the actions needed to make the government's aspiration of SDM to become a norm (175). Policies to promote SDM are becoming prominent in the United States, Canada, and United Kingdom (176). This is partly because of a recognition of the ethical imperative to properly involve patients in decisions about their care and there is also growing evidence that patient involvement improves the quality of care, including patient satisfaction, patient decisional comfort and quality of life (177-180). SDM, where clinicians involve patients in healthcare decisions makes a potentially significant and enduring difference to healthcare outcomes.

For UK surgical practice, the Montgomery ruling in 2015 redefined the standard of informed consent and disclosure. It stipulates that there is a duty of care to ensure that the patient is aware of any material risks involved in any recommended treatment and of any reasonable alternative or variant treatment (181). The test of materiality is ‘where a reasonable person in the patient’s position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it’. In order to undergo SDM all material risks need to be discussed as each patient would attach different significance to the risks.

Provision of EBPI regarding options, benefits, risks, uncertainties together with decision support counselling facilitate patients to make a decision that reflects their own values and preferences. Openly discussing the illness in a supportive environment may be of primary importance in the cognitive processing of cancer and thus promoting adjustment (182) and inevitably long-term wellbeing. Anticipation of life following surgery may influence initial decision making for treatment.

## **1.6 Conclusion**

LARC and LRRC are complex disease processes. The issues affecting exenteration patients are multi-faceted and complicated. Treatment interventions can be different between patients and thus outcomes including morbidity, mortality, survival and health related quality of life (HrQoL) are variable. Informed decision making is a legal obligation however SDM is ultimately a benchmark for improving patient satisfaction and overall outcomes. Clinical data are limited and factors influencing decision making in PE need to be evaluated to ultimately improve overall outcomes.

## **Chapter 2. Quality of Internet Information to Aid Patient Decision Making in Locally Advanced and Recurrent Rectal Cancer**

### **2.1 Background**

LARC or LRRC with contiguous organ involvement can be a devastating disease. The symptoms patients experience are variable and are determined by the extent and type of contiguous organ invasion. Left untreated LARC and LRRC frequently result in severe pain as a consequence of bony, muscle or nerve involvement. Fistulation into the bladder or genitals can cause recurrent urinary tract infection or colovaginal/colocutaneous fistulation. The pressure effect of a sizeable pelvic mass can cause renal failure by ureteric obstruction (183). Untreated the prognosis is poor with median survival of less than one year and 5-year survival of 5% (88, 121) Pelvic Exenteration (PE) is a technically demanding procedure that is the only potentially curative treatment option. Advances in radiological imaging, clinical care, operative techniques and neoadjuvant treatments have led to considerable survival improvements in this cohort of patients in recent times (184).

The most important prognostic indicator is to achieve complete surgical resection (R0) (94, 149). Whilst R0 resection has consistently been reported as the most important determinant on survival, results from the international multi-centre PelvEx study on LARC found R0 rates were only achieved in 55.4% of patients (157). Several studies have shown that an R0 resection for LRRC were 55–80% translating to a 5-year overall survival of 28–50% (118, 185, 186). Whilst surgery can afford the possibility of cure, it is not without risk, with morbidity rates of between 37 and 100% (median 57%) and a perioperative mortality rate of between 0 and 25% (median 2.2%) (118). Whilst data on survival and surgical complication rates have been frequently reported there is a paucity of high-quality and robust data on the impact of PE on quality of life, functional outcomes and survivorship (118). The majority of data currently available is extrapolated from patients undergoing pelvic exenteration for gynaecological malignancy (163, 166, 167).

Decision-making whether to undergo PE is complex and potentially requires patients to make trade-offs between curative treatment, treatment-related morbidity, survival and QoL. It is therefore essential that the clinical complexity underlying PE is appropriately communicated to patients and reflected in the decision-making process.

Ensuring patients have clear, EBPI, that is easy to understand and discusses all treatment options is a key part of the decision-making process (173). SDM requires the provision of EBPI about options, outcomes and uncertainties, together with decision support counselling and a system for recording and implementing patients' informed preferences. SDM is viewed as an ethical imperative by the professional regulatory bodies that expect clinicians to work in partnership with patients, informing and involving them whenever possible. It is important for patients because they want to be more involved than they currently are in making decisions about their own health and health care (187). There is also compelling evidence that patients who are active participants in managing their health and health care have better outcomes than patients who are passive recipients of care. Effective SDM is not yet the norm and many patients want more information and involvement in decisions about treatment, care or support than they currently experience (175).

Whilst the general principles of SDM are well documented a lack of guidance exists about how to adopt the approach into routine clinical practice. One method to do so is through the use of patient decision aids (PtDA). The PtDA model comprises a three-step process which promotes SDM by introducing choice, describing treatment options and by helping patients explore preferences and make decisions. This model rests on supporting a process of deliberation, and on understanding that decisions should be influenced by exploring and respecting "what matters most" to patients as individuals (188). This exploration in turn depends on them developing informed preferences (188). A good decision for the patient is one that is informed, consistent with personal values, acted upon and one with which patients are satisfied (172). Interventions targeted at systems or practices to implement SDM (189, 190) exist for many treatments and many involve the dissemination of PtDAs for situations where there is no single "best" choice. PtDAs are being developed in many areas of healthcare, their perceived benefit is that they provide patients with a greater understanding of their medical treatment options and empower them to participate in their own health decision making (191). Supplementing patient-education consultations with decision tools improves knowledge about the risks and benefits of a procedure which may help a patient make decisions that are in line with their personal values.

The majority of the currently available literature written for rectal cancer patients is limited to primary rectal cancer predominantly earlier stage disease, with limited patient-level literature written specifically for PE. When there is a paucity of dedicated clinical literature available, patients often seek alternative sources of information, with the majority using the internet to seek health information (192, 193). Online internet resources may provide extensive and complex information however, due to the lack of a peer-review process, there is significant variation in the quality and consistency of the published literature.

## **2.2 Aims**

The aims of this chapter were to assess the quality, content and readability of online health-related information available to patients with LARC or LRRC contemplating PE.

## **2.3 Methodology**

### **2.3.1 Search strategy**

The systematic review was carried out in accordance with Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines. This literature search was registered on the PROSPERO database CRD42019122933. Searches were carried out by two researchers (AW) and (AC) with any conflicts resolved by a third party, (DH).

The Decision Aid Library Inventory (DALI) database (194) was searched for any decision aids for PE. Additionally, an online search was performed using the Google Search™ engine. Google™ was chosen because the majority of patients choose this as an initial starting point when looking for online health information (195). Searches were undertaken between the 8<sup>th</sup> January 2019 and 16<sup>th</sup> January 2019 using the following terms:

1. 'Information about pelvic exenteration'.
2. 'Patient decision aid for pelvic exenteration'.
3. 'Treatment for advanced rectal cancer'.
4. 'Treatment for recurrent rectal cancer'.
5. 'Information leaflet pelvic exenteration'.

6. 'Consent for pelvic exenteration'.
7. 'Decision making in pelvic exenteration'.

Search terms were selected based on variations of search terms the researchers' believed patients would use. Between searches the prior internet history, cache and cookies were appropriately deleted. The search results were limited to the first two pages, based on the assumption that internet users rarely go beyond the first page of search results (195). The articles were screened against the eligibility criteria and all duplicates removed.

### **2.3.2 Eligibility criteria**

#### **Inclusion criteria:**

- 1) Discussed surgical management of PE in LARC and LRRC.
- 2) Aimed at patients.
- 3) Written in English.

#### **Exclusion criteria:**

- 1) Academic sources aimed at healthcare professionals.
- 2) Advertisements sponsored by Google™.
- 3) Articles written in a foreign language.

### **2.3.3 Selection of studies**

Websites were viewed and screened for relevance; studies that did not meet the inclusion criteria were excluded. Sources assessed as potentially relevant were analysed further.

### **2.3.4 Data extraction**

Websites were viewed, screened for relevance and checked for eligibility according to the defined inclusion criteria by two researchers (AW) and (AC). Any conflicts between the two researchers were resolved by a third party, (DH). Data were extracted by both researchers using a predefined extraction spreadsheet on Excel® version (16.16.16).

Extraction data from relevant references included:



1. Website Descriptor: descriptors URL, upload source, country of origin, format of website, and purpose of website.
2. Health condition: classification of disease (LRRC, LARC).
3. Decision-making: Description of surgical options, description of oncological treatments, comparison of surgery versus no surgery, benefits and risks of surgery, and a description of the preoperative and recovery periods, length of recovery, prognosis, QoL, pain and complications.

These domains were extracted based on previous qualitative work undertaken with patients and experts.

### **2.3.5 Data quality**

The methodological issues surrounding the quality of the materials, assessing and measuring sources as a decision aid were considered. Due to only a few information sources being available, a pragmatic approach was used to include all sources that fulfilled the eligibility criteria, and a quality analysis was performed. Data quality was assessed using three validated scoring systems; DISCERN, IPDAS and the Flesch-Kincaid Reading Ease test.

#### **2.3.5.1 DISCERN**

The quality of written health information was assessed using the validated DISCERN tool (Appendix A) (196). DISCERN is a brief questionnaire which provides users with a valid and reliable way of assessing the quality of written information on treatment choices for a health problem. DISCERN consists of 15 key questions plus an overall quality rating. Each of the 15 key questions represents a separate quality criterion – an essential feature or standard that is an important part of good quality information on treatment choices. The tool is formed from 16 questions; eight (Q1-8) that assess the reliability of the publication, seven (Q9-15) that assess the quality of information on treatment choice and one (Q16) that provides the overall rating of the quality of information (196).

Each question rates the information on a 5-point scale and is divided into poor (1-2), moderate (3) and excellent (4-5) quality scores. The rating scale helps to decide whether the quality criterion in question is present or has been 'fulfilled' by the publication. The global score indicates the assessor's overall conclusion of the quality

of the source in providing written health information and can only be scored a 1, 3, or 5.

The general guidelines are as follows:

- 5 is given if the answer to the question is a definite 'yes' - the quality criterion has been completely fulfilled.
- Partially (2-4) is given if the publication being considered meets the criterion in question to some extent. How high or low 'partially' is rated will depend on the judgement of the extent of these shortcomings.
- 1 is given if the answer to the question is a definite 'no' - the quality criterion has not been fulfilled at all (196).

#### 2.3.5.2 International Patient Decision Aid (IPDAS) scores

All identified patient information sources were scored using the International Patient Decision Aid (IPDAS) collaboration criteria (197) to assess their ability to guide patient decision-making. IPDAS was established in 2003 by establishing a shared evidence informed framework to guide developers and researchers in their development, content evaluations and implementation. Initially it formed a 74-item checklist and development over the years have resulted in the publication of a 44-item minimum standards for PtDA certification (IPDASi) This tool assesses the quality of PtDAs in terms of their development process and shared decision-making design components (198). The IPDASi assessment of PtDAs is reported in three categories: Qualifying (6 items), Certifying (10 items) and Quality (28 items) (Appendix B).

|               |                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|---------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Qualifying    | <p>Describes health condition or problem for which index decision is required.</p> <p>Explicitly states decision under consideration (index decision).</p> <p>Describes the options available for the index decision.</p> <p>Describes the positive features of each option.</p> <p>Describes the negative features of each option.</p> <p>Describes the features of options to help patients imagine the physical, social and/or psychological effects.</p> |
| Certification | <p>Shows positive and negative features of options with equal detail.</p> <p>Provides information about the funding source used for development.</p> <p>Provides citations to the evidence selected.</p> <p>Provides a production or publication date.</p> <p>Provides information about uPtDAte policy.</p> <p>Provides information about the level of uncertainty around outcome Probabilities.</p>                                                        |

|  |                                                                                                                                                                                                                                                  |
|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | Describes what the test is designed to measure.<br>Describes next steps taken if test detects a condition/ problem.<br>Describes next steps if no condition/problem detected.<br>Describes consequences of detection that would not have caused. |
|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**Table 8. Qualifying criteria of IPDASi assessment**

The qualifying criteria is required for an intervention to be considered a decision aid. The certifying criteria ensures the decision aid has no harmful bias. The 28 item quality criteria are believed to strengthen a decision aid but whose omission does not present a high risk of harmful bias (197). Only Qualifying and Certifying domains are mandatory to define a decision aid therefore sources were judged solely on these domains (Table 8). Items 7-10 in the certifying criteria were not applicable due to its relevance for screening tests and therefore were excluded from analysis. The maximum score was 12.

### 2.3.5.3 Flesh-Kincaid Reading Score

Readability was assessed using the Flesch-Kincaid reading ease score using an online tool (199, 200). Readability is scored 0-100 and corresponds inversely with school years. The results of the Flesch-Kincaid Reading Ease test are not immediately meaningful, therefore a conversion table is needed to make sense of the score (200) (Table 9). The Flesch-Kincaid Grade Level score was therefore used, that calculates a score that is proportional to school years i.e. grade 1 equates to age 6-7, grade 2 equates to age 7-8 etc. The results of the two tests correlate inversely: a text with a comparatively high score on the Reading Ease test should have a lower score on the Grade-Level test. Patient information is recommended to be written at a level of a 14 year old (201).

| Flesch-Kincaid Score | Flesch-Kincaid School level US | Age (years) | Notes                                                                   |
|----------------------|--------------------------------|-------------|-------------------------------------------------------------------------|
| 100.00-90.00         | 5th grade                      | 10-11 years | Very easy to read. Easily understood by an average 11-year-old student. |
| 90.0-80.0            | 6th grade                      | 11-12 years | Easy to read. Conversational English for consumers.                     |
| 80.0-70.0            | 7th grade                      | 12-13 years | Fairly easy to read.                                                    |
| 70.0-60.0            | 8th & 9th grade                | 13-15 years | Plain English. Easily understood by 13- to 15-year-old students.        |
| 60.0-50.0            | 10th to 12th grade             | 15-18 years | Fairly difficult to read.                                               |

|           |                  |     |                                                                  |
|-----------|------------------|-----|------------------------------------------------------------------|
| 50.0–30.0 | College          | >18 | Difficult to read.                                               |
| 30.0–0.0  | College graduate | >21 | Very difficult to read. Best understood by university graduates. |

**Table 9. Conversion of Flesch Kincaid reading ease to school level**

## **2.4 Results**

### **2.4.1 The Decision Aid Library Inventory (DALI) database**

The Decision Aid Library Inventory (DALI) database (194) was searched for any decision aids for PE and this found zero results.

### **2.4.2 Systematic review**

An online search yielded 27,782,200 potential resources, of which 131 sources fulfilled the eligibility criteria, 32 resources were duplicates and 19 were considered to be advertisements. Eighty resources were assessed in full. Seventy-four sources were excluded for the following reasons: 22 sources did not mention PE within the information, 24 sources were not aimed at LARC or LRRC, 25 sources were not aimed at patients and three sources had inaccessible websites at the time of analysis. Six resources were included in this systematic review (Figure 6 & Table 10).

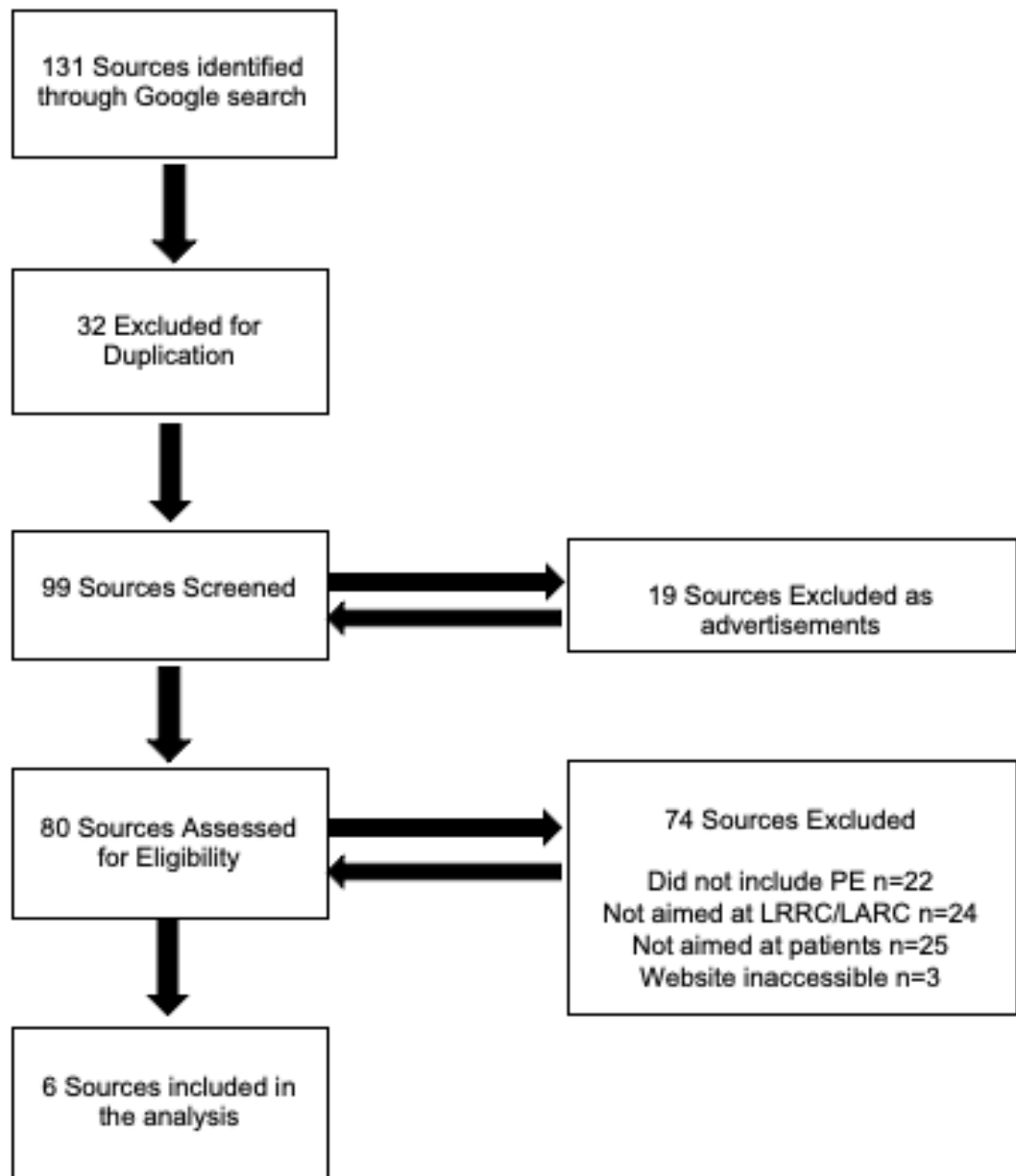


Figure 6. PRISMA flowchart of study selection

| Source                                                                            | Title of website                                                                 | Format | Country | Name of Uploader                              | Upload source type              |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------|--------|---------|-----------------------------------------------|---------------------------------|
| <a href="http://www.cancer.ca">http://www.cancer.ca</a>                           | Pelvic exenteration:<br>Information for<br>patients and their<br>families/carers | HTML   | Canada  | Canadian cancer charity                       | Cancer charity                  |
| <a href="https://www.ouh.nhs.uk">https://www.ouh.nhs.uk</a>                       | Pelvic exenteration information                                                  | PDF    | UK      | Oxford University Hospitals NHS<br>Foundation | Hospital/ specialty association |
| <a href="https://www.texasoncology.com">https://www.texasoncology.com</a>         | Recurrent rectal cancer                                                          | HTML   | US      | Texas Oncology                                | Hospital/ specialty association |
| <a href="https://www.mdanderson.org">https://www.mdanderson.org</a>               | Locally recurrent rectal cancer                                                  | HTML   | US      | MD Anderson Cancer Centre                     | Hospital/ specialty association |
| <a href="http://cancer.unm.edu">http://cancer.unm.edu</a>                         | Recurrent rectal cancer                                                          | HTML   | US      | Comprehensive cancer centre                   | Cancer centre                   |
| <a href="http://www.stmarkshospital.nhs.uk">http://www.stmarkshospital.nhs.uk</a> | complex cancer surgery for men                                                   | PDF    | UK      | London Northwest Healthcare<br>Trust          | Hospital/ specialty association |

**Table 10. Eligible sources identified from the systematic review**

The six eligible sources were designated webpages, of which 4 were HTML and 2 were PDF format. The sources were: 1) Canadian Cancer Charity; 2) Oxford University Hospitals NHS Foundation Trust; 3) Texas Oncology; 4) MD Anderson Cancer Centre; 5) Comprehensive Cancer Centre; 6) London Northwest Healthcare Trust (Table 10) (202-206). Patient targeted information was uploaded by four hospital/specialty associations, one specialist cancer centre and one cancer charity (Table 10).

### **2.4.3 Available information**

All sources provided information about LRRC or LARC, with three resources focusing specifically on LRRC (Table 11). Description of surgical options and oncological treatments were reported in the majority of sources (n=5). Five resources provided an outline of oncological treatments, however, only one resource provided comparative outcomes between surgical and non-surgical treatments. Important outcomes related to treatment including, benefits and risks of surgery, description of the preoperative and recovery periods, length of recovery, quality of life and pain had poor coverage across the identified resources.

Each source was scored individually to assess the percentage of decision-making domains discussed. For the purpose of this, classification of disease was excluded from the analysis as it was essential within the inclusion criteria and no discrepancy could be made between addressing either or both LRRC and LARC. This illustrated a significant discrepancy between each source (Table 12).

| Decision Making Domain                               | SOURCE                  |                                            |                |                           |                             |                                   |
|------------------------------------------------------|-------------------------|--------------------------------------------|----------------|---------------------------|-----------------------------|-----------------------------------|
|                                                      | Canadian Cancer Charity | Oxford University Hospitals NHS Foundation | Texas Oncology | MD Anderson Cancer Centre | Comprehensive Cancer Centre | London Northwest Healthcare Trust |
| Classification of disease                            | LARC<br>LRRC            | LARC<br>LRRC                               | LRRC           | LRRC                      | LRRC                        | LARC<br>LRRC                      |
| Description of surgical options                      | √                       | x                                          | √              | √                         | √                           | √                                 |
| Description of oncological treatments                | x                       | √                                          | √              | √                         | √                           | √                                 |
| Comparison surgery vs no surgery                     | x                       | x                                          | x              | x                         | x                           | √                                 |
| Benefits and risks of surgery                        | √                       | x                                          | x              | x                         | x                           | √                                 |
| Description of the preoperative and recovery periods | x                       | √                                          | x              | x                         | x                           | √                                 |
| Length of recovery                                   | x                       | √                                          | x              | x                         | x                           | √                                 |
| Prognosis                                            | x                       | x                                          | x              | x                         | x                           | x                                 |
| Quality of life                                      | √                       | x                                          | x              | x                         | x                           | √                                 |
| Pain                                                 | x                       | √                                          | x              | x                         | x                           | √                                 |
| Complications                                        | √                       | √                                          | x              | x                         | x                           | √                                 |

**Table 11. Decision making domains discussed within the identified source**

| Sources                     | Canadian Cancer Charity | Oxford University Hospitals NHS Foundation | Comprehensive Cancer Centre | Anderson Cancer Centre | Texas Oncology | London Northwest Healthcare Trust |
|-----------------------------|-------------------------|--------------------------------------------|-----------------------------|------------------------|----------------|-----------------------------------|
| Total domains discussed (%) | 40%                     | 50%                                        | 20%                         | 30%                    | 20%            | 90%                               |

**Table 12. Percentage of domains discussed within the identified sources**

#### **2.4.4 Quality of internet sources**

Overall, the quality of identified internet sources was of poor to moderate quality based on the combined DISCERN, IPDAS and Flesch-Kincaid scores (Table 13).



| Identified Source                          | Overall DISCERN Score | IPDAS Score | IPDAS Criteria Coverage (%) | Flesch-Kincaid Reading ease | Flesch-Kincaid Reading ease grade equivalent | Flesch-Kincaid Reading Grade level |
|--------------------------------------------|-----------------------|-------------|-----------------------------|-----------------------------|----------------------------------------------|------------------------------------|
| Canadian Cancer Charity                    | 3                     | 2           | 17                          | 53.5                        | 10 – 12                                      | 7.5                                |
| Oxford University Hospitals NHS Foundation | 3                     | 3           | 35                          | 80.8                        | 6                                            | 3.5                                |
| Texas Oncology                             | 3                     | 4           | 25                          | 48.2                        | College                                      | 7.8                                |
| MD Anderson Cancer Centre                  | 3                     | 3           | 25                          | 40.9                        | College                                      | 9.3                                |
| Comprehensive Cancer Centre                | 3                     | 4           | 35                          | 32.5                        | College                                      | 9.7                                |
| London Northwest Healthcare Trust          | 3                     | 5           | 42                          | 79.7                        | 7                                            | 3                                  |

**Table 13. Summary scores on quality of internet information**

#### **2.4.4.1 DISCERN**

The overall quality of the written information provided by all information sources was moderate, with all sources scoring a global DISCERN tool score of 3 (Figure 7). Identified internet sources performed poorly with regards to identifying clear aims (n=4) , highlighting appropriate sources used in their development (n=3) and their publication date (n=4) , referring to areas of uncertainty (n=3), clear description of risks (n=3) and benefits (n=3) associated with treatments, no description of outcomes associated with no treatment (n=5) and no provision of support for shared-decision-making (n=6).

Areas where the identified resources performed well included; relevance (n=5), provision of balanced and unbiased information (n=5), provision of additional sources of support and information (n=4) and highlighting more than one treatment choice (n=4).

Reliability and the quality of sources were analysed separately (Table 14). Despite the overall quality of the written information provided by all information sources was moderate, there was a wide range in the quality of information (range 31%-63%). The reliability also varied significantly between each source (range 45-85%).

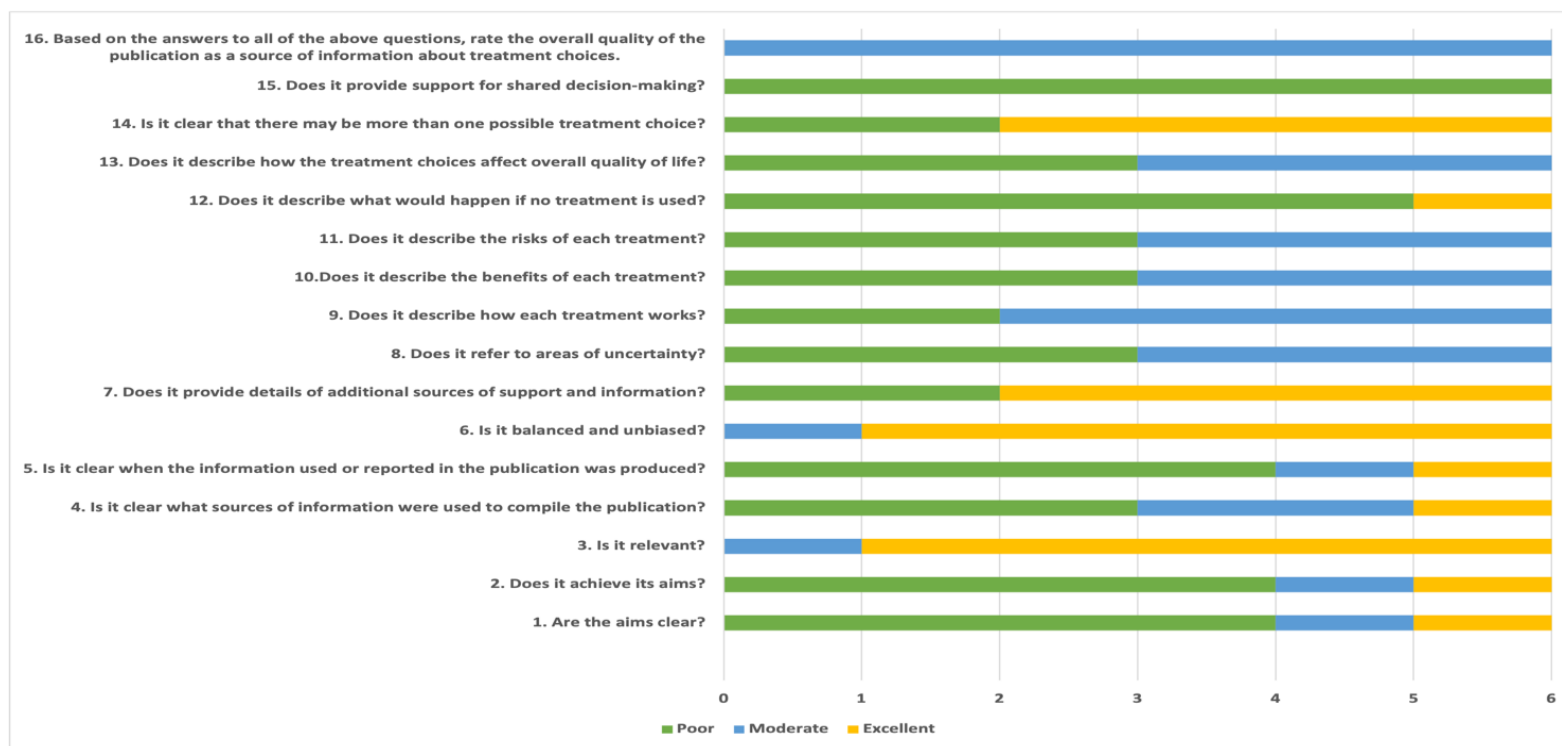


Figure 7. Overall DISCERN scores

|                                                            | Canadian Cancer Charity | Oxford University Hospitals NHS Foundation | Texas Oncology | MD Anderson Cancer Centre | Comprehensive Cancer Centre | London Northwest Healthcare Trust |
|------------------------------------------------------------|-------------------------|--------------------------------------------|----------------|---------------------------|-----------------------------|-----------------------------------|
| Q 1-8: reliability of the publication (max 40)             | 27 (68%)                | 19 (48%)                                   | 20 (50%)       | 18 (45%)                  | 20 (50%)                    | 34 (85%)                          |
| Q9-15: quality of information on treatment choice (max 35) | 12 (34%)                | 13 (37%)                                   | 14 (40%)       | 11 (31%)                  | 14 (40%)                    | 22 (63%)                          |
| Total (max 75)                                             | 42 (56%)                | 35 (47%)                                   | 37 (49%)       | 32 (43%)                  | 37 (49%)                    | 59 (79%)                          |

**Table 14. DISCERN score of each source identified**

#### **2.4.4.2 International Patient Decision Aid Standards (IPDAS)**

The quality of all identified sources was poor when assessed against the IPDAS criteria, with a median score of 3.5 (range 2-5) and a percentage domain coverage of 17-42%. Figures 8 and 9 highlight the coverage of the internet sources across the IPDAS criteria for the Qualifying and Certifying domains. Across the qualifying domain the only criteria fulfilled by all 6 sources was the description of the health problem, with only three sources explicitly describing the index decision in question and its associated treatment options (Figure 8). There was no coverage of the positive and negative features associated with treatments across the six sources and only two sources provided any patient level descriptors on the physical, social and psychological impact of treatments. For the certification domain the identified sources only covered three out of the six criteria; provision of citations for the selected evidence, provision of a publication date and provision of an update policy. There was no coverage of criteria describing equal discussion of positive and negative features associated with different treatment options, detail regarding funding sources and provision of data on uncertainty associated with outcomes.

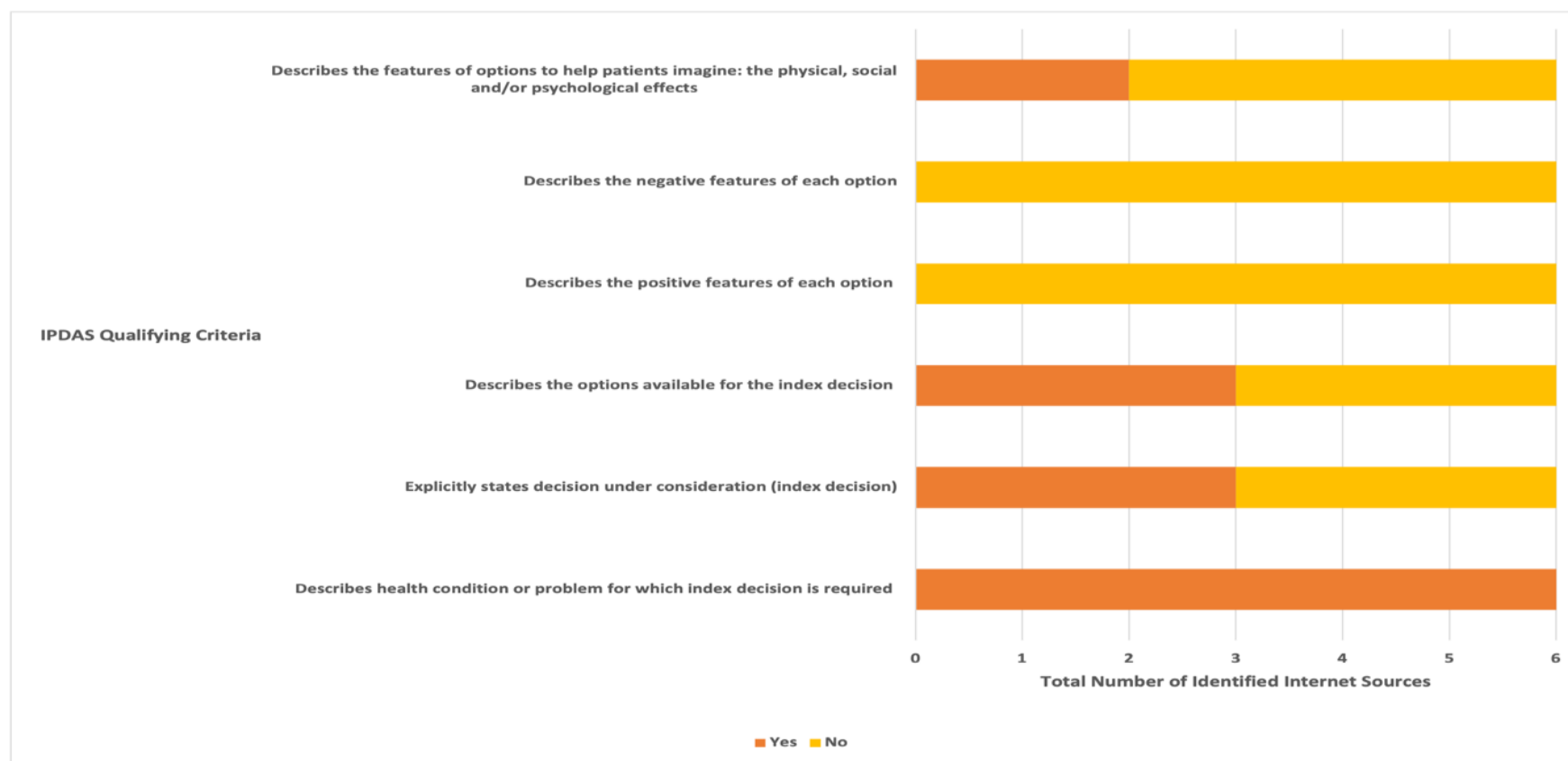


Figure 8. IPDAS Qualifying criteria

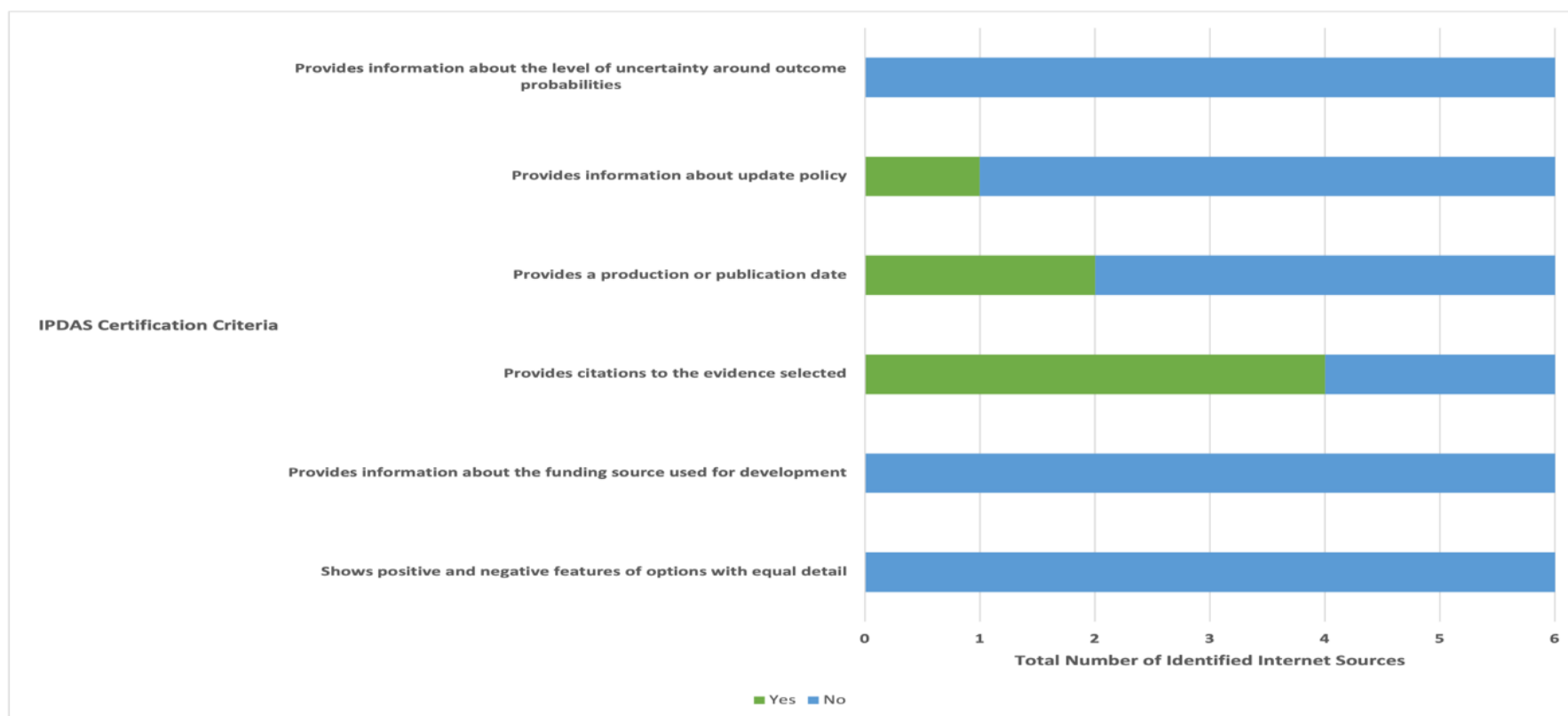


Figure 9. IPDAS Certification criteria

#### 2.4.4.3 Readability

The overall readability of the identified resources was considered to be high, with a median Flesch-Kincaid reading ease score of 50.85 (32.5 – 80.8). This equates to a school grade of 10-12 (year 11-13) and a reading age of age 15-18 years. The median Flesch-Kincaid grade level score was 7.65 (range 3-9.7), which equates to a reading age of 13-14 and school grade of 8 (year 9) (Table 15).

|                                                    | Canadian<br>Cancer<br>Charity | Oxford<br>University<br>Hospitals<br>NHS<br>Foundation | Texas<br>Oncology | MD<br>Anderson<br>Cancer<br>Centre | Comprehensive<br>Cancer Centre | London<br>Northwest<br>Healthcare<br>Trust |
|----------------------------------------------------|-------------------------------|--------------------------------------------------------|-------------------|------------------------------------|--------------------------------|--------------------------------------------|
| Flesch Kincaid<br>Reading ease                     | 53.5                          | 80.8                                                   | 48.2              | 40.9                               | 32.5                           | 79.7                                       |
| Flesch Kincaid<br>Reading ease<br>grade equivalent | 10-12                         | 6                                                      | College           | College                            | College                        | 7                                          |
| Flesch Kincaid<br>Reading Grade<br>level           | 7.5                           | 3.5                                                    | 7.8               | 9.3                                | 9.7                            | 3                                          |

**Table 15. Flesch Kincaid reading ease and grade for each source identified**

## 2.5 Discussion

The current online information available for patients considering PE surgery for LARC or LRRC is limited and fails to adequately capture the complexity and nuances of decision-making in this complex clinical arena. This chapter highlights six online resources, which are of poor quality. This emulates poor quality online health information about other conditions including perianal Crohn's fistulae (207), ulcerative colitis (208), breast surgery (209) and full thickness rectal prolapse surgery (210). These online resources do not adequately aid patient-decision-making, as reflected by their low DISCERN and IPDAS scores. Furthermore, these resources fail to comply with current recommendations to ensure ease of readability for patients and therefore, are generally considered unsuitable for all patient use.

The majority of resources highlighted by this review focus on the key clinical aspects of surgery, providing detailed information on the surgical aspects of PE and complimentary oncological treatments. This largely represents surgical decision-making in rectal cancer and fails to appropriately address patient priorities (211) (212) (213). Patients searching for online information on PE are likely to be taking active decisional control regarding their health and treatment choice and are seeking detailed

information regarding their diagnosis, treatment and prognosis (214). Two-thirds of patients go online to seek health information (215, 216) and previous work has shown the majority of patients choose Google<sup>TM</sup> as a starting point when looking for online health information (195). Surgeons are encouraged to allow time for patients to read further material on their condition and treatment, including accessing online information.

SDM is driven by the duties for NHS Wales and England set out in the NHS Act 2006 as amended by the Health and Social Care Act 2012 to promote individual participation in decisions about care, treatment; promote patient choice; and exercise its functions with a view to securing continuous improvement in the quality of services (217). Our identified resources failed to address SDM which reflects Coulter's findings that there remains confusion about why it is important, what it involves and what the implications might be for patients, clinicians and the wider health service (175) .

Patient priorities and information needs in PE are complex and centre around the consequences of cancer and treatment choices (218), including their physical impact and the overall impact on QoL. Our identified resources failed to adequately address key patient information needs with the majority (n=4) of internet resources failing to provide adequate information on risks associated with surgery, data on post-operative recovery, post-operative pain and impact on quality of life. This is further supported by the DISCERN scoring with a number of resources lacking adequate detail regarding treatment risk and benefit, treatment-related outcomes and a lack of acknowledgement regarding areas of uncertainty. This is reflective of clinical practice (219), with Steel et al, reporting that patients undergoing extended resection for colorectal cancer were adequately informed regarding the clinical aspects of treatment during pre-operative counselling with clinicians, however, were inadequately informed about treatment outcomes, recovery and lifestyle adjustment following surgery (220).

This work contributes to the growing body of evidence that high-quality, procedure-specific, patient-level information is required pre-operatively for patients undergoing complex pelvic surgery (171, 220, 221). Previous work by Wright et al highlighted the need for repeated, high-quality, accessible and understandable patient level information for patients undergoing extended pelvic resection for LARC and LRRC

(171). Similarly, Nelson et al, reported the need for ‘preparedness’ through high quality information pre-operatively in women undergoing pelvic exenteration for gynaecological malignancy (166). Providing patients with dedicated literature, which aids decision-making is associated with reduced uncertainty, decisional conflict and decisional regret and improved decisional quality (222). The current online resources identified do not adequately aid patient-decision-making, as reflected in the globally poor IPDAS scores and the failure of all resources to adhere to the DISCERN criteria of providing support for SDM, and therefore do not appropriately contribute to the decision-making process. This is likely a reflection of the design of the identified online resources, with the focus largely placed on clinical aspects of PE, a lack of information on broader outcomes of importance to patients and the relatively high level of literacy required to understand the online information, due to its excessively high readability score. It is clear that co-design with patients is required to improve the quality, content and readability of online resources.

The UK’s National Institute of Clinical Excellence (NICE) have developed 39 decision aids with surgical coverage of orthopaedics, gynaecology, melanoma and breast. The majority of these decision aids have been developed for medical use in diabetes, atrial fibrillation, coronary heart disease and stroke, heartburn, osteoporosis, rheumatoid arthritis (RA), endometriosis, urinary tract infections and dementia. PtDAs have been developed for hip and knee osteoarthritis (OA), stress incontinence, vaginal vault and uterine prolapse, lymphadenectomy and sentinel lymph node biopsy (SLNB) for melanoma, breast cancer radiotherapy and tamoxifen. The DALI holds six PtDAs for colorectal cancer, none of which are relevant for a cohort of patients contemplating PE or the index decision (194):

- Making decisions: Should I have a screening test for bowel cancer? University of Sydney
- Colon cancer: Which screening test should I have? Healthwise
- Should you have a test to screen for bowel cancer? Making decisions: Choices for men aged 55-64 years. University of Sydney
- Should you have a test to screen for bowel cancer? Making decisions: Choices for women aged 55-64 years. University of Sydney



- The fecal occult blood test (FOBT) to screen for colorectal cancer; La recherche de sang occulte dans les selles pour dépister le cancer colorectal Université Laval
- Understanding genetic tests for Lynch syndrome: Information and decision aid. Centre for Genetics Education, NSW Health

Despite the increasing acceptance and use for PtDAs there is little development of literature for surgery in rectal cancer. This may be due to the initial reluctance of surgeons to use such material however the emerging evidence of their benefit is indisputable (223). The development process of a decision aid is a long process, however, education to develop PtDAs has improved. The Ottawa Patient Decision Aid Development group have developed online, self-guided tutorials to guide people through the Ottawa patient decision aid development process. The IPDAS Collaboration has established and widely published an internationally approved set of criteria to determine the quality of PtDAs. Reporting Guidelines, Standards for UNiversal reporting of patient Decision Aid Evaluation (SUNDAE) studies, has been established for authors and researchers designing and reporting on studies evaluating PtDAs. All these recent developments together with emerging evidence of the benefit of decision aids may improve the development of further decision aids within surgical subspecialties.

Online patient resources provided by charitable organisations and healthcare organisations must contain high quality and relevant clinical content, whilst adhering to quality standards. However, it is important to acknowledge their role as an adjunctive to SDM within the clinical setting. It is clear from the review presented in this chapter that the aims of these resources are to provide patient-level information, with very limited role in aiding decision-making. Patient decision-making is a complex entity and requires appropriate, evidence-based information on treatment options and outcomes, coupled with a value-based assessment of patient preferences and priorities. There is emerging interest in improving the process and quality of decision-making in rectal cancer, balancing clinical priorities with QoL and functional outcomes. This can be potentially done in a number of ways, including, through the use of PtDAs and exploration of patient preferences. Wu et al explored the feasibility of implementing a decision-aid for patients with mid- or low rectal cancer in clinical practice (224-226).

They reported the use of a patient-decision aid was associated with improved patient knowledge and reduced decisional conflict (226). Kunneman et al explored patient preferences and values in when considering pre-operative radiotherapy in rectal cancer and found increased active engagement in the decision-making process by patients when their values and preferences were appropriately voiced and considered (227) .

Improved outcomes using SDM have also been observed amongst other healthcare conditions. In mental health it has been shown to result in better outcomes, including help-seeking behaviour (228) increased compliance with decisions (229), reduction in errors (230), and reduced stigma and increased involvement (231). In lung cancer and colorectal cancer Kehl et al. observed patients describing physician-controlled (rather than shared) decisions were less likely to report excellent quality of care (232). Similarly, Shabason et al. described patients experiencing SDM for radiotherapy treatment, were more likely to report feeling very satisfied with treatment (233). Integrating these strategies into existing patient resources will potentially help improve their utility and improve the process of decision-making.

Key limitations of this work include the search terms were devised by two researchers and incorporation of PPI may have resulted in different search terms which may have limited the number of sources identified in this study. Limitation to the English language alone may also contribute to the identification of such few resources. The use of one search engine and a limited number of internet pages may also have resulted in a small number of sources and potentially expanding our search strategy, use of other search engines and not limiting to the first 2 pages may have led to the identification of further resources.

## **2.6 Conclusion**

This work demonstrates the paucity of high-quality patient information to aid decision-making in PE LARC or LRRc. This work uses robust measures to benchmark current resources against, using a number of validated criteria reflecting the quality and readability of the written information, as well as its ability to aid in the decision-making process.

## **Chapter 3. Qualitative review of patient information needs based on online forums**

### **3.1 Background**

Traditionally, patients undergoing PE receive the majority of the information regarding their diagnosis, treatment and prognosis from their surgeon. The focus of this information is largely the clinical aspects of the disease and treatment, with limited emphasis on patients' emotional wellbeing and daily life (234) (Chapter 2). However, it is well recognised that patients increasingly use electronic media to obtain medical information and advice (235). One out of four Europeans search the Internet to receive information about health, and more than 40% consider this a reliable way to obtain information (236). In 2019, 93 % of UK households had internet access, and 63 % of adults reported using the internet for health-related information (237).

There is limited dedicated online health information that relates to PE for LARC or LRRC (Chapter 2), therefore patients are likely to seek information regarding the broader aspects of their care, including diagnosis or treatment options using alternative information sources, such as online health communities (238). Patients diagnosed with cancer, commonly use online forums to search for disease-related information, supportive communication, practical tips on daily living with cancer, to gain more about their disease, including diagnosis and treatment as well as other broader health issues (239-241).

Previous studies have reported 33% of internet users contribute to an online forum (242). Online discussion forums are websites that allow forum users to make contributions to discussions, including posting questions for informal answers and discussion (243) and to share experiences, concerns and ideas. They can serve as a socially constructive learning tool (244) and can facilitate collective knowledge-building and management (245, 246). Online forums function by enabling individuals to engage in supportive interactions with others facing similar experiences, challenges, or problems (247). They provide a forum of peer-to-peer learning, with users valuing these forums as a way of accessing emotional and informational support from others undergoing a similar experience (248-250) by easing patient distress via regular social interactions and emotional support shared with fellow patients (251, 252). The social cure theory hypothesises that identifying with a group of like-minded people helps individuals adapt to the role of illness in their lives, acting as a buffer from stressful

life events and becoming a ‘social cure’ to ease distress (253). It also enables individuals to receive informational and emotional support whenever they wish rather than waiting for a scheduled appointment (254).

Thus, unmet informational needs lead to the use of online forums. Meeting information needs increases treatment satisfaction (255) and aids informed decision making (256). Patient information has been found to be one of the most important factors of patient-centred care (257, 258) and impacts patient-reported outcomes (259-261). Most cancer patients want to be given all available information about their condition whether good or bad (262, 263). Unmet information needs are believed to increase emotional distress, anxiety, depression and subsequently to hamper patients’ adjustments to their illness.

The evidence base regarding the effectiveness of online cancer support is modest but positive (264). The online community use has been reported as a positive experience amongst small samples of cancer survivors in controlled community settings (265, 266). Online community participation has been linked to increased positive coping (267, 268). Communities allow individuals to share information resources and discuss their treatment-related decisions (269). Therefore, communities may act as an additional health engagement resource in oncology (270). Discussion forums and blogs provide a potentially rich source of data and insight into the complexities of decision-making in PE for patients with LARC and LRRC.

## **3.2 Aims**

The aim of this chapter is to undertake a narrative review of informational needs for patients undergoing or considering pelvic exenteration based on their use of online patient forums.

## **3.3 Methodology**

### **3.3.1 Search Strategy**

A Google search was performed independently by the PhD candidate (AW) and another clinical colleague (AWd), to identify patient internet forums discussing PE in English using the following search terms:

- ‘Pelvic exenteration discussion group AND rectal cancer’.
- ‘Pelvic exenteration discussion forum AND rectal cancer’.

- ‘Pelvic exenteration locally advanced rectal cancer discussion forum’.
- ‘Pelvic exenteration locally recurrent rectal cancer discussion forum’.
- ‘Pelvic exenteration locally advanced rectal cancer discussion group’.
- ‘Pelvic exenteration locally recurrent rectal cancer discussion group’.

Search terms were selected based on variations of search terms the researchers’ believed patients would use. Between searches the prior internet history, cache and cookies were appropriately deleted. Search results for the first two pages were used based on the fact that internet users rarely go beyond the first page of search results (195). The articles were screened against the eligibility criteria. Internet forums that were freely accessible by all members of the public and were in English were selected for inclusion into this study.

### **3.3.2 Eligibility criteria**

#### **Inclusion criteria:**

Identified sources were included in the study if the following criteria were fulfilled:

- 1) Discussed PE.
- 2) Freely accessible by all members of the public.
- 3) Written in English.

#### **Exclusion criteria:**

Sources were excluded from the study if any of the following criteria applied:

- 1) Subscription forums.
- 2) Private discussion forums.
- 3) Required login for access.

### **3.3.3 Selection of literature**

Websites were viewed and screened for relevance independently by both researchers. Any conflicts that arose were resolved by the clinical PhD supervisor (DH). Sources that did not meet the eligibility criteria were excluded. Sources assessed as potentially relevant were analysed further.

### **3.3.4 Data extraction**

The selected forums were searched for threads, which are defined as a set of posts on a newsgroup, composed of an initial post about a topic and all responses to it, between 17<sup>th</sup> November and 3<sup>rd</sup> December 2019, for the term ‘pelvic exenteration’. These threads were retrieved and checked for relevance. The initial message under each conversation (the ‘original post’) and threads linking these were also retrieved and analysed, provided they discussed pelvic exenteration. Blogs attached to the threads were accessed and analysed, if appropriate.

### **3.3.5 Data Analysis**

Data from internet forums were coded using the principles of inductive thematic content analysis, informed by Braun and Clarke (271), in NVIVO 11 (QSR International Pty Ltd., Melbourne, Australia) (271). Codes pertaining common themes were identified and synthesised across the internet forums. A category was determined by grouping similar findings reflecting similar underlying constructs. Categories were then synthesised into themes. All coding was iteratively undertaken by a second coder, a dedicated qualitative researcher at Swansea University (CON), to reduce subjectivity and potential bias with interpretation of findings. Any discrepancies were resolved through discussion.

## **3.4 Results**

A total of 63 internet ‘forums’ were identified, of which 6 were duplicates. Forty-seven were not discussion forums and excluded from the analysis. Ten sources were screened, of which four were excluded as not freely open to the public resulting in following six sources being included in the analysis (Figure 10):

1. <https://www.cancerforums.net>
2. <https://community.bowelcanceruk.org.uk>
3. <https://community.macmillan.org.uk>
4. <https://www.jostrust.org.uk>
5. <https://www.mumsnet.com>

6. <https://www.inspire.com>

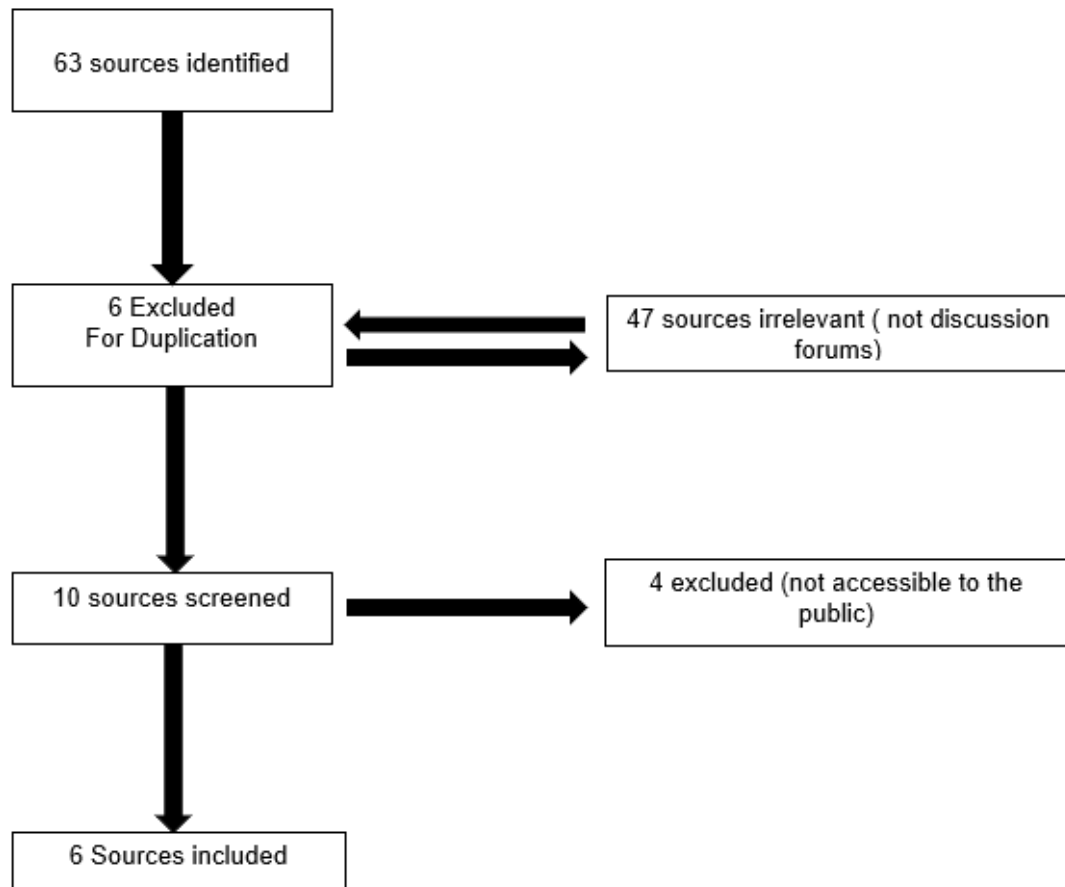


**Figure 10. PRISMA flowchart of source selection**

Attempts were made to gain access to closed sites for research purposes which were declined and therefore retrospectively included as an exclusion criteria.

### 3.4.1 Qualitative Results

Using the principles of content analysis for the online patient forums a total of 7 themes were generated from 42 categories and 148 findings (Table 16). Themes generated were physical recovery, psychological/emotional recovery, change in relationships, expectations, finance, support and communication.

| THEMES            | CATEGORIES     | Illustrative Quote                                                                                                                                                                                                                         |
|-------------------|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Physical recovery | General Health | ‘Dad was so fit and well before this operation but since he’s had it it’s been awful, he doesn’t want to eat, has no energy and is really weak.’<br>‘You never recover, if by that you mean return to what you were before the operation.’ |
|                   | Stoma issues   | ‘The pleasure of the exploding bag this morning.... You’ve never seen anything like it! It was as if I’d singlehandedly produced the European Shit Lake! I nearly sent out for                                                             |

| THEMES                           | CATEGORIES                                | Illustrative Quote                                                                                                                                                                                                                                                                                                                                                                                       |
|----------------------------------|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                  |                                           | wellington boots!.....‘I am not concerned about bags; I think living is more important.’                                                                                                                                                                                                                                                                                                                 |
|                                  | Gastrointestinal Symptoms                 | ‘He gets bad pains in his stomach which they say is wind and he’s feeling sick.’                                                                                                                                                                                                                                                                                                                         |
|                                  | Genitourinary Symptoms                    | ‘There was no mention of no bladder control or not being able to feel it being full.’                                                                                                                                                                                                                                                                                                                    |
|                                  | Musculoskeletal Symptoms                  | ‘He can’t move about as he is too weak.’<br>‘I looked down and my right leg had literally wasted away. It took months and months to build it back, but I was so aware of it and wore baggy trousers even through summer.’<br>‘He still has very limited mobility due to laying in a hospital bed for 2 months.’                                                                                          |
|                                  | Pain Descriptors                          | ‘She’s still in so much pain..... the pain she’s going through sucks everything away. No meds can really touch it. It’ll bring you to the bottom.’                                                                                                                                                                                                                                                       |
|                                  | Complications                             | ‘Loads of complications since the op. mainly being an open wound and constant leaking from a pelvic cavity. this has caused numerous infections and sepsis. he has been in and out of hospital since the op.’<br>‘Having major leaks from an open wound above his barbie bum. he has tried a vac pump, packing and absorbent pads. but nothing is working. it is having a major effect on his recovery.’ |
|                                  | Length of recovery                        | ‘You never recover fully, if by that you mean, you are pretty much the same as before.’<br>‘It’s a massive op but so worth it for the chance of cure. Allow yourself 6-12-month recovery. Everyone has ups and downs; you may take one step forward and 2 back.’                                                                                                                                         |
|                                  | Chemotherapy                              | ‘There was some talk about chemo, but I was so ill with the post op infection that I have not managed to see the oncologist.’                                                                                                                                                                                                                                                                            |
| Psychological/emotional recovery | Death                                     | ‘Unfortunately, this really was one operation too far. At 4.15pm today my beautiful, amazing, inspirational mummy lost her fight with this god-awful disease. I am beyond heartbroken, and my life will never be the same. In fact, I am not sure how I will put one foot in front of the other.’                                                                                                        |
|                                  | Mental health and psychological wellbeing | ‘Yes, the emotional part of this is a bit tough but the way I deal with it, is to keep in mind that TPE has given me the opportunity to hopefully live for many long years rather than having it curtailed prematurely.’                                                                                                                                                                                 |
|                                  | Coping mechanisms                         | ‘Be positive but be realistic.’<br>‘The cancer is out, I can cope with anything else because I know it’s a consequence of the cancer being out allowing me to have a chance at life.’                                                                                                                                                                                                                    |



| THEMES        | CATEGORIES                                         | Illustrative Quote                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|---------------|----------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|               | Future perspective                                 | <p>‘I can’t help go over and over in my head, what if it’s not really fully out, what if it comes back, what if I’ve put myself through this for nothing?’</p> <p>‘All in all, it was super outcome for me, and it has allowed me to once again lead an almost normal lifestyle and minimise further cancer issues. I count myself very fortunate that such lifesaving surgery was available to me and how it has given me a new lease of life. I feel happy and positive and will always be grateful to the marvellous surgical team that made it all possible.’</p> |
|               | Emotions                                           | <p>‘He did get quite snappy and angry when things were tough, unsurprising when your whole life changes like this.’</p> <p>‘He is so down and depressed and wishes he never had the pelvic exenteration op’</p>                                                                                                                                                                                                                                                                                                                                                       |
|               | Acceptance and health bargaining                   | <p>‘Now just over a year later, here I am with a permanent colostomy and also a permanent urostomy but at least I am alive, pain free and feeling fit and healthy again.’</p> <p>‘I can now look in the mirror and say I look like this because it’s out.’</p>                                                                                                                                                                                                                                                                                                        |
| Relationships | Loss of confidence                                 | <p>‘I can’t go out knowing that at any moment I could leak from my bags – I would be so embarrassed.’</p> <p>‘I hate looking in the mirror when all I can see is scars and bags. I don’t even know who I am anymore.’</p>                                                                                                                                                                                                                                                                                                                                             |
|               | Spousal dependence                                 | <p>‘The support I had from my husband is what got me to this point. I won’t lie and say it’s easy but it’s what you make of it. I depend on him. Without him this recovery is not possible.’</p> <p>‘I am completely reliant on him. I can’t even dress myself properly. I had no idea I would be reduced to this. I don’t know what will happen when he has to go back into the office to work.’</p>                                                                                                                                                                 |
|               | Emotional aspect of sex                            | <p>‘She asks me will I ever want to make love to her again (I will).’</p> <p>‘I won’t ever be able to connect physically with her ever again so why would I expect her to connect emotionally with me?’</p> <p>‘We can’t be intimate, but we talk, we connect, we caress and our relationship is stronger than ever.’</p>                                                                                                                                                                                                                                             |
|               | Technical aspects of engaging in sexual activities | <p>‘Having a good relationship with our partners doesn’t always mean the penetrative sex is the only option whilst things get back to normal, we can explore other ways to satisfy each other.’</p> <p>‘He was told he would lose all sexual function, but we said it was a small price to pay for getting a life.’</p>                                                                                                                                                                                                                                               |

| THEMES       | CATEGORIES                                     | Illustrative Quote                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|--------------|------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|              | Sexual pleasure                                | <p>‘They took some of my vagina, I can’t feel anything, is this normal?’</p> <p>‘Having a good relationship with our partners doesn’t always mean the penetrative sex.’</p> <p>‘He was told he would lose all sexual function, but we said it was a small price to pay for getting a life.’</p>                                                                                                                                                                                                                |
|              | Logistics of bed sharing                       | <p>‘We have not found it possible to share a bed, as the night drain means he must sleep in one awkward position. Even sharing a room is frankly very disturbing and not very pleasant.’</p>                                                                                                                                                                                                                                                                                                                   |
|              | Loss of identity                               | <p>‘My poor wife is struggling with her identity as a woman, post-operation. She wonders how I can still love her (I love her with all my being).’</p>                                                                                                                                                                                                                                                                                                                                                         |
| Expectations | Inaccurate portrayal of recovery and prognosis | <p>‘Recovery is going to take much longer and be much harder than I expected. They had made it clear this was a major piece of surgery, but it's only afterwards that I appreciated just HOW major it was.’</p> <p>‘My husband was sold this major, life changing procedure as a cure and a prevention -he died of recurrence 3 years later.’</p> <p>‘I was led to believe I would recover within 6-12 months. I have never recovered fully, if by that you mean, you are pretty much the same as before.’</p> |
|              | Inaccurate portrayal of extent of surgery      | <p>‘Despite being told this was much bigger surgery than I have been through in the past I didn’t really understand to what extent until now.’</p>                                                                                                                                                                                                                                                                                                                                                             |
|              | Inability to work within the same role         | <p>‘Before my surgery I was a very successful store manager for a major women’s retailer. I am no longer physically able to perform that job.’</p> <p>‘My wife can no longer work at this time I’m not sure she ever will.’</p> <p>‘I am due to return to work tomorrow, on reduced hours. My employers have agreed to this. I have to decide whether to return full or part time long-term which ultimately has implications on our income.’</p>                                                              |
|              | Returning to normal life                       | <p>‘Undergoing PE ‘is not easy but it is not nearly as bad as you think it’s going to be. I live my life more or less the same as before but I have to plan in advance.’</p> <p>‘Returning to normal?? All I can say is, they have a curious definition of normality. I needed to know that this was possible.’</p>                                                                                                                                                                                            |
|              | Social isolation                               | <p>‘no one can start to understand and I feel so alone.’</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|              | Social anxiety                                 | <p>‘I’m slowly getting used to life with a urostomy and colostomy but finding it overwhelming. I am worried about going out again.’</p>                                                                                                                                                                                                                                                                                                                                                                        |

| THEMES        | CATEGORIES                    | Illustrative Quote                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|---------------|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|               | Loss of social interest       | ‘I avoided all social activities I used to do before the operation like the plague.’                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Finance       | Delay in returning to work    | ‘Two years and I am not working, nor do I see this happening anytime soon.’<br>‘I can only work part-time now which has implications for our income and our future.’                                                                                                                                                                                                                                                                                                                                                                      |
|               | Expense of hospital stays     | ‘I just need to be near her even if I can’t spend most of the day with her. Being near and her knowing I am near is comforting even if every day is three hospital meals a day, which soon mounts up! although £20/day hospital parking seems somewhat ridiculous when my 2 course lunch costs £3.’                                                                                                                                                                                                                                       |
|               | Home adaptation               | ‘She goes up and down stairs on her bottom - Booked a few carpet fitters to pop round to give us a quote for new stair carpet to make the ascent and descent a softer experience.’<br>‘Went off to B&Q for a handrail and hardware for them (needed to make two short lengths) crikey the hardware is not cheap, and I bought a chair last week so she can sit in the shower.’                                                                                                                                                            |
|               | Financial difficulty          | ‘Her family is going through major financial problems now because she was the primary bread winner and, of course, insurance only pays 60% of average weekly bring home pay.’                                                                                                                                                                                                                                                                                                                                                             |
| Support       | Availability of DN            | ‘They are dressed twice a day by the district nurses who are brilliant. It makes a huge difference knowing there is a professional coming in who we can ask if there are any concerns. It has been a learning curve for them too.’<br>I’m getting hardly any support, the nurse comes 3 times a week for about 10 minutes, I have to change his dressings, flush his wounds, empty his drain and check his blood pressure and temperature, I’m working part time, so I have to get friends to sit with him. It’s so hard, I’m exhausted!’ |
|               | Dependence on stoma nurses    | ‘Stoma nurses have been amazing and are always the other side of the phone to change bags and improve any leakage.... they soon become your best friends. You couldn’t be without them.’                                                                                                                                                                                                                                                                                                                                                  |
|               | Lack of emotional support     | ‘Get all the help you can as the emotional support is somewhat harder to get. It’s so draining.’                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Communication | Need for accurate information | ‘I would like to know what life will be like for him following the operation and how long recovery is and how long is his life expectancy after operation. Also, when they say cure, do they mean forever or will the cancer come back..... if your surgeon has not given you this information before scheduling the surgery something has gone wrong somewhere. I can tell you one thing though which is that if I had my time over again, I would                                                                                       |

| THEMES | CATEGORIES                 | Illustrative Quote                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|--------|----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|        |                            | go back to that room and insist on answers to all of the questions.'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|        | Primary and secondary care | <p>'Trying to get a repeat prescription for my pain killers and no forth comers as the paperwork has not crossed over to GP. I can't help feel that the surgery thinks I'm not their problem and the hospital should be providing me with sick papers and insurance cancellation documents.'</p> <p>'If only they would have taken my symptoms seriously and referred me 18 months ago, I may not be in this position where I have to have this operation or leave my girls 2 and 3 years.'</p> <p>'Few weeks after my surgery I became unwell, and the GP treated me as a UTI. I returned to the hospital for routine FU..... My surgeon on just looking at me without saying a word said I needed to be readmitted as he was sure I had an internal collection. So, for anyone out there...never go back to your GP in the months after the operation.'</p> |
|        | Follow up                  | 'Leaving empty handed in the dark once the medication was ready meant that no solid follow up was explained. The waiting at home over the next few weeks was long. Thankfully the stoma nurse sorted everything out.'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|        | Second opinions            | <p>'I was told that there is nothing they can do for my recurrence but insisted on a second opinion then I was seen at Leeds who offered me surgery and am now 18 months down the road.'</p> <p>'I have asked for a second opinion and there is reluctance in sending me to another unit – advice please.'</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|        | Secondary care services    | 'No one knew what the left and right hand were doing. I would have an appointment at the local hospital and they had no idea I was planned for the op. No communication between the two whatsoever.'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |

**Table 16. Online forum themes and categories with illustrative quotes**

The content of original posts in the threads ranged from sharing personal narratives to posing questions about treatment or survivorship. Newly diagnosed patients or patients within the early post-operative period and their relatives were more likely to seek information due to uncertainty and search for experience-based information from fellow patients and survivors. Patients who were within the medium-term recovery process also were searching for information but also used the forums to seek support whilst those longer-term survivors used the forum to both advise and support users. Other users within the forums included caregivers including spouses/partners, friends and children seeking information regarding treatment and complications.

### **3.4.2 Physical recovery**

#### **3.4.2.1 General health**

Forum users requested information about post-operative physical restrictions including the prolonged and significant weakness in the weeks and months following surgery. Information regarding how much physical support they would need during recovery was questioned. Dependence on others for activities of daily living including washing, dressing, getting in and out of bed, and moving around the house were also discussed. Survivors advise on the unanticipated immediate post-operative decline and the extensive recovery process to regain general health described between 6 months and never,

#### **3.4.2.2 Stoma issues**

Forum users wanted information regarding the appearance, function, and impact of both colostomies and urostomies. Problems with stoma leakage are explored with survivors both from a practical and psychological point of view. Longer term informational need related to the stoma, included body image and difficulties engaging in sexual relationships and social activities.

#### **3.4.2.3 Gastrointestinal issues**

Forum users requested information regarding potential post-operative gastrointestinal issues including pain, nutrition, stoma function and vomiting. They reach out to establish what is 'normal' and expected following surgery.

#### **3.4.2.4 Genitourinary issues**

Forum users seek information and support regarding urostomy leakage, loss of sensation, urgency and incontinence. They question the effects of self-catheterisation on psychological health. Users seek reassurance and coping strategies from survivors regarding the practical and social considerations of having a urostomy.

#### **3.4.2.5 Musculoskeletal symptoms**

Forum users want to know about the effect of surgery on mobility and weakness. Information and advice regarding what to expect both in the short and long-term is examined with survivors. Muscle loss from prolonged bed rest and subsequent immobility are explored with survivors describing the potential effect of muscle wasting on body image.

#### **3.4.2.6 Pain Descriptors**

Forum users also indicated the need for information regarding post-operative pain management. They need reassurance that various levels of pain are normal within certain periods following surgery, especially during hospital admission and what pain relief will be available to them. Survivors discuss the potential sites of pain being abdominal, perineal, back and leg pain described as neuropathic or colicky in nature which can cause emotional distress. Questions regarding the need for long term analgesia was also topical.

#### **3.4.2.7 Complications**

Commonly forum users explore information regarding post-operative complications within the forums. They use survivors to discuss their own experiences of complications including delayed wound healing, sepsis, wound infections and the psychological impact. Those who experience post-operative complications seek validation from others regarding their experiences and find this to be supportive.

#### **3.4.2.8 Length of Recovery**

Forum users indicated the need of information regarding recovery to help meet expectations. Length of stay together with immediate and delayed recovery are discussed with survivors. Forum users are prepared for a recovery up to a year however they are made aware of the potential of never recovering fully.

#### **3.4.2.9 Chemotherapy**

Information regarding adjuvant chemotherapy including indication, necessity, timing and impact are sought out. They also want to understand the consequences and reason for delays to treatment. Treatment related side-effects are of a great concern and forum users indicated that they needed this information prior to accepting surgery.

#### **3.4.2.10 Death**

Death is a potential outcome from surgery discussed within the forums. Forum users identifying as patient relatives describe experiencing unexpected death of family members as a result of surgery. They seek comfort from other patients having been through the same surgery whilst highlighting the potential risk to be considered during decision-making.

### **3.4.3 Psychological/emotional recovery (immediate and delayed)**

#### **3.4.3.1 Mental health and psychological wellbeing**

Forum users seek information and advice regarding the impact of surgery on psychological wellbeing. They question how to be in the best mental state both prior to and following surgery. Patients wanted to know that feelings of frustration, low mood and anger were normal and used survivors to validate their feelings. Patients were more affected by mental health with prolonged recovery, complications, and dependence on others however trade poor psychological wellbeing for the chance of cure.

#### **3.4.3.2 Coping mechanisms**

Information about coping was another concern raised by forum users. Survivors advise newer patients to adopt a realistic approach to recovery and not to expect too much too quickly. They are also advised to reach out to the online community when they have difficulty coping. Survivors offer various advice on issues forum users are struggling with including leaking urostomies, ‘how to get through the dark days’ and ‘how to get back to normal life’. Patients frequently revisit the trade-off of cancer for their symptoms.

#### **3.4.3.3 Future perspective**

Obtaining information on cure and longevity was an expressed need. Forum users want to know information on recurrence, metastatic disease and remission both in the pre- and post-operative phase. Despite forum users describing surgery being the only chance of cure they want to discuss the chances of recurrence and express a fear of recurrence and metastatic disease. Those with concurrent metastatic disease want to know about adjuvant chemotherapy and the chances of survival with metastectomies. They utilise survivors amongst the group for validation of their decision-making.

#### **3.4.3.4 Emotions**

Forum users seek information and support regarding the normality of emotions. They need validation of their feelings including depression, sadness, anxiety, regret, fear and frustration. They want doctors to explain that various emotions are normal and to be expected. Some forum users discuss decisional regret as a result of depression and seek support from survivors.

#### **3.4.3.5 Body image and health bargaining**

Forum users want information about how their bodies will change and equally how they will feel about it. They express distress about their body image resulting in low self-esteem and a lack of confidence due to the physical changes of scars or having one or two stomas. Other physical components affecting body imaging are delayed healing, hernia, fistulae and loss of sexual organs. They want information regarding physical changes affecting self-confidence which can have an adverse result on relationships and social circles. Health bargaining and ‘trading cancer for bags’ allow patients to become more accepting of their appearance.

#### **3.4.4 Relationships**

##### **3.4.4.1 Loss of confidence**

Some forum users expressed the need for information regarding loss of self-confidence. They express concerns that unanticipated loss of confidence had a subsequent effect on their personal relationships. Emotional distancing is used as a protective mechanism due to loss of self-confidence; They want reassurance and support from survivors that such behaviours are normal and not long term. Forum users seek information on how to adjust and subsequently develop personal and social relationships to prevent becoming withdrawn and isolated.

##### **3.4.4.2 Spousal dependence**

Information about how much support from spouses was another concern raised by forum users. The amount of physical and emotional support required was not anticipated describing being fully dependent for up to 6 months. Many forum users indicated that they need information and support on the loss of independence and adapting to spousal dependence and its subsequent adverse effect emotionally. Being dependent on spouses for Activities of Daily Living (ADLs). Information on the negative effect these changes can have on personal relationships together with relationship advice and support needs to be highlighted for patients in the decision making.

##### **3.4.4.3 Emotional aspects of sex**

Some users expressed informational need about the change of emotional connection associated with sexual dysfunction. Forum users describe a fear in loss of intimacy and seek reassurance and advice amongst each other. Information regarding insecurities



and distancing within relationships need to be discussed. They want information and advice to deal with not only the physical but also the emotional changes of sex to improve their emotional relationships.

#### **3.4.4.4 Sexual pleasure**

Forum users want extensive information about sexual dysfunction. Men are usually prepared for the consequences of erectile dysfunction (ED) and are usually accepting but want information about potential interventions including penile pumps, implants and Viagra. They seek information about pursuing alternative ways for sexual gratification. Women need information about the physical impairment from pain, bleeding, non-functional neovaginas and loss of vaginas. Generally, forum users accept the trade-off between sexual function and the chance of cure.

#### **3.4.4.5 Logistics of bed sharing**

Obtaining information about problems with bed sharing is important to forum users. Unexpected difficulties in co-sleeping due to discomfort and practicalities of night drains and leakage are unanticipated and difficult to cope with. They seek advice about overcoming such difficulties as they experience a loss of connection being apart.

#### **3.4.4.6 Loss of identity**

Forum users wanted information about loss of identity following surgery. The loss of reproductive organs effects their perception of both masculinity and femininity and as a result they lose their identity as people. Informational needs about the effect this has on potential behaviours in withdrawing emotional or physical connections need to be discussed to prevent relationship breakdowns. They need support from survivors to adapt to their new lives and revise their identity.

### **3.4.5 Expectations**

#### **3.4.5.1 Inaccurate portrayal of recovery**

Forum users felt the greatest need to receive information on an accurate portrayal of recovery. Generally, there is an expectation of a long recovery process of up to a year however the extent of recovery is underestimated. They seek validation of their recovery from survivors by exchanging recovery narratives especially those with prolonged recoveries. Survivors outline that recovery is depicted as return to the normal pre-operative state however occasionally that is not possible. Patients and

families, including caregivers need information about support groups and counselling services to support emotional wellbeing.

#### **3.4.5.2 Inaccurate portrayal of extent of surgery**

The need for information regarding the extent of surgery is another concern raised by forum users. They want an accurate portrayal of recovery to fully prepare for surgery and make an informed decision. Some forum users expressed difficulties in comprehending the magnitude of surgery due to insufficient face to face consultation time and felt that more consultations and the opportunity to ask more questions after a period of processing would have resulted in a more realistic expectation of recovery.

#### **3.4.5.3 Inability to work within the same role**

The need to be informed about the potential inability to return to the same work and potential change in financial security is important to patients. Reasons for this are due to physicality, ongoing treatment, ongoing symptoms of lethargy and malaise. They need to be prepared and make appropriate arrangements for the potential loss of income. Forum users defined as caregivers express the need to be informed of the potential for them being unable to return to work for a period of time after surgery due to them taking on a care role for their spouses.

#### **3.4.5.4 Returning to normal life**

Information about being able to return to normal life was important to forum users. Some expected to return to normal function within 6 months which is often associated with disappointment. Survivors support other forum users with managing their expectations by sharing personal accounts of recovery and returning to normal life which is described between 6 months to years. Some patients describe not returning to baseline. However, many survivors do describe continuing with normal life which is crucial for forum users to appreciate for decision-making.

#### **3.4.5.5 Social isolation**

Information about potential social isolation is important to forum users. They need to understand that it is normal to feel isolated after an eventful period of neoadjuvant treatment followed by surgery. They feel healthcare providers should provide information regarding the ongoing care and strategies to prevent them becoming isolated. They describe grief being unable to do many social things they did before the

cancer treatment. Information regarding acceptance and help to overcome potential social isolation is important to patients for informed decision making.

#### **3.4.5.6 Social anxiety**

Forum users wanted to know about social anxiety and how that would affect their post-operative life. Anticipation of not wanting to engage within social circles for fear of embarrassment from leaking stomas, feeling weak or being physically unable to do normal activities would improve expectations. They need emotional support during social withdrawal and loneliness and seek ways to facilitate adaptation to regain a sense of normality.

#### **3.4.6 Finance**

##### **3.4.6.1 Delay in returning to work**

Information about the delay in return to work is needed by patients. They need to understand that potentially they may never be able to return to work and if they do it may not be to full time hours or even the same role.

##### **3.4.6.2 Expense of hospital stays**

Information about the cost of hospital stays was needed by forum users. The unanticipated expenses of considerable expenses including hotels, hospital dining and parking was a concern. Forum users identifying as patient relatives describe considerable financial pressures to be near the patient during the immediate recovery and seek both emotional and financial support from others.

##### **3.4.6.3 Home adaptation**

Forum users identifying as relatives or carers seek information regarding financial and practical support for home adaptation. Significant changes regarding accessibility are discussed describing the need for moving and changing beds, purchasing shower chairs, handrails and carpets. Adaptations at personal cost due to lack of occupational therapy input and to speed up discharge are unanticipated work and expenses that forum users seek both practical and financial support from the online community.

##### **3.4.6.4 Financial difficulty**

Many forum users indicated that they need information on the financial difficulty and potential financial assistance and support available. They look to survivors for assistance describing the need for extensive help. Information on mortgage holidays,

school fee reductions, car repayment holidays together with information for support groups to aid grants and sickness benefits was needed by forum users.

### **3.4.7 Support**

#### **3.4.7.1 Practical support**

Forum users need information about what practical support is available following discharge. It allows them to seek others experience and allow a safe environment to discuss their support provision. Support from district nurses ranged from twice daily visits to others getting no support and family having to perform the role for dressing changes. They need information on the role of the stoma nurse and how they support patients to be dependent of their stomas with advice on different appliances but also their role as the interface between the patient and secondary care services.

#### **3.4.7.2 Emotional support**

Many forum users need information about emotional support. Both patients and caregivers' express concerns about not being offered any emotional support throughout the cancer journey. Obtaining information on how to join a support group or get counselling was an expressed need.

### **3.4.8 Communication**

#### **3.4.8.1 Need for accurate information**

Patients wanted to have accurate information delivered through plain language rather than medical jargon. Further to this how the information was relayed was equally as important. They need information to be delivered in a sensitive way. They need consistency of information and cannot accept being told they have inoperable disease and subsequently being told they have resettable disease by means of exenterative surgery. Easy access to professionals to ensure sufficient face time with specialists for discussion is important to ask more questions to be fully informed of their decision.

#### **3.4.8.2 Primary and secondary care**

Forum users need information to cross easily between primary and secondary care both pre-and post-operatively. Delays in referrals, inaccurate diagnoses and failure to provide repeat prescriptions were a concern for adequate care and had an implication on trust.

#### **3.4.8.3 Follow-up**

Information about expected follow-up is important to ensure patients feel in control of their disease. Forum users turn to other patients to seek information about expected follow-up. Failure in this process in those who develop recurrence resulted in poor outcomes for both doctor-patient relationships and psychological wellbeing.

#### **3.4.8.4 Second opinion**

Patients want easy access to healthcare professionals for second opinions when faced with both recurrent and advanced disease. Access to information about potential surgical intervention and easy access to receive this is important to forum users. Online forums are used to seek out survivors and get support in achieving tertiary level opinions.

#### **3.4.8.5 Secondary care services**

The delivery of information between hospital departments is important. They expect to be fully informed of changes to any inpatient plans. There is an expectation that appropriate communication allows timely investigations. Failure to do so effecting discharge planning results in disappointment and questions decision-making.

### **3.5 Discussion**

This chapter highlights that patients and their relatives considering and recovering from PE use online forums for support regarding a broad range of issues, including physical recovery, psychological/emotional recovery, change in relationships, expectations, finance, support and communication. Forum users actively seek information and support about post-operative recovery and living with and beyond surgery. This study identified similar themes previously identified in the literature however the emphasis of themes was different. Patients pre-dominantly gather and exchange non-clinical information online including information on relationships, finances and support which centres around some of the QoL they experience.

Previous studies have identified that cancer survivors face a number of psychosocial challenges including sleep difficulties, pain, changes in sexual function, fear of cancer recurrence, financial hardship, and impaired QoL (272-274). Online cancer communities appear to allow individuals to actively engage with their cancer care, and to discuss potentially stigmatising, sensitive and highly personal concerns with a group of similarly situated individuals (275). Patients want a broad range of both clinical and

nonclinical information (276) and participate in online forums for three reasons; self-management, trust, and support (277). However, patient and survivor participants exhibit different information and emotional needs depending on their illness phase (278). Newly diagnosed patients, and those starting treatment or undergoing treatment, express more amplified feelings of uncertainty and seek out experience-based information from fellow patients and survivors.

Relationships and sexual function were extensively discussed online. Both physical and psycho-sexual aspects of relationships are addressed. Forum users describe the change in the physical nature of relationships with partners becoming carers due to immobility, fatigue and general decline. A physical dependence on others for activities of daily living and outpatient follow-up changes the dynamic of relationships. Patients expressed despondency in terms of weakness and dependence which inadvertently affect both their mental and psycho-sexual health. Sexual dysfunction is one of the most common long-term effects within colorectal cancer treatment yet is rarely discussed between patients and their providers (279). Erectile dysfunction, orgasm capacity, ejaculation ability and libido have been shown to be significantly impaired following beyond TME surgery (280). Male patients are expectant of the sexual morbidity however are less expectant of the associated psychological impact. Whilst women are less prepared, they appear less troubled by sexual dysfunction. Studies have shown that sexual dysfunction in women following PE are due to lack of sexual desire vaginal pain, bleeding and dryness, difficulties in engaging in intercourse with a neovagina, and stomas affecting sexual intercourse (170, 281-284). Women who undergo vaginal reconstruction are more concerned about sexual dysfunction. Studies have shown that neovaginas are not what the patients expected but have been found to increase a woman's self-confidence and provide the potential for continuity of sexual function (283, 285, 286).

Unanticipated emotions associated with sexual dysfunction including feelings of depression, emasculation and anger are discussed. Breakdown of physical and emotional relationships are described due to the inability to cope psychologically with sexual dysfunction. Patients have previously described being abandoned by their spouses following diagnosis and impending surgery, however the majority of partners expressed initial support and were hopeful of cure (282). Forum users develop online relationships seeking support, motivation, positivity and advice regarding sexual aids.

Studies have shown that men have double the odds of being depressed in cancer survivorship when they experience sexual dysfunction (287). Men report blaming themselves for post-treatment relationship difficulties leading to social isolation that worsens their depression (288). Patients report grief due to loss of their masculinity and loss of satisfying sexual relationships with a partner (289). Studies have shown that normalising grief about sexual losses and the need to use sexual aids, while encouraging realistic expectations may reduce anger and demoralisation during the recovery process (289). When faced with changes in sexual function, it is the couples with a long relationship history and strong communication skills who are more likely to adapt to changes in sexual function (290). The emotional bond during sex that may be most important to the recovery of intimacy (286). Studies show that 50%–75% of patients with a urostomy, colostomy, or ileostomy who were sexually active prior to stoma creation do not resume sexual activity following surgery (291). Patients with urostomies do especially poorly and have been identified to have worse psychological, social, spiritual, and overall QoL compared to their colorectal equivalents. Patients feel clinicians prioritise the medical aspects of their diagnosis, treatment, and prognosis over quality-of-life concerns such as sexual function. Studies have shown that patients want clinicians to initiate conversation about their sexual health, and that these conversations are unlikely to happen unless initiated by the clinician (292). If the information is not provided by Healthcare Practitioners (HCPs) patients are driven to online forums to gather and exchange information.

Patients seek strategies for self-management, support and technical knowledge from other forum users suggesting that there is a value placed on the experience of other patients (277). Experiences of living a different post-operative life is explored including technical knowledge of sharing beds, stoma support and home adaptation. Forum users value patient experience to acquire information. Various support mechanisms including psychological and financial help were discussed amongst forum users to reduce burden. They comfortably discuss finances online including the unexpected expenditure including hotels, car parking and dining together with home adaptation and the loss of income. Those expressing concerns with lack of both social and medical support were more affected with financial anxiety. Generally younger working patients expressed concerns with loss of employment, failure to return to work and inability to provide for the family. Blum-Barnett et al showed that the financial

impact of a colorectal cancer diagnosis affects; career trajectory, loss of earning potential, health insurance/benefits, and employment performance (293). Studies have shown that a cancer diagnosis results in high financial burden (294-297). Financial difficulty is related to lower QoL (298, 299). A study of over 2000 cancer survivors, aged 18-81, found that financial distress associated with cancer was the strongest predictor of lower QoL. All age groups suffer the financial burden of cancer (298, 299). However, a survey on financial hardship among 1,202 adult cancer survivors found that financial hardship was more common among those aged less than 65 years compared with those 65 and older (300). Other previous studies have similarly shown that those diagnosed at younger ages are more susceptible to financial difficulty. Zafar et al, found that significant or catastrophic subjective financial burden afflicted 42% of cancer patients, with younger patients more likely than older patients to experience financial hardships (299). Financial toxicity (FT) is an increasingly recognised consequence of cancer diagnosis and treatment. The term is used to describe both the out-of-pocket expenses and opportunity costs experienced by patients during the course of their illness and recovery (299). Potential consequences of financial toxicity include material loss, psychological distress, and/or maladaptive coping strategies (301).

The mistrust in the word or actions of their physician arose as a significant driver for becoming an information seeker. Information providers within the online community may be thought of as neutral parties without any ulterior motives (277). Forum users who were unhappy with clinician communication reached out to the online community and actively encouraged second opinions and discussed the various elements of the recovery process with each other. Pre-operative counselling is addressed online with the benefit of hindsight and experience especially in those experiencing communications with treating teams.

Individuals discuss a range of emotive experiences online including treatments, risks, side effects and personal impacts of cancer such as family or psycho-sexual concerns (269, 302) which would support the finding of this study. Forum users turn to online forums to discuss both complications and side effects of surgery. These varied from issues with short- and long-term recovery to side effects influencing social interaction. Despite patients being informed of morbidity, it was apparent they did not understand the magnitude of change, presumably due to insufficient pre-operative information or



the inability to retain information. Few patients divulge not being interested in potential risks as they are so focused on the chance of cure. Most patients and their relatives accept underestimating the significance of surgery. Salz et al established that CRC patients need more information to allow them to plan for the future, as opposed to more information on the treatment they have undergone (303) which could be addressed with more information on nutrition, recommended physical activity, and ways to improve long-term physical and mental symptoms (303-307). Wieldraaijer et al established that these patients feel well informed about their treatment, disease, follow-up program, and how to contact the hospital if necessary, however, future expectations, nutrition, recommended physical activity are perceived to be less well addressed and patients felt least informed about work resumption and patient organizations (308). The literature and this review would suggest that information regarding surgery is available but the long-term effects and how it influences life following surgery is not so well addressed.

Survivors of cancer have a higher risk of developing anxiety, depression, and post-traumatic stress disorder (PTSD) (309, 310). In colorectal cancer survivors, the prevalence of depression and anxiety symptoms appears to be closely related to physical functioning, financial concerns, cognitive functioning, lack of social support, and concerns about cancer recurrence (311, 312). Patients and their relatives expressed symptoms of depression and anxiety which were consistent with the deterioration in their general health especially in the early recovery phase.

The strengths of this study were that threads and blogs linked to original posts within the online forums were retrieved and analysed providing more data. Data was retrieved from patient testimony rather than interviews eliminating interviewer bias seen in qualitative work. Forums were studied worldwide provided they were discussed in the English language which recruited multinational data, however there may be concerns that data has not been captured for societal differences in the acceptance of PE and thus outcomes may be different. Key limitations of this study include the limitation to a limited number of internet pages on one search engine; expanding the search strategy further, using other search engines including Yahoo and Bing may have led to the identification of further resources. Other limitations included information captured from computer literature patients only potentially excluding a cohort with different information needs. Information gathered were from unknown patient characteristics

potentially resulting in uncertainty around the generalisability. Access to forums was limited by open access as opposed to password protected forums which may have revealed more personal data. The type or scale of surgery forum users had undergone could not be determined **in** this study to evaluate whether some themes were more relevant to specific resections resulting in an analysis of generalisability.

### **3.6 Conclusion**

Patients and their relatives actively seek information, support and guidance within online communities. They feel safe in reaching out to each other in a virtual community discussing personal and sensitive issues that they may not feel so comfortable in a face-to-face manner. Online cancer communities appear to allow individuals to actively engage with their cancer care, and to discuss potentially stigmatising, sensitive, and highly personal concerns with a group of similarly situated individuals. Clinical teams offering PE surgery should be made aware of the themes identified in this review of real-life forums to improve future patient interaction. However, further information should be sought from patients to identify what information is important to them when deciding to undergo surgery.

## **Chapter 4. Qualitative Interviews to identify important factors for patients in decision making to undergo surgical intervention**

### **4.1 Background**

Historically decision-making in LARC and LRRC has predominantly been based on disease resectability and the patient's fitness to withstand major surgery (313). However, greater understanding of patient priorities has fuelled a move towards the adoption and integration of the principles of SDM in patients requiring PE (314). To make an informed decision, patients need appropriate counselling about the available treatment options, treatment efficacy and associated benefits and risks of each treatment.

The long-term impact of exenterative surgery on patients has not been widely studied and there is a paucity of prospective qualitative information about the impact on patient-reported wellbeing. A reasonable and acceptable QoL has been reported following surgery (315) with overall QoL returning to baseline at 6 months (316, 317). However, the currently available QoL instruments are not disease specific for this group of patients, and therefore may not truly reflect the impact of exenterative surgery on relevant patient reported outcomes (PRO). Currently available QoL measures provides a measure of patients' overall wellbeing, but do not allow in depth exploration of the decision-making difficulties faced by patients. QoL in surgery often reflect informed consent and may not reflect true patient preferences made at the time of decision-making. Patients can adapt their attitudes to support their decision by increasing their preference for their treatment option when there is a discrepancy between actions and attitudes (i.e. cognitive dissonance reduction) (318-320).

Patients with LARC or LRRC eligible for PE have reported being unprepared for surgery (170) with issues of regret, trauma, ostomy challenges, loss of sexuality, social isolation, embarrassment/humiliation, and marked changes in routine described in the post-operative setting (170). This raises concern about the pre-operative counselling and possibly the patients' ability to understand, evaluate and retain the details of the complexity and impact of surgery as seen in Chapter 3. From an ethical perspective, information regarding diagnosis, prognosis and treatment has been emphasised as a key element to enable patients to make decisions which reflect their values and preferences (321).

Healthcare decisions about cancer treatments involve concepts that may be difficult to understand. For example, health risks and probabilities, unfamiliar technical medical information, and a multiplicity of treatment options. This may be overwhelming especially against a backdrop of the emotional challenge of a new or recurrent cancer diagnosis (322). These challenges that are inherent in cancer decisions are compounded by the psychological limitations of individuals (322). The difficulties which patients face in making a decision may include the costs and benefits of treatments with respect to duration of symptom-free survival, time spent with toxicity due to treatment, time to relapse, and impact on QoL and functional status (322). However this may not be reflected within the SDM process. Often patients prefer to rely on the opinion of their clinician to make the decision about treatment for them. However, previous research has found that patients' perspectives on priorities for disease treatment is often different to their health care providers (323-325).

Patients also have variable preferences in their desired level of involvement in decision-making, with some choosing to be more active than others. This is likely related to various factors, including gender, race/ethnicity, cancer type, prognosis, religion, education level, and level of medical knowledge or understanding. Racial minority groups are more likely to include family members in their decision-making (326) , whereas older patients commonly may choose a more passive role (327). Cancer type can also influence patient preferences in decision making with breast cancer patients having a more active role than patients with other types of cancer (328).

Frameworks regarding patient decision-making have evolved to support a more collaborative process using SDM (329). In order to implement this into routine practice clinicians need an understanding of factors important to patients at the decision-making phase. To date there has been limited research and understanding of the complexities of decision-making in patients undergoing multivisceral resection for rectal cancer. In 2006, Wright et al identified various issues important in the decision-making process including: unanticipated morbidity, limited options of treatment available, the importance of health, mistaken perception of cure and appropriate and timely information being provided (171). Whilst survival continues to improve in this cohort of patients, as a consequence of more radical 'higher and wider' surgery, this results in both more survivors living with the challenges brought on by surgery and potentially greater disability from the greater radicality of surgery (168, 330-333).

Treatment decisions in cancer care are complicated not only by uncertainty about their effectiveness and the balance of benefits and harms but by multiple potential outcomes that patients must consider. Another important consideration involves the potential for long-term and delayed effects of treatment.

It is important to capture patients' perceptions of the factors that are important to them when considering surgery to obtain informed consent. Ideally, decisions along the cancer continuum should be based on a full understanding of the benefits, harms, and uncertainties associated with alternative courses of action— an essential part of informed decision making (334). This ideal is difficult to achieve in cancer care due to the complexity of the risks and benefits of the available options, despite its ethical desirability.

Qualitative methods to identify patients' perceptions in decision-making can provide rich and in-depth information about the experiences of individuals (335). This level of detail can identify relationships between emotions, people, objects unlike many quantitative methods of research (336-338). Limited qualitative evaluation and decision-making evaluation in patients undergoing pelvic exenteration for LARC and LRRC exists. Interviews are among the most common strategies for collecting qualitative data. Individual in-depth interviews are widely used by health care researchers to co-create meaning with interviewees by reconstructing perceptions of events and experiences related to health and health care delivery (336). Qualitative interviewing gains insight into people's interior experiences, for example how people perceive and how they interpreted their perceptions and how events affected their thoughts and feelings. As a result, researchers can understand the process of an event instead of what just happened and how they reacted to it. This level of detailed description can show an otherwise hidden interrelatedness between emotions, people, objects unlike many quantitative methods of research (338). Examining an individual's experience makes explicit the perceptions, experiences, and meanings constructed by patients around a particular event (339). Further research to uncover the meanings, understandings and experiences for patients will allow better understanding and thus service provision.

## 4.2 Aims and objectives

The aim of this chapter is to explore patients and clinicians' perceptions on factors important during the decision-making process for LARC and LRRC.

## 4.3 Methods

### 4.3.1 Qualitative Study - Interviews

A prospective, cross-sectional, qualitative study was undertaken using in-depth virtual telephone audio recorded interviews across five UK centres between January 2020 and October 2020. All centres were members of the PelvEx collaborative and included Swansea, Leeds, Newcastle, London, and Edinburgh. A multi-centre approach was adopted to ensure heterogeneity in patient population. All interviews were recorded and transcribed verbatim. Notes were taken throughout the interviews. All patients were offered a debriefing service at the end of the interview.

A purposive sampling method was devised to aid recruitment, with sampling of patients targeted to key factors to reflect the range and diversity of the target population, including gender, disease pattern and subset of surgery. A minimum of 5 patients were consecutively sought per key factor (Table 17). This purposive sampling strategy was considered to ensure the broader generalisability of the findings.

| Factors                                | Number of patients |
|----------------------------------------|--------------------|
| Gender                                 |                    |
| Male                                   | 8                  |
| Female                                 | 7                  |
| Disease pattern                        |                    |
| Locally Advanced Rectal cancer (LARC)  | 8                  |
| Locally Recurrent Rectal cancer (LRRC) | 7                  |
| Subset Surgery                         |                    |
| Total Pelvic Exenteration (TPE)        | 5                  |
| Sacrectomy                             | 5                  |
| Partial Pelvic Exenteration (PPE)      | 5                  |

**Table 17. Purposive sampling strategy**

HCPs consisting of Surgeons, Oncologists and Clinical Nurse Specialists (CNS) were recruited for interview from all sites. A minimum of 2 HCPs were consecutively sought per stratification factor (Table 18).

| Role        | Number of professionals |
|-------------|-------------------------|
| Surgeons    | 2                       |
| Oncologists | 2                       |
| CNS         | 2                       |

**Table 18. Purposive sampling strategy**

#### **4.3.2 Data collection and analysis**

All interviews were conducted by the same facilitator with dedicated training in qualitative interview (University of Oxford 2019). All interviews were informed by a topic guide (Appendix C) based on previously identified literature and online discussion boards (Chapter 2 and 3) (340). The interview recordings were transcribed verbatim. All transcripts were reviewed by the facilitator for accuracy and clarification of ambiguities. The transcripts were imported into NVIVO 12 (QSR International Pty Ltd., Melbourne, Australia) and coded line by line. NVIVO 12 is designed to facilitate the storage, coding and retrieval of qualitative data using Boolean operators. All coding was iteratively undertaken by a second coder, a dedicated qualitative researcher at Swansea University (CON), to reduce subjectivity and potential bias with interpretation of findings. Any discrepancies were resolved through discussion.

The principles of thematic content analysis were employed to aid data analysis (271). This process involves interpreting data and creating codes, categories and themes (341) (342). Codes that pertain to the same phenomenon were grouped to form categories. Categories were further developed into themes. Analysis was an iterative process during the data collection process, with transcripts being analysed after every fourth interview. This enabled cessation of data capture at saturation and future interviews to be informed by the preceding interviews, thus ensuring confirmation of identified codes. Saturation is the point in data analysis process where no further information is elicited (343). To ensure sufficient data was collected to reach conceptual saturation, a saturation grid was devised to track emerging concepts (344). This method of analysis was chosen as it enables structured data collection combined with an explicit analytical procedure informed by a priori reasoning based on existing theory and literature (342, 345). Data were evaluated to ensure they met the qualitative recommendations for content analysis (346). This study is reported in keeping with the Standards for Reporting Qualitative Research (SRQR) (347).

## **4.4 Recruitment**

### **4.4.1 Eligibility**

#### **Inclusion criteria for patients**

Identified patients were included in the study if the following criteria were fulfilled:

- Aged  $\geq 18$  years.
- Patients who have undergone PE for LARC or LRRC within the last 12 months.
- Able to provide informed written consent to participate.
- Able to read and write in English.

#### **Exclusion criteria for patients**

Patients were excluded from the study if any of the following criteria applied:

- Have undergone palliative treatment of their LARC or LRRC.
- Have cognitive impairment.
- Are unable to speak/read and/or write English.
- Are unable to provide informed consent.

#### **Inclusion criteria for healthcare professionals**

Identified healthcare professionals were included in the study if the following criteria were fulfilled:

- Surgeon, Oncologist or CNS.
- Part of the PE MDT.
- Employed within 1 of 5 nominated UK centres as part of PelvEx collaborative.

#### **Exclusion criteria for healthcare professionals**

Healthcare professionals were excluded from the study if any of the following criteria applied:

- Invitation to participate on the development of the PtDA (Chapter 6).



#### **4.4.2 Patient recruitment**

Patients were identified from a prospectively kept PE database for LARC and LRRC at the five nominated centres. Patients that met the eligibility criteria were approached by the local Principal Investigator (PI) at each centre. They were provided with a patient information sheet (PIS) (Appendix D), which included details about the rationale, design, and personal implications of the study together with a consent form to be contacted by the researcher. Following receipt of the signed consent form (Appendix E), the researcher contacted the patient to arrange a mutually convenient time for interview.

#### **4.4.3 Healthcare professionals' recruitment**

HCPs were identified by the local PI at each site and those who met eligibility criteria were approached, informed about the study and provided with a clinician information sheet (CIS) (Appendix F) and written consent was obtained (Appendix G). Following receipt of the signed consent form, the researcher contacted the healthcare professional to arrange a mutually convenient time for interview.

#### **4.4.4 Ethical approval**

Ethical approval was gained prior to the commencement of this study by North of Scotland Research Ethics Committee 19/NS/0056 (IRAS 257890). Prior governance approvals were obtained by relevant research and development units within the hospital trusts.

#### **4.4.5 Baseline data collection**

The following data were collected:

- Patients initials and date of birth
- Gender
- Primary Cancer Details (location, recurrent or advanced, neoadjuvant/adjuvant treatments)
- Surgery details (date of surgery and histology)

## 4.5 Results

### 4.5.1 Patient demographics

Twenty-five patients who underwent pelvic exenteration for LARC or LRRC between January 2020 and October 2020 consented to participate. Individual telephone interviews were undertaken over a 5-month period. Patient demographics are outlined in Table 19. Patients were selected to ensure equal representation based on gender, surgery and disease subtype. A total of 25 patients participated, 13 male and 12 female with a median age of 59 years (range 36-73 years). Fifteen patients had surgery for LARC, and 10 patients had surgery for LRRC. Median time elapsed between operation and the interview date was 7 months (range 3-11). Fifteen and ten patients had total pelvic exenterations (TPE) and partial pelvic exenteration (PPE) respectively. Six of the 15 TPE's also had a sacrectomy. One of the 10 PPE had a sacrectomy. Four patients from the cohort also underwent extended lateral side wall excision (ELSIE). Neoadjuvant and adjuvant treatment was variable within the cohort. Median length of interviews was 57 minutes (range 22-80 minutes).

| Factor                                             | Number (n)    | Frequency (%) |
|----------------------------------------------------|---------------|---------------|
| Median Age (years)                                 | 59<br>(36-73) |               |
| Gender                                             |               |               |
| Male                                               | 13            | 52            |
| Female                                             | 12            | 48            |
| Median time from surgery (months)                  | 7<br>(3-11)   |               |
| Primary operation type                             |               |               |
| Total Pelvic Exenteration (TPE)                    | 15            | 60            |
| Partial Pelvic Exenteration (PPE)                  | 10            | 40            |
| Total Pelvic Exenteration (TPE) & sacrectomy       | 6             | 24            |
| Partial Pelvic Exenteration (PPE) & sacrectomy     | 1             | 4             |
| Extended Lateral Pelvic Side Wall Excision (ELSIE) | 4             | 16            |
| Disease subtype                                    |               |               |
| Locally Advanced Rectal cancer (LARC)              | 15            | 60            |
| Locally Recurrent Rectal cancer (LRRC)             | 10            | 40            |
| Neoadjuvant treatment                              |               |               |
| Chemotherapy (CTx)                                 | 8             | 32            |
| Radiotherapy (RTx)                                 | 1             | 4             |
| Chemoradiotherapy (CRTx)                           | 12            | 48            |
| None                                               | 4             | 16            |
| Adjuvant treatment                                 |               |               |
| Chemotherapy (CTx)                                 | 12            | 48            |

|                                                  |    |    |
|--------------------------------------------------|----|----|
| Radiotherapy (RTx)                               | 0  | 0  |
| Chemoradiotherapy (CRTx)                         | 1  | 4  |
| None                                             | 12 | 48 |
| Concurrent metastatic disease at time of surgery |    |    |
| Yes                                              | 2  | 8  |
| No                                               | 23 | 92 |
| Disease status                                   |    |    |
| Disease free                                     | 22 | 88 |
| Local recurrence                                 | 1  | 4  |
| Metastatic disease                               | 2  | 8  |
| Margin status                                    |    |    |
| R0                                               | 18 | 72 |
| R1                                               | 5  | 20 |
| R2                                               | 2  | 8  |

**Table 19. Demographics of patients recruited**

Eight HCPs representative of the multidisciplinary team were recruited in the same time period (Table 20). Median interview time was 36 minutes (range 22-48).

| Role        | Number of professionals |
|-------------|-------------------------|
| Surgeons    | 3                       |
| Oncologists | 2                       |
| CNS         | 3                       |

**Table 20. Demographics of healthcare professionals recruited**

Saturation of all emerging issues were achieved by the 8<sup>th</sup> analysis of four interviews with no further issues identified in the final group, however one further interview was conducted to ensure data saturation (Appendix H). Six themes emerged from 50 categories and 123 codes, with identified themes relevant to treatment decision-making including: communication, recovery, psychological impact, relationship, lifestyle, support (Figure 11). On scrutiny of the data and the emerging themes, the majority of the themes and categories addressed the recovery and QoL.

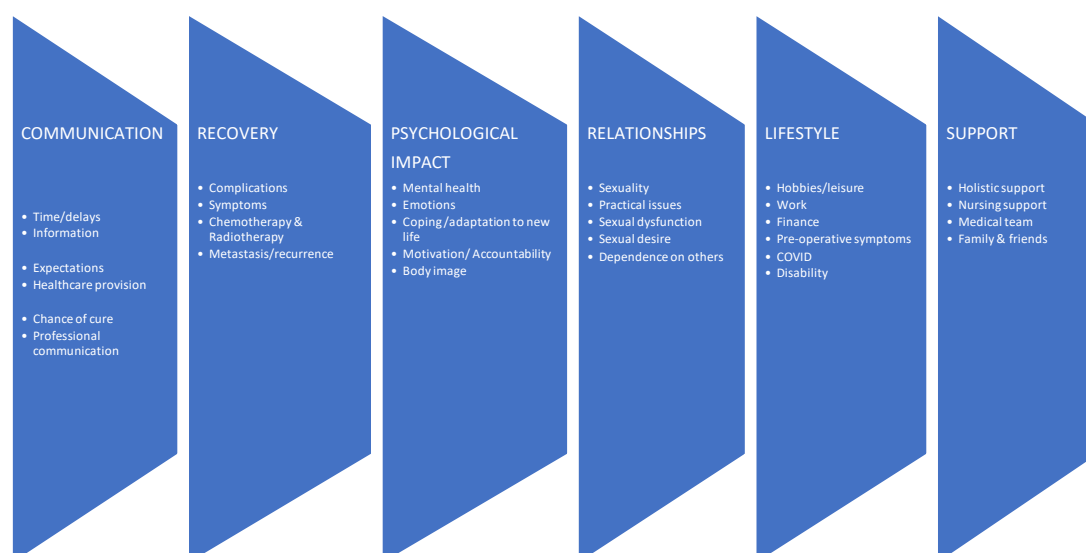


**Figure 11. Themes and categories identified from qualitative interviews**

The retrospective nature of interviews allowed patients to decipher what they would have wanted to know and how that would impact on their decision-making. Many patients specified the information would not have changed their decision to undergo surgery, however by being adequately informed would allow them to deal with the potential morbidity and its associated lifestyle change. Table 21 presents a list of quotations relevant to each category.

| Theme         |              | Illustrative Quote                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|---------------|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Communication | Time/delays  | <p>“They basically wrote me off at my local hospital and I demanded a second opinion which they were very reluctant to do which cost me a lot of time. I’m still angry about the delays in getting me to a proper unit where they sorted me out.”</p> <p>“It’s an awful long time between getting the cancer news to the chemo and radiotherapy to the big operation.”</p>                                                                                                              |
|               | Information  | <p>“I didn’t remember a lot of what he said but he did do some drawings, some wonderful drawings and even now I remember those drawings. He explained what the operation would involve, where the cuts were, what he would take out. I did feel in a tunnel though. I could hear him speak but didn’t know what he was saying.”</p> <p>“Everyone always spoke to me on my level, never patronising or using medical jargon.”</p> <p>“Nobody explained how I would feel afterwards.”</p> |
|               | Expectations | <p>“You can’t possibly know exactly what it’s going to be like when you wake up. It’s worse than you think. But if you’re armed with knowledge that’s all I need.”</p> <p>“I really wasn’t prepared for how disabled I am now.”</p> <p>“Before the operation, even though you have been told it’s a bigger operation, you don’t understand quite how much bigger until you’ve had it done. You think you got through the first</p>                                                      |

|          |                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|----------|----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|          |                            | one well so you will be fine, but this is a completely different kettle of fish.”                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|          | Healthcare provision       | <p>“I do feel slightly let down by the health service, but I understand why things happened the way they did. It doesn’t help my surgery was in a different trust to the one I live in. I’m not sure there was any transfer of information from one to another.....surely in these days, you know, transfer of information, it should be automatic. You know press send and that’s it.”</p> <p>“I do feel slightly abandoned. I think improvements could be made.”</p> <p>“You phone people, they’ve got you on hold then it’s the wrong department and can’t do anything without a referral, it’s just like, oh for goodness” sake and then it’s when I get angry. You just think different departments should be able to speak to each other instead of making it so difficult for the patient.”</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|          | Chance of cure             | <p>“The only decisions that I felt that I have, and even today, is the fact that its either black or white, do I want to be here, or do I not want to be here? And to me, I’m 62, I’m still functional, so it’s like no, I think I can live with a couple of bags or die in a couple of years, maybe not even a couple of years if I didn’t have the operation. So, I thought all the risks and all the rest of it were pretty much worthwhile.”</p> <p>“I mean at the end of the day I wanted to have a chance to be alive and see my kids grow up and do some more stuff before I die. I would still have wanted surgery.”</p> <p>“My choice was to have surgery and live or I don’t have surgery and I would die.”</p> <p>“I didn’t think too much about going forward- no bladder, no rectum, no prostate. I didn’t allow that- I’m quite good at burring that. I’ve mange managed to bury things all of my life, so I sort of stuffed those bits in the back of my mind and just kept thinking at least I’ll be cancer free.”</p> <p>“If there’s a treatment I can have, I’ll take it. If it’s pushing me towards a positive outcome, I’ll be having it. I want to be living another thirty years.”</p> <p>“I didn’t have a decision to make. I wanted it done and that was it. I wanted a chance at cure. This was my only chance. So, there was no decision to make.”</p> |
|          | Professional communication | <p>“I saw the NHS working, it was brilliant. From then on, they assigned me 3 nurses. This is what I can remember now, one of them took me in and just went through everything with me. They kept me up to date with all communication there on in.”</p> <p>“But then I was getting more and more information, and I then realised it wasn’t going to be straightforward. I wish that doctor hadn’t said it to me, being so blasé.”</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Recovery | Complications              | <p>“I ended up with a DVT.”</p> <p>“I was on a VAC dressing because my wounds on my bum had opened up so I couldn’t sit down.”</p> <p>“The urostomy failed. All the tissue around it wasn’t viable so they had to cut back all the black tissue.”</p> <p>“I had serious bleeding during the operation and had 20 pints of blood.”</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

|  |                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|--|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  |                             | <p>"I have stents put in my kidneys every few months to keep the working properly but its only day case."</p> <p>"I got readmitted 5 times since surgery. I had sepsis from a pelvic collection, so it's been rough."</p> <p>"There were 3 lads who went through the same surgery, me and the 2 other, and they both died postop."</p> <p>"He had a massive aneurism about 12 weeks after the operation and they just couldn't stop the bleed quick enough, and he died."</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|  | Symptoms                    | <p>"My nerves were damaged, so I get a dead leg and sometimes it completely gives way."</p> <p>"My bladder is not working properly so I have a suprapubic catheter the moment."</p> <p>"All down my right-hand side, from the cheek of my bottom and half my lady bits are numb."</p> <p>"I can walk 500 metres to the shops and 500 meters back with my sticks but have to take my wheelchair with me."</p> <p>"My waterworks – I have a real problem. I can't hold it like I used to and I'm getting accidents. It's so embarrassing."</p> <p>"I get very tired. Like a tired I've never experienced before."</p> <p>"I couldn't walk for weeks."</p> <p>"There's nothing more soul destroying than waking up covered in your own urine and your own poo."</p> <p>"The urostomy leaks now and again."</p> <p>"The rear wound leaks and has taken over 6 months to heal."</p> <p>"I can't move my foot. I've got a bad limp and I walk with a stick."</p> <p>"By the time I came out of hospital I was 2 and half stone lighter."</p> <p>"I've had a lot of painful fractures in my back probably caused by the radiation."</p> <p>"The pain in my back is awful. I can't do anything for more than 5 minutes."</p> <p>"I can't do very much for myself."</p> <p>"I was so poorly that my hair fell out."</p> <p>"I know I'm never going to walk properly again, and I've resigned myself to that, because of my leg, but it's better to be alive with a dodgy leg, I'm just thankful to be alive really."</p> |
|  | Chemotherapy & Radiotherapy | <p>"I probably do have an element of PTSD. Not at the time but now. And it's not the surgery, I was prepared for that but the extra chemo – I wasn't so prepared for. I was so ill with infection after infection. I remember the coarse hair, the aching body, the exploding stoma bag and being covered in diarrhoea in chemotherapy."</p> <p>"I was getting better from the surgery – walking more, eating more, the pain was better the suddenly I start chemotherapy and I'm back in a worse place."</p> <p>"The biggest emotional and psychological damage for me was the second round of chemo and not the big operation."</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|  | Metastasis/ recurrence      | <p>"They've just done a double ablation on the liver. They said it wasn't worth chopping out because they were pretty sure there was nothing left there."</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

|                      |                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|----------------------|--------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                      |                                | <p>“My friend’s cancer has already come back and she’s terminal now. She still doesn’t regret the surgery as it’s given her a year of normality.”</p> <p>“Since the operation, I’m scared, I’m scared I’m going to get something else.”</p> <p>“Every day I worry that its back or coming back.”</p>                                                                                                                                                                                                                                                                                                                                                                                     |
| Psychological impact | Mental health                  | <p>“It was that realisation of that part of me was missing. I sat there and cried.”</p> <p>“I’m a fit active man. I was a fit active man, a farmer, and I changed overnight after a month in hospital to basically an old bloke with a stick and it’s a shattering effect on my life to be honest.”</p> <p>“I am on an emotional roller-coaster and its ok no say you are not ok, and I wish I had asked for more support with the anxiety and depression (cries). My emotions are all over the place and my mental health is not good.”</p>                                                                                                                                             |
|                      | Emotions                       | <p>“I do get angry. I get angry at the cancer and what it’s done to me, it’s changed my body completely. I guess it makes me angry that I can’t have sex and I blow off the handle and that’s not good for my partner.”</p> <p>“I was depressed just lying in bed, crying all the time. They had to send the psychiatrist – I went into a real big depression.”</p> <p>“I don’t think I’ve recovered mentally; you know what I mean, emotionally. I am not sure I ever will. It is so life changing.”</p> <p>“It frightened me last time I had cancer but tis frightened me even more this time.”</p> <p>“I was distraught.”</p>                                                         |
|                      | Coping/ adaptation to new life | <p>“I have accepted I am a bit slower, a bit weaker, more tired and can’t quite do all the things I did around the house, and I think the quicker you accept that the better it is for you. I used to cry about it but when I accepted it that all changed.”</p> <p>“My new body is just the price I had to pay to live.”</p> <p>“I don’t want to put it on others, so the easiest way is to be “just fine”.</p> <p>“It is difficult but I’m grateful I am still here, and I can live some kind of normal life.”</p> <p>“I’m forever going to the toilet. I’m forever emptying these bags of poo and pee but it’s just something I have to plan around what I’m doing.”</p>              |
|                      | Motivation/ Accountability     | <p>“Life will not necessarily get back to full normal, but you’ll be able to pick things up again and get going. And I think that’s something I’ve always clung on to.”</p> <p>“Instead of going into hospital to be an ill person, I was going in to get fixed and get out.”</p> <p>“Every week that went by, I felt stronger and because of that I wanted to do more to be even stronger the following week.”</p> <p>“The speed of my recovery is down to the training I did before going in. It makes you more motivated- motivated to get out of bed, start walking and within a week I was up and down the ward all day. You have to take responsibility of your own recovery.”</p> |

|               |                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|---------------|----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|               | Body image           | <p>"I have no confidence wearing the colostomy bag because it is completely new to me. My body has completely changed. I hate looking in the mirror."</p> <p>"It's really demoralising, like it's really – it knocked my self-esteem so much having the stoma but with the right support I have started to make peace with it."</p> <p>"I feel self-conscious about my stick. I can walk without the stick, but I've got a dreadful limp. Somebody said once 'have you had a stroke or something?' which I found highly embarrassing."</p> <p>"My right leg has become very thin because of muscle wasting so I'm very conscious not to show it in public."</p> <p>"I had to change completely the way I dress, so I was one of these that used to wear little t-shirts but couldn't do that any longer as the bag showed and now, I've completely had to change as I have big bag stuck on my leg too."</p> <p>"When I came out of hospital everything had retracted. My penis was much smaller."</p> |
| Relationships | Sexuality            | <p>"I feel like I've lost my manhood, the thing that makes me a man."</p> <p>"I thought my new vagina would feel the same, but it leads to nowhere now, they've taken it all out. So, I feel I've lost what made me woman."</p> <p>"I think obviously getting all my reproductive system removed is very final. The infertility side of cancer is hard anyway but with pelvic exenteration there's no going back. I will never be able to have a baby or carry a baby and it feels like something massive has been taken away from you as a woman."</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|               | Practical issues     | <p>"We can't even share a bed. Between getting comfortable, night bag, stoma's, there is just no way."</p> <p>"We can't just go out like we used to. There's the whole preparation of spare clothes, spare bags, wet wipes. It's a true reflection of what has happened to my body. I have to think before doing everything."</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|               | Sexual dysfunction   | <p>"We can't be intimate anymore."</p> <p>"It's so frustrating and it's frustrating for my wife you know. 'It's not very nice not to have him working. It's a constant reminder and especially because the Viagra doesn't do anything. It's done anything for my self-confidence."</p> <p>"The urostomy has taken my sex life off me and that's one thing I wasn't really ready for at fifty years of age."</p> <p>"There's no sexual function. There's still no erection."</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|               | Sexual desire        | <p>"We've talked about it, but I haven't been able to have sexual intercourse as yet, but we do talk about it, and I want it. I want him."</p> <p>"I am young and still want to be sexually active, um, but actually I don't know that much about what my new vagina is, I don't know what I can do with it."</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|               | Dependence on others | <p>"I'm more dependent on my mum and girlfriend, cos at the minute I struggle to dress myself."</p> <p>"I still don't go upstairs without somebody with me, behind me or come downstairs."</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |



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|-----------|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|           |                        | <p>"I couldn't have done it without my husband. He was my rock. I needed him and he was there every step of the way."</p> <p>"I'm frustrated not being able to do what I should be able to and not being independent is killing me. The thought of being like this forever is breaking me too but I'd still rather that and be alive than have given in to it."</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Lifestyle | Hobbies/leisure        | <p>"Some days I will wake up thinking I'm going to go out, go for a walk and then 5 minutes later I'm in the armchair and I'm there for the day because I'm just so shattered. It's like my brain wants to but my body just won't move."</p> <p>"I will go for a walk with my stick, I know it takes ten times longer, but I go out and try to go out every day."</p> <p>"I used to go out on my bike quite a lot, I can't do that because it puts too much pressure on it."</p> <p>"Since my stomach muscles have been removed, I haven't been able to surf yet."</p> <p>"I've been walking loads. I've done a few bits of running. I can't manage to do any cycling but I'm back in the water and done a couple of mile swims."</p> <p>"I will never be able to do the walks we used to do. My right leg won't ever allow it."</p>                                                                                                                                                                                                                                                                          |
|           | Work                   | <p>"Whether I'd be able to do the same job as I used to, I don't know. It's always been my intention to go back or if physically I can't do that job, then I would perhaps look for an easier job."</p> <p>"I always thought I would get back to it. But knowing what I know now there is no way on earth I could do that job again."</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|           | Finance                | <p>"They've kept my job open for me but haven't paid me. So, I got statutory sick pay for six months and then it was a nightmare trying to get any financial support."</p> <p>"I'm down £300-£400 a month. I'll have to fill that form in again but there is generally a lack of support."</p> <p>"Macmillan nurses tried to get us help but it was all means tested and because my husband still had an income, I wasn't eligible."</p> <p>"The kids were at private school with costs of £26000 a year so they gave us 50% bursary whilst I was off work going through treatment."</p> <p>"In first year when I got cancer, we weren't getting any help from the government, there was no sick pay, my partner was working which was good. My friends ended up setting up a just giving page to help me pay the rent for the first year which felt awkward. But we literally would not have survived without that generosity of people giving money."</p> <p>"I'm just getting £300 a month and that is at the moment. As I say, I won't lie, I'm used to having quite a bit more than that obviously."</p> |
|           | Pre-operative symptoms | <p>"The pain going to the toilet before the operation was unbelievable. The pain was shocking and gaining all the time and I couldn't leave the house and it was awful."</p> <p>"My symptoms were getting worse and worse. I couldn't walk anywhere without basically weeing myself and it was so embarrassing. I couldn't sit for very long either because it was uncomfortable of where the mass was."</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

|         |                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|---------|------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|         |                  | <p>"I would still have gone ahead with surgery regardless. I mean I couldn't have lived how I was; I was in continuous pain."</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|         | COVID-19         | <p>"Having cancer in COVID time is the absolute worst. Everything shut down."</p> <p>"I just couldn't have the operation as the NHS shut down. I did more and more chemotherapy until they could get me a date. It was never ending."</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|         | Disability       | <p>"I've had the bed brought downstairs as I can't manage the stairs easily."</p> <p>"It took 6 months to get a car and get it adapted because I had to sell my existing car and get an automatic that had to be converted to a left-hand foot operation."</p> <p>"I really wasn't prepared for how disabled I am now."</p> <p>"When I came out of hospital, I couldn't do anything. I couldn't walk. I could get out of bed and just sit on a chair, but I couldn't do anything else."</p>                                                                                                                                                                                                                                                                                                                            |
| Support | Holistic support | <p>"I think I would have benefited in some counselling. Not when you get out of hospital but around 6 months later. Counselling starting when you are conscious enough to be dealing with it would have definitely helped me."</p> <p>"I was referred to a dietician but by the time I saw them I was eating alright and started to put some weight on."</p> <p>"The Macmillan nurse was super helpful. It's so comforting to have that someone by your side and guide you through your journey. She's been really supportive, and I think it makes all the difference."</p> <p>"I applied for sickness benefit – I'd never applied for a benefit in my whole life, then I applied again and got rejected and it made me not want to apply again."</p>                                                                 |
|         | Nursing support  | <p>"I had a lot of support from the stoma nurses. The help of a good stoma nurse at home is vital."</p> <p>"My nurse specialist has been amazing. She always turned the tables to being positive to get me out of the downers. I know I keep mentioning her but if I didn't have her then I think I would have a nervous breakdown."</p> <p>"I was never given a nurse specialist, I literally had nobody. Unless I sought it myself, there was nobody. And I can always remember when I went back for my 6-month check there was a new nurse specialist and she talked to me in a way nobody had talked to me before, in a way that was knowledgeable and reassuring. And I said to her 'I wish you had been here from the start'. And she was really apologetic and said, 'I feel like you have been let down'."</p> |
|         | Medical team     | <p>"My surgeon rang me and said 'you must- you must if you've got any problems at all, you must ring me and let me know.' So, although it's 11 months since I've had the operation, I know he's still there for me because he told me he is. So, it gives you that extra support, because you know you've got someone you can go to."</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|         | Family & Friends | <p>"I'm lucky as far as support from my partner and family, which has been a great help. It would have been a very different situation on my own."</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

|  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|--|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  |  | <p>“I hear from my mates now and again but not like it was. I do feel quite lonely in that respect. My relationships with them have changed since the operation.”</p> <p>“I think maybe as a family we might have benefited from support because none of us really got our heads around it when we were told I might die. It has been easy for any of us.”</p> <p>“A lot of my friends dropped off the radar. Because I think how do you-what do you say to that, like they don’t and obviously I’ve got some really good friends who sort of checked in and stuff but it’s like beyond anyone’s imagination. I think people don’t know what to say about it and that makes you feel alienated. So, I guess those circles have disappeared for me.”</p> <p>“My relationships have changed a lot with people. I guess having cancer you kind of – you find out who is there for you and who isn’t.”</p> |
|--|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**Table 21. Illustrative quotations from patients of each category**

## **4.5.2 Identified themes**

### **4.5.2.1 Patients**

#### **Theme 1: Communication**

A central part of decision-making is communication. The need for information needs to be communicated in a timely, appropriate and succinct manner. Various amounts of information were given to patients with some being told ‘all the ins and outs’ and with others feeling like ‘they had been told nothing’. Patients not aware of their advanced or recurrent diagnosis state that they would be in a better frame of mind of making decisions and listening to information if they ‘had some idea of what was coming’ with respect to the extent of surgery. Patients want information to be given in a stepwise manner to absorb the extent of information and facilitate balanced decision-making. Many patients acknowledge that despite being told information they could not recall it and rely on the person accompanying them to take in the information.

Patients want appropriate and accurate information to be delivered. Some patients feel let down by poor communication of expectations and the trivialising of the disease process and surgery ‘I wish my doctor hadn’t been so blasé’. Patients expressed the need for timely processing of information between primary and secondary care to ensure continuity of care and to avoid delays and misinformation of treatment intent.

Patients need information to be communicated in an appropriate setting with both the accuracy and delivery of information being equally as important to make an informed decision. Offering surgery feels like ‘hope’, ‘relief’ and a ‘chance of cure’ to the

patient. They express the feeling of hopelessness and futility when being told they have advanced or recurrent cancer and subsequently become fixated on 'going through with surgery so they would be cured'. They give very little regard to the risk of palliative surgery or recurrence and remain hopeful and optimistic of cure. Patients predominant factor in accepting PE is 'the chance of cure'. Most patients describe having 'no other options' and that 'there is 'no decision to be made' as 'surgery is the only chance of cure.' Patients focus on the expectation of cure with surgery at the detriment of retaining any information 'I could hear what he was saying but it was like I was in a tunnel, it was noise, I didn't want to hear what could happen, I wanted it out.' Very few patients consider the risk of incomplete resection and its associated morbidity to focus on 'being cancer free'.

Patients want realistic expectations communicated as the lack of preparation they have for their post-operative life are associated with decisional regret. Patients expect to prolong their lives with surgery and give no or little thought to long-term survival. They do however, report being unprepared for surgery. Their expectation of the recovery period is similar to previous surgery they have undergone 'even though you have been told it's a bigger operation, you don't understand quite how much bigger until you've had it done'.

Patients need certainty and consistency in the ability to access secondary care services regardless of geographical location. Failure to not provide adequate access results in vulnerability, disappointment, and disillusionment.

## **Theme 2: Recovery**

Complications and long-term morbidity are extremely important factors when considering PE. However, those with significant pre-operative symptoms find it much easier to decide to have surgery as they can no longer cope and 'any surgical intervention with whatever result that has must be better than what I'm suffering with now.' Those without symptoms find it difficult to justify such radical surgery in the absence of symptoms and feeling well. Some patients describe that they 'had no idea what surgery would mean' in terms of recovery with many reporting unexpected levels of disability within the first year. Some patients acknowledge they 'didn't want to know a thing' about surgery and with the benefit of hindsight if they had been told

‘you’d have needed a horse to drag me down there. I wouldn’t have wanted to go through that’.

Patients with recurrent disease need to know that exenterative surgery is significantly more of an undertaking than their primary surgery to make an informed decision and meet expectations. Patients experiencing complications don’t feel like they had made an informed decision due to the lack of understanding regarding the risk of potential complications and the impact on life. Delayed wound healing was associated with infuriation and disappointment which compromised patients’ ability to accept and adapt to their new lives. One patient described decisional regret to have surgery; ‘if I knew then what I know now then I wouldn’t have had it done’ due to prolonged perineal wound healing and months of experiencing VAC dressings and district nurses. Patients that don’t regain baseline QoL as soon as they expect describe hopelessness and recovery fatigue. The overall sentiment of experiencing significant complications was associated with damaging psychological recovery.

Most patients were expectant of their post-operative symptoms and considered them during the decision-making process. Symptoms described were genitourinary, gastrointestinal, musculoskeletal, mobility and pain. Some patients expressed feelings of disappointment despite being aware of the risks felt they ‘wouldn’t happen to me’. Others describe being completely ‘ignorant to what life would look like or feel like’ as they were disengaged with the counselling process of understanding potential symptoms as they were purely focused on having the surgery.

Patients expressed informational needs of ongoing treatment, including potentially requiring adjuvant chemotherapy as it would be integral to their decision-making process. Adjuvant chemotherapy is described as ‘more brutal than the surgery itself’ as they feel unprepared, ‘they prepare you for the huge surgery, but they don’t prepare you for the chemo’. Patients describe it being ‘the biggest emotional and psychological damage’. Patients express that the potential morbidity associated with adjuvant chemotherapy may have influenced their decision to undergo surgery.

Information regarding the risk of disease recurrence and overall prognosis is key information essential to make a decision as early metastasis leads to feelings of hopelessness and futility. Patients with pre-existing metastatic disease need both reassurance and realistic expectations regarding the potential of cure. Patients describe

hesitancy to undergo PE compared to chemotherapy prior to metastectomies as it provides patients with little reassurance for disease control and express wishes of combined surgery for both primary and secondary disease.

### **Theme 3: Psychological impact**

Patients stated that providing information regarding the psychological impact of surgery on patients is imperative in the decision-making process. They describe an emotional rollercoaster from diagnosis through to recovery. Some patients describe a 'shattering effect' when dealing with the acute physical deterioration which can result in decisional regret to have surgery. Inadequate information results in significant psychological morbidity including unanticipated anger, fear, depression, agitation, and sadness which is most prevalent in the first six months following surgery.

Informational needs should also focus on changes in body image and societal function and must be addressed at the time of shared decision-making, to enable patients to make trade-offs with survival and post-operative function and role. Patients report having to accept a significant change in how their body will look if they proceed with surgery. Those who just have a colostomy or have had a colostomy prior to a urostomy generally cope much better, 'I already had a colostomy. I was familiar with the psychological and physical issues of wearing a bag, so what's another bag? It's a bit trickier to deal with but it's just another bag'. Despite knowing the physical change surgery would entail they struggle to cope with 'how that feels emotionally, psychologically.' They struggle to look at their new body; 'its honestly quite depressing, looking in the mirror and seeing two bags hanging off your stomach. It's even more embarrassing when you look in the mirror and see that you've got two bags hanging off your stomach, and one or both of them are leaking. You know- it's a bit of a downer. It's a massive downer.' As patients progress in the recovery process, they become more accepting of the change but feel 'it's a constant reminder of the cancer'. The impact that the post-surgical body has on patients' self-confidence is underreported. At the time of pre-operative counselling, patients describe not 'even thinking about the impact it had on my body or mind because it was all about getting the cancer out'. However, following surgery they describe they 'hate looking in the mirror' and lose all self-confidence and become very conscious of their 'disfigurement'. Lack of clear information regarding these important aspects can lead

to significant decisional regret. Pre-operative peer- to-peer transfer of knowledge and information with post-treatment survivors resulted in better informed decisions, ‘if you’re armed with knowledge and psychological preparation that’s all you need to accept this huge change’.

Patients cope with their new life very well after the initial recovery. They accept the change in body image and lifestyle and see it as the ‘price to pay of having the cancer out’. Many patients accept this even prior to the surgery. Emphasising the importance of post-operative patient motivation and accountability facilitates improved recovery and stimulates psychological well-being which is important in the decision-making process. A duty and responsibility are described which ‘helps focus the mind’ to prepare to get home and ‘get back to normal.’

#### **Theme 4: Relationships**

A central part of decision-making is the effect surgery has on relationships with spouses, family members and friends. The impact of personal relationships on decision-making is complex. Addressing potential sexual dysfunction is described as one of the key informational needs in the pre-operative setting, with this considered especially important for decision making by male patients. Some men report losing their masculinity due to ED; ‘I feel like I’ve lost my manhood, the thing that makes me a man’. Non-parous pre-menopausal women who must choose whether to proceed with hysterectomy feel like they are sacrificing their femininity; ‘it was one thing being infertile from all the chemo and things, I did have my eggs frozen though, then to be faced with having it being taken out of you and never having the option of carrying your own child really brings it home. You are just a body. You are no longer a woman.’ Patients describe being prepared for what surgery sacrifices anatomically but the associated feelings of loss of sexuality isn’t expected when making the decision to have surgery. Some women reported such fears as having their partners see them nude or only partially clothed. Other women without partners were reluctant to initiate even friendly contact with men due to concerns about sexuality. This subsequently affects relationships which patients feel should be explored more prior to deciding to have surgery.

Men who have previously had a colostomy prior to exenterative surgery struggle particularly with ED; ‘the colostomy was just one bag, and it wouldn’t affect me

sexually. The urostomy however, it's taken my sex life from me basically and that was one thing I wasn't ready for'. The emotional change associated with ED is associated with anger and frustration; 'It makes me angry that I can't have sex and I blow off the handle. I knew I wouldn't be able to have sex. I just think 'why me?'. The unanticipated sexual dysfunction can have a significant impact of overall psychological function. The intrinsic link between sexual dysfunction and psychological function needs to be explained pre-operatively, with reassurance and appropriate support provided, including the provision of practical support and strategies to improve sexual function. Overall, female patients report underestimating the magnitude of sexual dysfunction especially with reconstruction due to a lack of pre-operative information. Reconstructed neovaginas have been reported to be 'a hole to penetrate' but physically not useable and insensate which is disappointing to the younger cohort of women. Some patients regret having reconstruction but appreciate that this may change with time.

Patients report maintaining a sexual desire and describe accepting loss of penetration at the time of deciding to undergo surgery. They describe changing the way they connect with their partners both emotionally and physically to maintain a 'physical closeness'. However, this comes at a cost to both partners; 'it's so frustrating, and it's frustrating for my wife you know. It's not very nice, with 'him' not working. It's a constant reminder and especially because the Viagra doesn't do anything it's not done anything for my self-confidence'. Some patients are very accepting and come to terms with this at the point of making the decision to have surgery; 'they told me they would make me impotent. I accepted very early on I wouldn't be able to have sex again and my partner is brilliant.' Couples describe being accepting prior to undergoing surgery; 'She never found it a problem because it was more important that I was alive'. However, physical contact is also compromised due to leaking stomas, leg bags and discomfort in sleeping positions.

The impact of personal relationships on decision-making is complex, with a spectrum of complex feelings expressed, with some patients wanting to prolong their lives to increase time with families; 'I would do everything in my power to spend as long as possible alive with my grandchildren. Whilst others felt coerced and pressured by family members to endorse surgery as a potentially curative treatment option, 'I am fearful of dying too soon from complications, but my family wanted me to have the



surgery'. Some patients report distancing themselves from their children and immediate family 'to protect them from the reality'. 'For the first month I didn't want to see anyone because I didn't want people to see me like that. I didn't like how I was' which with hindsight is described as 'a big mistake on reflection because it got to a point where I was really quite down and just not happy with progress'. Accepting the inevitable dependence on spouses is important, 'I genuinely couldn't have done it without him. He had to do everything for me. He was even washing and dressing me in the early days. I still can't put my socks on 4 months later. I couldn't carry a cup of tea so he would leave flasks and snacks in the living room when he eventually had to go back to work'. Frustration is experienced by being dependent; 'frustrated I am too, not being able to do what I should be able to do and not being independent is killing me'. To maintain the quality of key personal relationships, patients require information regarding their evolving role in the post-operative function, including the dependence on others, change in spousal relationships and the introduction of the care giver role within a relationship.

### **Theme 5: Lifestyle**

Understanding the impact of PE on overall lifestyle, including ADLs and social, recreational and occupational activities should be a fundamental issue that is discussed in the pre-operative setting to facilitate the process of SDM. Some patients accept and sacrifice lifestyle choices to have surgery. However, patients that don't anticipate a change in lifestyle such a change report it 'being very depressing not being able to do what I love'. Those in good physical health pre-operatively find it very difficult to accept; 'I was a fit active man and did all sorts of stuff around the farm. Now I have to pay someone, and I stand there and watch them which doesn't feel very good'. The inability to perform routine activities including walking results in a fear of judgement; 'I'm quite certain people's perception of me has changed because all they see is the disability and its – you know, difficult at times'. The inability to perform usual leisure activities or hobbies is upsetting but having to justify themselves to friends becomes very frustrating; 'it becomes really draining having to explain to people I can't walk very far, I can't sit for very long, I can't really leave the house for very long. It's frustrating having to keep going over that'.

The occupational impact of PE including the risks of potential unemployment, delayed return to work, change in role and the potential financial implications should be discussed. Patients potentially sacrifice their jobs and accept they may not be able to return to the same role following surgery. Potential unemployment was a considerable concern especially amongst those with young families. Patients that do return to work occasionally return much later than they anticipated which occasionally raises financial anxiety. Some patients are adamant of their return to work after surgery and view it as a success in their battle against cancer and a return to normality especially when they have witnessed other colleagues return after a cancer battle; 'There's a few people in the same office who've had cancer before and – different cancers, but they've made it back to work and one of them was 65/66 when he came back. People were saying 'what are you doing back' he said, 'I had to come back. I love work.' And that's it for me I am back and it's like I've won' I've won the battle and I'm back to normal. You just want your normality back'. However, in the cases where this is not possible despite best intentions it's associated with defeat, failure and regret which prolongs the emotional and psychological recovery. Patients are unprepared for their post-operative lifestyle including change in employability. Changes in employment has financial implications and patients feel unsupported with available support of Personal Independence Payment (PIP) and 'feel let down by the system' when seeking support. Patients report having 'to jump through hoops' which makes them 'worry more about money more than the cancer.' Some patients question their decision to have surgery when they start to struggle financially as they 'feel like a failure not being able to provide for my kids' especially when the spouse 'has to do overtime and basically work 2 jobs'. There is a lack of financial insight, with patients expressing feelings of financial anxiety and personal failure in the post-operative period.

### **Theme 6: Support**

Dedicated support is highlighted as being an integral resource for patients during the pre-operative decision-making process when considering surgery. Patients feel family is the main source of support with patients feeling 'wouldn't have been able to cope' without their spouse or children as both a physical and emotional backing. Family members are described as the 'rock' being present emotionally to 'fight away the tears' and partaking in caring roles in helping to wash and dress the patient during the early recovery. Friends are described as having a really important role for being reintroduced

socially. Some patients chose not to share the intricacies of surgery for the risk of them not understanding or being repulsed by the extent of surgery and as a result ‘pretend to be ok’. However, there are many people who rely on friendships for getting back to a sense of normality.

Patients describe being unaware of the magnitude of support they will require post-operatively and would benefit from being aware of this prior to agreeing to undergo surgery. Psychological support is predominantly what patients struggle to acquire and feel that ‘chatting to someone not directly involved with you’ could be helpful. Many patients disclose being uncomfortable in discussing personal issues and find it difficult to acquire psychological support. Trust, confidence and accessibility are considered to be important characteristics of medical teams during this period. Patients require support and high-quality information from a range of health care professionals. A key contact, such as a CNS, who is accessible and can bridge information between patients and surgeons is considered essential. Patients form a close relationship with their CNS ‘if I didn’t have my CNS, I would have had a nervous breakdown’ and feel they are crucial in listening and discussing options of treatment. They feel this because ‘the doctors are all so busy and you don’t feel like you can talk to them in the same way’ as they ‘never feel rushed’ and ‘talk to you in a way you understand’. Stoma nurse specialists are key providers of information during the pre-operative phase, with high quality stoma education considered to be essential for physical and mental preparation for surgery. Patients need to feel they have access to the medical team for reassurance and the knowledge that if they need to discuss something before or after surgery, they have that ongoing support.

#### **4.5.2.2 Clinicians**

Three specific themes were identified through the HCPs interviews illustrated in Table 22.

|                        |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|------------------------|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Treatment expectations | Co-morbidities | “When presenting the options of exenteration to patients, both they and I need to have a full picture of known co-morbidities to understand whether they have the capacity to undergo such radical surgery. It’s more difficult for the tertiary referrals that come to us as they usually have had downstaging treatment and when presented as potentially curable in the outpatient setting their performance status may have never recovered and may not be fit enough to withstand the surgical insult.” |
|------------------------|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|  |                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|--|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  |                        | <p>“CPEX testing and comorbidities need to be assessed prior to offering surgery.”</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|  | Resectability          | <p>“The most important element of decision making for surgery is whether I can get a clear margin and I make that clear to the patient.”</p> <p>“If I think the margins are close then it’s part of the decision making and planning with the patient.”</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|  | Curative intent        | <p>“Patients need to know that surgery is with curative intent.”</p> <p>“Survival data is all historic and I present my own data in the discussion.”</p> <p>“Patients can get quite upset when faced with adjuvant treatment. They undertake a significant recovery process and to be faced with more chemotherapy can be very challenging. It is almost an easier decision for those who have had an R1 resection. They should probably understand the potential need for adjuvant treatment in the decision-making phase.”</p>                                                                                                                                                                                                                                                                                             |
|  | Holistic impact        | <p>“Patients need to understand the overall impact of surgery. It’s very easy to say we can get the cancer out but at what cost to the patient. Some patients decide they don’t want to live with a urostomy and/or colostomy but providing them with relevant information to them and how it can potentially change their lives is important, so they make the right decision whether or not to undergo surgery.”</p> <p>“The impact exenteration has on individuals is significant and discussion regarding how it changes their lifestyle and the way they currently live is important. They tend to understand the operation itself, but they can’t connect the biology to what it means for them. It takes time to ensure they appreciate the implications and more importantly what support is available to them.”</p> |
|  | Overall support        | <p>“What is more important is that we discuss the support available to them to aid the recovery.”</p> <p>“Patients need resources to turn so they are appropriately supported during the decision making. Meeting similar patients who have had similar surgery so they can discuss true implications. Knowing there is financial help, especially for those younger patients supporting young families and unable to work for prolonged periods of time.”</p> <p>“Patients need to understand they have access to various holistic support services within cancer care prior to surgery which can help support them in the decision-making process.”</p>                                                                                                                                                                    |
|  | Multiple consultations | <p>“What I have learnt over the years is that people need more time. The role of the CNS has allowed patients to access time as well as receive support historically they were not given. It gives them access back to the surgeon. I am more than happy to see patients time and time again when contemplating surgery.”</p> <p>“I insist on at least 2 consultations prior to consenting. They are overloaded with information and rarely retain the potential</p>                                                                                                                                                                                                                                                                                                                                                         |

|                      |                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|----------------------|---------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                      |                           | complications which is important so that I can meet their expectations.”                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Recovery             | Morbidity                 | <p>“Patients need to understand the risks and potential complications with exenteration before proceeding. I always copy them in to the clinic letter so they can appreciate in black and white what has been discussed.”</p> <p>“Unfortunately morbidity is not uniform, and complications cannot be extrapolated to individuals. Patients are informed of all potential complications and are advised they will develop complications whether major or minor during the recovery process.”</p> |
|                      | Mortality                 | “During the consent process I always mention the risk of death with such radical surgery. It allows patients to understand the extent and significance of undertaking surgical intervention.”                                                                                                                                                                                                                                                                                                    |
|                      | 12-month recovery         | <p>“Recovery is a slow process, and I always quote that they will not get back to pre-treatment activity until 12 months, although at 6 months they can feel close to normal.”</p> <p>“It is important that they understand the complexities of recovery and what that means to them. That should be important in the decision-making process.”</p>                                                                                                                                              |
|                      | Symptom burden            | <p>“I discuss symptom burden with the patients to allow them to make a decision that’s right for them. Surgery comes at a cost to patients. Survival at a price. Especially the more complex cases with bone resection and major neurovascular excision.”</p> <p>“They need to be informed of longer-term problems such as delayed wound healing, potentially mobility issues.”</p>                                                                                                              |
|                      | Long term quality of life | “Quality of life is expectedly affected. They are reassured that most regain baseline in 12 months, however, living with 2 stomas and the potential complications and/or implications that can arise from that can affect these patients longer term.”                                                                                                                                                                                                                                           |
|                      | Prognosis                 | <p>“I am very clear that surgery is the only potential cure of the disease.”</p> <p>“I tend to quote our unit data in terms of prognosis and survival data.”</p>                                                                                                                                                                                                                                                                                                                                 |
|                      | Recurrence                | “Despite being curable disease, patients should be informed of the risk of recurrence and should be part of their decision making although most patients do not want to know.”                                                                                                                                                                                                                                                                                                                   |
| Psychological impact | Body image                | <p>“Body image is one of the greatest informational needs especially within the younger cohort. How they will feel with a stoma. How they will do normal activities.”</p> <p>“Many patients biggest fear is how a stoma will change the way they feel about themselves.”</p>                                                                                                                                                                                                                     |

|  |                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|--|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  |                      | “Surgery changes their body. Most patients understand this, and we ensure they spend time with the stoma nurses prior to surgery but it can affect how they feel about themselves.”                                                                                                                                                                                                                                                                                                                                                                                                                       |
|  | Emotions             | <p>“Patients need to understand that experiencing a range of emotions is normal especially within the immediate post op recovery period.”</p> <p>“A range of emotions from diagnosis to recovery are normal. I have appreciated a range from anger, gratitude, desperation, sadness and relief. Over the years I have appreciated that if they expect this and understand it’s normal, then they comprehend the process much better, and that acceptance almost allows them to dissociate the emotion and concentrate on the decision making and appreciate the potential consequences of treatment.”</p> |
|  | Adaptation to stomas | “Pre-operative counselling for stoma(s) is imperative for education, however, patients need a period of adjustment following surgery.”                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|  | Sexual dysfunction   | “Sexual dysfunction is a major implication for men. Invariably erectile dysfunction has a significant psychological impact which patients need to understand prior to exenteration.”                                                                                                                                                                                                                                                                                                                                                                                                                      |

**Table 22: Illustrative quotations from HCPs of each category**

### **Theme 1: Treatment expectations**

Presenting appropriate treatment expectations to patients is imperative for clinicians to facilitate the decision-making process. They feel patients need adequate information that needs to be presented over multiple consultations to retain information. Patients need to hear information repeatedly to process the magnitude of surgery prior to deciding whether to proceed. HCPs also feel that patients need certainty and consistency in the ability to access secondary care services regardless of geographical location with many patients travelling a significant distance to tertiary level units. Clinicians uniformly consider resectability, co-morbidities and patient age as key factors for decision-making and believe that these factors are important in managing expectations with the patient when discussing potential treatment options. PE being the only potential curative option is also important for HCPs in the SDM process.

### **Theme 2: Recovery**

Clinicians feel that a central part of decision-making for patients is the comprehension of potential complications and side-effects. Patients need to understand that their QoL will be impaired significantly initially with a return towards baseline by 6-12 months.

From an HCP perspective, symptom burden, prognosis and recurrence were considered important points of discussion in the pre-operative phase to help aid decision-making in this 'potentially vulnerable' cohort. This was to balance the benefit of improvement in pre-operative symptoms against the uncertainty of cure and recurrence. They acknowledge that some patients fail to engage and acknowledge the risks and complications described to them as they are so focused on a chance of cure, however, they ensure consultations are accompanied, when possible, to reiterate the information and ensure they can meet the patients' expectations.

### **Theme 3: Psychological impact**

The psychological impact of surgery was an important pre-operative informational need by HCPs. However, the emphasis was mainly on body image, including its impact and the need for adjustment in the post-operative setting. The psychological impact associated with sexual dysfunction, predominately in males was also important an important factor considered in the SDM process. Clinicians comprehend the necessity to discuss the wider aspects of the emotional impact of surgery during the pre-operative period to facilitate the SDM process. Accessing formal support for patients was also highlighted with recognition of the limitations of service provision within some areas.

## **4.6 Discussion**

Decision-making in PE for LARC and LRRC is complex. This study identified that patient informational needs for SDM prior to PE are centred on six key themes; communication, recovery, psychological impact, relationships, lifestyle and support. HCPs currently focus on treatment expectations, recovery, and psychological impact during the counselling process. These key themes provide a framework to ensure both patients and clinicians priorities are appropriately addressed during pre-operative counselling. This will ensure the principles of SDM can be implemented by balancing risk and benefit with patient priorities when considering PE as a treatment option for LARC and LRRC.

Within the qualitative methodology the sample size of 33 is considered appropriate and rigor was assessed by approaching all subtypes within the stratification factors. Themes uncovered emphasise the challenging decision-making process for patients offered surgical intervention.

Currently, treatment preferences and priorities have not been documented in PE surgery. This study benefits from its retrospective nature, using patients having been through surgery and thus issues perceived during their recovery identified as important when understanding the extent of surgery and the decision to undergo surgery. Only one study, to our knowledge, has performed a qualitative assessment of decision making in patients undergoing extended pelvic resection for rectal cancer. In 2006 Wright et al. completed a 10-patient qualitative assessment of patient experiences related to extended pelvic resection for rectal cancer (171) which reflected many of our findings several years later. Wright describes treatment as challenging to complete, and that patient understanding of pre-operative information is incomplete which has been highlighted within our patient interviews and Chapter 3. Themes in both studies reflected patients' highly focused desire to seek wellness and cure with this cohort of patients uniformly expressing the need to have surgery for a chance of cure. Both studies also revealed misunderstanding by patients of their disease biology, probability of cure, therapeutic options, and treatment morbidity (171). Supportive care is also highlighted in both cohorts with a fundamental need for multidisciplinary care. In contrast, this study identified more holistic informational needs in terms of impact on financial implications, relationships and lifestyle. Wright established a need for technically skilled delivery of surgery, chemotherapy, and radiotherapy (171) whereas the focus of our cohort was trust and access to multidisciplinary HCPs.

Complexity in decision making for cancer treatment arises from many factors. Various treatment options often exist; both clinicians and patients must carefully weigh the risk of treatment-related morbidity versus the potential for benefit as measured by improvement in symptoms, prolonged survival, or disease control. Other studies have demonstrated that the delicate balance between toxicity and benefit is influenced by other issues permeating the patient's life, including work responsibilities, family commitments, and financial burdens, with additional inputs from culture and social norms, and spirituality (348-351). Some of these established domains in decision making are resonated by the surgical impact of HrQoL domains including physical, psychological and social domains as well as upon body image, sexual function, communication, relationships, work and finance (168). The impact on each of these domains in the present study was found to be variable, with a reduction in initial HrQoL, which however could be transitory following a period of adjustment (168).



Many patients with cancer want detailed information about their cancer diagnosis and treatment options (352, 353). Most patients want to be involved in decision making about treatment, however patient preferences for information and involvement in their care is variable and dependent on the stage of their illness (354, 355). However, it has been shown (356-358) that not all cancer patients wish to participate in decision-making, and the level of participation can vary on a continuum ranging from total passivity to extreme activity (359). Some studies indicate that active engagement in the decision-making process is not a role that all patients feel comfortable adopting, including women with breast cancer, men with prostate cancer and renal patients, the doctor has been preferred as the primary decision maker (360-362). Beaver et al found that two thirds of patients with colorectal cancer preferred a passive decision making role (363). Having a well-informed patient who is engaged with their own decision-making in their treatment journey is central to ensuring high quality cancer care (364). Health outcomes are better if patients are active participants in decision-making and believe they have control over treatment decisions (365).

The present study identifies the critical importance of patient-doctor communication when a cancer diagnosis is being made. Patients deal simultaneously with a life-threatening diagnosis and the loss or altered appearance of a valued body part. Patients described being emotionally overwhelmed about the disease and treatment options which has been shown to influence decision making (366). Patients reported that the setting and the way information was delivered to them was important when contemplating surgery. Henman et al found that 'personal' factors were important to women with breast cancer in their decision-making (366). These included the feeling that the doctor cared for, understood and respected them; that they could trust and have confidence in their doctor; that the doctor would give them enough time, that they would be listened to; and that the doctor would be open and honest. If these factors were felt to be present, many women were happy to accept the doctor's recommendation, confident that they would receive optimum treatment.

This work identifies communication as a central tenet to decision-making in patients considering PE. The volume and complexity of information provided at preoperative consultation has been found to be overwhelming (171). Information overload has been shown to influence decision making (366). Patients cannot express informed preferences unless they are given sufficient and appropriate information, including

detailed explanation of the condition and likely outcomes from treatment options (367). Failure to provide this is the most frequent source of patient dissatisfaction (368, 369). In keeping with our findings Henman et al identified that their patients did not want information to assist them in making a treatment decision but rather to assist them in coping and preparing for treatment (366). Patients also need sufficient time to make informed decisions that may require multiple consultations. Previous studies have identified cancer patients who reported having insufficient time to consider the options available for treatment of their disease (370) which supports the notion of ‘bounded rationality’ (371). Rather than seeking an optimal solution for them, the decision maker ‘satisfices’ by choosing the first solution that meets the desired objectives (371). Only when patients are given the time and opportunity to understand the information they have been given about surgical treatment alternatives, can their decision be considered informed. Patients need to be assured that they have time to make informed decisions, and delaying the surgical treatment for several weeks in most cases does not jeopardise their chances of survival (370).

The overwhelming reason for patients undergoing surgery was survival. This emerged as a theme throughout the study as the most important factor contributing to decision-making for surgery. All other factors were deemed unimportant compared to survival and the chance of cure despite these having life changing or significant QoL implications. Many patients felt they had no real treatment options as they perceived that doing nothing was not an option. Potentially curable cancer and treatment with high morbidity is readily justified by the patients who are initially more likely than their physicians to accept greater risk for lesser benefit from treatment. This is consistent with the findings of Little et al (372) where colorectal cancer patients expressed the view that they wanted the best chance of cure and Beaver *et al* (363) where these patients ranked cure as the most important factor to them.

The HCPs interviews provided important perspectives about their roles in decision making and illustrated the importance of the interdisciplinary approach to care in advanced and recurrent disease. HCPs adopted a biological approach to decision-making in PE. Tumour resectability and biologic characteristics including stage and presence, and location of metastases are usually the primary determinants in surgical decision making. R0 resection is the most important factor influencing overall survival and thus guides surgeon decision making (315, 373, 374). This biological approach is

reflected in the pre-operative counselling for PE, with surgeons discussing post-operative recovery largely in the context of complications, symptom burden, progression, and prognosis. In comparison, patient priorities were centred on a psychosocial model, with an emphasis on requiring information, counselling, and support with regards to post-operative psychological responses and adaptation, modifications in lifestyle, financial implications of complex surgery, changes in relationship status and sexual dysfunction. Age and comorbidities impact on the decision-making process. HCPs describe patients often unable to fully understand their prognoses and the treatment intent and have a lower threshold to undergo surgery. A qualitative study on decision-making in cancer found that even when patients report a desire for collaborative decision-making, they rely heavily on their doctor's opinion and seek rather to understand the rationale behind the doctor's recommendation than to make the decision themselves (366).

Surgeon bias toward surgery may also contribute to patient interest in surgery especially in light of patients' passive decision-making in cancer care which reflects the general trust in medical expertise (360, 361). This exemplifies the concept of "entrustment" described by McKneally and colleagues (375). The patients rejected the concept of weighing risks and benefits and other processes aimed to maximize their autonomy. They were also resigned to the risks of treatment and accepted the expert recommendation to consent to surgery. In essence, the patients universally trusted 'the competence and willingness of their surgeons to make good treatment decisions on their behalf' (375, 376).

Surgery was generally considered as the only option and patients saw surgical risks as inherent and not major influences in decision making. Our patients underestimated the morbidity associated with surgery including complications and the longer-term QoL also seen in Wright et al, describing a common theme of 'unanticipated morbidity' despite discussions about the risks of surgery. This raises concerns about patients' ability to fully understand what is involved in exenterative surgery and its functional implications. Other studies have shown that preoperatively, patients are focused on the immediate ramifications of a major operation, including ability to walk, bowel and bladder function, as well as a potential for cure and long-term survival (377). As a result, other long-term impacts of the surgery such as chronic pain, and the long-term

impact on ability to work, sexual function and social interactions may not be fully appreciated in the perioperative period (378).

Our patients indicated several psychological issues during their recovery that would have influenced their decision making to undergo surgery again. The literature on the psychological impact of cancer and its treatment has identified a variety of concerns: fear of cancer, pain, anaesthesia, surgery, death; changes in body image; self-image distortions; becoming dependent or being abandoned; and fear of possible sexual and reproductive changes. Our patients experienced all these concerns together with a breadth of emotion during the early post-operative phase, which was unexpected however, these emotions and subsequent QoL improved quickly after the first 3 months. Patients who suffered a complication describe being angry following surgery despite acknowledging their morbidities were unavoidable and express the desire to have been given a more realistic understanding about the consequences of surgery (171). The disconnect between patients' pre-operative understanding and post-operative experience may be attributed to:

1. Surgery being so complex that despite counselling patients still have difficulty comprehending the procedure and as a result are unable to question and potentially offend the surgeon which could potentially break down doctor-patient relationship or
2. Patients are so blinded by cure that nothing mattered at the time of decision making until post-operatively when patients are experiencing morbidity (379).

In patients undergoing PE for gynaecological malignancy, Arnaboldi et al found that women with recurrent disease do well psychologically following surgery as they are women with a prominent fighting spirit, with a fatalist attitude developed from facing recurrent illness (332). However, it is thought from a psychocognitive perspective, specific attention needs to be devoted to the state of mind with which women experience such a devastating procedure after a long history of illness characterised by numerous previous treatment regimens. Some of our patients perceived that psychological care together with motivation and accountability was their own responsibility. Other studies have shown that maintaining a positive attitude was considered important together with relying on family and friends for psychological support (380).

Stoma patients have to cope with the loss of an important body function, a distortion of body image and a change in physical functioning and personal care. Bekkers et al showed that patients with a stoma are more depressed, experienced more changes in body image and had lower rates of work resumption compared with those without a stoma (381). Presenting patients with treatment choices has been shown to have positive benefit in reducing psychological morbidity (382, 383) by allowing them to express their own personal preferences which allows them to exercise some control over the situation (384). Furthermore, in an area where it is difficult to balance the benefits of treatment with the associated risks, increasing patient involvement facilitates the decision-making process.

Rezk et al suggest that, although QoL declines after PE, on longer follow up most patients adjust well both physically and psychologically with restoration to baseline of most domains defining QoL. Near pre-exenterative levels of function were achieved within 12 months of surgery in the overall QoL and body image domains. This adaptation was also reflected in the improvement of the patients' comfort with the changes in their bodies, with half of the patients reporting being very to extremely comfortable by 12 months following PE (331).

Sexuality and sexual dysfunction have been studied previously in the scientific literature, however, our study indicates the significance this has on decision making especially amongst males. After survival, sexual dysfunction is the most important factor in the decision-making process for men whereas women are less affected with sexual function but more affected by sexuality and desire. The majority of studies regarding sexuality are amongst gynaecology patients. Previous studies have resonated our findings amongst women. These studies report that PE greatly affected the sex life of many of the patients especially those younger than 60 years who were sexually active prior to surgery (385). Fifty percent of those with reconstruction noted that it was not what they had expected but would advise another patient to undergo neovaginal reconstruction (385) as it increases a woman's self-confidence and provides continuity of the sexual function (283, 386). Other studies have suggested the complete loss of sexual activity for some patients and its significant disruption in life (281, 387-389) which was associated with emotional responses and behaviours that also hindered sexual adjustment (386). Not knowing how to describe their bodily changes, for fear of being seen as repulsive and thus being rejected, kept some women from male

companionship even aside from any sexual involvement that might ensue (283). An area of importance for these women is sexual identity.

Most of the evidence on treatment for ED and the impact of treatment on men's experience has emerged from studies focusing on prostate cancer. However, the physical and psychological causes of ED in men with colorectal cancer and prostate cancer is not the same (390). Dowswell showed most men with ED following rectal resection were profoundly stressed and it affected self-image, behaviour, and relationships, although did not see it as a health priority (391). Many men were uninformed about ED and were unprepared for it (391). This is thought to be because during treatment patients generally focus on tackling cancer and only consider the side effects of treatment at a later stage (382). Previous work has shown that HCPs often avoid discussing ED because they have other priorities, may not recognise its importance to men's health related QoL, and feel embarrassed themselves about discussing sexual matters (392) (393). However, this was not reflected amongst our patients as most men addressed this very early in the decision-making process.

Our study showed that considerable lifestyle factors need to be considered when contemplating surgery. Life following surgery is described as very different with patients refraining from activities, unable to return to work and the financial implication this brings. Szczepkowski et al describe that colorectal cancer resections cause significant changes in patients' QoL at a social level, with, a reluctance in restarting their professional activity after surgery, refraining from social contacts and changes in their leisure activities, choosing activities that allow passive role-playing or limited contact with others (394). Patients with more extended resections in exenterative surgery may be further burdened than their straightforward resection contemporaries.

This study emphasised the importance of support on patients and their decision-making including family, nursing, medical and holistic care. Studies have shown that patients value family as a crucial adjunct to the health care team, recognising three specific roles for family members (collaborators, interpreters and supporters) that enable and influence decision-making while reducing the burden on patients and enhancing their overall experience (395). Family involvement has been shown to influence patients' decision making. Preferences of the patient's partner or children

have been shown to play an important role in patient decision making (396). Being married and having children impacts preferences (397). Patients with children living at home are much more likely than those without children at home to trade QoL for a survival advantage (398). In addition, patients living alone are less likely than those living with others to pursue treatment for advanced-stage malignancies (398). A colorectal cancer diagnosis among family members influences the treatment-related decision process (399).

Interview time varied greatly within this cohort. Qualitative interviews typically take between 20 minutes to an hour to complete, depending on context (400). Several factors have been found to contribute to variations in interview time. Previous research has shown that some participants may be more articulate or have more experience with the topic, which can lead to shorter interviews whereas others may require more prompting to share details (401). Educational level and age may both be relevant in terms of the respondent's cognitive abilities (402). It is thought that older people need more time to answer questions and that respondents with a higher educational level are more familiar with answering questions, and as a consequence will need less time (403). It is also thought that an interview with highly motivated respondents (making greater efforts to answer questions to the best of their ability) will take more time (401). These factors may have influenced this study, however, other factors contributed to varied interview time. Many patients were grateful to be able to speak to clinician at length to share their personal story contributing to longer interview time. Patients with uncomplicated decision making and recovery had less to disclose and resulted in shorter interview times. In terms of HCPs interviewees, shorter interview times may have been contributed by tight schedules and other work commitments.

The present study highlights the differing perspectives of patient and HCPs priorities during the decision-making process for PE. HCPs are focused on the expectations, recovery and psychological impact whereas patient factors in decision making are more holistic focusing on the impact of surgery, both short and longer term on daily life. The potential disconnect between patients' pre-operative understanding and informational needs and post-operative experience may be attributed to several factors, including pre-operative counselling being too difficult to comprehend, the lack of delivery of patient-specific information with a failure to address patient information needs or the emphasis on immediate cure rather than longer-term consequences (379).

Our study highlights this disparity between patient information needs and delivery of pre-operative counselling, by identifying key themes important to both groups. Incorporating this information into a future decision aid to help employ the principles of SDM in this context, incorporating treatment options with clinical uncertainty with patient priorities will be of value in improving patient experience and expectations.

#### **4.6.1 Strengths**

The key strength of this national, multicentre qualitative study is its generalisability, given the broad demographics of patients included across a range of geographical pelvic exenteration centres with appropriate multidisciplinary input. Taking the perspectives of all key stakeholders including patients, surgeons and specialist nurses offers further insight into the complex process of decision-making for PE.

#### **4.6.2 Limitations**

The key limitation of our study is the inclusion of patients who have undergone surgery alone, with no information available for patients who decided against surgery, thus introducing the potential of selection bias. To reduce recall bias interviews were conducted early in the follow up period following surgery and therefore it is possible that some themes relevant to longer term issues may not have been identified. The sample size is small partly because of PE being a relatively uncommon procedure despite this being a multicentre study. Despite the small sample size, after recruitment of 24 patients there was saturation of the themes identified in the structured interviews, this suggests that a large sample size was unlikely to identify any further useful information.

#### **4.7 Conclusion**

This qualitative study provides insights to the information important for decision-making in PE for LARC and LRRC. Decision making about surgery is complex. The findings have direct relevance to framing pre-operative counselling discussions in helping patients decide whether PE surgery is an appropriate option for them. This study has identified areas of weakness in preparing patients for PE and identified instrumental themes that need to be communicated with patients when counselling about surgery. Policy makers and clinicians need to ensure we are meeting patients' informational needs by investing into a dedicated service. The service needs to provide patients with sufficient information for informed decision-making by standardising



care across the UK using a dedicated PE CNS, patient support groups, patient decision aid (PtDA) and potentially an audio-visual (AV) resource.

## **Chapter 5. Analysis of available written patient information for pelvic exenteration**

### **5.1 Background**

The UK's National Institute of Clinical Excellence (NICE) place emphasis on providing patients with good quality written or visual health information (404). This is believed to encourage better patient participation in their healthcare, particularly with reference to managing long-term conditions or promotion of wellbeing. Patient participation is generally viewed as allowing patients to play a more active role in their health care, including sharing information on their healthcare priorities and taking an active part in decision making regarding their care (405, 406). To play a part in the decision-making process patients need clear, concise, and easy to understand information about their condition or treatment. Good quality written patient health information about treatment choices should be accurate and based on the best and most up-to-date scientific evidence. This helps patients consider all aspects of a treatment choice, including the associated outcomes and any areas of uncertainty. It is well recognised that patients forget or misunderstand much of what is discussed verbally during a consultation. On average, patients forget half of what a doctor has told them within five minutes of leaving the consultation room (407). In general, people may only retain about 20% of the information presented audibly, which can be increased to 50% with visual or written input (408).

PE surgery is a major undertaking associated with significant morbidity and mortality. Patients have very complex information needs which need to be addressed adequately to reduce psychological morbidity in the post-operative stage. A systematic review of 976 patients who had undergone exenterative surgery for various advanced pelvic malignancy identified the surgery impacts upon several HrQoL domains including, physical, psychological and social domains as well as upon body image, sexual function, communication, relationships, work and finance. The impact on each of these domains is variable, with a reduction in initial HrQoL, however this can be transitory following a period of adjustment (168). Patients need to understand and retain information regarding surgical morbidity and use this appropriately to inform decision-making.

The concept of health information needs and how they are met is recognised as a key coping and adjustment strategy in response to illness (409), this has not previously

been studied in LARC and LRRC. However, a few studies have been performed in colorectal cancer. In 2019 Vu et al. conducted a cross-sectional study to evaluate unmet emotional, relationship, financial, logistical, treatment-related, and surveillance-related informational needs of 99 individuals with CRC after they had completed treatment (410). The authors reported 74% of participants indicated at least one unmet need, with individuals with rectal cancer having more unmet need than those with colon cancer. Dau et al also found that during treatment, health information needs were met to a greater extent among those with colon cancer as compared to those with rectal cancer. The consistency between the two papers reflects differences between rectal and colon cancer (411) with individuals with rectal cancer undergoing more complex treatment regimens and experiencing more side effects than those with colon cancer (412), which would have implications for health information needs. Van der Sijp et al also found that general information needs, and treatment specific information needs were not always met and suggestions for improvement included unmet needs regarding items such as bowel activity, long-term side effects of treatments, work/employment, mental health, sexual activity, nutrition and diet, and experiences of other individuals with CRC (412). Whilst these two studies did not focus on PE for LARC/LRRC, as treatment in these areas is more complex and morbid than for rectal cancer it seems reasonable to assume patients approaching PE would have more unmet informational needs than patients with rectal cancer.

Patient Information Leaflets (PILs) remain the most frequently used sources of medical information (413, 414) to address health information needs. The purpose of a PIL is for patient education and information, and patient empowerment (406, 415) to facilitate informed choices about their health care (416). Written information reinforces information discussed within consultation rooms. PILs can be referred to by patients away from the stressful environment of the consultation room to refresh and review their knowledge at all stages of their condition.

The purpose of PILs has been widely described ‘as part of patient education or health promotion; supporting preventative, treatment and compliance objectives’ (417). An effective PIL must be ‘noticed, read, understood, believed, and remembered’(418). These resources are usually accepted as patients value and access these health information materials (417). The quality of patient information encompasses a range of issues including accuracy and comprehensiveness, accessibility, acceptability,

presentation style, comprehensibility, relevance and utility and attention to health literacy (419). The ease with which patient information is understandable or comprehensible will be influenced by a range of factors such as the way information is presented, the language used and the health literacy of the reader. Health literacy is defined as the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions (420). Health literacy includes a range of skills such as numeracy and reading. Studies have shown that the majority of patient information booklets have a readability beyond the recommended reading level for the general population (Flesch Kincaid Grade 6, equivalent to reading age 10–11) (421-423). When both skills of literacy and numeracy are required to interpret text then comprehensibility is diminished further (424). This mismatch between complexity of information and health literacy impacts on access to healthcare and affects health outcomes. The quality of patient information improves by; ensuring adequate font size, ordering information so that it is intuitive to the user, using passive language, providing headings to aid navigation, chunking information into more manageable sizes, repetition, use of imagery and making space for frequently asked question sections (425, 426).

There is general agreement that PILs should be handed out by the physician at an opportune moment during the consultation, should target patient expectations and that the form should consider the patient's preferences. The PILs should back up what the physician says but should in no way be a substitute for oral information, preferred by the majority of patients (407, 414, 427-436). PIL together with clinician counselling are therefore acceptable ways to inform patients of their illness and options available to them.

## **5.2 Aims and objectives**

The aims of this study were to:

1. Establish what PILs were available to patients worldwide with LARC or LRRC being offered PE surgery.
2. Assess the quality of the PILs available using DISCERN criteria.
3. Compare the information provided within the PILs to the information needs based on online forums.

### **5.3 Methodology**

All 44 English-speaking institutions performing pelvic exenteration were identified through the PelvEx collaborative and through the Association of Coloproctologists of Great Britain and Ireland (ACPGBI) IMPACT (Improving outcomes for advanced colorectal tumours) initiative. The IMPACT initiative consists of a group of clinicians and healthcare professionals in Great Britain and Ireland interested in patients with locally advanced and metastatic colorectal cancer.

All centres were approached by email to identify whether they performed PE for LARC and LRRC and whether they had any patient specific information leaflets or other relevant literature available to assist patients in the decision-making process.

#### **5.3.1 Literature inclusion**

##### **Inclusion criteria:**

Identified sources were included in the study if the following criteria were fulfilled:

1. Discussed surgical management of PE in LARC and LRRC.
2. Written in English.

##### **Exclusion criteria:**

Sources were excluded from the study if any of the following criteria applied:

1. Information leaflets from units where English is not the primary language.

Patient information leaflets were viewed and screened for relevance. Sources that did not meet the eligibility criteria were excluded. Sources assessed as potentially relevant were analysed further.

#### **5.3.2 Data extraction**

Data were extracted from all patient information leaflets using a predefined extraction spreadsheet on Microsoft® Excel version 16.16.16. Data were extracted across the following decision-making categories: Description of surgical options and oncological treatments, comparison of surgery versus no surgery, benefits and risks of surgery, and a description of the preoperative and recovery periods, overall length of recovery, prognosis, QoL, pain and complications. These domains were extracted based on previous qualitative work undertaken with patients and experts. Sources were scored

independently by the PhD candidate (AW) and another clinical colleague (AWd). Any conflicts that arose were resolved by the clinical PhD supervisor (DH).

### **5.3.3 Data quality**

The quality of written health information was assessed using the validated DISCERN tool (discussed in Chapter 2).

### **5.3.4 Data analysis**

Data from PILs were coded using the principles of thematic content analysis (271) described in Chapter 4. Themes and categories were compared between PILs and qualitative interviews (Chapter 4) and online forums (Chapter 3).

## **5.4 Results**

Members registered on the PelvEx database identified 14 international institutions of which nine were excluded as English was not their first language. Five international institutions and eight UK institutions (n=13) were identified. ACPGBI IMPACT identified members from 39 institutions of which 8 were excluded (n=31) as replicates from the PelvEx database. Forty-four institutions in total were approached with an overall response rate of n=36 (81%) (Appendix I). Twenty-one of the 36 institutions that responded perform PE. Four UK institutions (St Marks London, The Christie Manchester, Swansea University Health Board and the Imperial London) and one international institution Royal Prince Alfred Australia) (24%) use centre specific patient literature which was used in the analysis. Three institutions (14%) sent patients copies of the clinic letters, one institution (5%) used Microsoft® PowerPoint in addition to their own literature, one international institution (5%) used Macmillan sources as a reference and one centre (5%) used point of care internet-based discussions to aid the decision-making process.

### **5.4.1 Source information**

All sources provided 70% or more (70-90%) of the essential information. All sources provided information about LARC and LRRc, description of pre- and post-operative periods, length of recovery, QoL, pain and complications (Table 23). However, only one resource discussed oncological treatments. Outcomes on surgical and non-surgical treatments were reported in the majority of sources (n=3). Prognosis was not discussed within any resource.

When compared with online information (Chapter 2), there is significantly more information within the PILs. 38% of domains were covered between the six identified internet sources compared to 78% of domains between the five PILs.

| <b>Decision Making Domain</b>                        | <b>Christie</b> | <b>Imperial</b> | <b>Royal Prince Alfred</b> | <b>Swansea</b> | <b>St Marks</b> |
|------------------------------------------------------|-----------------|-----------------|----------------------------|----------------|-----------------|
| Classification of disease                            | √               | √               | √                          | √              | √               |
| Description of surgical options                      | √               | √               | √                          | √              | √               |
| Description of oncological treatments                | x               | x               | x                          | x              | √               |
| Comparison surgery vs no surgery                     | √               | x               | x                          | √              | √               |
| Benefits and risks of surgery                        | √               | √               | √                          | √              | √               |
| Description of the preoperative and recovery periods | √               | √               | √                          | √              | √               |
| Length of recovery                                   | √               | √               | √                          | √              | √               |
| Prognosis                                            | x               | x               | x                          | x              | x               |
| Quality of life                                      | √               | √               | √                          | √              | √               |
| Pain                                                 | √               | √               | √                          | √              | √               |
| Complications                                        | √               | √               | √                          | √              | √               |

**Table 23. Decision making domains discussed within the patient information leaflets**

#### **5.4.2 Quality of source DISCERN**

The overall quality of the identified PILs were scored from acceptable to excellent quality based on the DISCERN criteria (Table 24). There was little variation in the reliability of information (score range 27-32) however, the quality was variable (score range 17-30). When compared to online information, the reliability was higher within the PILs (score range 18-34) ( $p=0.21$ ). The quality of information, however, was significantly better within the PILs ( $p<0.01$ ) (score range 11-22).

Information provided in all the PILs was extensive with all achieving discussion in more than 12 of 15 DISCERN domains. All sources met the criteria for highlighting and achieving clear aims, being relevant and balanced and unbiased. Most sources did not highlight appropriate references used in their development nor document their publication date. All sources scored 3-4 for describing benefits of each treatment and describing how each treatment works. Four of five sources performed very well in providing support for shared decision making, highlighting more than one treatment

choice, describing treatment choices affecting quality of life and referring to areas of uncertainty and signposting sources of support and information. There was significant variation in provision of details of additional sources of support and information and describing what would happen if no treatment was chosen by the patient (range 1-5).

|                                                                                                                                                         | <b>Christie</b> | <b>Imperial</b> | <b>RPA</b> | <b>Swansea</b> | <b>St Marks</b> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|-----------------|------------|----------------|-----------------|
| 1. Are the aims clear?                                                                                                                                  | 5               | 5               | 5          | 5              | 5               |
| 2. Does it achieve its aims?                                                                                                                            | 5               | 5               | 5          | 5              | 5               |
| 3. Is it relevant?                                                                                                                                      | 5               | 5               | 5          | 5              | 5               |
| 4. Is it clear what sources of information were used to compile the publication?                                                                        | 3               | 1               | 1          | 3              | 1               |
| 5. Is it clear when the information used or reported in the publication was produced?                                                                   | 1               | 1               | 1          | 1              | 1               |
| 6. Is it balanced and unbiased?                                                                                                                         | 5               | 5               | 5          | 5              | 5               |
| 7. Does it provide details of additional sources of support and information?                                                                            | 5               | 1               | 5          | 5              | 5               |
| 8. Does it refer to areas of uncertainty?                                                                                                               | 3               | 4               | 3          | 3              | 5               |
| 9. Does it describe how each treatment works?                                                                                                           | 4               | 4               | 3          | 4              | 4               |
| 10. Does it describe the benefits of each treatment?                                                                                                    | 4               | 4               | 3          | 4              | 4               |
| 11. Does it describe the risks of each treatment?                                                                                                       | 4               | 3               | 3          | 4              | 3               |
| 12. Does it describe what would happen if no treatment is used?                                                                                         | 4               | 1               | 1          | 4              | 5               |
| 13. Does it describe how the treatment choices affect overall QoL of life?                                                                              | 4               | 4               | 2          | 4              | 4               |
| 14. Is it clear that there may be more than one possible treatment choice?                                                                              | 5               | 5               | 1          | 5              | 5               |
| 15. Does it provide support for shared decision-making?                                                                                                 | 5               | 1               | 4          | 5              | 4               |
| 16. Based on the answers to all of the above questions, rate the overall quality of the publication as a source of information about treatment choices. | 3               | 3               | 3          | 3              | 5               |

**Table 24. DISCERN assessment of each PIL identified (answers: 1 no, 3 partially, 5 yes) (RPA – Royal Prince Albert)**



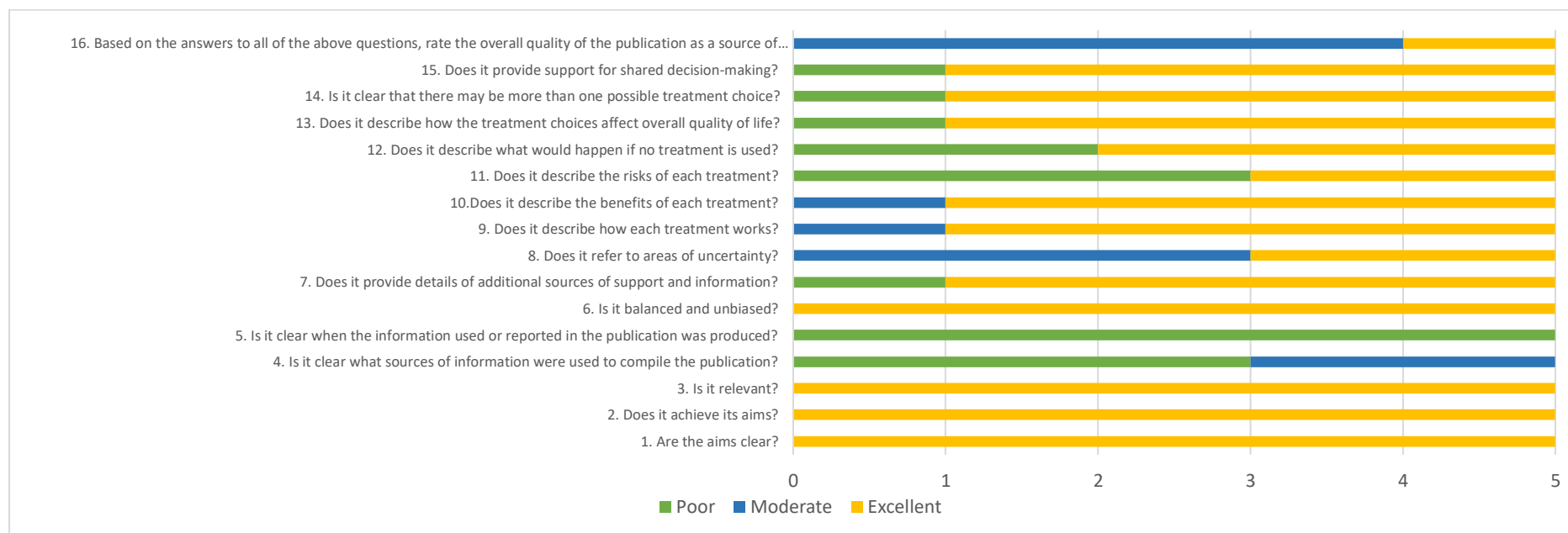


**Figure 12. Overall DISCERN score for patient information leaflets**

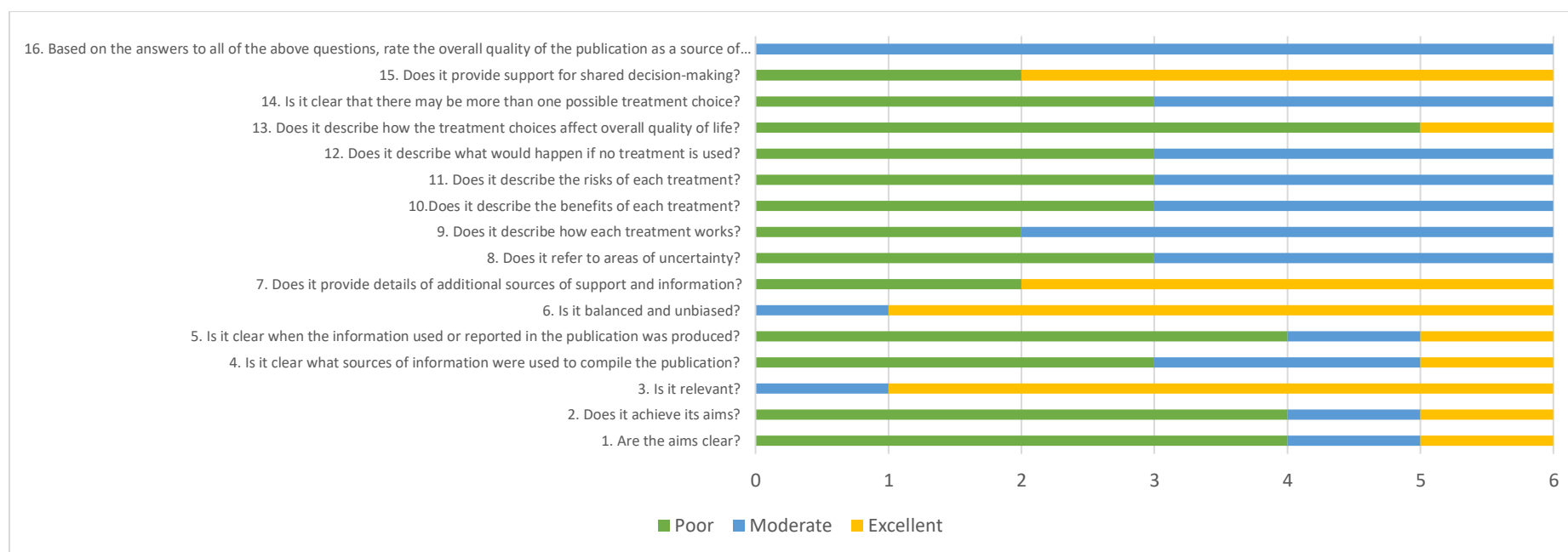


**Figure 13. Overall DISCERN score for quality of internet information**

Overall, the PILs were visibly superior in their content when compared to online information (Figure 12 and 13).

### 5.4.3 Qualitative Results

Using the principles of content analysis for the patient information leaflets, a total of eight themes were generated from 38 categories and 148 findings (Table 25). Themes generated were classification of disease and surgery, benefits and risks, immediate recovery, delayed recovery, social functioning, expectations, communication and support links.

| PATIENT INFORMATION LEAFLETS          |                            |                                                                                                                                                                                                                                                                                                                       |
|---------------------------------------|----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| THEMES                                | CATEGORIES                 | Illustrative Quote                                                                                                                                                                                                                                                                                                    |
| Classification of disease and surgery | Explanation PE             | ‘A total pelvic exenteration is a medical term for removal of your bladder and the lower bowel along with other organs in the pelvis.’                                                                                                                                                                                |
|                                       | Type of PE                 | ‘Surgery can differ depending on the position and involvement of the disease. TPE, anterior exenteration, posterior exenteration, lateral (left or right) exenteration, central exenteration.’                                                                                                                        |
|                                       | Types of stoma             | ‘During your operation your surgeon will create two stomas, one for your faeces and wind (colostomy) and a second for your urine (urostomy).’                                                                                                                                                                         |
|                                       | How surgery is performed   | ‘An incision will be made in the middle of your abdomen from the belly button to the top of your pubic bone. It may be necessary to make a second incision around the anal area..... the organs affected by cancer are then removed.’                                                                                 |
|                                       | Decision making            | ‘The decision whether to have surgery can be a difficult one and it is important that you have all the information you need to make an informed choice.’                                                                                                                                                              |
|                                       | Future fertility           | ‘We also offer sperm banking that can be arranged prior to surgery.....we offer egg preservation for those affected by fertility secondary to the operation.’                                                                                                                                                         |
| Benefits and risks                    | Outcomes without procedure | ‘If you decide not have surgery, the cancer will continue to grow, and your symptoms may get worse. The team will discuss this with you, and if appropriate will discuss other treatments that may be suitable for you such as chemotherapy.’                                                                         |
|                                       | Alternative treatments     | ‘Surgery is thought to be the best form of treatment to remove this type of cancer. However, if you decide not to go ahead with surgery, chemotherapy may be suitable for you. Alternatively, you could opt for a ‘watch and wait’ policy; this involves deciding on a treatment plan for controlling your symptoms.’ |
|                                       | Risks and side effects-    | ‘As with any operation, there are risks of complications due to anaesthesia, wound infection or injury to adjacent organs or structures. In the case of advanced pelvic cancer surgery,                                                                                                                               |

|                    |                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|--------------------|---------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                    | immediate and delayed     | there may be major complications that can occur during or following this surgery, such as: haemorrhage (bleeding) that may result in blood transfusion, injury to the bowel, injury to the urinary tract or failure of the kidneys.'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Immediate recovery | ICU/HDU                   | 'You will stay in hospital for approximately three weeks, initially in the high dependency unit. There you are closely monitored in order to help prevent any complications or address any side effects. Recovery from the operation can be difficult both physically and emotionally.'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                    | General Health            | <p>'General care – after surgery you will have a number of drips in place for fluids and drugs. It can take time for bowel function to return (usually 5-7 days). Throughout the period that your bowel is resting and recovering a drip will be used to keep you hydrated. Sometimes it takes longer in which liquid food will be provided through a drip. To help prevent you feeling sick a tube is placed in your stomach via the nose to drain your stomach. Your wound is joined with stitches or staples. You may have a drain in your abdomen to remove fluid. During your stay you will wear stockings and receive a daily injection of blood-thinning agent. You will be discharged home with these usually for 28 days.'</p> <p>'These operations are very big and can be difficult to cope with, so it is important that you are prepared for a long period of recovery afterwards. It is unlikely that you will begin to get over the changes to your body for at least three months. The time taken to get back to normal activities varies a lot for different people, but it could take up to a year to fully recover.'</p> |
|                    | Pain management           | 'Pain relief – the anaesthetist will discuss your pain management with you before the operation. Two options are epidural or PCA.'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|                    | Gastrointestinal symptoms | 'You may find that you do not have much of an appetite at first. There are no rules about what you should or shouldn't eat. Eating little and often is usually better than large heavy meals.'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|                    | Genitourinary symptoms    | <p>'Urinary changes: If you don't have a urostomy, initially you will have a catheter in place that drains your urine from your bladder. This is a temporary measure. Urinary incontinence, urgency or stress incontinence can occur after this type of surgery.'</p> <p>'It may take several months for the bowel to settle after surgery and for you to develop a normal pattern for you.'</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|                    | Stoma care                | 'The stoma nurses will provide you with support so that you can start changing your stoma bags soon after surgery.'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|                    | Mobility issues           | 'Physiotherapy early after your operation can reduce the risks of chest infection as well as preventing blood clots forming in your lungs. Physiotherapy will start the day after your operation<br>Counselling and psychological support: Patients and relatives may have difficulty in coping with illness, the effects of treatment, and the effects of surgery on self-image and may benefit from counselling and psychological support.'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|                    | General health            | 'Recovery time after surgery varies. You may find it takes weeks, sometimes months, to feel better, however, you can expect a gradual improvement over the next 6-12 months.'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |

|                  |                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|------------------|--------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Delayed recovery | Musculoskeletal symptoms             | ‘Lower limb weakness is common following surgery following a period of immobility. Physiotherapists will assist in regaining muscle strength.’                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|                  | Pain management                      | ‘Some patients need to take pain relief for weeks and months following surgery. The dose and type of medication will be reviewed and changed with time.’                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                  | Mobility issues                      | ‘If there is nerve or bone involvement, sometimes longer-term mobility can be a problem. Some patients may need to walk with aids or be unable to walk long distances.’                                                                                                                                                                                                                                                                                                                                                                                                                      |
|                  | Psychological impact                 | ‘When things are uncertain, worry is a natural thing for us to do.’<br>‘You may feel angry at others around you, or just at your situation. This is a normal part of dealing with something as challenging as going through surgery.’<br>‘It’s normal to feel a little wary and anxious at first but if difficulties persist, please discuss with your doctor.’<br>‘You can expect to have a range of emotions about your cancer journey and surgery. All these emotions are natural reactions to a significant life event: Fear, Worry, Anger, Sadness, Depression, Loneliness, Disbelief.’ |
|                  | Body image                           | ‘Body image: some patients may experience distress about their body image following surgery. Low self-esteem or lack of confidence may arise as a result of physical changes such as scars or having a stoma.’                                                                                                                                                                                                                                                                                                                                                                               |
|                  | Fatigue                              | ‘It is common to feel tired for some months after surgery.’                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|                  | Sexual function                      | ‘Sexual activity: erectile dysfunction may occur. Treatment is available for this. Women may experience vaginal dryness. We encourage you to talk to your partner to express how you are feeling about intimacy and sex.’                                                                                                                                                                                                                                                                                                                                                                    |
|                  | Emotional and psychological recovery | ‘In the first few weeks at home you may have some days when you feel quite low, and this is normal. Some people find that it can take months to adjust emotionally to the surgery.’                                                                                                                                                                                                                                                                                                                                                                                                          |
| Expectations     | Physical recovery                    | ‘Sometimes, surgery can be more successful if we start your treatment with a course of radiotherapy and/or chemotherapy to shrink the size of the tumour.’<br>‘You will be admitted to a surgical ward the day before your operation, for a stay of approximately 14 to 21 days.’                                                                                                                                                                                                                                                                                                            |
|                  | Social changes                       | ‘If you work, plan to take at least 3 months off sick but this will depend a little on what type of work you do. You should try to avoid excessive walking or sitting still until your wounds have healed. It is unwise to go swimming or undertake vigorous exercise until the area is healed.’                                                                                                                                                                                                                                                                                             |
|                  | Getting back to normal               | ‘Whilst most patients feel able to resume most of their normal routines and activities within six months of surgery, some report that that it takes them twelve months to feel completely back to their normal selves.’                                                                                                                                                                                                                                                                                                                                                                      |
|                  | Social function                      | ‘You may not be able to return to usual social activities immediately and need a period of adjustment.’                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|                  | Clinical journey                     | ‘Before the operation you will attend a pre-admission clinic to check a number of things in preparation for surgery……                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |

|               |                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|---------------|-------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|               |                                                                   | MRSA test swab, blood, heart and lung tests. Before your operation members of the team will visit you.... surgeons, anaesthetists, junior doctors, surgical nurse practitioners and specialist nurses including a stoma nurse specialist.'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|               | Short- and long-term FU                                           | <p>'You will return to clinic 2-3 weeks following discharge to assess: your wound, stoma(s), how you are eating and drinking, mobility and how you are managing at home. We will also review your results and discuss the plan for your future care.'</p> <p>'We will review your progress at regular intervals in the outpatient clinic. Routine blood tests and X-rays and scans at three months then yearly. CT scans every six months and then yearly'</p> <p>'Stoma care: your stoma nurse will provide information and training on stoma care prior to your surgery. Whilst in hospital, your stoma nurse will see you regularly to help you manage your stoma. You can also receive continued support in the community whilst you are home'</p> |
|               | Advice on post discharge complications                            | 'If you are unwell or have a fever please contact your General Practitioner (GP). If this is outside normal working hours, then please either contact the out of hours service GP or attend your local accident and emergency department.'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|               | Hospital contact details – stoma nurses, secretaries, on call SpR | 'Contact numbers – ward, registrar, secretary, CNS, stoma nurses, MacMillan, ITU.'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|               | Adjuvant chemotherapy                                             | 'You may need more chemotherapy after surgery.'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|               | Macmillan                                                         | 'Useful links – hospital information, well-being and support, Macmillan, Bowel Cancer UK, Beating Bowel Cancer, Bladder and Bowel Foundation, College of Sexual Relationship Therapists, Colostomy Association.'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Support links | E resources                                                       | Well-being and support - 'stomal therapy support, mental health information and resources, cancer information and support, access to online psychological assessment and treatment programmes, mindfulness information and exercise.'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

**Table 25. Themes and categories generated by content analysis of PILs.**

Within the analysed PILs there is significant emphasis placed on the procedural aspects of PE surgery. Removal of various organs is highlighted to provide patients with a better understanding of the physical aspects of surgery. Various types of PE are discussed within the resources outlining what organs are removed in various procedures. Descriptions and comparisons of both urostomies and colostomies are detailed to ensure that together with consultation and stoma nurse input patients are prepared for living with a stoma. Emphasis is made on the complexity and the multidisciplinary nature of the surgery. One PIL also describes the decision-making

process and highlights that patients need adequate information to make an informed choice about having surgery.

#### **5.4.3.1 Benefits and risks**

One resource discusses the options of not undergoing surgery including palliation and palliative chemoradiotherapy. Risks and side effects are described extensively to prepare patients and include risks of complications due to anaesthesia, wound infection, injury to adjacent organs or structures – bowel, urinary tract, haemorrhage requiring blood transfusion and kidney failure.

#### **5.4.3.2 Immediate recovery**

The initial recovery is described in terms of care in high dependency and what to expect in terms of nutrition, tubes, pain and symptoms. Pain management is discussed from immediate post-operative epidural or PCA to oral analgesia. General care is also discussed in detail so that patients can anticipate the weakness and fatigue for days following surgery and what is expected of them in terms of early mobilisation with physiotherapy. Gastrointestinal symptoms are described from ileus and the need for TPN to poor appetite. Change in diet over the course of recovery is also discussed. Catheter care and urostomy care are also described. PILs are informative in signposting stoma support to stoma nurses with emphasis made on the support from stoma care nurses who will educate patients in self-care of their stoma and support them through the process. PILs also detail a psychological impact on patients.

#### **5.4.3.3 Delayed recovery**

Following the immediate recovery and being discharged, different issues for delayed recovery are discussed. General health is said to be significantly impaired following operative management of LRRC and LARC. Issues with weakness, fatigue and poor mobility following surgery are discussed with symptoms gradually improving three months after but taking up to a year to fully recover. Surgery has a significant psychological impact on patients with some PILs discussing the impact more than others. Various emotions are described as normal during the recovery which become more noticeable as patients get through the initial recovery.

Physical body changes result in changes in patient perception both psychologically and physically with some PILs describing the effect of altered body image. Other physical components consist of delayed healing, herniae, fistulae and loss of sexual

organs resulting in feelings of self- confidence. It is advised pre-operatively that patients talk to their partners about the change in body image and its effect on sex. Impairment of sexual function including ED or gynaecological cause i.e. pain, bleeding, non-functional neovagina or loss of vagina are detailed.

#### **5.4.3.4 Expectations**

The expectations of a long physical and emotional recovery are outlined. Patients are prepared for potential neoadjuvant treatment. Following surgery recovery is described as a long process which can take up to a year. An emotional adjustment is described following surgery. A physical adjustment to usual activities is discussed. Social anxiety and a loss of social interest is referred to with PILs. Some comment on a loss or reduced social function, especially in the earlier part of recovery.

#### **5.4.3.5 Communication**

PILs ensure that patients know what to expect and how to reach out to the medical team. Short and long term follow up are summarised including initial outpatient clinic appointments for review, 3, 6 then 12-monthly reviews which include blood tests and CT scans. This allows the patients to have some personal responsibility as they know what to expect and in the event, appointments are lost they have the contact details of the team. Advice on potential complications after discharge are outlined and how to contact the appropriate service. With patients being referred to tertiary units, contact details of secretaries, stoma nurses, on call registrars are documented so that they can feel they have open communication channels with the team both in the event of an emergency and for longer term follow up. Relevant contact details are provided for patients including the ward, specialist registrar, medical secretary, CNS, stoma nurses and MacMillan nurses in the event they need to contact the team.

#### **5.4.3.6 Support links**

Macmillan is a resource clearly signposted for ongoing support whether emotional, psychological or financial. Relevant links to well-being and support including Macmillan, Bowel Cancer UK, Beating Bowel Cancer, Bladder and Bowel Foundation, College of Sexual Therapists and the Colostomy Association are signposted within PILs.



| <b>PILs</b>                           |                                                                                                                                         | <b>Online forums</b>   |                                                                                                                                                                                                                                                   | <b>Qualitative interviews</b> |                                                                                                       |
|---------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|-------------------------------------------------------------------------------------------------------|
| Classification of disease and surgery | Explanation PE<br>Type of PE<br>Types of stoma<br>How surgery is performed<br>Decision making<br>Future fertility                       |                        |                                                                                                                                                                                                                                                   |                               |                                                                                                       |
| Benefits and risks                    | Outcomes without procedure<br>Alternative treatments<br>Risks and side effects-<br>immediate and delayed                                |                        |                                                                                                                                                                                                                                                   |                               |                                                                                                       |
| Immediate recovery                    | ICU/HDU<br>General Health<br>Pain management<br>Gastrointestinal<br>Symptoms<br>Genitourinary Symptoms<br>Stoma care<br>Mobility issues | Physical recovery      | Physical restrictions<br>General Health<br>Stoma issues<br>Gastrointestinal Symptoms<br>Genitourinary Symptoms<br>Musculoskeletal Symptoms<br>Pain Descriptors<br>Mobility issues<br>Complications<br>Length of recovery<br>Chemotherapy<br>Death | Recovery                      | Complications<br>Symptoms<br>Chemotherapy & Radiotherapy<br>Metastasis/recurrence                     |
| Delayed recovery                      | General health<br>Musculoskeletal symptoms<br>Pain management<br>Mobility issues<br>Psychological impact<br>Body image                  | Psychological recovery | Mental health and psychological wellbeing<br>Coping mechanisms<br>Future perspective<br>Emotions                                                                                                                                                  | Psychological impact          | Mental health<br>Emotions<br>Coping/adaptation to new life<br>Motivation/Accountability<br>Body image |

|               |                                                                                                                                                                               |               |                                                                                                                                                                                                                      |               |                                                                                                                    |
|---------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|--------------------------------------------------------------------------------------------------------------------|
|               | Fatigue<br>Sexual function                                                                                                                                                    |               | Acceptance and health bargaining                                                                                                                                                                                     |               |                                                                                                                    |
|               |                                                                                                                                                                               |               |                                                                                                                                                                                                                      | Lifestyle     | Hobbies/leisure<br>Work<br>Finance<br>Pre-operative symptoms<br>COVID-19<br>Disability                             |
| Expectations  | Emotional and psychological recovery<br>Physical recovery<br>Social changes<br>Getting back to normal<br>Social function                                                      | Expectation   | Inaccurate portrayal of recovery<br>Inaccurate portrayal of extent of surgery<br>Inability to work within the same role<br>Returning to normal life<br>Social isolation<br>Social anxiety<br>Loss of social interest |               |                                                                                                                    |
| Communication | Short- and long-term FU<br>Contact details -emergency and team<br>Advice on post discharge complications<br>Hospital contact details – stoma nurses, secretaries, on call SpR | Communication | Need for information<br>Primary and secondary care<br>Follow up<br>Second opinions<br>Secondary care services                                                                                                        | Communication | Time/delays<br>Information<br>Expectations<br>Healthcare provision<br>Chance of cure<br>Professional communication |

|               |                          |                       |                                                                                                                                                                                               |               |                                                                                              |
|---------------|--------------------------|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|----------------------------------------------------------------------------------------------|
| Support links | Macmillan<br>E resources | Support               | Availability of DN<br>Dependence on stoma nurses<br>Lack of emotional support                                                                                                                 | Support       | Holistic support<br>Nursing support<br>Medical team<br>Family & Friends                      |
|               |                          | Relationships         | Loss of confidence<br>Spousal dependence<br>Emotional aspect of sex<br>Technical aspects of engaging in sexual activities<br>Sexual enjoyment<br>Logistics of bed sharing<br>Loss of identity | Relationships | Sexuality<br>Practical issues<br>Sexual dysfunction<br>Sexual desire<br>Dependence on others |
|               |                          | Financial implication | Delay in returning to work<br>Expense of hospital stays<br>Home adaptation<br>Financial difficulty                                                                                            |               |                                                                                              |

**Table 26. Comparison of themes identified from PILs, online forums and qualitative interviews**

Wellbeing and support consist of stomal therapy support, mental health information and resources, cancer information and support, access to online psychological assessment and treatment programmes, mindfulness information and exercise.

#### **5.4.3.7 Comparison of PIL and patient information needs**

Information unavailable within PIL or patients not in receipt of written information will seek information within online forums (Chapter 3). Qualitative interviews (Chapter 4) also highlighted information important to patients during the decision-making process. Similar themes were established between online information, online forums and patient information leaflets (Table 26).

PILs fail to address the effect PE surgery has on relationships, lifestyle and finances which have been highlighted important in decision-making within the qualitative interviews and online forums. They do, however, address the remainder of the themes identified.

### **5.5 Discussion**

This study highlights that most units offering patients PE have no currently available written information for their patients. Only five available PILs were available internationally in the English language, which are all good quality and support SDM reflected in their high DISCERN scores. However, the National Bowel Cancer Audit (NBOCA) identified fifty units across the UK in the 2022 organisational survey as performing PE for LARC of which 40 were performing PE for LRRC (437) signifying the inadequate access to written information. The available literature has some limitations but does address most of the complexity and nuances of decision making in this complex clinical area. Sources identified in this chapter are of much better quality with significantly more relevant content than the information previously identified in the review of the grey literature undertaken in Chapters 2 and 3 of this study. The identified resources address most of the key patient information needs with most providing adequate information on risks associated with surgery, data on post-operative recovery, post-operative pain and impact on QoL. This is further supported by the DISCERN scoring with all resources providing adequate detail regarding treatment risk and benefit, treatment-related outcomes, and a lack of acknowledgement regarding areas of uncertainty. However, the currently available PILs are limited in

the following domains: relationships, lifestyle and financial implications. This resulted in patients seeking information elsewhere.

Many themes generated within this study emulate previous findings within the literature. In 2004 themes of concerns about recovery, complications, ostomies, social support, sexuality, disclosure and fear were reported in qualitative interviews by gynaecology patients undergoing PE (170). Further work investigating HrQoL in patients undertaking PE resulted in nine themes being identified: body image, social impact, sexual function, treatment expectations, symptoms, communication, psychological impact, relationships, work and finance (168). The present study and the results in chapter 3 highlight that relationships and sexuality are not addressed by the PILs and patients are seeking this information through online forums. Qualitative interviews in Chapter 4 also established the need for this information and its importance in decision-making for patients contemplating exenterative surgery.

Previous studies have shown that the existence of a stoma has an inevitable impact on the quality of sexual life (438). Intimacy between patients with a stoma and their spouses is still a major challenge seen in 42.6% of ostomates (439). Sörensson showed that only 29% of women and 41% of men are sexually active after an enterostomy usually due to the inability to adapt to a new sexual life (440). Qin established that 63.1% of stoma patients have a moderate stigma regarding their sexual experience due to inability to self-disclose their embarrassment and difficulties in their life behaviours leading to conflicts between partners (441). In 1983 Anderen found that sexual functioning continued as the area of greatest disruption for women undergoing PE and, as a group, they resemble severely sexually dysfunctional healthy women (385). A systematic review found between 50% and 100% of women who were sexually active pre-operatively deteriorated to 12.5%-18% in the postoperative period (168). Reasons for which were found to be sexual dysfunction following PE including lack of sexual activity, lack of sexual desire, vaginal pain, bleeding and dryness, difficulties in engaging in intercourse with a neovagina and stomas affecting sexual intercourse (170, 281, 283, 284, 388). PILs discuss sexual dysfunction, predominately in males but fail to address more detailed information. Patient information needs to reflect the significance of sexual dysfunction, in both genders and its sequelae to improve patient education and preparation for decision-making.

Cancer is recognised as a ‘family disease’ with spouses worrying more about patients’ futures than the patients do themselves (442). Spousal dependence and its effect are underestimated by both patients and clinicians. Cancer and its treatment has a positive effect on both patients’ and partners’ QoL in those with a strong marital relationship whereas those who are single or in a low quality relationship have a greater negative impact on their QoL, distress, general and mental health (443). Despite progress in PROs and HrQoL studies indicate that there is a marked negative impact on relationships, as a consequence of PE, patients don’t comprehend the full effect of these and start seeking the information online. PILs fail to address these issues and development of resources need to include the impact on relationships.

This work has highlighted finances as being an important theme for patients undergoing PE (Chapter 3 and 4) yet its absence from PILs is unambiguous. The impact of PE on general health, combined with a potentially lengthy recovery has obvious implications on return to work and overall financial status. Colorectal cancer patients incur cancer related out-of-pocket expenses (e.g. for medical visits or treatment) (444-447) and/or loss of income because of cancer related work absence (448, 449) which can lead to cancer-related financial hardship. Sharp et al showed that 4 in every 10 colorectal cancer survivors reported experiencing either cancer-related financial stress or cancer-related financial strain, and one third experienced both (450). The increased morbidity associated with PE compared to TME resections would result in a more significant financial burden. Previous work has established that financial worries are worse within the exenterative cohort compared to the APR cohort even at 24 months following surgery (317). Vera et al demonstrated a decline in overall income in 53% of PE patients due to physical illness or disability, followed by limitations imposed by the surgery (388). Qualitative research has shown a potential interplay between the financial and emotional impacts of colorectal cancer such that financial distress may exacerbate emotional distress (451), including anxiety, depression and impaired quality of life (298, 452, 453). Patients have been shown to seek financial support and information within online forums (Chapter 3) potentially because it feels like a safe place to do so discussing financial worries with strangers. Financial hardship after PE is likely to be greater than after CRC in general due to the greater morbidity and longer recovery time associated with PE surgery.

Patient information materials have been shown to affect patient health outcomes. Previous research has demonstrated that patients want and use them (414). Therefore, it is important that medical professionals have a provision of EBPI regarding options, benefits, risks, uncertainties together with decision support counselling that facilitate patients to make a decision that reflects their own values and preferences. A full provision of information allows the anticipation of life following surgery which can influence initial decision making for treatment. Without any pre-existing literature covering all domains it is very difficult for the patient to be part of a SDM process and as a result, informed consent in keeping with Montgomery (454) cannot be achieved. Medicolegal influence has also impacted on the promotion of SDM with an increasing number of clinicians believing the process to be medicolegally protective (455). SDM, where clinicians involve patients in healthcare decisions makes a potentially significant and enduring difference to healthcare outcomes. Patients are encouraged to read and think about treatment options together with likely benefits and harms to engage in decision making, and a validated tool would help this process.

The strengths of this study are that all centres worldwide registered with ACGBI IMPACT and PelvEx were approached to declare their use of PILs. However, limitations arose based on the person registered at each centre. Despite reminder emails being sent at two and four weeks, there was no facility to contact an alternative individual at the same site for non-responders which may have reduced the declared available number of PILs in publication and being used in practice.

## **5.6 Conclusion**

PE is one of the most invasive radical procedures a patient can undergo and despite this there are very few available PILs to assist patients in the decision-making process. The value and quality of currently available PILs are indisputable, however they do not address all the information patients need. Developing a PtDA using data extracted from qualitative interviews together with online literature and patient forum searches would provide patients with EBPI that this cohort of patients require to make an informed, balanced decision on whether to proceed with surgical intervention. It would achieve compliance with informed consent thus potentially reducing medicolegal issues in clinical practice within this cohort of patients.

## **Chapter 6. Development of the patient decision aid**

### **6.1 Background**

It has been shown that patients have difficulty understanding and retaining information conveyed during a standard cancer consultation (456). Various interventions have been shown to promote patient engagement, including PtDAs. PtDAs are standardised, evidence-based tools intended to facilitate the process of SDM. A three-step model to achieve SDM using a PtDA has been established by: 1) introducing choice, 2) describing options, often by integrating the use of patient decision support and 3) helping patients explore preferences and make decisions (197). This model rests on supporting a process of deliberation, and on understanding that decisions should be influenced by exploring and respecting ‘what matters most’ to patients as individuals, and that this exploration in turn depends on them developing informed preferences (188). For a PtDA to effectively aid SDM these key aspects must be appropriately reflected in the design, ensuring that the PtDA is relevant, acceptable, user-friendly and valid (188).

PtDAs are designed to help patients make specific and deliberated choices about healthcare options as they represent accurate and unbiased information about management options and relevant outcomes (197). PtDAs outline different treatment options and their associated outcomes, whilst aiming to improve the quality of care delivered. There is emerging evidence to suggest their use is associated with an avoidance of unnecessary procedures and a reduction in complications and costs (457). PDAs can help improve patients’ knowledge of and expectations regarding healthcare outcomes, reduce decisional conflict, increase decision quality and increase patient participation in decision making (223).

A systematic review of 55 studies on the use of decision aids as an adjunct to counselling have shown consistently superior effects relative to usual practices. Knowledge increased by 19%, improvements in the proportion of patients with realistic perceptions of the chances of benefits and harm by 40%, reduced decisional conflict by 9%, a reduction in the proportions of patients who were passive with decision-making of 30% was observed and a reduction in the proportion of people who remained undecided after counselling of 57% was observed (458). These findings have been reproduced in a Cochrane systematic review from 105 randomised controlled



trials that showed PtDAs help create better informed patients who are clearer about their health values, have more accurate risk perceptions and are more likely to actively participate in decision-making (223). Patients are more likely to choose conservative treatment options with 20% less likely to choose major elective surgery after using a PtDA compared to counselling alone (459).

PtDAs used by the clinician within the clinical encounter, to provide structure to consultations, but also by the patients outside the encounter to aid their deliberation which is a key step to informed consent (460). The 2015 Montgomery ruling redefined the standard of informed consent and disclosure in the United Kingdom stipulating that there is a duty to take care to ensure that the patient is aware of any material risks involved in any recommended treatment and of any reasonable alternative or variant treatment (454). The test of materiality is where a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it ' (454). International organisations such as the Australian Commission on Safety and Quality in Health Care, UK National Institute for Health and Care Excellence (NICE) and US National Quality Forum recommend the use of high-quality PtDAs in clinical practice (461-463).

### **6.1.1 IPDAS**

The International Patient Decision Aid Standards (IPDAS) Collaboration was established in 2003 to enhance the quality and effectiveness of PtDAs. They established a shared evidence-informed framework with a set of criteria for improving the content, development, implementation, and evaluation of PtDAs. Key features common to the development of a PtDA by IPDAS include scoping and design, development of a prototype, 'alpha' testing with patients and clinicians in an iterative process (testing by people directly involved in the development process), 'beta' testing in 'real life' conditions (field tests with patients and clinicians not involved in the development process), and production of a final version for use and/or further evaluation (172). PtDAs should be carefully developed, user-tested, and open to scrutiny, with a well- documented and systematically applied development process. Users require assurance that the development process has been carried out to acceptable standards. Poor quality decision aids have the potential to cause harm to patients by causing doubt to be cast on the concept of SDM. Therefore, it is essential

that those not involved in developing PtDAs are provided with sufficient documentation to check the validity and reliability of their development processes (172).

### **6.1.2 Agile developmental methodology**

Agile Developmental Methodology (ADM) is a dynamic and flexible approach employed in software programming, whereby new programmes are developed over a series of short cycles (sprints) by harnessing user feedback (464) (465). ADM focuses on collaborations between developers and stakeholders, flexible methodology, and the ability to respond quickly to change through multiple iterations (466). This approach results in a product that can quickly adapt to clients' changing needs, whilst delivering a high-quality and high-value project within the constraints (i.e. cost, schedule, and scope) (467). The use of ADM results in higher performance, satisfaction, and product quality compared with more structured nonfluid approaches (468). ADM projects were reported to be 28% more likely to succeed than other methodologies in terms of completion time, budget and including originally outlined specifications (469). To our knowledge, ADM has not hitherto been used for developing written patient information resources, but this approach lends itself to evolving a patient centred and flexible end user product.

At present there is no available PtDA to assess informed and SDM for patients with LRRC or LARC outlining treatment options. As a result, there is a paucity of literature to support and assist patients in the decision on whether to proceed with this extensive, life-changing surgery. Insufficient research has been conducted into the decision-making process for undergoing PE with regards to available support networks, clinician consent process and whether patients are fully aware of the implications of surgery. The development of a PtDA will empower informed decision making between patients and clinicians, validate informed consent as well as informing health care providers of current services and encourage the future development of services.

## **6.2 Aims and objectives**

This study's objectives were to:

1. Design a PtDA for use by surgical teams (consultant surgeons, clinical specialist nurses (CNS), oncologists palliative care specialists, and stoma nurses) to support patients in their decision-making regarding PE surgery

2. Develop this resource in line with the systematic development process specified by IPDAS, ensuring the decision aid meets minimum standards (172) (470).

### **6.3 Methodology**

#### **6.3.1 Development of the PtDA**

The development of the PtDA was theoretically grounded in the Ottawa Decision Support Framework (ODSF) and practically guided by IPDAS guidance (172) (470), to ensure appropriate balancing of options (471), risk presentation (471) (431) (472) (473), eliciting patient values (474), use of patient stories (475) and enabling readability (476). The ODSF is an evidence based, mid- range theory for guiding patients to make health decisions, incorporating insights on decision making from general psychology, social psychology (477), decision analysis (478), decisional conflict (479), social support (480, 481), and economic concepts of expectations and values (482). The framework uses a three-step process to 1) assess client and practitioner determinants of decisions to identify decision support needs; 2) provide decision support tailored to client needs; and 3) evaluate the decision making process and outcomes (483).

#### **6.3.2 Recruitment**

A core-steering group was established of HCPs and patient and public involvement (PPI) who informed the design of the PtDA. The steering group was established to reflect those participating in the multi-disciplinary team meeting (MDT) together with patient representatives. Patients and healthcare professionals over five sites were identified and recruited to ensure a representative sample. Patients were identified through pre-existing prospectively kept databases at each centre. Clinicians were identified at local sites by the local PI.

##### **6.3.2.1 Eligibility**

##### **Inclusion criteria for steering group**

Individuals were included in the study if the following criteria were fulfilled:

- Participating in a PE MDT or had performed PE.
- Within one of five nominated study sites.

### **Exclusion criteria for patients**

Individuals were excluded from the study if any of the following criteria applied:

- HCPs having participated in other parts of the study.

#### **6.3.2.2 Steering Group**

Three patients, two exenterative colorectal surgeons, one urology surgeon, one plastic surgeon and one gynae-oncology surgeon, one oncologist, one Nurse Consultant and one CNS were recruited over the five nominated study sites:

Mr Ian Jenkins – Consultant Colorectal surgeon, St Marks Hospital, London

Mr Ben Griffiths – Consultant Colorectal surgeon, Royal Victoria Infirmary, Newcastle

Mr Nicholas Gill – Consultant Urology surgeon, Morriston Hospital, Swansea

Mr Peter Drew – Consultant Plastic surgeon, Morriston Hospital, Swansea

Mr Nidal Ghaoui - Consultant Gynae-oncology surgeon, Western General Hospital Edinburgh

Dr Claire Taylor - Macmillan Nurse Consultant in Colorectal Cancer, St Marks Hospital, London

Dr Alexandra Gilbert – Consultant Oncologist, St James University Hospital, Leeds

Mrs Lorraine Chitambo – Gynae-oncology CNS, Western General Hospital, Edinburgh

PPI consisted of two males and one female. All participants had undergone varying exenterations; TPE and side wall, posterior PPE and TPE with sacrectomy. Age was between 38 and 58 years. Geographical locations included Swansea and London.

Clinician involvement were five male surgeons, one female oncologist, one nurse consultant and one CNS. Participants represented all five centres: London, Swansea, Newcastle, Edinburgh and Leeds.

### **6.3.3 Rules of engagement**

The rules of engagement included commitment to fortnightly Zoom meetings until the end of the process. In the event of being unable to join the meeting they were asked for their comments to be directed via email prior to the meeting for further discussion within the group.

The aim of the steering group was to develop a PtDA for LARC and LRRC suitable for patient use.

### **6.3.4 Design of the PtDA**

An inductive (top down) and deductive (bottom up) approach (7, 28) was utilised to inform the content and design of preliminary PtDA based upon a review of the online literature (Chapter 2), online forums (Chapter 3), qualitative interviews (Chapter 4) and PIL currently in use (Chapter 5). Each theme identified in Phase I informed an individual component of the initial PtDA. The PtDA was designed in consultation with a graphics designer.

Semi-structured cognitive interview guide was utilised to steer the steering group meetings (Appendix J). ADM was employed to iteratively develop the PtDA and to achieve agreement on a final version ready for alpha testing. Each component of the PtDA was assessed by the core-steering group in a stepwise manner to assess its relevance, acceptability, comprehensibility and usability on a fortnightly basis over a period of 10 weeks. Each cycle of design and assessment of the PtDA was referred to as a sprint.

Each steering group was recorded and transcribed verbatim. Qualitative data was analysed as described in previous chapters. This guided subsequent changes to the PtDA, and the process of assessment was repeated until no further changes were required. Changes were grouped according to major (structure, content, acceptability, comprehensibility and desirability) and minor changes (spelling and grammar)

## **6.4 Results**

The content of the preliminary PtDA was informed by eight themes extracted from our systematic review, internet forums, qualitative interviews and available PILs. (Chapters 2-5). The themes used to develop the PtDA were recovery, psychological impact, expectations, communication, relationships, lifestyle, financial implications

and support. The PtDA was developed for a moderate health literacy populations, with a reading age of 15-17 years (Flesh-Kincaid grade 7.4, Flesh- Kincaid reading ease 55.4).

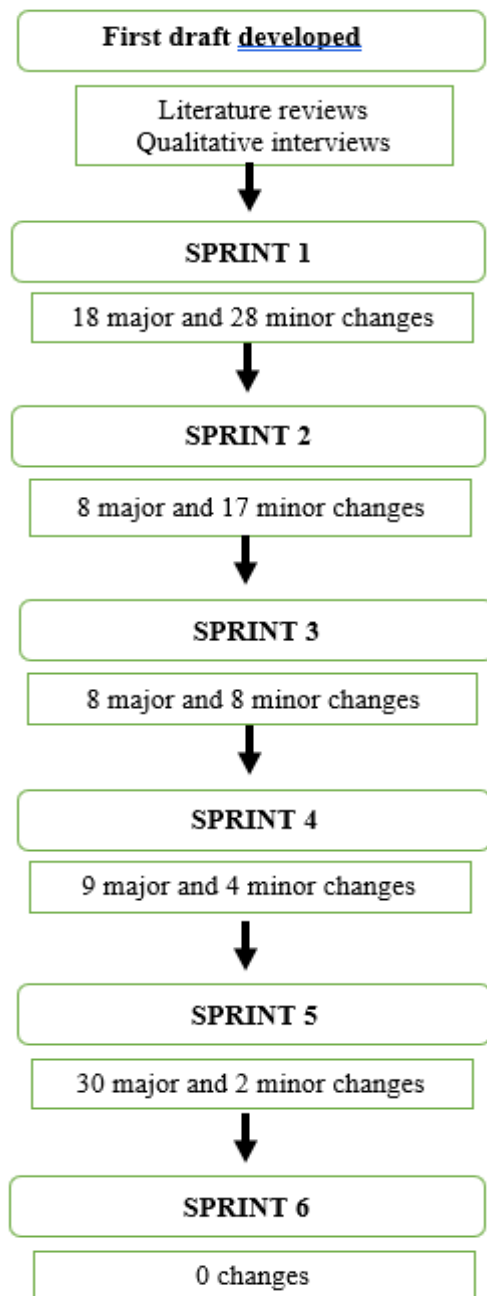


Figure 14. Sprint cycles illustrating changes

| SPRINT 1             | Structure<br>Layout<br>Presentation                                          | Content<br>Missing items<br>Incorrect info<br>Clarification of info                                                                                                                                                             | Acceptability<br>Balanced info<br>Beneficial                                                | Comprehensibility<br>Spelling & grammar<br>Wording<br>Technical terms<br>Readability                 | Desirability<br>Visuals<br>Illustrations                      |
|----------------------|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|
| Recovery             | Long- and short-term consequences of surgery incorporated into table format. | Separate chemotherapy and radiotherapy side-effects.<br>Major and minor complications to be moved into appropriate sections.<br>Missing information: long term urostomy issues including renal failure and ureteric strictures. | No changes.                                                                                 | No changes.                                                                                          | No changes.                                                   |
| Psychological impact | No changes.                                                                  | No changes.                                                                                                                                                                                                                     | No changes.                                                                                 | No changes.                                                                                          | Photographs of stomas too graphic but illustrations adequate. |
| Expectations         | Organ specific table.                                                        | Different treatment options available to patients.<br>Length of stay up to 3 months rather than an average.<br>Add in 30- and 90-day mortality.<br>Add in 3- and 5-year survival.                                               | No changes.                                                                                 | Clarification on what is a stoma and a stoma bag                                                     | No changes.                                                   |
| Communication        | No changes.                                                                  | Adjuvant chemotherapy to be added.                                                                                                                                                                                              | 3 main treatment options to be highlighted with a more positive emphasis on palliative care | Improve terminology to be more patient friendly<br>'perineum and bottom end' 'anus and back passage' | No changes.                                                   |

|                        |             |                                                                                                                                                                              |             |             |             |
|------------------------|-------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|-------------|-------------|
| Relationships          | No changes. | Further information required regarding male sexual dysfunction including what that meant from a relationship point of view and mechanical and chemical aids being available. | No changes. | No changes. | No changes. |
| Lifestyle              | No changes. | Further discussion for QoL regarding lifestyle.                                                                                                                              | No changes. | No changes. | No changes. |
| Financial implications | No changes. | Further discussion for QoL regarding work and financial implications.                                                                                                        | No changes. | No changes. | No changes. |
| Support                | No changes. | Signpost websites to help with decision making.                                                                                                                              | No changes. | No changes. | No changes. |

**Table 27. Summary of Sprint 1 feedback**



| SPRINT 2               | Structure<br>Layout<br>Presentation                                                | Content<br>Missing items<br>Incorrect info<br>Clarification of info             | Acceptability<br>Balanced info<br>Beneficial | Comprehensibility<br>Spelling & grammar<br>Wording<br>Technical terms<br>Readability | Desirability<br>Visuals<br>Illustrations |
|------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|----------------------------------------------|--------------------------------------------------------------------------------------|------------------------------------------|
| Recovery               | ELSIE & sacrectomy to be incorporated into organ table.                            | Add wound/flap healing, complications.<br>Add postoperative physical changes.   | No changes.                                  | No changes.                                                                          | No changes.                              |
| Psychological impact   | No changes.                                                                        | Add postoperative psychological impact.                                         | No changes.                                  | No changes.                                                                          | No changes.                              |
| Expectations           | Summary treatment pathways, summarise options and decisions available to patients. | Inaccurate portrayal of surgery being a cure rather than 'potentially curable'. | Rename 'complex pelvic cancer treatment'.    | No changes.                                                                          | No changes.                              |
| Communication          | No changes.                                                                        | No changes.                                                                     | Best supportive care remains too negative.   | No changes.                                                                          | No changes.                              |
| Relationships          | No changes.                                                                        | No changes.                                                                     |                                              | No changes.                                                                          | No changes.                              |
| Lifestyle              | No changes.                                                                        | No changes.                                                                     | No changes.                                  | No changes.                                                                          | No changes.                              |
| Financial implications | No changes.                                                                        | No changes.                                                                     | No changes.                                  | No changes.                                                                          | No changes.                              |
| Support                | No changes.                                                                        | No changes.                                                                     | No changes.                                  | No changes.                                                                          | No changes.                              |

**Table 28. Summary of Sprint 2 feedback**

| SPRINT 3<br>Gynae subgroup | Structure<br>Layout<br>Presentation | Content<br>Missing items<br>Incorrect info<br>Clarification of info                                                               | Acceptability<br>Balanced info<br>Beneficial | Comprehensibility<br>Spelling & grammar<br>Wording<br>Technical terms<br>Readability | Desirability<br>Visuals<br>Illustrations |
|----------------------------|-------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|--------------------------------------------------------------------------------------|------------------------------------------|
| Recovery                   | No changes.                         | No changes.                                                                                                                       | No changes.                                  | No changes.                                                                          | No changes.                              |
| Psychological impact       | No changes.                         | Add pros and cons of vaginal reconstruction.<br>Add emotional aspect of sex.                                                      | No changes.                                  | No changes.                                                                          | No changes.                              |
| Expectations               | No changes.                         | Add physical changes with and without vaginal reconstruction.                                                                     | No changes.                                  | No changes.                                                                          | No changes.                              |
| Communication              | No changes.                         |                                                                                                                                   | No changes.                                  | No changes.                                                                          | No changes.                              |
| Relationships              | No changes.                         | Discuss menopause and pharmaceuticals.<br>Discuss physical and psychosexual adjustment.<br>Discuss feeling and expressing desire. | No changes.                                  | No changes.                                                                          | No changes.                              |
| Lifestyle                  | No changes.                         | Identify gender appropriately including cis-gender, transgender.                                                                  | No changes.                                  | No changes.                                                                          | No changes.                              |
| Financial implications     | No changes.                         | No changes.                                                                                                                       | No changes.                                  | No changes.                                                                          | No changes.                              |
| Support                    | No changes.                         | Signpost various support groups.                                                                                                  | No changes.                                  | No changes.                                                                          | No changes.                              |

**Table 29. Summary of Sprint 3 feedback**

| SPRINT 4               | Structure<br>Layout<br>Presentation | Content<br>Missing items<br>Incorrect info<br>Clarification of info                                                                                | Acceptability<br>Balanced info<br>Beneficial                          | Comprehensibility<br>Spelling & grammar<br>Wording<br>Technical terms<br>Readability | Desirability<br>Visuals<br>Illustrations                                 |
|------------------------|-------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|--------------------------------------------------------------------------------------|--------------------------------------------------------------------------|
| Recovery               | No changes.                         | Differentiate high and low sacrectomy and subsequent complications.<br>Add LARS.                                                                   | No changes.                                                           | No changes.                                                                          | No changes.                                                              |
| Psychological impact   | No changes.                         |                                                                                                                                                    | Reiterate the latter part of the document focus' on surgical aspects. | No changes.                                                                          | Cultural insensitivity regarding survival illustrations – colour change. |
| Expectations           | No changes.                         | Survival stats to be clarified.<br>Clarification of meanings in 3- and 5-year survival.<br>Surgical approach to surgery to include minimal access. | Include provision of best supportive care – its aims and objectives.  | No changes.                                                                          | No changes.                                                              |
| Communication          | No changes.                         | No changes.                                                                                                                                        | Best supportive care remained too negative.                           | No changes.                                                                          | No changes.                                                              |
| Relationships          | No changes.                         | No changes.                                                                                                                                        | No changes.                                                           | No changes.                                                                          | No changes.                                                              |
| Lifestyle              | No changes.                         | No changes.                                                                                                                                        | No changes.                                                           | No changes.                                                                          | No changes.                                                              |
| Financial implications | No changes.                         | No changes.                                                                                                                                        | No changes.                                                           | No changes.                                                                          | No changes.                                                              |
| Support                | No changes.                         | No changes.                                                                                                                                        | No changes.                                                           |                                                                                      | No changes.                                                              |

**Table 30. Summary of Sprint 4 feedback**

|                      |                                     |                                                                                                                                |                                              |                                                                                      |                                                                |
|----------------------|-------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|--------------------------------------------------------------------------------------|----------------------------------------------------------------|
| SPRINT 5             | Structure<br>Layout<br>Presentation | Content<br>Missing items<br>Incorrect info<br>Clarification of info                                                            | Acceptability<br>Balanced info<br>Beneficial | Comprehensibility<br>Spelling & grammar<br>Wording<br>Technical terms<br>Readability | Desirability<br>Visuals<br>Illustrations                       |
| Recovery             | No changes.                         | Add ELSIE complications – leg numbness and foot drop.<br>Add weight gain with menopause.<br>Mention graduated sitting program. | No changes.                                  | Observation to ‘looked after’                                                        | Posterior clearance with sacrectomy missing from illustrations |
| Psychological impact | No changes.                         | Donor sites leaving a deformity and issues with body image.                                                                    | No changes.                                  | Psychological impact reworded to emotional impact.                                   | No changes.                                                    |
| Expectations         | LARC to precede LRRC in survival.   | Complete response to be included in flow.<br>Reduce info adjuvant chemotherapy.                                                | Rename complex rectal cancer.                | Stoma bag clarified.                                                                 | No changes.                                                    |
| Communication        | No changes.                         | Clarify complete response.<br>Surgery may be something the patient doesn’t want or need<br>FU for each option individualised   | Survival as x in y as well as %              | Best supportive care rather than palliative care.<br>Clarify best supportive care.   | Survival figures colour change.                                |
| Relationships        | No changes.                         | Removal of cervix – no further smears<br>Need HRT<br>Egg and sperm retrieval<br>Discuss orgasm.                                | No changes.                                  | No changes.                                                                          | Annotation mons pubis and labia minora.                        |

|                        |             |                                                                                                                       |             |                                            |             |
|------------------------|-------------|-----------------------------------------------------------------------------------------------------------------------|-------------|--------------------------------------------|-------------|
|                        |             | Discuss lubrication and dilation.<br>Vaginal reconstruction is a choice.                                              |             |                                            |             |
| Lifestyle              | No changes. | Reasons for not having surgery to include not wanting a stoma.<br>Discuss pain and lack of energy affecting exercise. | No changes. | Mobility to 'your ability to move around'. | No changes. |
| Financial implications | No changes. | Short term loss of income.                                                                                            | No changes. | No changes.                                | No changes. |
| Support                | No changes. | No changes.                                                                                                           | No changes. | No changes.                                | No changes. |

**Table 31. Summary of Sprint 5 feedback**

|                        |                                     |                                                                     |                                              |                                                                                      |                                          |
|------------------------|-------------------------------------|---------------------------------------------------------------------|----------------------------------------------|--------------------------------------------------------------------------------------|------------------------------------------|
| SPRINT 6               | Structure<br>Layout<br>Presentation | Content<br>Missing items<br>Incorrect info<br>Clarification of info | Acceptability<br>Balanced info<br>Beneficial | Comprehensibility<br>Spelling & grammar<br>Wording<br>Technical terms<br>Readability | Desirability<br>Visuals<br>Illustrations |
| Recovery               | No changes.                         | No changes.                                                         | No changes.                                  | No changes.                                                                          | No changes.                              |
| Psychological impact   | No changes.                         | No changes.                                                         | No changes.                                  | No changes.                                                                          | No changes.                              |
| Expectations           | No changes.                         | No changes.                                                         | No changes.                                  | No changes.                                                                          | No changes.                              |
| Communication          | No changes.                         | No changes.                                                         | No changes.                                  | No changes.                                                                          | No changes.                              |
| Relationships          | No changes.                         | No changes.                                                         | No changes.                                  | No changes.                                                                          | No changes.                              |
| Lifestyle              | No changes.                         | No changes.                                                         | No changes.                                  | No changes.                                                                          | No changes.                              |
| Financial implications | No changes.                         | No changes.                                                         | No changes.                                  | No changes.                                                                          | No changes.                              |
| Support                | No changes.                         | No changes.                                                         | No changes.                                  | No changes.                                                                          | No changes.                              |

**Table 32. Summary of Sprint 6 feedback**

The PtDA was developed as sex-specific documents to reduce the burden of unnecessary information irrelevant for each sex. Each section was subdivided and developed into sections:

1. A general introduction to LARC and LRRC
2. The purpose of the aid.
3. Treatment options including surgery, oncological treatment, and best supportive care.
4. A detailed comparison discussion of each treatment option.
5. A detailed discussion on what surgery involves, recovery and implications of surgery.

#### **6.4.1 Agile development methodology**

The preliminary PtDA was tested over 6 sprints over 12 weeks between January 2021 and April 2021. Seventy-three major changes and 59 minor changes were generated throughout the cycles (Figure 14, Tables 27-32).

##### **6.4.1.1 Sprint 1**

###### **Structure**

Overall, the structure was considered good. However, the table structure outlining the various types of PE was felt to be complicated. The group felt that the PtDA should be personalised for each patient due to the complexity and heterogeneity associated with the anatomy of the disease and surgery. It was suggested that the organs being removed for each patient should be highlighted using an organ specific tick box. Clinicians would then be able to highlight, at the time of consultation, which organs would need to be removed during their specific surgery. Participants also felt that the structure of the ‘potential things to expect after surgery’ could be improved by incorporating short- and long-term consequences in a table.

###### **Content**

The document was believed to be advocating surgery rather than being a balanced decision aid. Further emphasis was required on different treatment options being available to patients including oncological treatments and palliative care. Combined chemotherapy and radiotherapy were considered to be confusing, and treatment

induced side effects needed to be specific to each treatment modality. Participants felt that length of stay should be extended from approximately 14 days to up to 3 months to reflect the complexity of post-operative recovery in this cohort of patients. Major and minor complications were clarified and moved to the appropriate sections. The group felt it was important to highlight that despite survival being important, QoL needed to be discussed further regarding identity, work, and the future. Further information was required regarding sexual dysfunction in men including what that meant and what mechanical and chemical aids were available. It was suggested that websites needed to be signposted to help with decision making.

Some information was believed to be missing from the document which included: long term urostomy issues including renal failure and ureteric strictures. Participants felt that it was important to include 30- and 90-day mortality together with 1-, 3- and 5-year survival. It was noted that survival would be different in different units. Factors of age, comorbidities and type of surgery, pre-existing metastasis would also contribute to survival, but it was agreed that published data figures should be used for the PtDA. Participants stated that adjuvant chemotherapy should be included in the document as patients should be aware of it being a potential option following major surgery, which could potentially influence decision making.

### **Acceptability**

Overall, the group felt that with the suggested changes the document would help in the decision-making for patients and benefit both clinicians and patients within the consultation. They acknowledged that there would be a small cohort of patients who would not engage in the process of using the PtDA, however, it was felt that it would be a very useful document for the family in this scenario. It was also acknowledged that patients would benefit in using the document following surgery as a source of information.

### **Comprehensibility**

Largely the group felt that the PtDA was easy to read, however, minor changes to some terminology was required to become more patient friendly i.e. perineum and bottom end, anus and back passage. It was felt that the PtDA would be read during an emotionally challenging period and therefore confusing medical terminology should be avoided. It was also acknowledged that family members absent at consultation may



be reading the document, and therefore needed to be aimed at laypersons. Participants felt that further clarification on what is a stoma, and a stoma bag should be undertaken.

## **Desirability**

Participants felt that overall, the document wasn't quite balanced regarding the three main treatment options. The group believed that the choice of supportive treatment was written very negatively and wasn't portrayed as a real option. Further work was developed to ensure all options were portrayed evenly and it was highlighted that each patient is different and various treatment options were available to them. Participants also felt that photographs were too graphic, and the consensus was that they should be available at their request but within the PtDA illustrations were adequate. Changes are illustrated in Figure 15.

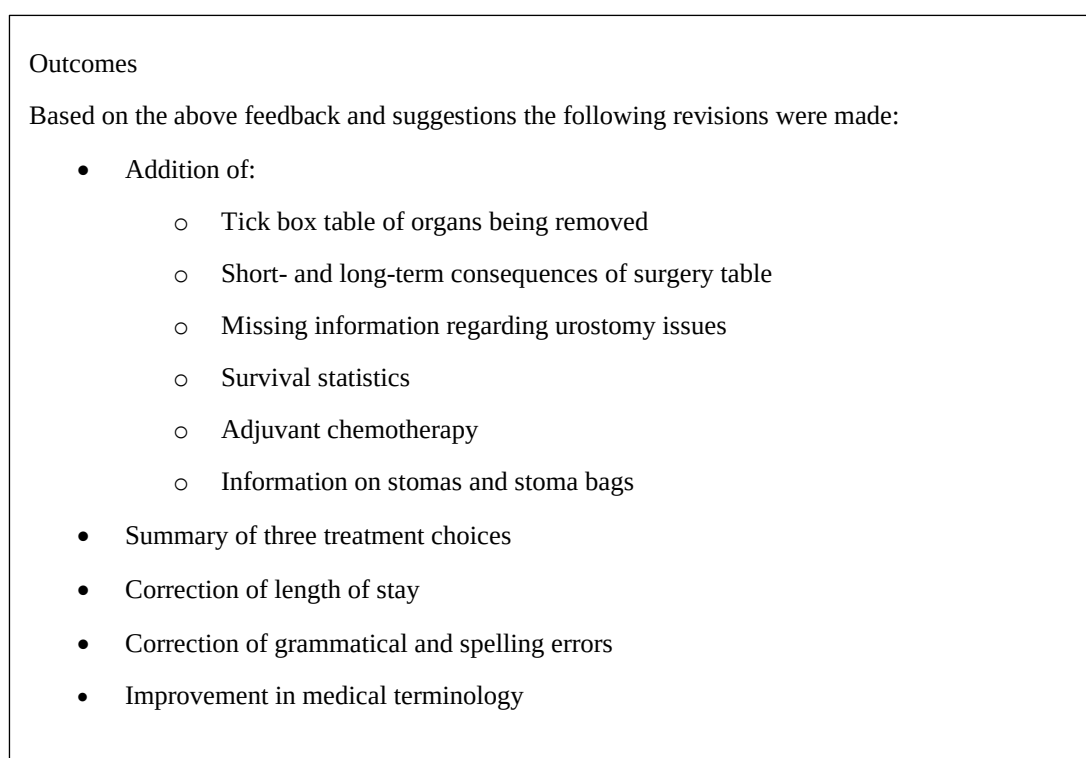


**Figure 15. Outcomes of Sprint 1**

### **6.4.1.2 Sprint 2**

#### **Structure**

Participants felt that the overall flow of the document was adequate. Participants felt that a summary of treatment to understand the treatment pathway, and to summarise options and decisions should be available to them. It was felt that these changes would make the tool easier to follow. Participants felt that sections of information were

inappropriately placed and could be moved to improve the flow. Participants also felt that information regarding ELSIE and sacrectomy would be more suitably placed if they were incorporated into the table format.

### **Content**

Participants identified and corrected spelling and grammatical errors. The group also felt that it was an inaccurate portrayal of surgery being a cure and further work needed to be done to highlight surgery as an option which potentially would be curable. Participants identified information missing in the document. Reconstructive surgery was lacking information regarding its impact on QoL. Specific information regarding wound/flap healing, complications, wound breakdown, and potential hernia was required. Further information was also required regarding the post-operative impact on the body and physical changes endured following surgery.

The female participants within the group believed that further information regarding sexual dysfunction with and without vaginal reconstruction needed to be discussed in more significant detail. It was felt that male sexual dysfunction was more readily addressed than female sexual dysfunction. The female PPI participant explained how it was uncomfortable for women to discuss sexual dysfunction in a male dominated clinical team.

### **Acceptability**

Participants felt that information on palliative care remained too negative, and that this required revision to improve its acceptability. There was a perception that the title was too medical, and the consensus was to change it to ‘complex pelvic cancer treatment’ from ‘locally advanced or locally recurrent rectal cancer treatment options for women/men’.

### **Comprehensibility**

Further changes were made by the group regarding some medical terminology to ensure readability.

### **Desirability**

The appearance of the PtDA was deemed acceptable by the participants. Comments were made regarding illustrations aiding the written explanations which were helpful

to patients. The PtDA was deemed to be visually acceptable to both patients and clinicians to be used in clinical practice in its current format. Changes are illustrated in Figure 16.

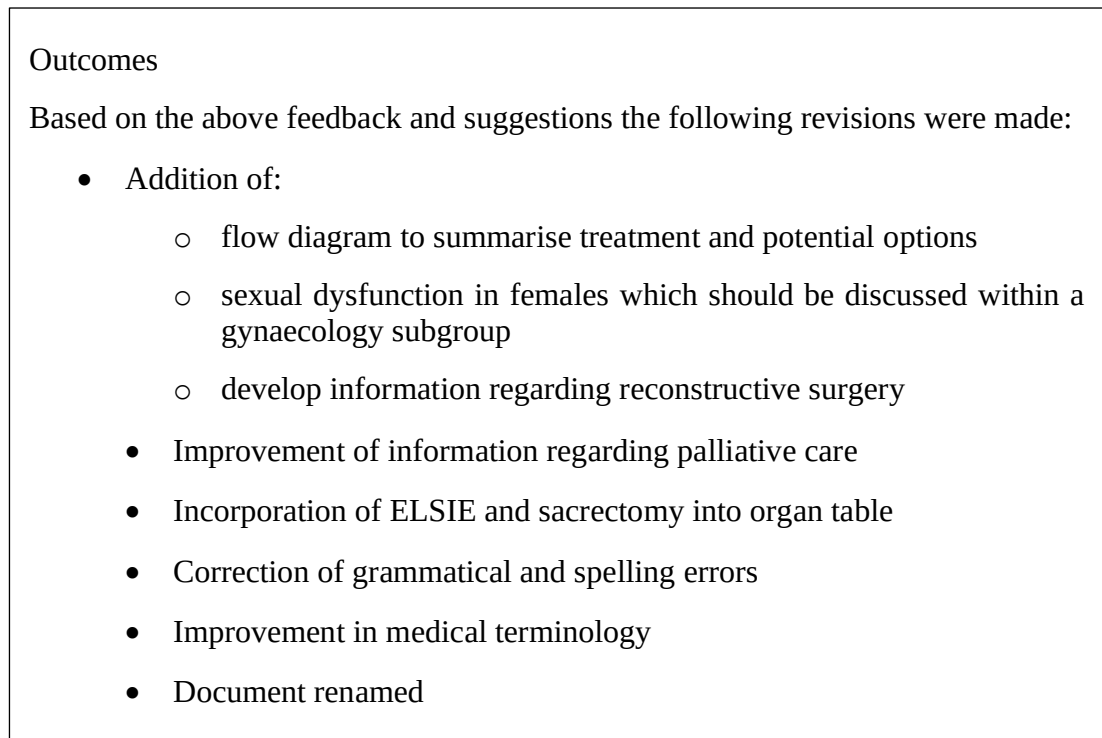


**Figure 16. Outcomes of Sprint 2**

### **6.4.1.3 Sprint 3**

#### **Gynae subgroup changes**

A subgroup of professionals with a specialist interest in gynae-oncology were recruited to develop the female PtDA. Those present included:

Alex Gilbert – Consultant Oncologist, St James University Hospital, Leeds,

Claire Taylor – Macmillan Nurse Consultant in Colorectal Cancer, St Marks Hospital, London

Isabella White - Psychosexual therapist, Royal Marsden Hospital, London

Jessica Vett – Consultant Gynae-oncology surgeon, Singleton Hospital, Swansea

Andreia Fernandes – Gynae-oncology lead nurse, Royal Marsden Hospital, London

## Content

Members of the gynae subgroup discussed the current content of the PtDA and explored other important information missing for women. The psychological, anatomical, physical, sexual and relational impact was discussed and developed as a group. Participants felt that information regarding proactively managing menopause needed to be discussed including pharmaceuticals treatment of HRT, oestrogen cream, lubrication and dilation. The group developed content regarding physical changes with and without vaginal reconstruction. Information without reconstruction needed to include change in lie or angle of the vagina and loss of cushioning which could potentially result in dyspareunia. Further information regarding change in vaginal sensation was developed in the content including the potential negative sensation to remaining labia. Information regarding vaginal reconstruction needed to be further developed as a potential surgical option. Information regarding the pros and cons of vaginal reconstruction, loss of sensation and the need for dilatation together with support for dilatation were developed. Participants felt it was important to signpost patients to other resources to help physical and psychosexual adjustment. The group also felt it important to identify gender appropriately, including cis-gender, transgender etc and to highlight appropriate sources of support. The group discussed the emotional aspect of sex and developed content regarding feeling and expressing desire. Participants discussed that any sexual changes were dependent on a pre-existing sexual status and consequences of surgery and radiotherapy were all relative to the baseline. Changes are illustrated in Figure 17.

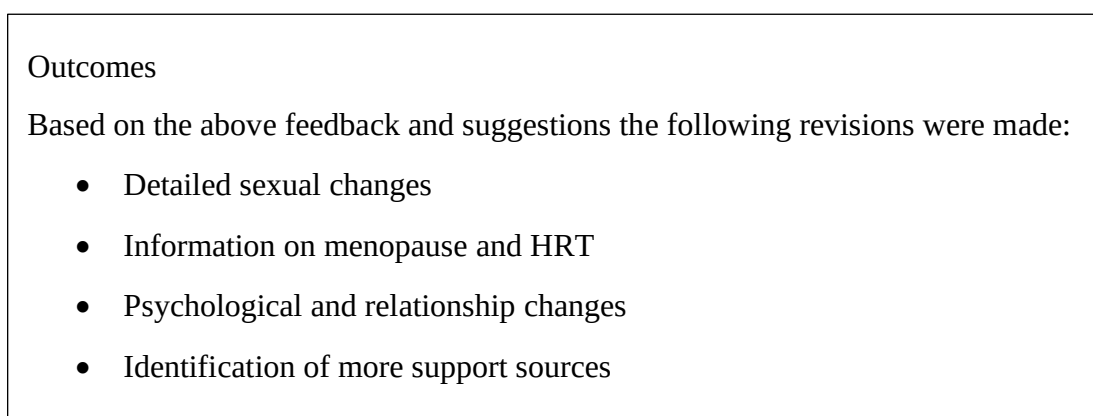


Figure 17. Outcomes of Sprint 3

#### **6.4.1.4 Sprint 4**

##### **Structure**

Participants agreed that the flow and structure of the PtDA was acceptable, and no further changes were required.

##### **Content**

Participants discussed the accuracy of the survival statistics and felt that the numbers did not reflect both clinician personal data and statistics specific to patients. It was highlighted that only peer-reviewed data could be incorporated which was historic based on PelvEx collaborative data which is the largest series of data published to date (157) (156). However, to address both issues, the group emphasised survival being a very general statistic based on historical groups of people. It was highlighted that data was not individualised. Participants also felt that 3- and 5-year survival needed to be explained. It was highlighted that patients should ask their team for information specific about their disease.

Participants identified some missing information, including, surgical approach, highlighting that laparoscopic or robotic approaches may be appropriate in a few patients. Further differentiation was required between high and low sacrectomy, including their complication profiles. The omission of low anterior resection syndrome (LARS) in select patients who had a coloanal/low rectal anastomosis was also identified.

##### **Acceptability**

Participants agreed that the information within the PtDA would benefit the patient both to understand the choices presented to them and aid in their decision-making process. They felt that it would also help patients understand the surgery and the implications of surgery. The group felt that it was important to highlight that following the section on choices that the reminder of the booklet provided more detail about the surgical procedure when considering surgery as an option.

##### **Comprehensibility**

The language in some areas was felt to be too complicated and needed to be further simplified, for example ‘may have grown outside the part of the lower bowel (rectum)

that it started in’ would be clearer to the layperson if it read ‘may have spread to other organs nearby’. It was also noted that surgery was giving a certainty of cure and further qualification of potential cure was added. Participants felt that the wording of ‘plastic surgery’ was unsuitable in this context and the wording of ‘reconstructive surgery’ gave a more accurate reflection. The diagrams representing reconstructive surgery were discussed and the consensus was that they were not easily understood by the patients. Further guidance of illustrations was negotiated by the group. It was also noted that it was important to denote parts of unchanged anatomy.

### **Desirability**

Participants agreed that the survival illustration may have cultural insensitivity which could potentially affect the document’s desirability. Illustrations were changed from black to blue to correct any potential misrepresentation.

Information surrounding best supportive care was still felt to be negative, missing certain information and generally not an option that was portrayed as desirable to any patient. The group developed information regarding the principles of the provision of best supportive care. Further information regarding what supportive care is going to offer to the patient, what does it mean if they don’t decide to have surgery, what can they expect, what’s going to happen to them next, details of follow-up, further imaging and symptom management and QoL was developed. Changes are illustrated in Figure 18.

## Outcomes

Based on the above feedback and suggestions the following revisions were made:

- Addition of:
  - Flow
  - Missing information- minimal access approach, LRS
- Development of survival data
- Improvement of palliative care information and renaming to best supportive care
- Differentiation between high and low sacrectomy
- Highlighting surgery as a potential cure
- Improvement in reconstructive illustrations
- Improvement in survival illustrations
- Simplification of language

**Figure 18. Outcomes of Sprint 4**

## **Sprint 5**

### **Structure**

Consistency of the document's structure was checked and modified accordingly. Participants felt that navigation of the document could be improved with a content page.

### **Content**

The accuracy of the document was reevaluated. Participants identified further typographical errors throughout the document which were rectified. Consistency of words and layperson terms were reevaluated within the document, for example the use of best supportive care rather than palliative, close monitoring rather than surveillance. Typographical errors were corrected. Direct comparison of generic information between the male and female specific documents were also performed for consistency.

Participants felt that it was important to highlight that patients had a choice to make with complete response within the flow diagram which was annotated. Complete response was clarified. Further information regarding follow-up was described to be

individualised for each patient irrespective of the treatment pathway. Missing information included: no further smears following a total abdominal hysterectomy (TAH) and bilateral salpingo-oophrectomy (BSO) within the screening population and the need of HRT for pre-menopausal ladies. Participants felt that it was important to separate the ability to get pregnant and suffering menopause. Other information missing from the PDA included: leg numbness and foot drop following an extended lateral side wall excision (ELSIE) procedure, weight gain as a result of new/early onset menopause, information regarding egg and sperm collection with subsequent IVF/surrogacy, information regarding lubrication and dilation for women, short term loss of income, pain and lack of energy affecting exercise and information regarding graduated sitting programme. Annotation of the mons pubis and labia minora of the illustration was also noted to be missing.

The group noted that other reasons that patients did not want surgery needed to include not wanting a stoma. It was also noted that patients who don't undergo radical treatment need to be informed that the tumour could grow externally. Participants felt it was important to highlight that the vulva would usually not be removed during the operation, however, it could affect the way the area felt and could change the way patients were able to orgasm. Further information was developed by the group regarding vaginal reconstruction being a choice, however, highlighting that if a flap had been discussed it is usually necessary to fill the empty space. Information regarding donor sites potentially leaving a deformity was noted and incorporated.

The group felt there was too much information regarding adjuvant chemotherapy. It was therefore omitted and edited to read 'it may be necessary but following oncologist discussion'.

## **Layout**

Participants felt overall the layout was acceptable. Clarity on the latter part of the document providing more detail on the surgical element was highlighted. Generic modifications regarding justification of paragraphs and centralising of texts to improve appearance was noted. It was agreed to format and highlight the subheadings within the 'potential things to expect after surgery' to highlight the consequences of surgery. The layout within 'emotional changes' was considered visually unappealing, and changes were suggested. The benefit of reconstruction was confusing and



improvements for wording and layout of this section were agreed by the group. Participants felt that the bullet points for effects of surgery on exercise were inconsistent with the rest of the document and modified accordingly.

### **Acceptability**

The group believed that the document needed to be renamed ‘complex rectal cancer’ to ensure that its use was specific for LARC and LRRC. Participants felt that this would make the document more acceptable to this cohort of patients. With a document having been developed with such a rigorous methodology participants felt that it was important for its use not to be misrepresented for gynaecological, urological or other advanced pelvic malignancies.

Participants felt the section on survival needed improvement. Figures of overall survival using black colour format could potentially be culturally insensitive and changes recommended. Survival needed to be read as numbers as well as percentages. Full annotation of female anatomy was required.

### **Comprehensibility**

Participants studied the PtDA for comprehensibility. Laypersons terms and descriptions were added where individuals felt the wording would affect understanding e.g. mobility changed to ‘your ability to move around’, observation changed to ‘be looked after’. Best supportive care as a treatment option was clarified as an option of no further active cancer treatment. Psychological impact was changed to emotional impact. The group felt it important to highlight that the surgery would most likely result in having a permanent stoma and further descriptions of stomas were developed.

### **Desirability**

Participants felt that the PtDA was visually appealing with its layout, tables, and illustrations. It was highlighted that within variations of surgery, an illustration of a posterior clearance with sacrectomy was missing. It was also suggested that a description should be annotated before the illustrations. Changes are illustrated in Figure 19.

## Outcomes

Based on the above feedback and suggestions the following revisions were made:

- Addition of:
  - Content page
  - Missing information – no further smears following TAH, ELSIE complications, loss of income, lifestyle changes, fertility, orgasm, deformity from donor site
  - Reasons for not wanting surgery
  - Posterior clearance and sacrectomy illustration
- Clarification of complete response
- Follow up for each treatment option clarified
- Improved layout of emotional changes
- Justification of paragraphs, centralising text to improve appearance
- Annotation of female anatomy illustration
- Simplification of adjuvant chemotherapy
- Highlight permanence of stoma(s)
- Document renamed
- Improvement in survival illustration
- Improvement in survival statistics wording
- Correction typographical errors
- Consistency of words highlighted

**Figure 19. Outcomes of Sprint 5**

## **Sprint 6**

No further comments or changes were suggested following the changes of sprint 5 and the PtDA finalised (Volume 2).

### **6.5 Discussion**

This chapter describes the design of the first paper based PtDA using the principles of ADM. We developed this PtDA for LARC/LRRC in patients considering PE using a

MDT, including patients, over a 10-week period. This PtDA is considered to be comprehensive and acceptable and is ready for alpha testing.

ADM has been used consistently within contemporary software engineering as it allows for neater partition of development work related to current and future software capabilities, helping to streamline maintenance flows, product documentation, and development team communication (484). Developing the right thing (requirements analysis) and building the thing right (design) remain enduring challenges of new product development. The PtDA development process included a requirement analysis, planning, design and development. Previous work had concluded the need for an evidence based PtDA for patients being offered PE surgery and subsequent employment of ADM allowed the group to do this in a short timeframe (340).

The benefit of using ADM in the development of the PtDA was working in short sprints and iteratively. Short sprints allowed most of the significant changes to be done early in the process and subsequent changes were usually minor and less time consuming. Quick releases are a major benefit of using ADM (485). Focusing on the five areas of content, layout, acceptability, comprehensibility and desirability meant that we were able to focus on detailed yet high-quality development. Being able to deliver short sprints of work over a short period encouraged collaborators to become more engaged, provide quality feedback, and ensured deadlines were met. Kannan et al developed clinical decision support tools using ADM as it consistently outperformed a traditional waterfall approach (486). Its iterative incremental development, with the goal of delivering value early and often in the form of working software developed each iteration, in a short time periods of typically one to four weeks in length (487). Delivering short sprints of work allowed an uncomplicated recruitment of collaborators who were more engaged and provided good quality feedback. The format also produced required changes within a certain deadline to proceed with the next sprint.

Involving PPI within the development team was essential for the study. PPI is thought to improve the way research is undertaken, communicated and used (488). Active involvement of patients has been shown to lead to work of a greater quality and relevance owing to the unique perspective that users can bring to the group (489-492). The methods embraced change in response to feedback from actual users, to

progressively improve a product's usefulness. Patients 'have the right and duty to participate individually and collectively in the planning and implementation of their health care' (493) and the development of patient tools should actively involve patients (494). The ADM process is developed to cater for patient involvement. Patient participation in the development of patient information material is thought to result in more appropriate, sensitive, readable, and understandable information (493).

Robertson et al demonstrated the utility of ADM in the development of a web-based decision aid for paediatric oncology clinical trial enrolment (228). They highlighted the benefit of using ADM in the development of the PtDA allowed for a higher level of collaboration between the lead development team. Given that research collaborators are often chosen based on their individual expertise and the success of agile projects is largely dependent on the expertise of the team involved, it is unsurprising this methodology is successful in new product development. One of the major difficulties of this study was to ensure full participation on a fortnightly basis. To ensure high quality of the PtDA, involvement of clinicians from all multidisciplinary aspects and patient representative was imperative. We used the same day and time for every sprint to reduce any conflicts within timetables however, it was not always possible to get the full group together during all sprints. To overcome the difficulty of absences, all team members were required to give written feedback via email prior to the sprint session in order to discuss collectively. ADM in software development emphasises communication and close collaboration. Such methodologies are particularly suitable for development projects facing high degree of uncertainty. Many of the agile practices are built on face to face communication and collocation is assumed (495), however given geographical limitations this was not possible within this group, however this was overcome by using Zoom meetings..

Limitations of this study included the lack of palliative care input during the development process however, our consultant oncologist did have experience within her training in this area. The main limitation of this study is its readability with a Flesh-Kincaid grade calculated for a reading age of 15-17 years, presumably due to the medical terminology within the PtDA. These calculations rely on sentence length and number of syllables in a word. There are obvious limitations with this: a well-understood word may have multiple syllables, such as 'television', whereas a less well-known medical term may have fewer, such as 'stoma' (421). The formulas also do not

take account of coherence. It is well known that layout and style such as font size, use of colour, and capital letters can affect the readability of a document, and these are not assessed by the formulas used in this study (496) (497). However, PPI felt that as medical terminology was described in detail, and it was easy to read at a low literacy level.

## **6.6 Conclusion**

This study highlights the design of a paper based PtDA using the novel ADM principles. This streamlined co-designed process resulted in a comprehensive and acceptable document ready for further testing in a short timeframe.

## **Chapter 7. Alpha testing of the Patient Decision Aid**

### **7.1 Background**

Development of a PtDA is a potentially time-consuming and complex process that requires the involvement of several stakeholders including healthcare professionals and patients (172). A transparent and robust PtDA development process is essential to ensure validity and reliability. PtDAs can have significant impact on choices patients make, with the risk that poor quality PtDAs could cause harm to patients(172, 197, 498) . Additionally, clinicians who disagree with the content of the PtDA are unlikely to use it or encourage their patients to do so, thus obstructing clinical implementation.

A need for systematic and transparent processes for developing patient decision aids (PtDA) was recognised by the original version of the International Patient Decision Aid Standards (IPDAS) (197). Specific developmental steps are:

1. Assessing decisional needs, including analysis of the characteristics of the decision, specification of treatment options, outcomes and probabilities, and of patients' information needs and their requirements for decisional support.
2. Formation and composition of groups to develop and review decision aids.
3. Methods for drafting, reviewing and revising.
4. Field testing with patients.
5. External peer review or critical appraisal by people not involved in its development (172).

These steps were developed through appraisal of 55 trial reports that were included in the second update of a Cochrane Collaboration review on the effectiveness of patient decision aids (499). Since then, several more groups have published details of their PtDA development process including; Ottawa Decision Support Framework (500, 501), Cardiff University (502), Dutch Institute for Healthcare Improvement (503), Mayo Clinic (504), Informed Medical Decisions Foundation (505). While different authors have placed greater or lesser emphasis on particular aspects, key features common to all include scoping and design, development of a prototype, 'alpha' testing with patients and clinicians in an iterative process (testing by people directly involved in the development process), 'beta' testing in 'real life' conditions (field tests with patients and clinicians not involved in the development process), and production of a

final version for use and/or further evaluation (Figure 20). The process is often overseen by a multidisciplinary steering group that includes patient and clinician representatives and other relevant stakeholders.



**Figure 20. Development stages of a PtDA**

Alpha testing is described by Coulter et al as a quality criteria for the development of PtDA (172), on behalf of the IPDAS group. This involves co-creating a draft in an iterative process among experienced patients and professionals (506). Patients who have faced the decision in question in the past are included together with clinicians working for the target population (502). Thus, alpha testing addresses usability, comprehensibility and acceptability of the PtDA. Usability is defined as ‘the extent to which a product is used by a specific group to achieve certain goals effectively, efficiently and satisfactorily in a particular context’ (507). Recommendations for usability testing include running many small tests with no more than five users per test round (508). Comprehensibility has been defined as ‘the way the information is understandable’ and was especially tested among patients (509). Acceptability, tested only among the professionals, has been defined as ‘adequate to satisfy a need, requirement or standard’ and refers to ratings regarding the comprehensibility of components of a PtDA, its length, the amount of information, balanced presentation of information about options, and overall suitability for decision making (510).

Alpha testing with patients and professionals ensures the validity and reliability of the development process and thus stimulates future ownership and implementation of the PtDA.

The aim of this study was to alpha test and improve a PtDA for treatment options for LARC and LRRC and ensure that usability, comprehensibility and acceptability of the tool itself met the standards and requirements of professionals and patients.

## **7.2 Aims and objectives**

The aim of this phase is to reach consensus regarding the format, structure and content of the pre-test PtDA to measure its face validity. It is essential that the information is

clear, understandable, relevant, and reflects information that the patients felt they required to make an informed decision.

## 7.3 Methodology

### 7.3.1 Cognitive interviews

Telephone cognitive interviews were undertaken to investigate the cognitive process involved whilst reading the PtDA. There are two types of cognitive interview: concurrent and retrospective (511). Concurrent interviewing involves the respondent providing a verbal account of their thinking as they work through the PtDA. Retrospective interviewing involves questioning the respondent upon completion of the PtDA. In this study both methods were employed, with concurrent interviewing used to assess responder understanding with regard to content, wording and format. Retrospective interviewing was used to evaluate question design with emphasis on overall format, completion time, recall period and response options. The interview techniques of ‘think aloud’ and verbal probing were both incorporated when undertaking cognitive interviews (Table 33). The think -aloud technique enables respondents to verbalise thoughts during the completion of the questionnaire, this is interpreted as a representation of the respondents memory, language, comprehension and problem solving process (511, 512). Verbal probing involves asking respondents to paraphrase questions, to clarify the definitions of wording within questions, explain the rationale behind responses and identify areas of the questionnaire that pose difficulty in understanding, interpretation or completion (511).

|                                                                                   |                                     |
|-----------------------------------------------------------------------------------|-------------------------------------|
| Think Aloud                                                                       | Verbal probing                      |
| Respondent driven                                                                 | Interview driven                    |
| Lower interview burden                                                            | Lower respondent burden             |
| Potential for difficulty to be experienced by the respondent during the interview | Easier interview for the respondent |

**Table 33. Summary of think-aloud and verbal probing interview techniques**

A standardised semi-structured cognitive interview guide informed all cognitive interviews (Appendix K). All interviews were recorded and transcribed verbatim. The transcripts were then reviewed by two members on the research team and verified against the original recording to confirm accuracy. The interviews addressed themes identified in previous studies: structure, content, acceptability, comprehensibility and usability (513-515). Participants were guided through each section whilst encouraged



to engage in a think-aloud process followed by verbal probing with questioning using pre-prepared interview scripts and standardised probes. The use of scripted questions and probes ensured standardisation across all interviews and ensured overall consistency and objectivity.

### **7.3.2 QQ-10 questionnaire**

Patients were also invited to complete the QQ-10 questionnaire (Appendix L) relating to their views on the new PtDA. The QQ-10 is a validated measure of face validity which was specifically designed to assess the face validity of a PROM (516). It has been used in previous studies and includes Likert scales relating to the acceptability and utility of questionnaire use from the patient's perspective, producing valid scales relating to value and burden. The first six questions comprise the value score (helped me communicate about my condition, relevant to my condition, easy to complete, included all the aspects of my condition I am concerned about, was enjoyable, would be happy to complete as part of routine care), and the last four questions comprise the burden score (too long, embarrassing, complicated, upset me). Qualitative analysis (517) was performed on comments received in response to the three free-text questions at the end of the QQ-10:

1. Do you have any comments or suggestions on how the questionnaire you used could be improved (e.g., its structure, appearance or design)?
2. Were any of your important symptoms, problems or concerns missed out by the questionnaire you used?
3. Do you feel that any areas or problems in the questionnaire you used were over-represented?

Questions were assessed using Likert scoring of 0=strongly disagree, 1=mostly disagree, 2 neither agree nor disagree, 3=mostly agree and 4=strongly agree. Median scores were calculated for each question and the average median score calculated to evaluate value and burden as a whole.

Mean score percentage was calculated by accumulating each respondents Likert score for each question 1- 6 and 7-10 to calculate value and burden respectively and dividing by the maximum score (24 and 16 value and burden respectively) and multiplying by 100 to achieve a percentage.

Mean percentage scores were calculated by totalling all responses of each question into each Likert category and converting to a percentage of all participants.

### **7.3.3 Data analysis**

Data analysis of interviews was reviewed and analysed after a minimum of three interviews. Patient and clinician interviews were interspersed throughout the process. An iterative process of mapping comments was incorporated into a data saturation table (Appendix M) and continued up to the point of saturation in both patient and clinician groups. Changes were made to the PtDA at the end of the process prior to re-engaging with the steering group to ensure no new problems had been introduced secondary to the revisions. Each comment was individually considered when deciding whether to retain, revise, eliminate or add further items to the PtDA. Decisions were made by consensus. A lay person was subsequently asked to proofread the PtDA following changes ensued by alpha testing. This was to ensure the PtDA provided comprehensible, transparent, unbiased, and complete information to the average reading level (518).

Quantitative analysis of the QQ-10 scores was undertaken according to the authors guidance (516). Likert ratings from strongly disagree to strongly agree (coded as 0–4) were analysed separately for questions 1-6 comprising the value score: helped me communicate about my condition, relevant to my condition, easy to complete, included all aspects of my condition I am concerned about, was enjoyable to read, would be happy to use in routine care) and from questions 7-10 comprising the burden score (too long, embarrassing, complicated, upset me).

### **7.3.4 Recruitment**

Patients and HCPs over five sites were identified by the local PI. Ethical approval was obtained from the North of Scotland ethics committee 19/NS/0056. A written invitation letter and participant information sheet was sent via postal mail to eligible patients allowing them sufficient time to consider participation. The potential participants were asked to return the willingness to participate form back to the research team within two weeks. Written informed consent was obtained prior to interviews. Following receipt of the signed agreement form, the researcher contacted the patient, informing them of a mutually convenient time for a telephone or face to face interview. Information regarding the study and the interview was provided, any

questions were answered by the researcher and emphasis was placed on the voluntary nature of the study participation, with freedom to withdraw at any time.

Prior to the commencement of the interview the aims of the study were reiterated together with the freedom to withdraw at any stage with no adverse effect on subsequent healthcare. The patients were informed that the interviews were recorded digitally with all information anonymised.

HCPs were identified by the nominated research assistant at each site. Consent was obtained verbatim and liaison between the researcher and each healthcare professional was via NHS e-mail. A study information leaflet together with copy of the ethics approval and study design was sent via email and subsequent correspondence facilitated the set-up of a mutually convenient time for a telephone interview.

### **7.3.5 Eligibility**

#### **7.3.5.1 Patients**

##### **Inclusion criteria**

Patients were included if they:

- Had undergone PE for LARC or LRRC within the last 12 months.
- Aged  $\geq 18$  years.
- Able to provide informed written consent to participate and able to read and write in English.

##### **Exclusion criteria**

Patients were excluded if they:

- Had undergone palliative treatment of their LARC or LRRC.
- Had cognitive impairment.
- Participated in an earlier phase of the study.
- Were unable to speak/read and/or write English or were unable to provide informed consent.

### 7.3.5.2 Healthcare Professionals

#### Inclusion criteria

HCPs were included if they:

- Worked as a surgeon, oncologist or CNS participating in the PE MDT.
- Had a substantive contract.
- Worked within one of five nominated UK centres as part of the PelvEx collaborative.

#### Exclusion criteria

HCPs were excluded if they:

- Had participated in the earlier part of the study.

## 7.4 Results

### 7.4.1 Patient demographics

A total of 19 patients participated in this study between October 2021 and January 2022. Patient demographics and operative data are outlined in Table 34. Median time elapsed between surgery and interview was 20 months (range 11-29 months). Median interview time was 50 minutes (range 35-88 minutes). Patients were selected to ensure representation of disease subsite and subsequent variation in surgery.

| Factor                 | Median (range)         |               |
|------------------------|------------------------|---------------|
| Age (years)            | 64 (36-80)             |               |
|                        | Number of patients (n) | Frequency (%) |
| Gender                 |                        |               |
| Male                   | 8                      | 42            |
| Female                 | 11                     | 58            |
| Disease subtype        |                        |               |
| LARC                   | 13                     | 68            |
| LRRC                   | 6                      | 32            |
| Primary operation type |                        |               |
| PPE                    | 3                      | 16            |
| PPE & sacrectomy       | 2                      | 11            |
| TPE                    | 9                      | 46            |
| TPE & sacrectomy       | 3                      | 16            |
| ELSIE                  | 2                      | 11            |
| Neoadjuvant treatment  |                        |               |

|                    |    |    |
|--------------------|----|----|
| None               | 3  | 16 |
| Chemoradiation     | 13 | 68 |
| Radiotherapy       | 3  | 16 |
| Adjuvant treatment |    |    |
| None               | 8  | 42 |
| Chemotherapy       | 11 | 58 |
| Chemoradiation     | 0  | 0  |
| Radiotherapy       | 0  | 0  |
| R                  |    |    |
| R0                 | 15 | 79 |
| R1                 | 4  | 21 |
| R2                 | 0  | 0  |
| Metastatic disease |    |    |
| Yes                | 1  | 5  |
| No                 | 18 | 95 |

**Table 34. Patient demographics**

### **7.4.2 HCP demographics**

A total of nine HCPs participated in the study between November 2021 and February 2022. Four surgeons, three CNS' and two oncologists were recruited to participate. Median interview time was 50 minutes (range 33-72 minutes).

### **7.4.3 Qualitative interviews**

#### **7.4.3.1 Summary feedback**

The PtDA indicated an overwhelmingly positive response to the decision aid with patients saying they had wished they had the document prior to surgery, that they learnt a lot despite having been through surgery and that they would highly recommend it for their partners and family to read. Patients found the PtDA easy to understand and appreciated the illustrations. Despite some patients finding it a long document they appreciated that all the information was important and relevant and appreciated that certain sections were not relevant for everyone. Clinicians indicated that the PtDA was very well written and easy to understand. Some omissions in information and flow in parts were adjusted to improve both the content and readability. Both patients and clinicians, overall, felt the document would be helpful when used in combination with a consultation.

#### **Content**

Patients wanted 3- and 5-year survival to be omitted from the document for several reasons: 1) they felt that data were harsh and very negative 2) they felt that the numbers

weren't indicative of information given to them at the time of contemplating surgery  
3) they misunderstood the terms 3- and 5-year survival thinking five-year survival was the best they could expect. Clinicians also felt that these data did not represent their own unit figures. Terminology was changed and further changes were made throughout the document for consistency. Clinicians wanted a flow-chart to highlight a choice of having treatment or no treatment regardless of whether the outcome was curative or non-curative. Corrections and modifications were executed according to feedback.

#### Layout/design

Both patients and clinicians overall felt the design of the PtDA was good and visually appealing. The graphics and illustrations were positively received. Some improvements were suggested to improve the flow and reduce duplication. Clinicians felt that ELSIE needed to be split by compartment to improve patient understanding which was in keeping with some patient feedback of the term not meaning anything to them. Several participants commented on further information being in various sections which were navigated in the document.

#### Missing items

The interviewer specifically asked, 'what do you think is missing from the booklet'. Participants identified numerous items that needed adding:

1. Further specialities involved in support.
2. Further side effects of chemotherapy, radiotherapy and surgery.
3. Further information on physical changes.
4. Further risks of surgery.
5. Further information on nursing positions.
6. Section on prehabilitation and aftercare.

#### Readability

Patients felt the PtDA was an easy read and targeted well at a layperson. Clinicians agreed but did find improvements in some wording. Both grammar and spelling corrections were discovered and corrected. Clarification on medical terminology was

completed where both patients and clinicians felt there were words difficult to comprehend. Numerical data were expressed in both percentage and numbers ( i.e. x in y) to improve readability and health literacy.

### Usability

Patients were specifically asked ‘What concerns do you think other patients would have that we have not covered?’ and ‘What concerns do you think other patients would have that we have covered?’. Patients identified that the PtDA would need to be used at the appropriate time in the appropriate setting i.e. at the time of consultation to discuss treatment options including surgery. They felt that the document would be a frightening read if they had not had the appropriate consultation with the surgical team. Overall, participants felt that the use of the PtDA in combination with a consultation would both improve their understanding and recall. HCPs also felt that it could potentially improve expectations as they could revisit the risks and morbidity associated with surgery on demand. HCPs also accepted that a lot of information was covered that they would not necessarily discuss in the clinical setting. However, a few participants felt that the information was too much and personally would be too scared to read it although acknowledged that it would have been useful for their partners.

Three main messages came to light for participants:

1. Patients have multiple options to consider, and everyone will have their own individual reasons in choosing their treatment option.
2. Those who choose surgery have the complexity and significance of surgery reinforced within the PtDA.
3. Patients are supported regardless of the treatment option they opt for with various support networks highlighted in the PtDA.

Feedback from each interview exploring each theme of the cognitive interview is illustrated in Appendix M. Modifications were made accordingly based on user feedback (Table 35).

| Domain  | Modifications made                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Illustrative quote                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Content | <p>3- and 5-year survival omitted from the booklet.</p> <p>Change terminology to impotence throughout the document and discussion of mechanical and chemical aids.</p> <p>Type of flap determined by surgeon.</p> <p>Cystoprostatectomy removed from illustrations.</p> <p>Correction of timeframe adjuvant chemotherapy.</p> <p>Clinical trials renamed from national trials.</p> <p>Redesign of flow-chart.</p> <p>Oncological treatments identified as both neoadjuvant and palliative.</p> | <p>NEGATIVE</p> <p>‘I think the survival aspect is over-represented. I didn’t like it and as it’s not specific to each person those statistics could put off people having surgery. I’m not sure I would have surgery being faced with those 3- and 5-year survivals.’</p> <p>‘I’m not sure what is meant by short- and long-term symptoms.’</p> <p>‘Erectile dysfunction doesn’t mean much to anyone, but everyone knows what impotent means. Also, a discussion about different things that can help’</p> <p>‘It needs to be clear that it is the surgeon choosing the flap.’</p> <p>‘Cystoprostatectomy not for rectal cancer so replace with TPE and sacrectomy illustration rather than using current illustrations with narrative.’</p> <p>‘Adjuvant chemotherapy only beneficial between 8-12 weeks not up to 6 months.’</p> <p>‘Palliative chemoradiotherapy is treatment. Maybe the question at this point should be do they want treatment at all whether curative or palliative.’</p> <p>‘It would appear that poor response from chemoradiotherapy do not have surgery which is incorrect and need clarification.’</p> <p>‘Palliative surgery is an option in some cases.’</p> <p>Oncological treatment should be divided to neoadjuvant and palliative therapy.’</p> <p>POSITIVE</p> <p>‘Document explains in detail every part and what to expect. I wish I had this before the surgery and its even good to use now 6 months after to remind me that my symptoms are normal for this stage in the recovery.’</p> <p>‘Love the tick box for what organs will be taken away. Explains really well what is coming out and the consequences of that are for me.’</p> <p>‘If I had this booklet before the op, it would have been a different story.’</p> <p>‘Very informative.’</p> <p>‘The information about the anus – I wish I had read this before the surgery. It still a weird thing now. And not that I need it. And he did tell me he was taking it out, but I didn’t really know what that would mean for me.’</p> |



|               |                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|---------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|               |                                                                                                                                                                                                                                                                                                  | <p>‘There is clearly a lot of information but all very relevant. What I like about it is that the patient has something to revisit after leaving that clinic room. It gives them the opportunity at home to discuss with their sons/daughters, husbands/wives and bring all the questions that it arises to clinic.’</p> <p>‘A lot of good information.’</p> <p>‘There is some stuff here that gets forgotten and missed at the consultation, I was reading it and thought ‘oh I didn’t know that about leg weakness and mobility with the sacrectomy before surgery. I know now. It happened to me.’</p> <p>‘It did cover questions I did have.’</p> <p>‘This booklet is amazing at addressing relationship changes. It something that’s not done very well in real life, and you read this and get a good idea of how that changes but more importantly it stimulates conversations between you and that’s what I found. It was important to talk about sexual aspects. And the partner can take away the book, have a read and then start conversations. I didn’t know if I could have sex again and this book covers everything on things moving around, it not being the same and its reassuring that that’s normal for me.’</p> <p>‘Covered things I didn’t even know about. If I had the document before surgery, it would have been really useful.’</p> <p>‘Recovery stuff is excellent. Gives you a good idea of what’s going to happen before it happens. It puts you in a really good standing to know what to expect.’</p> <p>‘Some information frightening – survival.’</p> |
| Layout/design | <p>Addition of questions pages at the end of PtDA.</p> <p>Addition of scale to stoma appliance illustration.</p> <p>Improvement of section on what to expect immediately post-op.</p> <p>Separation of ELSIE to vessels, lymph nodes and nerves.</p> <p>Signposting of correlating sections.</p> | <p>NEGATIVE</p> <p>‘Questions pages at the end of the booklet would be very useful.’</p> <p>‘Real life stoma pictures would give a better idea of what it will look like in real life.’</p> <p>‘You don’t really have an idea of the size of the stoma bag so maybe measurements would give people a better idea.’</p> <p>‘The tables are difficult to read as they appear to be in the wrong orientation.’</p> <p>‘Pages 12 and 30 are very repetitive and needs to be condensed into one section in the earlier part of the document.’</p> <p>‘ELSIE doesn’t mean much to people and would read much easier if elements were separated out.’</p> <p>‘Short- and long-term consequences need to be clarified by a time frame.’</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |

|               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|---------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <p>‘Really good coverage on all aspects. Would be helpful to navigate patients from ‘organ being removed’ to the page with further detail e.g., vagina to sexual changes, reconstructive surgery to further detail later in document.’</p> <p>POSTIVE</p> <p>‘I like it shows diagrams of stomas, what it looks like, where they sit and the different bags.’</p> <p>‘Sketches are good. I was fascinated.’</p> <p>‘Excellent diagrams. Really good resource as I had a hand drawn diagram in clinic which doesn’t have the same detail. Really visually pleasing.’</p> <p>‘Really like the contact details.’</p> <p>‘Very visually appealing. Great use of illustrations.’</p> <p>‘The standard of this document is excellent with the use of very good graphics.’</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Missing items | <p>Addition physiotherapists in support.</p> <p>Further side effects of chemo and radiotherapy included.</p> <p>Inclusion of ITU delirium.</p> <p>Development of section on menopausal symptoms.</p> <p>Addition of prehabilitation section and resource.</p> <p>Further information on CNS role.</p> <p>Addition of skin irritation from stoma bag.</p> <p>Addition of dietary changes.</p> <p>Addition of improvement/change in QoL following surgery.</p> <p>Addition of frequent post-operative urostomy leakage in early recovery and infrequent leakage in longer term.</p> <p>Addition of chronic wound and wound healing issues with sacrectomy.</p> <p>Addition of further reasons of not wanting surgery.</p> <p>Highlight changes in urine from urostomies.</p> <p>Improvement in emotional changes for men.</p> <p>Addition of nursing positions.</p> <p>Improvement in physical changes section.</p> <p>Addition of omitted section on bone as an organ being removed.</p> <p>Further information on complications.</p> | <p>PATIENT</p> <p>‘More information on menopausal symptoms is needed.’</p> <p>‘It’s missing information on cold extremities for chemo and skin soreness for radiotherapy.’</p> <p>‘Need to mention what the patient can do to prepare for surgery and add in the resource ‘maximising recovery’ by Sarah Russell.’</p> <p>‘Need to discuss further the role of the specialist nurse and how they can deal and discuss with your concerns further.’</p> <p>‘It missed out on the fact that sometimes surgery can improve quality of life in some areas. I can now walk miles whereas before I couldn’t walk further than a kilometre and was very SOB and dependent on iron transfusions. I think we get used to a certain way of life and put up with symptoms which suddenly go away after surgery.’</p> <p>‘More information on help at home would be useful. I live alone and when asked about what help I would need I was assured I wouldn’t need any. Actually, I am normally quite a fit woman, and I was so weak I couldn’t do anything for myself so a section about the help you would potentially need to prepare people.’</p> <p>‘It’s important to highlight that some men feel less of a man within the emotional changes.’</p> <p>‘Urine from urostomies smell and look different – it was a shock to me so knowing about that would be important.’</p> |

|             |                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             | Name various flaps.                                                                                                                                                                                                                                                                                                                                                                                                                                       | <p>CLINICIAN</p> <p>‘The section on sacrectomy doesn’t cover details of chronic wound and wound healing issues with sacrectomy.’</p> <p>‘Patients also decline surgery as they do not want surgical intervention.’</p> <p>‘Following surgery patients are often nursed side to side which should be highlighted prior to surgery.’</p> <p>‘Patients need to know that pain following surgery is normal and that we treat it with x, y and z.’</p> <p>‘Section on bones being removed is missing from the male version.’</p> <p>‘Further information within physical changes is need including nausea and vomiting, poor sleep, delirium, weight loss, need for nutrition.’</p> <p>‘Anastomotic leak has been omitted from risks.’</p> <p>‘Complications will also depend on age, other medical conditions and type of operation.’</p> <p>‘Not only surgery will affect your ability and desire to have sex but also the tumour and previous radiotherapy.’</p> <p>‘Naming the flaps would be helpful for the patients for cross referencing and discussion purposes.’</p> |
| Readability | <p>Spelling and grammar corrections.</p> <p>Improving language.</p> <p>Clarification of: fistula, collection, post-menopausal and complete response.</p> <p>% expressed as x in y.</p> <p>Qualification of long and short term.</p> <p>Description of stoma appliance sticking to the skin.</p> <p>Rewording of ‘flap may die’.</p> <p>Qualify disfigurement of donor site to altered appearance.</p> <p>Rewording support section with a positivity.</p> | <p>NEGATIVE</p> <p>‘Some terms need clarifying for the layman – explain what a fistula and collection are. Post-menopausal is also very medical and needs to be simplified or explained.’</p> <p>‘Some of the wording is clumsy in sections and could be improved.’</p> <p>‘Data in % should also be expressed in numbers to make it easier for the patient.’</p> <p>POSITIVE</p> <p>‘I think the whole thing is very well done. It is very well written for the layman. Very very well done.’</p> <p>‘Easy to understand, easy to follow.’</p> <p>‘There is nothing confusing in it. Very easy to read. Very easy to follow. Absolutely kept my attention.’</p> <p>‘Nothing confusing – easy to follow.’</p>                                                                                                                                                                                                                                                                                                                                                             |

|           |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-----------|--|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|           |  | <p>‘Some technical terms are made easy to understand which is helpful when you are being told about surgery.’</p> <p>‘Good flow. Easy to understand.’</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Usability |  | <p>NEGATIVE</p> <p>‘All good valid information but an awful lot to read through – any way of individualizing it to the patient?’</p> <p>‘I don’t think it would be a good document to give to someone without having had a consultation.’</p> <p>POSITIVE</p> <p>Even though doctors don’t know it will happen they need to tell you it can happen, and this leaflet does that. It answers questions I even had now, after the operation.’</p> <p>‘This booklet needs to be given before surgery. I could have asked the questions then. But I didn’t have the opportunity to ask the questions because I didn’t know.’</p> <p>‘It allows patient to prepare themselves. Be prepared mentally before surgery.’</p> <p>‘I found it really interesting.’</p> <p>‘It explains to the patient exactly what can happen and exactly what they will do. It allows you to make a decision based on the facts.’</p> <p>‘This document needs to be freely available. I think it’s fascinating. I think it’s wonderful.’</p> <p>Really good source to read even post-surgery. Reassuring you are feeling normal things.’</p> <p>‘It’s great document and I would have loved it to be able to show my husband/friends so they could have had more of an understanding without having to bombard me.’</p> <p>‘In combination with a consultation, this document would improve patient understanding of surgery and its morbidity. The ability to take this comprehensive document home to re-address information would also improve patient expectations.’</p> |

**Table 35. Modifications and illustrative quotes from patients and clinicians from each domain**

#### 7.4.4 QQ-10

All patients that conducted cognitive interviews also completed the QQ-10. The average median value scores for value and burden was 4 (strongly agree) and 0 (strongly disagree) respectively (Appendix N).

Mean scores for value and burden were 89% (SD=12.1) and 8% (SD=8.5), respectively, suggesting high value and low burden for most patients. Of the six items relating to value, ‘relevance’ and ‘happiness to use again’ were the most highly rated responses (100% and 89% respectively). Of the four burden items ‘upset me’ was the most frequently reported response (11%) (Table 36).

| Item                                      | Strongly agree | Mostly agree | Neither agree nor disagree | Mostly disagree | Strongly disagree |
|-------------------------------------------|----------------|--------------|----------------------------|-----------------|-------------------|
| Positive statements                       |                |              |                            |                 |                   |
| Help communicate                          | 63%            | 26%          | 11%                        | 0%              | 0%                |
| Relevant to my condition                  | 95%            | 5%           | 0%                         | 0%              | 0%                |
| Easy to read                              | 74%            | 21%          | 5%                         | 0%              | 0%                |
| Included all aspects I am concerned about | 52%            | 37%          | 11%                        | 0%              | 0%                |
| Enjoyed reading                           | 37%            | 32%          | 26%                        | 5%              | 0%                |
| Happy to use again                        | 89%            | 0%           | 11%                        | 0%              | 0%                |
| Negative statement                        |                |              |                            |                 |                   |
| Too long                                  | 0%             | 5%           | 16%                        | 16%             | 63%               |
| Too embarrassing                          | 0%             | 0%           | 0%                         | 11%             | 89%               |
| Too complicated                           | 0%             | 0%           | 0%                         | 11%             | 89%               |
| Upset me                                  | 0%             | 11%          | 11%                        | 11%             | 67%               |

**Table 36. QQ-10 scores expressed as a percentage of participants responding to an item**

Most patients strongly or mostly agreed with value questions (Figure 21) whereas most patients strongly disagreed with burden questions (Figure 22).

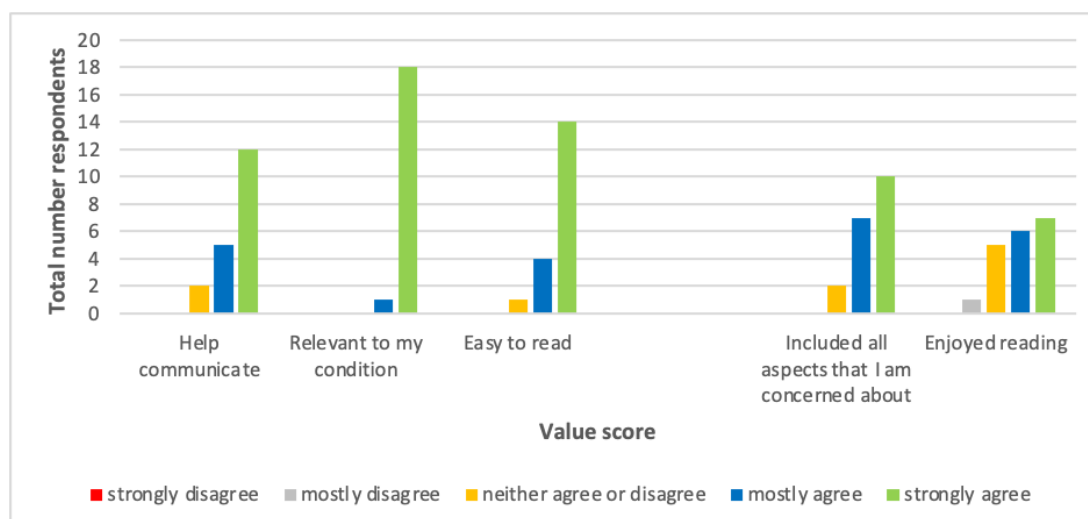


**Figure 21. Value score QQ-10**

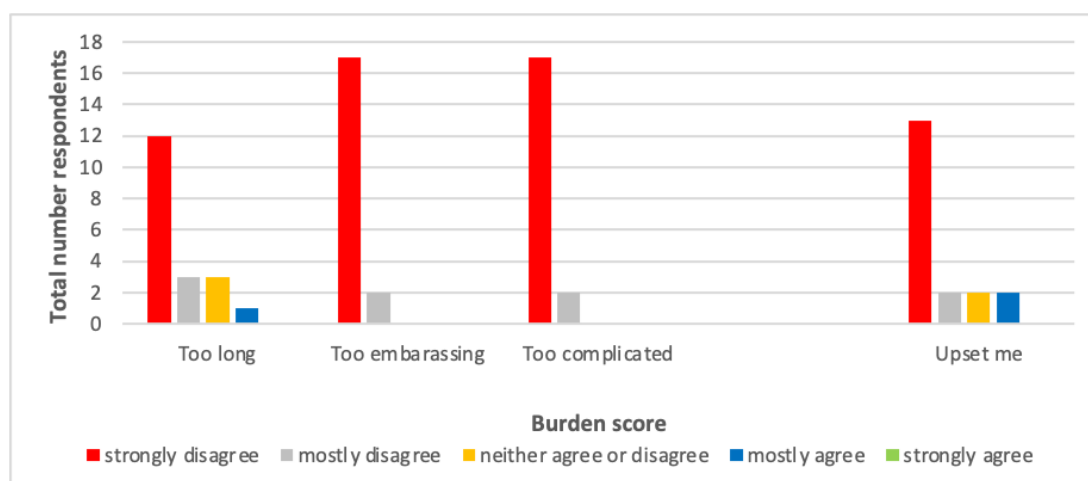


**Figure 22. Burden score QQ-10**

The free text in the QQ-10 were analysed separately according to the interview themes identified in previous studies: structure, content, acceptability, comprehensibility and usability (513-515). Table 37 outlines the illustrative quotes from patients and subsequent modifications. Not all suggested modifications could be incorporated into the PtDA due to technicalities with patient consent and ethics. For example, some participants recommended including photographs of various stomas, however these comments conflicted with previous consensus from stakeholders and thus additional changes were not made through REC. Additionally, those comments already discussed in qualitative interviews and subsequent modifications completed were omitted from the analysis.

|               | <b>Modifications made</b>                                                                                                                | <b>Illustrative quote</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|---------------|------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Content       | Highlight recovery takes up to 12 months.                                                                                                | <p>NEGATIVE</p> <p>‘Doesn’t really highlight that it takes up to a year to get everything under control.’</p> <p>‘No. Covers everything and it needs to. It does almost give the worst-case scenario which is obviously scary to read but equally I appreciate you have to cover it because it could happen. I’m just glad a lot of what could have happened to me didn’t happen to me.’</p> <p>POSITIVE</p> <p>‘Very good document. Structured in a logical order with a good mix of diagrams and wording’</p> <p>‘Structure is very good – easy to follow. Looks very professional.’</p> <p>‘Good flowing booklet. Would not change anything of its structure.’</p> <p>‘A lot of good information. Some information I wasn’t given before surgery that I wish I had known regarding the sacrum and mobility. A lot of my questions have been answered by this booklet.’</p> <p>‘Excellent source of information – wouldn’t change a thing other than getting it out to patients asap.’</p> |
| Layout/design | Cover title reworded.<br>Re-design of flap illustrations.                                                                                | <p>NEGATIVE</p> <p>‘Don’t like the design of the front page – not visually appealing. Needs softening up. Maybe ‘helping you make your decision.’</p> <p>‘Nice visuals but would change pictures to real people. It needs to be real so people can connect with it. The stoma pictures don’t look anything like my stoma’s.’</p> <p>‘The illustrations on flaps aren’t very clear. It doesn’t reflect the changes clear enough.’</p> <p>‘It needs to be clearer where the flap is coming from and what the area the flap is taken from looks like afterwards.’</p> <p>POSITIVE</p> <p>‘Flows well from one section to another.’</p> <p>‘Looks really professional. Like the schematics of the organs throughout. Really well illustrated’</p> <p>‘Good large simple font with adequate spacing.’</p> <p>‘Good use of figures and images.’</p>                                                                                                                                                |
| Missing items | Addition of skin irritation from stoma bag.<br>Discussion of inpatient radiology is normal and expected.<br>Addition of dietary changes. | <p>NEGATIVE</p> <p>‘Need to mention that scans are normal after surgery and skin irritation around the bag after surgery.’</p> <p>‘There is a change in dietary needs so more detail would be helpful.’</p> <p>‘Expect urostomy to leak quite a bit due to drips in first week.’</p> <p>POSITIVE</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

|             |                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-------------|---------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             | Addition of frequent post-operative urostomy leakage in early recovery and infrequent leakage in longer term. | <p>‘No, I don’t think it has missed out anything. Such a thorough, comprehensive document.’</p> <p>‘Everything I could have thought of that was an issue to me was discussed in the booklet.’</p> <p>‘All my symptoms were talked about in this document.’</p>                                                                                                                                                  |
| Readability | Clarification for adjuvant chemotherapy.                                                                      | <p>NEGATIVE</p> <p>‘Also, maybe to highlight that chemo after surgery isn’t because it’s failed to give best possible chance of preventing recurrence.’</p> <p>POSITIVE</p> <p>‘The wording and diagnosis were clear enough to understand.’</p> <p>‘It is well written and very easy to read.’</p> <p>‘Reads like a story and easy to follow.’</p> <p>‘Everything on PtDA is very informative and precise.’</p> |
| Usability   | Modification to flowchart to highlight choices.                                                               | <p>NEGATIVE</p> <p>‘Flowchart may need highlight box where patient decision to be made i.e. like OPTIONS – drawn to that first – just to make it a bit more user friendly.’</p> <p>POSITIVE</p> <p>‘No. I think this booklet absolutely needs to be given to people before surgery.’</p> <p>‘Very user friendly.’</p>                                                                                           |

**Table 37. QQ-10 free-text and resulting modifications made to the PtDA**



## **Content**

Patients felt the content of the PtDA was ‘excellent’ and feedback included the need for this document to be openly available to patients. However, despite a vast amount of information some patients felt it wasn’t clear on the length of recovery and that it could take up to 12 months, which was modified accordingly.

## **Layout/design**

The design and layout of the PtDA was very professional with patients commenting on the flow, visually pleasant illustrations, and the readability of the text. However, patients did feel that some of the flap illustrations needed to be made clearer regarding donor sites. Illustrations were modified and narrative added to make it more acceptable to the reader. Some patients would have liked to have seen photographs rather than illustrations of stomas, however, this was not possible within the remit of this study discussed earlier. The front cover was also felt to be ‘cold’ and unappealing therefore modifications were made using more gentle terminology to describe the use of the PtDA.

## **Missing items**

Patients were specifically asked ‘were any of your important symptoms, problems or concerns missed out by the PtDA you used?’ which identified various issues. Further information on dietary change and per-stomal skin changes were introduced. Patients felt that during their inpatient stay it would have been important for them to know that CT scans were common which was introduced. Patients also commented that urostomy leakage was very common in the early recovery, however, in the longer term was infrequent which was modified.

## **Readability**

Patients wanted some information about adjuvant chemotherapy and its role. Given that previous deletion of the section on adjuvant chemotherapy was decided within the development of the PtDA, a small modification was made to include its use to reduce the risk of recurrence rather than due to failure of surgery. Overall, patients felt the PtDA was very readable and easy to follow.

## **Usability**

Patients overall felt that the PtDA was very user friendly and would be a good source of information to be given prior to deciding whether to have surgery. However, patients felt that improvements could be made within the flowchart on page 5. It was felt that it wasn't clear where there were patient options and decisions to be made which was modified to improve its usability.

Modifications were rediscussed within the steering group and found to be acceptable with no further changes suggested.

### **7.5 Discussion:**

This is the first PtDA systematically developed and validated for patients with LARC or LRRc. Alpha testing in this study outlined distinct, patient and clinician orientated developments using a standardised methodological approach following IPDAS guidelines.

The iterative process of ongoing data collection proved to be a well-chosen way to involve end users and to improve the PtDA (519). Patients had valuable views, sometimes conflicting between patients but also with professionals, about the presentation of relevant risks and values, for which we succeeded to find a common denominator. Clinicians being engaged in the alpha testing increased the professionals' sense of ownership, especially with the knowledge of clinician involvement in the ADM development phase. This will also encourage future implementation. Working with stakeholders resulted in a shared ownership of the PtDA which ensured content maintenance and updates for modifications within the final stage.

The majority of patients disliked the survival data, both in its layout and its content and thus a decision was taken to omit this in the final edit. It was challenging to reach consensus among the professionals in the development phase regarding data on risks and outcomes due to the evolving nature of surgery, surgical techniques and radiotherapy contributing to evolving survival statistics in this arena. The PPI overall felt it was important to include the data, however during this phase the overwhelming feedback was negative with a drive to delete it from the PtDA.

The high value score and low burden score obtained from the QQ-10 data suggested that our patients had a positive experience using the PtDA and found that it was making

a positive impact on their health care. These scores were similar to scores obtained when the QQ-10 was used in other studies including the Edmonston frail scale (520), questionnaire for polymyalgia rheumatica (521), questionnaire for menstrual and pelvic pain and gynaecological hormone disorders (522) which are currently used routinely in clinical practice. This face validity is useful to how the PtDA appears to users but also is important to prove relevance and gives future HCP users greater confidence in implementing the new tool.

The strengths of this study include the use of the validated instrument (QQ-10) to assess face validity, feasibility and utility of the PtDA for treatment choices of LARC and LRRC. The QQ-10 was rigorously developed using standard psychometric methods and has been shown to have high internal consistency and item correlation and to be acceptable and understandable to patients (516). The use of the validated QQ-10 measure embeds patient perspectives at all stages within the PtDA developmental process, moving beyond the paradigm of clinician-orientated information.

The limitations of our study were this stage was tested with patients from only five participating units involving only 19 patients, however data saturation was reached. Other limitations included that face validity is the most basic test of validity and further, more rigorous and robust testing will need to be carried out in the form of beta testing in the next phase of the study.

## **7.6 Conclusion**

This study focused on alpha testing with both patients and professionals. Alpha testing resulted in some minor design changes, grammatical and spelling corrections, rewording, deletions, and addition of missing items. Patients and professionals provided positive feedback about the content of the PtDA in general.

## **Chapter 8. Beta testing**

### **8.1 Background**

Interventions to transform the delivery of health and social care are being implemented widely, such as those linked to integrated care systems in the UK (523). Assessing the impact of these health interventions enables healthcare teams to learn and to improve services, and can inform future policy (524). Field-testing is increasingly recognised as an important step in the quality assurance of PtDAs. This was underlined by the IPDAS who developed nine domains of quality criteria, one of which was field-testing in order to show that a decision aid was acceptable to patients (197). However, there was no guidance on field-testing, and, the decision aid literature gives very little guidance in this respect (525).

Field testing by end users is a critical component of PtDA development (526) . As opposed to alpha testing, field testing seeks feedback on the PtDA from patients in a typical clinical setting. The main aim of field testing is to evaluate the feasibility of using the PtDA in the ‘real world’ and to guide a final revision. The other aim is to assess acceptability, and whether the PtDA has the desired impact without adverse consequences. In healthcare, assessment of the PtDA its intended environment is essential to discover and remove any difficulties before the PtDA is put into general use. It is performed under the same working conditions for which it was designed. It provides a real-time example of the document’s performance under working conditions.

The use of process evaluation, defined as the evaluation of ‘individual, collective or management perceptions and actions in implementing any intervention and their influence on the overall result of the intervention’ has served to increase focus on the evaluation of the specific intervention processes and not only the outcomes (527) Clinical validation is the act of acquiring evidence to support the utility of specific procedures for diagnosis or treatment. To analyse intervention processes two methodological approaches have been widely used: quantitative or qualitative. Both methods are established tools of validation but offer distinct properties to inform different aspects of interventions. The use of quantitative data enables the comparison of items of implementation across different contexts (528). Various validated tools have been used to evaluate new implementations to ensure any new intervention meets

its goals. The EORTC PATSAT-C33 is a 33-item questionnaire (Appendix O) that is reliable, validated internationally, and widely used in assessing patients' appraisal towards services provided by hospital doctors, nurses, and radiotherapy technicians. It is also used to assess specific organisational and structural aspects of the service delivery and to highlight aspects of care needing improvement in the outpatient oncology setting. The doctor section comprises three sub-domains addressing technical skills (three items), information exchange (three items), and affective behaviour (four items). The nurses or radiotherapy technicians section encompasses two subdomains addressing information provision and responsiveness (three items) and affective behaviour (four items). The service and care organisation section comprises three sub-domains including coordination (four items), interaction with health care team (seven items) and five single items. The specific outpatient satisfaction module includes a single item addressing continuity and two sub-domains addressing convenience (three items) and another addressing transition (three items) (529). Each item is rated on a 5-point Likert scale (1="poor," 2="fair," 3="good," 4="very good," and 5= "excellent")(529).

The 'Preparation for Decision Making' scale (Prep-DM) (Appendix P) assesses a patient's perception of how useful a decision aid or other decision support intervention is in preparing the respondent to communicate with their practitioner at a consultation focused on making a health decision (194). This validated questionnaire has been shown to have high internal consistency with alpha coefficients of 0.92–0.96, and good item discrimination (range 2.12-3.80) between patients who reported the patient decision aid was or was not helpful (530). Within its 10 items four are used to determine the perceptions of patients about support received as part of the process of decision-making; help in recognising a decision needs to be made (q1), help knowing the benefits and risk of each option (q3), help with knowing that the decision depends on what matters most to the patient (q5) and help with thinking about how involved the patient wants to be in the decision (q7). Each item has a Likert 5-point response ('not at all', 'a little', 'somewhat', 'quite a bit' and a 'great deal'). Several authors suggest that people with high decisional conflict (individual perception of uncertainty about which course of action to take) are more likely to delay the decision, to change their mind, or to express decisional regret (531) (532). The decisional conflict related to treatment decision making arises from the inherent complexity of the choice

involving trade-offs between benefits and risks, from scientific uncertainties, and from modifiable factors such as inadequate knowledge, unclear values, and insufficient support for decision making (533). These modifiable factors can be addressed using PtDAs (534) .

Understanding implementation processes is essential to ensuring that complex interventions in healthcare are taken up in practice by all stakeholders and thus maximise intended benefits for service provision and subsequently care to patients. Implementation of healthcare interventions is influenced by multiple factors including the organisational context, implementation strategies and features of the intervention as perceived by people delivering and receiving the intervention (535). Previous research has highlighted the barriers that may impair implementation of SDM and PtDAs such as time constraints, HCPs attitude, perceived legitimacy of the PtDA, lack of applicability due to patient characteristics, clinic capacity, processes of care and the healthcare environment (536-538). Innovations in healthcare are complex and the Normalization Process Theory (NPT) has been widely used to understand these complex interventions (539) (540). It provides a framework for understanding how a new intervention becomes part of normal practice. NPT describes generative processes that underpin three core problems: implementation (bringing a practice or practices into action); embedding, (when a practice or practices may be routinely incorporated in everyday work of individuals and groups); and integration (when a practice or practices are reproduced and sustained in the social matrices of an organization or institution) (541-544). In NPT, it is proposed that practices become routinely embedded in social contexts ('normalized') as the result of people working, individually and collectively, to enact them (545). A substantial body of evidence supports NPT as a means of explaining processes associated with implementation of complex interventions ranging from telecare and e-health (546, 547) to maternity services (548) to management of depression (549, 550). As a result the Normalisation Measure Development questionnaire (NoMAD) was developed (Appendix Q); a pragmatic, psychometrically tested 23-item instrument which measures implementation activities (551). It assesses implementation processes from the perspective of professionals directly involved in the work of implementing complex interventions in healthcare. The 23-item questionnaire is addressed in three parts. Part a is question about the duration of the participant in their current role using multi-

choice answers. Part b is three general questions about the PtDA reflected on a 0-10 Likert scale. Part c includes detailed questions about the PtDA; a 5 part Likert scale strongly agree to strongly disagree or option B; not relevant to the role/at the current stage/to the intervention (551, 552). NoMAD will address the ease of implementation of the PtDA into clinical practice and identify barriers and facilitators to the incorporation of the PtDA into clinical practice.

## **8.2 Aims and objectives**

The aim of this phase is to assess the feasibility and efficacy of the PtDA prototype in real-life clinical use with individuals who have not been involved in the design of the PtDA and to assess implementation issues into clinical practice.

## **8.3 Methodology**

### **8.3.1 EORTC PATSAT-C33 questionnaire (553) and the Preparation for Decision-Making Scale**

A before and after study was completed to assess the impact of the introduction of the PtDA in clinical practice. Patients were asked to complete two questionnaires to assess patient decision-making and satisfaction with decision making: the EORTC PATSAT-C33 questionnaire (553) and the Preparation for Decision-Making (Prep-DM) Scale (194). PtDA evaluation using before and after studies have demonstrated PtDA effect on choice, patient comfort with decision making, outcomes of decisions and patient acceptability (554).

#### **8.3.1.1 Recruitment**

Patients were prospectively recruited from the five participating sites over a 6-month period (January 2022- July 2022) as described in Chapter 4. Patients who had been offered a PE as part of their treatment were invited to participate.

The cohort recruited in the first three months made up the ‘before’ group. Subsequently, the ‘after’ group were recruited in the following 3 months. The PtDA was introduced into routine clinical practice for use in consultations with patients being counselled for exenterative surgery. All sites agreed to use the PtDA to facilitate decision-making. The aim was to recruit a maximum sample size of 40 patients between both cohorts.

The ‘before’ stage of the study included a written invitation letter and participant information sheet to eligible patients allowing them sufficient time to consider

participation. The potential participants were asked to return the consent form to the research team within two weeks and were provided with the EORTC PATSAT-33 and the preparation of decision-making scale to ensure anonymity. The 'after' stage of the study involved an individualised PtDA being provided to the patient in conjunction with a standard clinic consultation. Patients were given a pack including the written invitation letter, participant information sheet together with a consent form (modified from Appendix D & E) and the EORTC PATSAT-33 and the Prep-DM scale and asked to return the consent form together with the questionnaires in the enclosed stamped self-addressed envelope.

### **8.3.1.2 Eligibility**

#### **Inclusion criteria**

Patients were included if they were:

- Being offered treatment for LARC or LRRC.
- Aged  $\geq 18$  years.
- Able to provide informed written consent to participate.
- Able to read and write in English.

#### **Exclusion criteria**

Patients were excluded if they:

- Had undergone palliative treatment of their LARC or LRRC.
- Had cognitive impairment.
- Participated in an earlier phase of the study.
- Were unable to speak/read and/or write English or were unable to provide informed consent.

### **8.3.1.3 Data collection & analysis**

EORTC PATSAT-C33 and the Preparation for Decision-Making Scale

Patient satisfaction questionnaire EORTC PATSAT-C33 and the Prep-DM were analysed according to the developers guidance (553).



Items within the Prep-DM were summed and scored (sum all 10 items/10) and then scores converted to a 0-100 scale (-1 from summed score x 5). Higher scores indicate higher perceived level of preparation for decision making (555).

The satisfaction responses for EORTC PATSAT-C33 were categorised into satisfaction towards doctors' technical skills (items 1–3), information exchange (items 4–6) and affective behaviour (items 7–10); nurses information (items 11–13), nurses affective behaviour (14-17), coordination (items 18–21), interaction with all hospital staff (items 22–28), and hospital organisation and environment (items 18–32); and finally overall satisfaction with the hospital (items 1–33). Raw scores were calculated for each multi-item scale using:

$$\text{Raw Score} = RS = (I_1 + I_2 + \dots + I_n/n)$$

Linear transformation to obtain the Score S (standardised raw score), used the following transformation:

$$S = (RS - 1/\text{range}) \times 100$$

The higher scores indicated a higher satisfaction level and vice versa (553).

Summary scores were calculated and analysed using unequal variances t-test (Welsh's t-test) for Prep-DM and EORTC PAT-SAT C-33 comparing for two populations which are normally distributed but an unequal sample size.

### **8.3.2 NoMAD**

A study was conducted following dissemination of the PtDA to assess implementation using the NoMAD 23-item questionnaire. Surveys are amongst the methods that can be appropriately employed to study the process of improvement initiatives (556). It was customised to our intervention 'the PtDA' and transferred to the electronic platform of JISC online questionnaire software (557). JISC is an online survey tool designed for academic research, education and public sector organisations. Clinicians undertaking PE were asked to complete the online questionnaire.

#### **8.3.2.1 Recruitment**

Clinicians were identified from the PelvEx collaborative and through the Association of Coloproctologists of Great Britain and Ireland (ACPGBI) IMPACT (Improving outcomes for advanced colorectal tumours) initiative members database. A beta tested

copy of the PtDA was circulated to all members identified within the databases. All clinicians performing PE in the UK and Republic of Ireland (ROI) were invited to complete a piloted, anonymous, online modified NoMAD survey following introducing the PtDA to clinical practice.

#### **8.3.2.2 Eligibility**

##### **Inclusion criteria**

Clinicians were included if they were:

- Performing PE.
- Within the UK or ROI.

##### **Exclusion criteria**

Clinicians were excluded if they:

- Participated in the development of the PtDA.

#### **8.3.2.3 Data collection and analysis**

Questionnaire responses were collected and stored online within JISC. The developer does not provide specific instruction on how to generate scale or construct at this time (551). While the NoMAD does not have a structured scoring template, we applied a five-point Likert scale to all responses (1 = strongly disagree, 3 = neither agree nor disagree, 5 = strongly agree) used by Gillespie et al (558). Descriptive statistics summarised responses and cross-tabulations examined perceptions of intervention fit and NPT domains.

### **8.4 Results**

#### **8.4.1 EORTC PATSAT 33 and the Preparation for Decision-Making Scale.**

##### **8.4.1.1 ‘Before’ study**

Thirty-two patients consented to participation with a response rate of n=24 (75%). All participants completed both EORTC PATSAT 33 and the Prep-DM score.

For the evaluation of doctors with regard to their technical skills, information exchange, and affective behaviour, domain mean scores of participants were 85% (SD=14.74), 88% (SD=13.25) and 79% (SD=21.77); whereas domain mean score with regard to nurses’ information provision and responsiveness and affective behaviour

were 89% (SD=12.66) and 88% (SD=13.83). For the hospital organisation or physical environment, the domain mean scores ranged from 67.5 to 80.8. In general, the mean overall satisfaction score was 87.5 (SD=14.22) (Appendix R).

Most of the study participants reported that services provided by doctors were good (29%), very good (13%) or excellent (58%). However, the frequency of consultations was reported as fair in 21% (n=5). The overall services provided by nurses were better being reported good (9%), very good (28%) and excellent (63%).

Regarding the coordination of hospital care service, most patients ranked the hospital as very good (46%) or excellent (38%) although 4% ranked the way doctors, nurses and other caregivers worked together as a team fair.

Most rated the interaction of hospital health workers with other health-care team members as very good (35%) or excellent (35%). However, 8% and 21% of patients rated the time waiting for medical tests as poor and fair respectively. The opportunity for the family to be involved in their care was mixed with 17% and 4% reporting as poor and fair. With respect to the ease of access to parking and means of transport 21% rated this as fair. 17% of patients felt the ease of finding different departments was poor. The environment of the building like cleanness, spaciousness, and calmness, most participants rated these as very good or excellent. The overall care provided by the hospital was rated as good (12%), very good (38%) or excellent (50%). Regarding the interaction with other health-care team members, most of the patients were less satisfied with the waiting time to obtain results of medical tests (8% fair and 46% good) and also about the waiting time to undergo medical tests and/or treatment (8% poor and 21% fair). The information provided on scheduling of tests, treatment or care and overall support services were fair (4%) and good (25%). Most patients felt the kindness and helpfulness of the technical, reception, laboratory personnel, etc., were excellent (42%) or very good (29%) (Figure 23 & Appendix R).

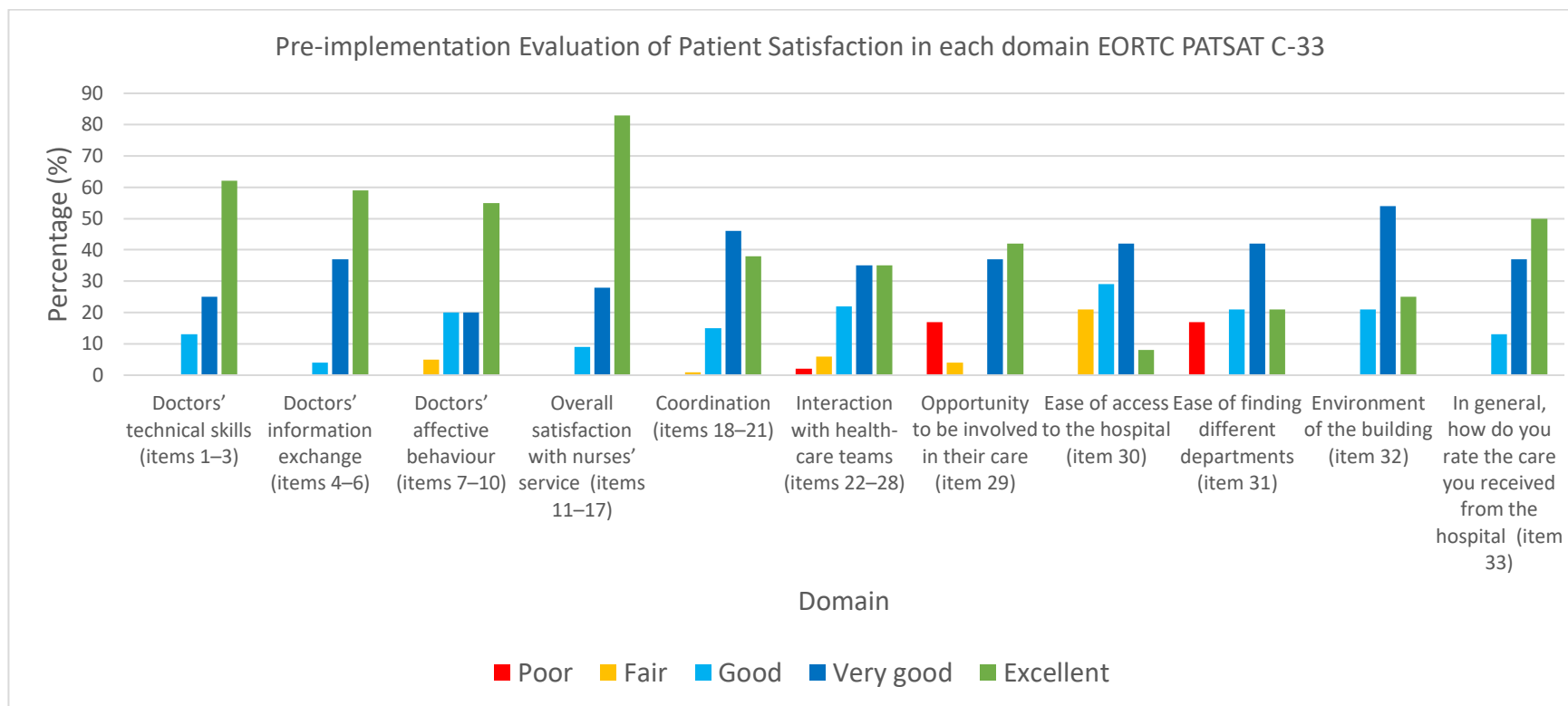


**Figure23. Pre-implementation Evaluation of Patient Satisfaction in each domain (%)**

#### **8.4.1.2 ‘After’ study**

Twenty-eight patients were recruited with a response rate of n=22 (79%). All participants completed both questionnaires.

For the evaluation of doctors with regard to their technical skills, information exchange, and affective behaviour, domain mean scores of participants were 95% (SD=7.18), 98% (SD=4.18) and 99% (SD=4.18); whereas domain mean score with regard to nurses’ information provision and responsiveness and affective behaviour were 96% (SD=7.62) and 96% (SD=8.04). In general, the mean overall satisfaction score was 99% (SD=4.26).

Most of the study participants reported that services provided by doctors were very good (10%) or excellent (90%). The overall services provided by nurses were reported good (1%), very good (14%) and excellent (85%). Regarding the coordination of hospital care service, most patients ranked the hospital as very good (16%) or excellent (81%). Although 5% ranked the way doctors, nurses and other caregivers worked together as a team good and 9% felt that recognition in the roles and responsibilities of different caregivers were good.

Most rated the interaction of hospital health workers with other health-care team members as very good (12%) or excellent (86%). However, only 5% of patients felt the information provided on the scheduling of medical tests, treatment or care were good. Most patients report the opportunity for the family to be involved in their care was excellent (95%). With respect to the ease of access to parking and means of transport 27% rated this as very good and 73% as excellent. 9% of patients felt the ease of finding different departments was good. The environment of the building like cleanness, spaciousness, and calmness, most participants rated these as very good (27%) or excellent (73%). The overall care provided by the hospital was rated as very good (5%) or excellent (95%). Regarding the interaction with other health-care team members, most of the patients were satisfied with the waiting time to obtain results of medical tests (14% very good and 86% excellent) and also the waiting time to undergo medical tests and/or treatment (18% very good and 82% excellent). (Figure 24 & Appendix S).

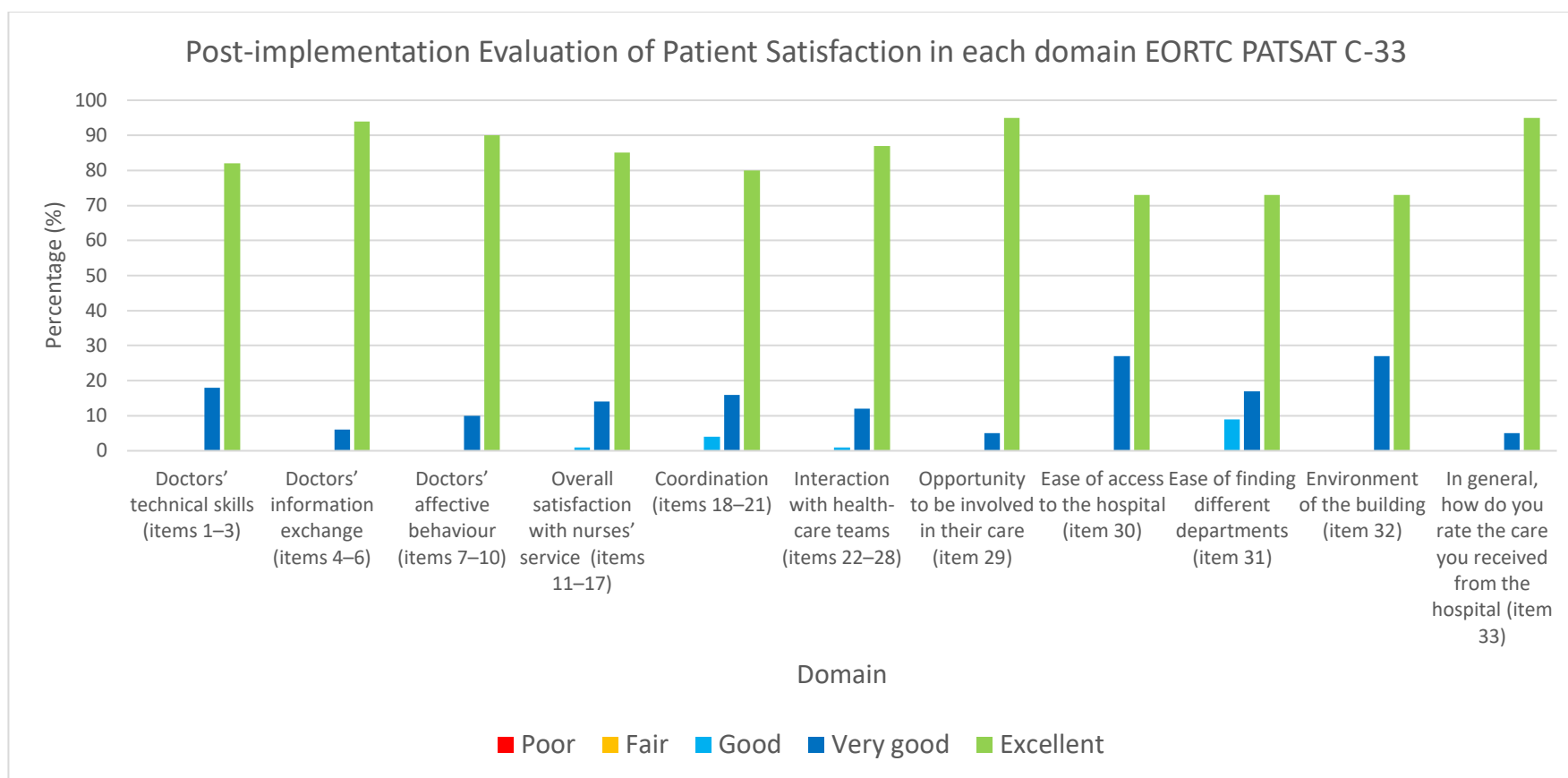


**Figure 24. Post-implementation Evaluation of Patient Satisfaction in each domain (%)**

#### **8.4.1.3 ‘Before and after’**

Scores were compared from both before and after cohorts for all six domains (doctors technical skills, doctors information exchange, doctors affective behaviour, overall satisfaction with nurse’s service, coordination and interaction with health-care teams) and five single items (opportunity to be involved in their care, ease of access to the hospital, ease of finding different departments, environment of the building, general care received from the hospital).

Patients’ perception for the quality of care received within the hospital improved following the use of the PtDA across all domains. Doctors’ technical skills, information exchange and affective behaviour was perceived as significantly higher with the use of the PtDA ( $p=0.02$ ,  $p<0.01$ ) and  $p<0.01$  respectively). Nurses’ information exchange and affective behaviour was also perceived to be better using the intervention ( $p=0.03$ ). Coordination and Interaction with health-care teams were significantly better amongst the post-implementation cohort ( $p<0.01$ ) (Table 38).

Patients in the post-implementation cohort perceived that most of the single items were significantly better. The ease of access improved as well as the ease of finding the way to different departments in the hospital ( $p<0.01$ ), presumably by potentially capturing patients who had previously attended the hospital or could easily navigate new organisations together with improved patient satisfaction overall. The opportunity for someone close to be involved in their care was better using the PtDA ( $p<0.01$ ) which could be due to the nature of the PtDA encouraging conversations within their support network. Alternatively, the restrictions of COVID-19 were diminishing and potentially previous policies for inhibiting relatives or constricting to one relative were lifted. The environment of the building also was perceived to be statistically better ( $p<0.01$ ) likely due the higher scores in perception of doctors and nurses and the coordination of medical care. Patients overall experienced better care from the hospital when the consultation was done using the PtDA ( $p<0.01$ ).

| Domain                                                                                       | Mean score (pre) | Mean score (post) | P value (t test) |
|----------------------------------------------------------------------------------------------|------------------|-------------------|------------------|
| Doctors' technical skills (items 1–3)                                                        | 4.5 ± 0.7        | 4.8 ± 0.4         | 0.02             |
| Doctors' information exchange (items 4–6)                                                    | 4.5 ± 0.6        | 4.9 ± 0.2         | <0.01            |
| Doctors' affective behaviour (items 7–10)                                                    | 4.2 ± 1.0        | 4.9 ± 0.4         | <0.01            |
| Nurses' information exchange (items 11–13)                                                   | 4.6 ± 0.5        | 4.8 ± 0.4         | <0.01            |
| Nurses' affective behaviour (items 14–17)                                                    | 4.5 ± 0.7        | 4.8 ± 0.4         | 0.03             |
| Coordination (items 18–21)                                                                   | 4.3 ± 0.8        | 4.8 ± 0.5         | <0.01            |
| Interaction with health-care teams (items 22–28)                                             | 4.0 ± 1.0        | 4.9 ± 0.4         | <0.01            |
| Single items                                                                                 |                  |                   |                  |
| The opportunity for your family or those close to you to be involved in your care? (item 29) | 3.8 ± 1.5        | 5.0 ± 0.2         | <0.01            |
| Ease of access to the hospital (item 30)                                                     | 3.4 ± 0.9        | 4.7 ± 0.5         | <0.01            |
| Ease of finding different departments (item 31)                                              | 3.5 ± 1.3        | 4.6 ± 0.7         | <0.01            |
| Environment of the building (item 32)                                                        | 4.0 ± 0.7        | 4.6 ± 0.6         | <0.01            |
| In general, how do you rate the care you received from the hospital (item 33)                | 4.4 ± 0.7        | 5.0 ± 0.2         | <0.01            |

**Table 38. Significance of pre-post implementation on each domain within EORTC PATSAT C33**

Introduction of the PtDA improved patient satisfaction overall with pre/post matched samples mean difference of 8.2 -8.44 (95% CI 5.4, 10.9.  $P < 0.001$ ).



### 8.4.2 Preparation for decision making scale

Implementation of the PtDA improved Prep-DM within all subscales, all of which were statistically significant (Table 39). Among the subscales, 91% of patients expressed the recognition that a decision needs to be made following the use of the PtDA compared to 50% without the PtDA ( $p < 0.01$ ). 62% of patients felt somewhat prepared to make a better decision without the intervention which improved to 95% being very prepared with the PtDA ( $< 0.001$ ). More than 90% of patients felt the PtDA helped them think of the pros and cons to each option, helped them know the decision depended on what mattered most to them, helped them think of how involved they wanted to be in the decision compared to 25% and 42% respectively without the intervention ( $p < 0.001$ ). 100% of patients felt the PtDA helped them identify what questions they wanted to ask their doctor and helped them organise their own thoughts about the decision ( $p < 0.001$ ). Patients reported the intervention helped them think what pros and cons were most important and helped them prepare to talk to the doctor about what matters most to them (86%) ( $p = 0.005$ ). Only 50% of patients without the PtDA felt prepared for follow up with the doctor which improved to 73% ( $p = 0.03$ ) (Appendix R & Appendix S). Overall, pre and post implementation Prep-DM score was 59.27% and 89.32% respectively. Welch's t-test for unequal variances for 24 pre and 22 post samples mean difference = 12.0 (95% CI, 8.9 - 15.1)  $p < 0.001$ .

| Question                                                    | Pre (N=24) | Post (N=22) | Total (N=46) | p value |
|-------------------------------------------------------------|------------|-------------|--------------|---------|
| Q1 - Recognise a decision needs to be made                  |            |             |              | 0.009   |
| Not at all                                                  | 0 (0.0%)   | 0 (0.0%)    | 0 (0.0%)     |         |
| A little bit                                                | 4 (16.7%)  | 1 (4.5%)    | 5 (10.9%)    |         |
| Somewhat                                                    | 8 (33.3%)  | 1 (4.5%)    | 9 (19.6%)    |         |
| Quite a bit                                                 | 6 (25.0%)  | 5 (22.7%)   | 11 (23.9%)   |         |
| A great deal                                                | 6 (25.0%)  | 15 (68.2%)  | 21 (45.7%)   |         |
| Q2 - Prepare you to make a better decision                  |            |             |              | < 0.001 |
| Not at all                                                  | 1 (4.2%)   | 0 (0.0%)    | 1 (2.2%)     |         |
| A little bit                                                | 3 (12.5%)  | 0 (0.0%)    | 3 (6.5%)     |         |
| Somewhat                                                    | 15 (62.5%) | 1 (4.5%)    | 16 (34.8%)   |         |
| Quite a bit                                                 | 5 (20.8%)  | 5 (22.7%)   | 10 (21.7%)   |         |
| A great deal                                                | 0 (0.0%)   | 16 (72.7%)  | 16 (34.8%)   |         |
| Q3 - help you think of all the pros and cons to each option |            |             |              | < 0.001 |

| Question                                                                 | Pre (N=24) | Post (N=22) | Total (N=46) | p value |
|--------------------------------------------------------------------------|------------|-------------|--------------|---------|
| Not at all                                                               | 1 (4.2%)   | 0 (0.0%)    | 1 (2.2%)     |         |
| A little bit                                                             | 4 (16.7%)  | 0 (0.0%)    | 4 (8.7%)     |         |
| Somewhat                                                                 | 13 (54.2%) | 1 (4.5%)    | 14 (30.4%)   |         |
| Quite a bit                                                              | 6 (25.0%)  | 5 (22.7%)   | 11 (23.9%)   |         |
| A great deal                                                             | 0 (0.0%)   | 16 (72.7%)  | 16 (34.8%)   |         |
| Q4 - help you think which pros and cons were most important              |            |             |              | < 0.001 |
| Not at all                                                               | 1 (4.2%)   | 0 (0.0%)    | 1 (2.2%)     |         |
| A little bit                                                             | 4 (16.7%)  | 0 (0.0%)    | 4 (8.7%)     |         |
| Somewhat                                                                 | 13 (54.2%) | 3 (13.6%)   | 16 (34.8%)   |         |
| Quite a bit                                                              | 6 (25.0%)  | 5 (22.7%)   | 11 (23.9%)   |         |
| A great deal                                                             | 0 (0.0%)   | 14 (63.6%)  | 14 (30.4%)   |         |
| Q5 - help you know that the decision depends on what matters most to you |            |             |              | < 0.001 |
| Not at all                                                               | 1 (4.2%)   | 0 (0.0%)    | 1 (2.2%)     |         |
| A little bit                                                             | 1 (4.2%)   | 0 (0.0%)    | 1 (2.2%)     |         |
| Somewhat                                                                 | 12 (50.0%) | 2 (9.1%)    | 14 (30.4%)   |         |
| Quite a bit                                                              | 7 (29.2%)  | 4 (18.2%)   | 11 (23.9%)   |         |
| A great deal                                                             | 3 (12.5%)  | 16 (72.7%)  | 19 (41.3%)   |         |
| Q6 - help you organise your own thoughts about the decision              |            |             |              | < 0.001 |
| Not at all                                                               | 0 (0.0%)   | 0 (0.0%)    | 0 (0.0%)     |         |
| A little bit                                                             | 0 (0.0%)   | 0 (0.0%)    | 0 (0.0%)     |         |
| Somewhat                                                                 | 10 (41.7%) | 0 (0.0%)    | 10 (21.7%)   |         |
| Quite a bit                                                              | 9 (37.5%)  | 4 (18.2%)   | 13 (28.3%)   |         |
| A great deal                                                             | 5 (20.8%)  | 18 (81.8%)  | 23 (50.0%)   |         |
| Q7 - help you think how involved you want to be in the decision          |            |             |              | < 0.001 |
| Not at all                                                               | 0 (0.0%)   | 0 (0.0%)    | 0 (0.0%)     |         |
| A little bit                                                             | 4 (16.7%)  | 0 (0.0%)    | 4 (8.7%)     |         |
| Somewhat                                                                 | 10 (41.7%) | 1 (4.5%)    | 11 (23.9%)   |         |
| Quite a bit                                                              | 5 (20.8%)  | 9 (40.9%)   | 14 (30.4%)   |         |
| A great deal                                                             | 5 (20.8%)  | 12 (54.5%)  | 17 (37.0%)   |         |
| Q8 - help you identify what questions you want to ask your doctor        |            |             |              | < 0.001 |
| Not at all                                                               | 0 (0.0%)   | 0 (0.0%)    | 0 (0.0%)     |         |
| A little bit                                                             | 1 (4.2%)   | 0 (0.0%)    | 1 (2.2%)     |         |
| Somewhat                                                                 | 8 (33.3%)  | 0 (0.0%)    | 8 (17.4%)    |         |

| Question                                                               | Pre (N=24) | Post (N=22) | Total (N=46) | p value |
|------------------------------------------------------------------------|------------|-------------|--------------|---------|
| Quite a bit                                                            | 11 (45.8%) | 2 (9.1%)    | 13 (28.3%)   |         |
| A great deal                                                           | 4 (16.7%)  | 20 (90.9%)  | 24 (52.2%)   |         |
| Q9 - prepare you to talk to your doctor about what matters most to you |            |             |              | 0.005   |
| Not at all                                                             | 0 (0.0%)   | 0 (0.0%)    | 0 (0.0%)     |         |
| A little bit                                                           | 2 (8.3%)   | 0 (0.0%)    | 2 (4.3%)     |         |
| Somewhat                                                               | 8 (33.3%)  | 3 (13.6%)   | 11 (23.9%)   |         |
| Quite a bit                                                            | 12 (50.0%) | 7 (31.8%)   | 19 (41.3%)   |         |
| A great deal                                                           | 2 (8.3%)   | 12 (54.5%)  | 14 (30.4%)   |         |
| Q10 - prepare you for a FU with your doctor                            |            |             |              | 0.029   |
| Not at all                                                             | 4 (16.7%)  | 0 (0.0%)    | 4 (8.7%)     |         |
| A little bit                                                           | 3 (12.5%)  | 3 (13.6%)   | 6 (13.0%)    |         |
| Somewhat                                                               | 5 (20.8%)  | 3 (13.6%)   | 8 (17.4%)    |         |
| Quite a bit                                                            | 10 (41.7%) | 6 (27.3%)   | 16 (34.8%)   |         |
| A great deal                                                           | 2 (8.3%)   | 10 (45.5%)  | 12 (26.1%)   |         |

**Table 39. Table showing significance in each domain after implementation of PtDA within Prep-DM**

### **8.4.3 NoMAD**

Twenty-eight clinicians completed the NoMAD questionnaire. Just over half of respondents (53.6 %) had been in post for over six years. Most respondents (60.8%) felt that the PtDA was unfamiliar and new. As a result, they felt that the PtDA was currently not a part of their work (64%). However, 85.7% felt that it could become part of their routine work. 71.4% of respondents felt that using the PtDA in clinical practice was different to their usual way of working. Most staff (62.9%) had a shared understanding of the PtDA. Respondents felt that the intervention did affect the nature of their own work (75%) with 85.7% seeing potential value in its use in clinical practice.

Most clinicians (85.7%) felt that the PtDA could be easily integrated into their existing work with 92.8% disagreeing that the PtDA could disrupt working relationships. 57.2% had confidence in other people's ability to use the PtDA with 64.2% feeling that work is assigned to those with skills appropriate to use the PtDA. Over half the participants (57.2%) were aware of the report of PtDA and 71.4% felt it was worthwhile. 75.7% valued the effects that the PtDA had on their work with 82.1% feeling they could modify how they worked with the PtDA. Any future feedback could be used to improve its use (71.9%).

Many felt that there would be sufficient training to enable the staff to implement the PtDA but given its very early use in clinical practice 21.4% felt that it wasn't relevant at this stage. 53.5% felt there were sufficient resources available to support its use, whilst some felt (17.9%) it wasn't relevant at this stage. Its use being supported by healthcare/hospital management was largely unknown with 46.4% neither agreeing nor disagreeing (Appendix T).

## **8.5 Discussion**

This chapter represents the first evaluation of a PtDA in the treatment for LARC and LRRC. The findings suggest that the PtDA improved patient knowledge and satisfaction and improved their preparation for decision making. This result is in keeping with other trials of PtDAs in other diseases/interventions in the literature, where people exposed to a PtDA in comparison with the usual care or simpler form of information delivery have a higher satisfaction with decision making (559, 560). Overall, clinicians, despite being unfamiliar with the PtDA, felt there was potential value in the resource and would implement this into a normal part of their work.

In this study, we field-tested the PtDA across five organisations, which demonstrated evidence of its utility in different units and geographical locations. Patient evaluations are widely used in quality assessment of health services (561, 562). The perception of patients' quality of health care (563, 564) and their satisfaction has become an important tool to gain attention and value amongst health care users and providers. It is widely recognised that both patients and professionals have a different perspective on quality. Patient satisfaction has an important role in improving treatment outcomes and quality of care in the service delivery system (565). The experience of care evaluation is essential to provide the opportunity for improvement of health services as feedback from the patient's perspective is a benchmark for health-care quality improvement. This study found that the satisfaction of this cohort of patients using normal standard of care was acceptable or good in many domains, however, with the use of the PtDA this improved significantly.

This study showed the mean score of overall patient satisfaction in EORTC PATSAT C-33 was 87.5 prior to the implementation of the PtDA which increased to 99 subsequently ( $p < 0.001$ ). PATSAT-C33 is a newly developed questionnaire and very few studies have utilised its use for comparison. Abate et al reported that patient

satisfaction at an adult oncology centre was much lower reporting a satisfaction of 44.8. However, this difference might be due to the low socioeconomic status and only one oncology centre providing comprehensive cancer care (566).

Cancer patients are at high risk for a variety of emotional disorders including anxiety, traumatic stress and depression (567-569). The patients stress can be amplified by long waiting room times, lack of information, poor communication between clinic staff and patients and the absence of psychosocial care (570). The lowest satisfaction items have been shown to be related to general provision of information and coordination by the team on supportive services, post-treatment care planning, communication with the team, and hospital access (571). This study showed that doctors information exchange, coordination, hospital access all increased significantly with the use of the PtDA. A recent cross-sectional survey found similar unmet informational needs among colorectal cancer patients however colon cancer patients were more likely to have met health information needs regarding their treatments as compared to those with rectal cancer ( $p=0.051$ ) (572). The significant improvement in information exchange with both nurses and doctors following the use of the PtDA would suggest that health information needs improve in this cohort of LARC and LRRC patients.

This study shows that communication improves with the use of the PtDA. Mole et al have previously reported high patient satisfaction with specialist nurse follow up for colorectal cancer patients (573). The ease of communicating with a health professional the ease of accessing hospital services from home was very satisfactory. The implementation of nurse led follow up increased continuity of care, ease of access and convenience to patients (573). This study may not be directly comparable however, it shows that patient satisfaction improves when healthcare is accessible via specialist nurses. Given that the PtDA increased patient satisfaction within the same domains, this seems likely to be due to the ease of reference to contact information that the PtDA provides and also using the information provided in the PtDA to stimulate areas for further discussion with subsequent contacts with nurse specialists.

Coordination also improved significantly with the use of the PtDA. For many cancer patients, unsatisfactory interactions with the health care system can pose an additional burden at a time when they are debilitated and vulnerable. Many patients describe medical care as disorganised and feel they must be the primary source of information

about their illness, requiring them to communicate the technical details of their disease to their physicians and to coordinate their own treatment plan (574). Patients who receive a written pre-treatment plan have a significantly higher care coordination score (575). The evidence for the use of written follow-up care plans, has been well recognized since the landmark Institute of Medicine report *From Cancer Patient to Cancer Survivor: Lost in Transition* (330). The PtDA informs patients of follow up and thus are consistent with this study.

The Prep-DM shows a significant improvement following the introduction of the PtDA to clinical practice ( $p < 0.001$ ). This has been reproduced in other studies with Wu et al reporting that patients with mid or low rectal cancer facing a decision for treatment have low knowledge and supports and the need to use interventions such as PtDA enhances education about options to prepare patients for discussions with their surgeons and to prepare them to provide informed consent to the surgical procedure (226). Patients facing potential exenterative surgery, however, have more complex information regarding surgery and morbidity to comprehend and a PtDA could be even more beneficial within this cohort. Similarly, Volk et al showed the effect of patients receiving a PtDA for lung cancer screening showed they scored higher on the preparation for decision making scale than the non-intervention group (576) indicating that education in the format of a PtDA improves decision making amongst cancer patients.

Implementation results suggest that the intervention has good coherence (makes sense to participants), and that cognitive participation (specific aspects of engagement) is good. Potential barriers to facilitate the use of the PtDA have been identified as management support and resources available. However, a review by Elwyn et al. on the implementation of PtDAs identified different organisational barriers: the PtDA not fitting into the workflow of the clinic and lack of leadership might hinder implementation (537, 577). This study identified that although using the PtDA was a different way of working it could be easily facilitated into the clinicians' practice. Previous studies have shown that a concern among a few HCPs was that the PtDA would increase the consultation time (578), which has been known as one of the major barriers in the implementation of SDM and PtDAs (579) which may account for our response of a different way of working but did not appear to hinder the implementation amongst our cohort. However, some studies have not found a difference in

consultation length between patients who did and did not use a PtDA (580-582). A systematic review by Dobler demonstrated that the duration of outpatient consultations did not significantly differ whether an encounter decision aid was used or not in nine out of 13 studies with three studies reporting a longer and one study a shorter consultation time in the decision aid group (583). Stacey et al demonstrated within a Cochrane review, a median consultation length of 24 min (range 3.8–68.3) vs 21 min (range 4.2–65.7) in the decision aid versus usual care groups, respectively (difference of 2.6 min longer in the decision aid group) (223). Clinicians have also described a clear learning curve among clinicians as they became increasingly familiar with the tool and confident to use it (584). It can be assumed that it is presumably a longer learning curve rather than a longer duration of consultation that may be more of an issue with the implementation of PtDAs. However, if in some cases it is a longer duration of consultation, given the morbidity and life changing sequelae of PE surgery the impact of a longer consultation should not be a barrier to implementation. Also, the PtDA can be used by CNS who can offer more time to explore patient specific concerns utilising the intervention following surgeon consultation.

The PtDA was developed by clinicians involved in PE; surgeons, CNS, oncologists and patients which may have facilitated confidence in the PtDA by clinicians. Confidence in an intervention, or feeling of ownership, is important in the Consolidated Framework For Implementation Research (CFIR) where it is described as “commitment, involvement and accountability of leaders and managers with the implementation” (585). Glenn et al. found that a positive personal experience and patient satisfaction motivates clinicians more to use a support tool than scientific evidence (586) which also may have helped implementation, given the positive patient feedback. Scholl et al. who reviewed organisational characteristics as barriers for the implementation of shared decision-making noted the importance of taking characteristics of health care facilities into account to achieve practice changes (587). One clinician disagreed with the potential value of the PtDA within their work and that it differed from usual ways of working. This study appreciates that it will be difficult to implement this PtDA into all clinicians’ way of counselling. A comparative trial in prostate cancer patients showed large differences in PtDA uptake with different approaches of PtDA dissemination (588). They found the highest uptake in sites with an electronic version of the PtDA and sent routinely by email or postal mail. This

involved high support from the organisation and colleagues with adequate access to PtDAs (588) to ensure implementation, consistent with evidence indicating the need to have strong leadership support for successful implementation of innovations in clinical practice (587, 589). The lowest uptake was in surgeons with mixed views on their willingness of giving their patients a PtDA, inconsistent scheduling of nurses that interfered with nurses providing the PtDA, and use of a hardcopy PtDA that was loaned to the patient (588). Highlighting this work within the PE community will be essential in order for organisations to support its implementation and thus ensure appropriate dissemination. Implementation within other specialities i.e. oncologists were due to lack of trust about the information on treatment options presented within the PtDA consistent with the systematic review of implementation of PtDA in clinical practice that showed confidence in PtDA content as a barrier to implementation (537). However, this should not influence the implementation of our PtDA given its development amongst multi-specialities within the MDT.

Specific theories have been developed to explain why and how PtDAs are successfully implemented into routine healthcare settings. Joseph-Williams et al have recommended implementation strategies derived from the program theory including; 1) co-production of PtDA content and processes (or local adaptation), 2) training the entire team, 3) preparing and prompting patients to engage, 4) senior-level buy-in, and 5) measuring to improve (590). Similarly other studies have shown facilitators to influence the implementation of PtDAs including 1) provider's motivation, 2) provision of training and skills development for providers, 3) identification of a clinical champion, 4) introduction of a system to identify eligible patients to use PDAs ahead of clinical consultations and 5) positive impact on the clinical process and patient outcomes (537, 538). It is likely that there will be enthusiasts who support its use or were involved in its development, but there are likely to be clinicians who forget that it exists. To improve its use it is important to have a plentiful supply of printed PtDA in the clinic environment to eliminate issues seen in previous studies (588). Empowering the CNSs to suggest its use would also be a strategy and targeting them through CNS networks may be useful. Highlighting this work at conferences would also highlight the work to the exenterative surgical community. The number of patients who require PE are low and their treatment tends to/should be centralised to specialist centres facilitating targeting patients and developing a routine pathway for its use.



A cancer diagnosis is a time of great stress for patients when their ability to comprehend and retain information is suboptimal (591-593) but their need for information is great (594). The PtDA appropriately informs patients of the treatment options. However, it is anticipated, given the findings from the qualitative interviews (Chapter 4), that introduction of the PtDA within this cohort would not significantly change the choice preference of patients. This is seen in other clinical trials examining invasive surgeries on topics of prostate cancer, bariatric surgery, coronary angiography, and breast cancer, where the preferred option is not altered by the use of PtDAs (595-598). However, PtDAs are designed to raise decision quality and improve the decision-making process (191).

### **8.5.1 Limitations**

Interrupted time series studies, comparing changes in outcomes for successive groups of patients before and after receiving an intervention are useful when it is not possible to include an unexposed control group. However, they are inherently susceptible to bias since changes observed may simply reflect regression to the mean (any changes in outcomes that might occur naturally in the absence of the intervention), or influences or secular trends unrelated to the intervention, e.g., changes in the economic or political environment, or a heightened public awareness of issues. (599). The study was also conducted succeeding the COVID pandemic and usual practice may not have resumed. However, given the complexity of PE and overall surgical conformity of surgical intervention we do not believe that this had a significant impact on the results presented in this chapter. Further limitations were that implementation was only assessed amongst clinicians and only through the NoMAD questionnaire and further evaluation using qualitative interviews may give more answers about the facilitators and barriers to implementing the PtDA. The PtDA has also only been developed in a paper format and subsequent electronic use may be beneficial. However, video booklet decision aids and online web based decision aids have shown there are no significant differences in mean scores on the Prep-DM (600), which has also been demonstrated in other published different clinical context studies (191, 531, 601-604)

## **8.6 Conclusion**

Patients contemplating PE surgery are faced with a healthcare decision with limited knowledge and support. There is a need to use interventions such as PtDA to enhance education about options to prepare patients for discussions with their surgeons and to

prepare them to provide informed consent. The PtDA for LARC and LRRC was found to improve preparation for decision making and improve the perception of quality of care. Patients found it to be highly valuable with low burden and felt better prepared for discussion with their surgeon. Clinicians reported value in its use and would implement it in clinical practice. Use of the PtDA during the process of surgery consultation is recommended for the demonstrated benefits on patients. The PtDAs are still in use in the participating units after completion of the study. To sustain practice changes into daily routine future studies are needed to test the sustainability of the PtDAs.

## **Chapter 9. General discussion**

### **9.1 Overview**

The aims of this thesis were to establish what available literature exists for patients undergoing PE for LARC and LRRC as part of the SDM process. Having appraised the existing literature, the specific aim of this thesis was to develop a PtDA for use in clinical practice.

The project was designed as a multicentre, four phase mixed methodological project. Phase I developed a conceptual framework utilising qualitative and quantitative data. Phase II developed the PtDA.

Phase III alpha tested the PtDA with patients and clinicians

Phase IV beta tested the PtDA in real-life conditions and evaluated its implementation.

#### **9.1.1 Phase I: Development of a prototype**

Phase I established a conceptual framework using data from two systematic reviews that examined the quality of internet information available to aid patient decision making in the treatment of LARC and LRRC (Chapter 2) and a qualitative review of patient information needs based on online forums (Chapter 3). This was performed due to the absence of any decision aids being available on the Decision Aid Library Inventory database. The data obtained from the synthesis of existing information informed the qualitative interviews to identify factors important to patients in decision making to undergo surgical intervention (Chapter 4). This established that the conceptual framework that underpins decision making in LARC and LRRC consists of recovery, psychological impact, expectations, communication, relationships, lifestyle, financial implications, and support. To ensure clinical relevance of the decision-making domains an analysis of available health information leaflets used in clinical practice was undertaken. This identified eight domains including classification of disease and surgery, benefits and risks, immediate recovery, delayed recovery, social functioning, expectations, communication, and support links. These data in this phase informed the content of the PtDA.

#### **9.1.2 Phase II: Development of the PtDA**

The development of the PtDA was theoretically grounded in the Ottawa Decision Support Framework and practically guided by the International Patient Decision Aid

Standard guidance. A draft PtDA was composed informed by the data from Phase I which was developed further using a core steering group of eleven healthcare professional and three representatives for patient and public involvement using a new technique of Agile Development Methodology. Six sprint cycles over ten weeks resulted in 73 major changes and 59 minor changes. Content, layout, acceptability, comprehensibility and desirability were acceptable at the completion of the sprint cycles.

### **9.1.3 Phase III: Alpha testing the PtDA**

The quality of the PtDA was assessed and co-created in an iterative manner by nine healthcare professionals and nineteen patients. Telephone cognitive interviews were conducted using concurrent and retrospective methods using a standardised semi-structured cognitive interview guide. A total of 41 modifications were made from the feedback received from qualitative interviews, including changes to the layout/design, missing items, readability, and usability. The validated QQ-10 questionnaire measuring face validity from the patient's perspective demonstrated high value and low burden of the PtDA and the free text feedback resulted in a further nine changes.

### **9.1.4 Phase IV: Beta testing and implementation of the PtDA**

The PtDA was validated for use in United Kingdom patients with LARC and LRRC. In the beta testing the PtDA demonstrated good validity in field testing using a before and after study model by 60 patients using EORTC-PATSAT-C33. Patients' perception for the quality of care received within the hospital improved significantly following the use of the PtDA. Doctors' technical skills, information exchange and affective behaviour was perceived as significantly higher with the use of the PtDA. Nurses' information exchange and affective behaviour was also perceived to be better using the intervention. Coordination and interaction with health-care teams were also significantly better amongst the post-implementation cohort. The preparation for decision making score indicated that patients in receipt of the PtDA were significantly more prepared for decision making than the patients without the aid.

Implementation of the PtDA to clinical practice indicated good coherence and cognitive participation. Clinicians who appraised the PtDA valued its use in clinical practice and felt that it is easily integrated into their existing work. Potential barriers to facilitate the use of the PtDA have been identified as management support and

resources available. The resource remains to be identified as new and unfamiliar to many healthcare professionals, however, with further education and promotion of the PtDA, implementation in daily clinical settings could be improved and potential barriers resolved.

## **9.2 Methodological strengths and limitation**

### **9.2.1 Phase I**

The prototype was informed using a variety of sources including available online information, online patient forums and qualitative interviews with healthcare professionals and patients and patient information leaflets in current use. This ensured the developed prototype appropriately reflected the perspectives of patients and clinicians in decision-making for PE. PE encapsulates multi-specialties including colorectal, gynaecological, urology and sarcoma surgeries, however exclusions to all subspecialties other than LARC and LRRC were made to reflect the decision-making within this specific patient population.

#### **9.2.1.1 Online information and patient forums**

The strengths of this study were that threads and blogs linked to original posts within the online forums were retrieved and analysed to provide more data. Data was also retrieved from patient testimony rather than interviews therefore eliminating interviewer bias seen in qualitative work. The key limitations of this study were the search terms were devised by two researchers which may have limited the number of sources identified in this study. Incorporation of PPI may have resulted in different search terms and thus the identification of different sources. Other limitations were the use of a limited number of internet pages on one search engine; expanding the search strategy further, using other search engines including Yahoo and Bing may have led to the identification of further resources. Other limitations included limitation to the English language and information captured from computer literate patients only potentially excluding a cohort with different information needs. Information gathered was from unknown patient characteristics potentially resulting in bias that could have led to uncertainty around the generalisability.

Given the limitations associated with online information and online forums, the use of in-depth cognitive interviews were used in conjunction to elicit concepts and themes

of decision-making. Data extracted in the earlier part informed the inductive (top down) approach to telephone cognitive interviews.

#### **9.2.1.2 Qualitative interviews**

The key strength of this national, multicentre qualitative study is its generalisability, given the broad demographics of patients included across a range of geographical PE centres with appropriate multidisciplinary input. A purposive sampling strategy ensured that all subcategories of PE were represented within the analysis (60% TPE and 40% PPE of which 28% underwent sacrectomy and 16% had an ELSIE). It also ensured that a fair representative of genders (male 52%, n=13 and female 48%, n=12) and disease pattern of LARC and LRRC had similar representation (60% LARC, n=15 and LRRC 40%, n=10). Taking the perspectives of key stakeholders including surgeons and specialist nurses offered further insight into the complex process of decision-making for PE. However, the numbers were small (surgeon n=3, oncologist n=2 and CNS n=3) and expanding this cohort may have provided further information. The key limitation of our study was the inclusion of patients who have undergone surgery alone, consequently, themes extracted were limited primarily to patients who undergo operative treatment alone and therefore may not truly encapsulate all relevant themes for those who may undergo palliation of their LARC or LRRC, thus introducing the potential of selection bias. To reduce recall bias interviews were conducted early in the follow up period following surgery and therefore it is possible that some themes relevant to longer term issues may not have been identified. The sample size was small partly because PE is a relatively uncommon procedure despite this being a multicentre study. Despite the small sample size, after recruitment of 24 patients there was saturation of the themes identified in the structured interviews, suggesting that a larger sample size would have been unlikely to identify any further useful information.

There was adequate representation of patient factors, disease pattern and surgical intervention within this sampling population that allowed the analysis of extracted themes within this heterogeneous patient population. However, it should be noted that the exclusion of palliative patients may mean relevant themes may have been missed. Despite being able to secure ethical approval to include patients who had refused surgical intervention (but were potentially treatable), we were unable to recruit any patients in this cohort to the study.

The COVID pandemic impacted on the qualitative phase. Recruitment was slow to this phase of the study due to COVID regulations and restructuring within the NHS. Research departments were unable to support open studies as staff were redeployed to clinical areas. Patients were receiving longer courses of neoadjuvant treatment and as a result time to clinic to discuss surgical intervention was longer. Patient facing activities were less than previous and as a result recruitment was more difficult.

Conducting this study on a multi-centre platform had both advantages and disadvantages. The main advantage was obtaining a diverse sample that was representative of the population of interest, thus making the obtained results generalisable. A further advantage of employing more than one centre that manages this patient cohort was that it enabled faster recruitment due to the combined patient pool available. Telephone interviews were used to overcome the logistical difficulty of travelling to various parts of the UK. The advantages of collecting the data in this manner were that it was cost-effective, eliminated travel time and had environmental benefits. However, the use of telephone interviews may have led to missing key pieces of non-verbal communication that could potentially impact the data collected. Interviews were conducted on an individual basis rather than focus groups due to the potential advantage of identifying sensitive and/or personal information, which some participants may be uncomfortable sharing in a group setting (605). In-depth cognitive interviews allow the interviewer to explore topics in a more detailed manner, thus gathering more qualitative data that informed the development of the conceptual framework overall. Further advantages of cognitive interviews over focus groups, included the process of data analysis with the transcripts easier to analyse from the individualised nature of these interviews. A further limitation was that only UK patients were recruited limiting the data used for phase II. Further global involvement may have revealed other factors important in decision-making including cultural and socio-economic factors which may not have been exposed within this cohort.

### **9.2.2 Phase II**

The design of the PtDA was based on themes identified in phase I. Patient information leaflets currently used in practice across the world were also analysed prior to drawing all the information together. Subsequently a draft PtDA was produced, theoretically grounded in the Ottawa Decision Support Framework and practically guided by International Patient Decision Aid Standards guidance. A professional medical

illustrator was used to optimise the layout and visual appeal of the PtDA. One of the greatest strengths of this study was the development of the PtDA using Agile Development Methodology. This is a dynamic and flexible approach employed in software programming, whereby development occurs over a series of short cycles (sprints) by harnessing user feedback (464, 466). ADM focuses on collaborations between developers and stakeholders, flexible methodology, and the ability to respond quickly to change through multiple iterations (466). This allowed the delivery of high quality and high value project within a short time frame and small cost. Stakeholders were not paid for their time. Involvement of all stakeholders including multidisciplinary surgeons, CNS, oncologists and PPI allowed iterative changes to the content, layout, acceptability, comprehensibility and desirability. Following phase I it was apparent that one of the greatest areas of unmet need was in the counselling about the implications that PE has on sexual function. Males understood the physical change in terms of erectile dysfunction but failed to understand its psychological impact and subsequent effect on relationships. Females were generally uncomfortable discussing sexual function with male clinicians and felt unprepared for changes in their sexuality and relationships. Most of the literature regarding sexual function following PE also comes from women undergoing exenterative surgery for cancers of gynaecological origin. It was felt that sexual dysfunction and change in sexuality was not addressed adequately within the female PtDA and further work needed to address missing information relevant for women. A decision was made to perform a breakaway session to include a subgroup of professionals with a specialist interest in gynaecology to develop the area of sexual dysfunction and associated psychological change within the female PtDA.

Limitations in phase II of this study included the lack of palliative care input during the development process, however, the consultant oncologist who was part of the ADM process had experience within their training within this subspecialty. PE is a complex surgical procedure with numerous complex medical terms. The complexity of the procedure and the language made production of an easily readable aid challenging (using the Flesh-Kincaid grade). The final version has a calculated reading range of 15-17 years, presumably due to the medical terminology within the PtDA. Although the Flesh-Kincaid grade is the most commonly used test of readability, it is important to acknowledge it has limitations; the calculations rely on sentence length



and number of syllables in a word. The obvious limitations with this is that a well-understood word may have multiple syllables, such as ‘television’, whereas a less well-known medical term, like stoma may have fewer (421). The formulas also do not take account of coherence. It is well known that layout and style such as font size, use of colour, and capital letters can affect the readability of a document, and these are not assessed by the formulas used in this study (496) (497). The developed PtDA tried to minimise the impact that medical terminology had on patient understanding by describing each term in detail. The feedback from the PPI felt that it was easy to read at a low literacy level.

### **9.2.3 Phase III**

The strength of this phase was the methodological analysis used a validated instrument (QQ-10) to assess face validity, feasibility and utility of the PtDA for treatment choices of LARC and LRRC. The QQ-10 was rigorously developed using standard psychometric methods and has been shown to have high internal consistency, item correlation and to be acceptable and understandable to patients (516). The use of the validated QQ-10 measure embeds patient perspectives at all stages within the PtDA developmental process, moving beyond the paradigm of clinician-orientated information. The techniques of ‘think aloud’ and ‘verbal probing’ were also both incorporated when completing the questionnaire to optimise validity. This allowed for representation of the respondents memory, language, comprehension and problem solving process (511) (512) and for respondents to paraphrase questions, to clarify the definitions of wording within questions, explain the rationale behind responses and identify areas of the questionnaire that pose difficulty in understanding, interpretation or completion (511) respectively.

Cognitive interviews were another strength to this phase (see 9.2.1 phase I). Both concurrent and retrospective interviewing was performed. Concurrent interviewing allows the respondent to provide a verbal account of their thinking as they work through the PtDA with retrospective interviewing allowing the questioning of the respondent upon completion of the PtDA. As both methods were employed in this phase it allowed the assessment of responder understanding of content, wording and format and evaluation of question design with emphasis on overall format, completion time, recall period and response options.

The limitations of this phase were that face validity is the most basic test of validity. However, further, more rigorous and robust testing was carried out in the form of beta testing in the next phase of the study.

#### **9.2.4 Phase IV**

Beta testing involved using interrupted time series studies, comparing changes in outcomes for successive groups of patients before and after receiving an intervention, this is thought to be useful when it is not possible to include an unexposed control group. It may have been possible to recruit other sites as the unexposed groups however due to time limitations of setting up new sites, this was not feasible within the time constraints of the project. It was also perceived that before and after comparison within the same units would facilitate direct comparison allowing for more meaningful assessment of change in patient satisfaction. It needs to be recognised that this method is inherently susceptible to bias since changes observed may simply reflect any changes in outcomes that might occur naturally in the absence of the intervention, or changes in the economic or political environment, or a heightened public awareness of issues (599). Any potential changes were limited given the short period of time within this phase and two consecutive three-month study periods and given the complexity of PE and overall surgical conformity of surgical intervention this was thought not to apply to our cohort of patients.

Further limitations were that implementation was assessed only through the NoMAD questionnaire and further evaluation using qualitative interviews may give more answers to the facilitators and barriers to implementing the PtDA. However, this instrument has been tested to good face validity, construct validity and internal consistency (606). The PtDA has also only been developed in a paper format and subsequent electronic use may be beneficial. However, video booklet decision aids and online web based decision aids have shown no significant differences in preparation for decision making (600), supported by the findings of other published studies comparing written and audio-visual information aids in different clinical context studies (191, 531, 601-604).

### **9.3 Future Applications of the PtDA**

The PtDA for LARC and LRRC has been developed in response to a need within exenterative practice, both from patients and HCPs. However, limitations for its use

have been identified and barriers to implementation need to be addressed to improve future applications of the PtDA.

### **9.3.1 Clinical application**

Both alpha and beta testing the use of the PtDA into clinical practice were found to improve patient overall satisfaction (pre and post implementation 87.5 and 99.1 ( $p < 0.001$ )). Its high value and low burden score showed that it was making a positive impact on their healthcare, similar to scores obtained in other studies (520-522). Patients with a diagnosis of LARC or LRRC face difficult choices that will either render their care palliative in intent or undergo life changing surgery with the hope of cure and need improves preparation to make informed treatment decisions. Using the PtDA in routine clinical practice should improve expectations, disclose, and identify relevant implications of exenterative surgery. For the patients that chose surgery it should allow preparation for short and long-term recovery. It encapsulates the wide range of potential complications, complex recovery and impact on relationships and lifestyle that can help guide clinical decision making. The PtDA should be used in clinical practice in conjunction with discussions with the HCP to make a shared decision, ensuring that individuals are supported to make decisions that are right for them. The current format of the PtDA requires manual individualisation to each patient specifying which organs will/ may be resected which potentially may be a barrier to its use.

The use of the PtDA was found to improve patient-clinician communication through helping patients identify concerns and discuss issues most important to them as part of SDM. Establishing all the potential complications and effect on QoL and providing these in a format that patients can revisit away from their consultation, empowers the patient in the decision-making process. In other clinical domains clinicians have reported added value from the use of a decision aid, for example, by positively challenging patients' preconceived ideas, by providing visual representations of choices and by facilitating more structured and coherent consultations (583). Previous studies have shown that clinicians value having additional tools for patients to view and take home (607) and that their patients were more satisfied with care after using a decision aid that adds value to a consultation (608).

When it comes to implementation of PtDAs into clinical practice there is often concern that they may increase consultation time however, systematic reviews that have evaluated the impact of encounter decision aids on clinician outcomes and consultation length, and found that the use of decision aids can improve satisfaction with medical decision making and provide helpful information without negatively affecting other measures of clinician satisfaction and length of consultation time (583). Early experience with the PtDA developed in this thesis suggest that consultation time when counselling patients about whether they wish to proceed with exenterative surgery has not been increased.

### **9.3.2 Health service outcomes**

The identification of information required by patients to make an informed choice to undergo PE for LARC and LRRC is essential for SDM. PE is complex surgery with significant associated morbidity and mortality. Previous work has concentrated on surgical outcomes rather than clinical outcomes which is slowly being addressed by QoL work. This work in combination with HrQoL can appropriately educate both clinicians and patients to make balanced judgements regarding exenterative surgery.

Since the introduction of Montgomery's verdict, in the United Kingdom, a doctor is under a legal duty to take reasonable care to ensure his or her patient is aware of any material risks involved in the recommended treatment, and of any reasonable alternative or variant treatments (454). According to NHS Resolution, NHS compensation pay-outs in 2021/22 amounted to £ 2.6 billion, an increase on the previous year's figure of £2.4 billion with just over 25% spent on legal costs (609). Based on Montgomery and a number of relevant published cases, practice caveats for surgeons require them to document several outcomes including: the objective and subjective elements regarding the materiality of risks; postoperative risks, follow-up and management and timing and adequacy of risk disclosure (610). The introduction of the PtDA for patients undergoing PE surgery would appropriately inform them, and thereby minimise the risk of litigation in the area of practice where morbidity, mortality and complications are unfortunately common.

### **9.3.3 Clinical research**

Currently there are two large population-based registries, BeyondTME and the PelvEx collaborative measuring clinical and oncological outcomes in patients undergoing PE.

Recent work to identify HrQoL frameworks for LRRC have been developed which could potentially be incorporated as a secondary endpoint (611). Further development for such frameworks need to be also developed for LARC. The PtDA, if validated amongst other populations, could be adopted by these institutions involved in these collaboratives to improve SDM within their cohorts. This could improve HrQoL in PE patients globally by managing expectations, achieving informed consent, and better preparing patients for the magnitude of surgery. Further adaptations to the PtDA could subsequently be incorporated as the range of surgery continues to develop with higher and wider resections and the consequences of more radical surgery.

## **9.4 Future perspectives**

### **9.4.1 Digitalisation**

The interface between the internet, mobile technology applications and healthcare is rapidly evolving. Digitalisation offers the opportunity to design PtDA in an interactive, personalised, and possibly more effective way to better engage patients and facilitate SDM for decisions regarding current and future care (612-614). Future applications of the PtDA will allow individualisation on an electronic platform which may be more user friendly for clinicians and technologically able patients that may have the potential to empower patients and orient healthcare towards patient- and value-orientated practice (613-615).

### **9.4.2 Large field validation**

The next step in developing the PtDA from a methodological perspective is a large-scale validation within the UK. Further works to assess implementation including HCP interviews are needed to address and evaluate any further issues in implementing the tool within daily clinical practice.

### **9.4.3 International collaboration, translation and cross-cultural validation.**

The PtDA was developed using English only online resources, patient information leaflets currently in use worldwide and qualitative data from UK English speaking HCP and patients which limits its use internationally. The development of the PtDA is with targeted content (language, value-based framing of information, evidentiary information relevant to a cultural group), and its use is optimal in the original context and amendments are necessary to make the material suitable in another cultural context. Health communication research demonstrates the importance of addressing

cultural differences to optimise intervention effectiveness (616-618). Decision making is likely to be moderated by cultural differences. There are currently no guidelines on how to culturally adapt and validate PtDAs. However, Chenel et al established eleven main procedures for the cultural adaptation and validation of PtDAs: appraisal of the original PtDA; assessment of the new cultural context; translation; linguistic adaptation; cultural adaptation; usability testing; exploration of PtDA acceptability; test-retest reliability; content validity; construct validity; and criterion validity (619). Further work to translate and validate this PtDA amongst the international community would allow its use on an international platform.

We have been approached by other disciplines including gynae-oncology to use the PtDA within their speciality. Further validation amongst this cohort of patients would be required to use in clinical practice.

## **9.5 Conclusions**

This thesis has established and validated a PtDA for patients undergoing PE for LARC and LRRC in the United Kingdom. This is the first measure to be developed exclusively for this cohort of patients. The PtDA has been developed and validated in a methodologically robust, stepwise manner based on IPDAS guidelines and ODFS. Currently the PtDA only exists in paper format but will be developed on an electronic platform for the use of all clinicians within relevant patient population. Although developed and validated within a UK population it could be developed further through international collaboration. This study shows that the use of the PtDA in clinical practice improves patient experience and outcomes. It is hoped that implementation into clinical practice continues to broaden the reach of this work.

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# APPENDICES

## APPENDIX A: DISCERN tool

| Number | Question                                                                                                                                       | Score |   |   |   |   |
|--------|------------------------------------------------------------------------------------------------------------------------------------------------|-------|---|---|---|---|
| 1      | Are the aims clear?                                                                                                                            | 1     | 2 | 3 | 4 | 5 |
| 2      | Does it achieve its aims?                                                                                                                      | 1     | 2 | 3 | 4 | 5 |
| 3      | Is it relevant?                                                                                                                                | 1     | 2 | 3 | 4 | 5 |
| 4      | Is it clear what sources of information were used to compile the publication (other than the author or producer)?                              | 1     | 2 | 3 | 4 | 5 |
| 5      | Is it clear when the information used or reported in the publication was produced?                                                             | 1     | 2 | 3 | 4 | 5 |
| 6      | Is it balanced and unbiased?                                                                                                                   | 1     | 2 | 3 | 4 | 5 |
| 7      | Does it provide details of additional sources of support and information?                                                                      | 1     | 2 | 3 | 4 | 5 |
| 8      | Does it refer to areas of uncertainty?                                                                                                         | 1     | 2 | 3 | 4 | 5 |
| 9      | Does it describe how each treatment works?                                                                                                     | 1     | 2 | 3 | 4 | 5 |
| 10     | Does it describe the benefits of each treatment?                                                                                               | 1     | 2 | 3 | 4 | 5 |
| 11     | Does it describe the risks of each treatment?                                                                                                  | 1     | 2 | 3 | 4 | 5 |
| 12     | Does it describe what would happen if no treatment is used?                                                                                    | 1     | 2 | 3 | 4 | 5 |
| 13     | Does it describe how the treatment choices affect overall quality of life?                                                                     | 1     | 2 | 3 | 4 | 5 |
| 14     | Is it clear that there may be more than one possible treatment choice?                                                                         | 1     | 2 | 3 | 4 | 5 |
| 15     | Does it provide support for shared decision making?                                                                                            | 1     | 2 | 3 | 4 | 5 |
| 16     | Based on the answers to all of these questions, rate the overall quality of the publication as a source of information about treatment choices | 1     | 2 | 3 | 4 | 5 |

Each question is rated on a 5-point scale ranging from No to Yes. 5 should be given if your answer to the question is a definite 'yes' - the quality criterion has been completely fulfilled. Partially (2-4) should be given if you feel the publication being considered meets the criterion in question to some extent. How high or low you rate 'partially' will depend on your judgement of the extent of these shortcomings. 1 should be given if the answer to the question is a definite 'no' - the quality criterion has not been fulfilled at all

## APPENDIX B: IPDAS criteria

|                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Qualifying</b>    | <ol style="list-style-type: none"> <li>1. Describes health condition or problem for which index decision is required.</li> <li>2. Explicitly states decision under consideration (index decision).</li> <li>3. Describes the options available for the index decision.</li> <li>4. Describes the positive features of each option.</li> <li>5. Describes the negative features of each option.</li> <li>6. Describes the features of options to help patients imagine the physical, social and/or psychological effects.</li> </ol>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Certification</b> | <ol style="list-style-type: none"> <li>7. Shows positive and negative features of options with equal detail.</li> <li>8. Provides information about the funding source used for development.</li> <li>9. Provides citations to the evidence selected.</li> <li>10. Provides a production or publication date.</li> <li>11. Provides information about update policy.</li> <li>12. Provides information about the level of uncertainty around outcome probabilities.</li> <li>13. Describes what the test is designed to measure.</li> <li>14. Describes next steps taken if test detects a condition/problem.</li> <li>15. Describes next steps if no condition/problem detected.</li> <li>16. Describes consequences of detection that would not have caused problems if the screen was not done.</li> </ol>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Quality</b>       | <ol style="list-style-type: none"> <li>17. Development included needs assessment to determine what patients need to make the decision.</li> <li>18. Development included needs assessment to determine what health professionals need to discuss decision.</li> <li>19. Development included review by patients not involve in producing the DSI.</li> <li>20. Development included review by professionals not involve in producing the DSI.</li> <li>21. DSI was field tested with patients facing the decision.</li> <li>22. DSI was field tested with practitioners who counsel patients facing the decision.</li> <li>23. Includes author/developers credentials or qualifications.</li> <li>24. Evidence that DSI improves match between patient preferences and chosen option.</li> <li>25. Evidence that DSI helps patient improve knowledge about options' features.</li> <li>26. Describes how research evidence was selected/synthesized.</li> <li>27. Describes the quality of research evidence used.</li> <li>28. Provides step by step way to make decision.</li> <li>29. Includes tools to use when discussing options with practitioner.</li> <li>30. Describes the natural course of the condition.</li> <li>31. Makes it possible to compare features of available options.</li> <li>32. Reports readability levels.</li> <li>33. Provides information about outcome probabilities (OPs).</li> </ol> |

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>34. Specifies reference class of patient for which OPs apply.</p> <p>35. Specifies event rates for Ops.</p> <p>36. Specifies the time period over which OPs apply</p> <p>37. Allows to compare OPs using the same denominator.</p> <p>38. Provides more than one way of viewing probabilities.</p> <p>39. Asks patients to consider which positive and negative features matter most to them.</p> <p>40. Includes information about chances of having a true positive result.</p> <p>41. Includes information about chances of having a true negative result.</p> <p>42. Includes information about chances of having a false positive result.</p> <p>43. Includes information about chances of having a false negative result.</p> <p>44. Describes the chance the disease is detected with and without use of the test.</p> |
|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## **APPENDIX C: Topic guide for participant interviews for the development of a patient decision aid**

### **1. Welcome**

- a. Introduction.
- b. Ground rules including confidentiality, anonymity and voluntary withdrawal of participation at any time.

### **2. Interview**

#### Opening Statements

1. Tell me about your initial experiences of LARC/LRRC when you were first diagnosed.

#### Prompts

- What made you seek medical help?
- What was involved in getting a diagnosis?
- When did it become apparent to you it was cancer?

2. Tell me about your experiences of your treatment of LARC/LRRC

#### Prompts

- How did you feel in the outpatient appointments?
- What do you remember about being told about your cancer diagnosis?
- What were told about options for treatment?
- What support did you have? Family, friends, nurses etc
- Did you feel like there was a choice of treatments available to you? Do you think your preferences/beliefs/culture/lifestyle etc played a part in the decision? Who made the final decision? Do you think it was a shared decision-making process?
- Did you feel like you were prepared adequately for the procedure?
- Did you fully understand what you were going to undertake?
- Was there anything in the recovery process that had not been discussed with you?

3. Tell me about your feelings and experiences following the treatment of LRRC.

#### Prompts

- What have been the major problems and benefits?
- With hindsight what advice would you give to another patient you wish you had received prior to undergoing treatment?
- In retrospect, would you have the same treatment today?
- What support was or would have been helpful both prior and after treatment – educational, social, spiritual, economic?

For each phase of the management and treatment of LRRC/LARC the following key issues will be touched upon.

- Treatment process.
- Communication with health care professionals throughout the process.
- Physical recovery.
- Psychological recovery.
- Impact on social life.
- Impact on relationships.
- Expectations.
- Financial implication.
- Support networks.

Cognitive probes will be used to further explore the themes and issues raised by the patients.

Example cognitive probes:

- change in relationships.

What relationships were affected?

- How were they affected?
- Could anything have been done to help you adjust within these relationships?
- How often do you experience pain?
- How does the change within the relationship change your life?

Expectations

- What were your expectations of treatment?
- How did they differ from reality?
- What would you have wanted to know that you didn't know with the benefit of hindsight?
- Did your medical team give you realistic expectations?

### **3. Debrief**

At the end of the interview:

- Debrief the patient.
- Explain their role in the development of PtDA.
- Thank the patient for their time and help.
- Provide them the opportunity to ask further questions and/or comment.



## APPENDIX D: Patient information sheet

IRAS ID: 257890

v5 02/2020



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**Study Name - Decision making in pelvic exenteration – patient and clinician perspectives.**

**You are being invited to take part in a research study. Before you make a decision to take part, we would like to explain to you why the study is being carried out, what it will involve and your role. Please read the information leaflet carefully and discuss it with your family and friends. If there are any aspects of the information sheet that are not clear then please contact the named health care professionals listed at the end of the sheet.**

### **What is the purpose of the study?**

The aim of this study is to evaluate the decision-making process in patients who have had the same diagnosis as you and have either undergone the same operation as yourself (pelvic exenteration) or other treatment in the way of chemoradiotherapy. In particular we are interested in the patients' perspective of the consent process, did you feel it was a shared decision-making process, what information was important to you, was there enough information and were you prepared for the treatment and life after treatment. With your hindsight we are keen to analyse what information was or would have been important to you as part of the decision-making process. This will be evaluated during a one off 30–60-minute telephone or face to face interview. The findings from this study will help us inform future patients about what life really is like after surgery and counsel them appropriately so they can make the correct decision for them on whether to pursue surgery and what to expect afterwards.

### **Do I have to take part?**

- **You do not have to take part.** However, if you decide to take part you can keep this information sheet, you will be asked to sign a consent form that shows us that you have understood what the study involves and that you are happy to take part. The Principal Investigator Miss Anwen Williams will make telephone contact with you within a week if you have expressed interest in participation.
- You can change your mind and withdraw from the study at any time. Your withdrawal from the study will not affect your standard of care.

### **What will happen to me if I take part?**

- The study involves an interview with a doctor exploring your decision making in undergoing surgery. This will take 30-60 minutes and the interview will be recorded in order that it can be analysed properly (from transcription) after you have finished speaking to the doctor. It will not affect your normal care with the doctor looking after you.

#### **What will I have to do?**

- Once you have had all your questions answered, we will ask you to sign a consent form to say you are happy to participate.
- Your follow-up care will continue without any changes. Agreeing or not to be a part of this research project will not affect the standard of care you receive, or your long term follow up.

#### **What are the possible disadvantages of taking part in the study?**

- There are no medical disadvantages or risks to participating in this study. The interview may enquire about your physical symptoms, personal feelings and current limitations, which may cause you minor distress.

#### **What if there is a problem?**

- Any clinical problems will be addressed in the standard manner, no clinical problems will result from this study. Medical staff are available on site 24 hours of the day.
- If you have any concerns about the study, please feel free to contact Miss Deena Harji, Co-Investigator, Colorectal Registrar, The Royal Victoria Hospital, Newcastle [REDACTED] or Prof Martyn Evans, Chief Investigator, Consultant Surgeon, Morriston Hospital Swansea [REDACTED] to discuss your concerns. If we cannot resolve your concerns or problems, then the hospital has an NHS complaints procedure.

#### **What are the alternatives if I don't take part?**

- If you choose not to take part, your care will continue without any change.

#### **What are the benefits of taking part?**

- We hope that the study will improve the information that future cancer patients are given. There will be no direct clinical benefits to you, although you may find participating in research of interest.

#### **Will my taking part in the study be confidential?**

- Any details about you will remain strictly confidential. Data from the study may be used and presented to regulatory bodies; however, your name and personal details will be removed.

- Your hospital consultant will be informed about your participation in the study with your prior consent.

### **What will happen to the results of the study?**

- We hope that the results of the study will help determine how to improve the management of patients undergoing bowel surgery for cancer. It is our aim to present our findings at local, national and international meetings and to publish the results of this study in the medical press. You will not be identified in any report. Overall results of the study can be made available to participants upon request.

### **Who is organizing the study?**

- The study is being organized by the Department of General and Colorectal Surgery at **Swansea Bay** University Health Board, Swansea.

### **Who has reviewed the study?**

- The South West Wales Research Ethics Committee and the Joint study Review Committee have reviewed the study.

### **Contact Information details.**

- The study team contact details are available below. Please contact the team if you have any questions regarding the study. If following the study, you have any symptoms that you think may be related to the study please do not hesitate to contact the team.
- Thank you for considering taking part in this research study. **If you do wish to take to part, please contact Miss Anwen Williams, Principal Investigator**  
[REDACTED]

You will receive a copy of this information sheet and a signed consent form to keep should you wish take part.

### **Contacts for further information:**

**Miss Deena Harji, Colorectal Registrar, Royal Victoria Hospital, Newcastle Tel**  
[REDACTED]

**Professor Martyn Evans, Consultant Surgeon, Morriston & Singleton Hospital, Swansea.**  
[REDACTED]

**Professor Dean Harris, Consultant Surgeon, Morriston & Singleton Hospital, Swansea.**  
[REDACTED]

Swansea Bay University Health Board (SBUHB) is the sponsor for this study based in the United Kingdom. They will be using information from your medical records in order to undertake this study and will act as the data controller for this study. This means that they are responsible for looking after your information and using it

properly. SBUHB will keep any identifiable information about you for five years after the study has finished.

In accordance with new General Data Protection Regulations (GDPR) guidelines, your right to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

You can find out more about how we use your information at:

<http://www.wales.nhs.uk/sitesplus/documents/863/Research%20privacy%20notice%20-%20final.pdf>.

SBUHB will make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from SBUHB and regulatory organisations may look at your medical and research records to check the accuracy of the research study. SBUHB will pass these details to their Research and Development department along with the information collected from your medical records. The only people in SBUHB who will have access to information that identifies you will be people who need to audit the data collection process.

## APPENDIX E: Patient consent form



GIG  
CYMRU  
NHS  
WALES

Bwrdd Iechyd Prifysgol  
Abertawe Bro Morgannwg  
University Health Board

CONSENT FORM (v4 , 04/04/19)

**IRAS ID: 257890** Research Study ID number:

Patient Identification Number:

Date:

**Title of Project: Decision making in pelvic exenteration – patient and clinician perspectives.**

**Name of Principal Investigator:**

**Professor Martyn Evans, Abertawe Bro Morgannwg University Health Board**

|                                                                                                                                                                                             | Initials                      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
|                                                                                                                                                                                             | <b>Please initial the box</b> |
| 1. I confirm that I have read and understood the information sheet (V3 02/19) for the above study and have had the opportunity to ask questions and have had these answered satisfactorily. | <input type="checkbox"/>      |
| 2. I confirm that I have had sufficient time to consider whether or not I want to be included in the study.                                                                                 | <input type="checkbox"/>      |
| 3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.           | <input type="checkbox"/>      |
| 4. I agree to the researchers accessing my medical records                                                                                                                                  | <input type="checkbox"/>      |
| 5. I agree to my hospital consultant and GP being informed about my participation in this study                                                                                             | <input type="checkbox"/>      |
| 6. I agree to take part in the above study.                                                                                                                                                 | <input type="checkbox"/>      |

Name of patient

Date

Signature

Name of person taking consent

Date

Signature

**Professor Martyn Evans, Consultant Surgeon, Morriston & Singleton Hospital, Swansea. Tel [REDACTED] (to be contacted if there are any problems).**

## APPENDIX F: Clinician information sheet

IRAS ID: 257890



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(v5, 02/2020)

**Study Name - Decision making in pelvic exenteration – patient and clinician perspectives.**

**You are being invited to take part in a research study. Before you make a decision to take part, we would like to explain to you why the study is being carried out, what it will involve and your role. Please read the information leaflet. If there are any aspects of the information sheet that are not clear, then please contact the named health care professionals listed at the end of the sheet.**

### **What is the purpose of the study?**

The aim of this study is to evaluate the decision-making process for both patients and clinicians with patients who are eligible for a pelvic exenteration for locally recurrent or locally advanced rectal cancer. In particular we are interested in the clinician's perspective of the consent process, do you use a shared decision-making process, what information was important to relay to the patient, what treatment option you felt would be most beneficial for the patient. With your hindsight we are keen to analyse what information was or would have been important to you as part of the decision-making process. This will be evaluated during a one off 30–60-minute telephone or face to face interview. The findings from this study will help us understand what factors from the clinician's point of view are important in establishing a treatment plan with a potentially curable patient.

We will also approach you to identify eligible patients to participate in this study, a patient information leaflet is attached. We would ask you to approach your patients on site and recruit locally or alternatively email their details to us at SBUHB to contact the patient for consent to the study if they have already expressed an interest. Patient information will be requested for each recruited patient to include:

- Identifiers – initials and date of birth
- Gender
- Primary cancer
- Adjuvant/neoadjuvant therapy
- Date of surgery/oncological intervention
- Histology if applicable

**Do I have to take part?**

- **You do not have to take part.** However, if you decide to take part you can keep this information sheet, you will be asked to sign a consent form that shows us that you have understood what the study involves and that you are happy to take part.
- You can change your mind and withdraw from the study at any time.

**What will happen if I take part?**

- The study involves an interview that will take 30-60 minutes. It will be recorded in order that it can be analysed adequately.
- The study also involves recruiting patients at your centre who are eligible to participate. A copy of the study protocol is attached for your attention.

**What will I have to do?**

- Once you are happy to participate, we would ask that you sign a consent form to say you are happy to participate.

**What if there is a problem?**

- Any clinical problems will be addressed in the standard manner, no clinical problems will result from this study. Medical staff are available on site 24 hours of the day.
- If you have any concerns about the study, please feel free to contact:

Miss Deena Harji, Chief Investigator, Colorectal Registrar, The Royal Victoria Hospital, Newcastle [REDACTED] or  
Professor Martyn Evans, Co-Investigator, Consultant Surgeon, Morriston Hospital Swansea [REDACTED] to discuss your concerns. If we cannot resolve your concerns or problems, then the hospital has an NHS complaints procedure.

**What are the benefits of taking part?**

- We hope that the study will improve the information that future patients with LARC and LRRC are given and also identify factors for selection criteria to undergo exenterative surgery.

**Will my patients taking part in the study be confidential?**

- Any details about your patients will remain strictly confidential. Data from the study may be used and presented to regulatory bodies; however, all identifiable information will be anonymised.
- Your personal interview regarding decision-making will be also anonymised.

**What will happen to the results of the study?**

- The results of this study will be published locally, nationally and internationally as well as be published within peer reviewed journals.

**Who is organizing the study?**

- The study is being organized by the Department of General and Colorectal Surgery at Swansea Bay University Health Board, Swansea.

**Who has reviewed the study?**

- The South West Wales Research Ethics Committee and the Joint study Review Committee have reviewed the study.

**Contact Information details.**

- The study team contact details are available below. Please contact the team if you have any questions regarding the study. If following the study, you have any symptoms that you think may be related to the study please do not hesitate to contact the team.
- Thank you for considering taking part in this research study. You will receive a copy of this information sheet and a signed consent form to keep should you wish take part.

**Contacts for further information:**

**Miss Deena Harji, Colorectal Registrar, Royal Victoria Hospital, Newcastle Tel**

**[REDACTED]**

**Professor Martyn Evans, Consultant Surgeon, Morriston & Singleton Hospital, Swansea.**

**Tel [REDACTED]**

**Professor Dean Harris, Consultant Surgeon, Morriston & Singleton Hospital, Swansea.**

**Tel [REDACTED]**

Swansea Bay University Health Board (SBUHB) is the sponsor for this study based in the United Kingdom. They will be using information from your medical records in order to undertake this study and will act as the data controller for this study. This means that they are responsible for looking after your information and using it properly. SBUHB will keep any identifiable information about you for five years after the study has finished.

In accordance with new General Data Protection Regulations (GDPR) guidelines, your right to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

You can find out more about how we use your information at:

<http://www.wales.nhs.uk/sitesplus/documents/863/Research%20privacy%20notice%20-%20final.pdf>.



SBUHB will make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from SBUHB and regulatory organisations may look at your medical and research records to check the accuracy of the research study. SBUHB will pass these details to their Research and Development department along with the information collected from your medical records. The only people in SBUHB who access to information will have that identifies you will be people who need to audit the data collection process.

**APPENDIX G: Clinician consent form:**



**GIG**  
CYMRU  
**NHS**  
WALES

Bwrdd Iechyd Prifysgol  
Abertawe Bro Morgannwg  
University Health Board

CONSENT FORM (v4, Apr 2019)

Research Study ID number:

Clinician Identification Number:

**Title of Project: Decision making in pelvic exenteration – patient and clinician perspectives.**

**Name of Chief Investigator:**

**Professor Martyn Evans, Abertawe Bro Morgannwg University Health Board**

**Name of Principal Investigator:**

**Miss Anwen Williams, Abertawe Bro Morgannwg University Health Board**

|                                                                                                                                                                                             | Initials                      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
|                                                                                                                                                                                             | <b>Please initial the box</b> |
| 1. I confirm that I have read and understood the information sheet (v4 04/19) for the above study and have had the opportunity to ask questions and have had these answered satisfactorily. | <input type="checkbox"/>      |
| 2. I confirm that I have had sufficient time to consider whether or not I want to be included in the study.                                                                                 | <input type="checkbox"/>      |
| 3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.                           | <input type="checkbox"/>      |
| 4. I agree to releasing my patients' medical records once patient consent is obtained                                                                                                       | <input type="checkbox"/>      |
| 5. I agree to direct anonymised quotes being used for publication                                                                                                                           | <input type="checkbox"/>      |
| 6. I agree to my interview being recorded and subsequently transcribed for further analysis                                                                                                 | <input type="checkbox"/>      |
| 7. I agree to be contacted via telephone, email and post when appropriate to take part in the above study.                                                                                  | <input type="checkbox"/>      |

Name of Clinician

Date

Signature

**Professor Martyn Evans, Consultant Surgeon, Morriston & Singleton Hospital, Swansea. Tel [REDACTED] (to be contacted if there are any problems)**

# **APPENDIX H: Saturation table of themes for qualitative interviews**

| THEMES               | Group 1                                                                                                                                                                                                                                                                                           | Group 2                                                                                                                    | Group 3                                                                    | Group 4                                                                                  | Group 5        |
|----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|------------------------------------------------------------------------------------------|----------------|
| Communication        | Delayed referral<br>Decision making<br>Pre-op preparation<br>Retaining information<br>Identification of the team<br>Healthcare delivery service<br>Expectations<br>Pre-op symptoms<br>Potential complications                                                                                     | Schedule of events<br>Dismissal<br>Denial of complications<br>Long wait<br>Professional communication<br>Delayed diagnosis | Inaccurate information<br>Lack of information<br>Communication with family | Cancellations<br>Follow-up<br>Delayed presentation<br>Co-morbidities                     | Family history |
| Recovery             | Symptoms – numbness, mobility, GI, GU, vascular, pain, body image<br>Focus of recovery<br>Neoadjuvant chemotherapy side effects<br>pain, skin loss, peripheral neuropathy, cold intolerance<br>Adjuvant chemotherapy side effects – pain, skin loss, hair loss, stoma issues, unexpected recovery | Memory loss<br>Driving<br>Death                                                                                            | Radiotherapy                                                               | Anticipation recovery<br>Return to theatre<br>Discharge<br>Prognosis<br>Positivity staff |                |
| Psychological impact | Pre-operative mental health (anxiety)<br>Fear of recurrence<br>Survivor guilt<br>Control<br>Focus and hope of cure<br>Emotions- regret, fear, anger, numbness, denial, acceptance                                                                                                                 | Cabin fever<br>Independence                                                                                                | Hope                                                                       | Trading places<br>Family history                                                         |                |

|               |                                                                                           |                                                                                    |                                                         |                                                                              |             |
|---------------|-------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------|------------------------------------------------------------------------------|-------------|
|               | Coping strategies<br>Health bargaining<br>Revisiting literature                           |                                                                                    |                                                         |                                                                              |             |
| Relationships | Change of role and relationships<br>Attractiveness and body image<br>Dependence on others | Sexual dysfunction<br>Sexual desire<br>Dependence on others                        | Communication with partner                              | Effect on family                                                             |             |
| Lifestyle     | Change in lifestyle<br>Work<br>Hobbies<br>Exercise                                        | COVID-19<br>Leisure activities                                                     | Change on occupational status<br>Pre-operative symptoms | Motability                                                                   |             |
| Support       | Private healthcare<br>Accommodation<br>Protective equipment<br>Home adaptation            | Sickness benefit<br>Unemployment<br>Clothing<br>Inability to continue in same role |                                                         | Patient advocate<br>Cancer charity<br>COVID<br>Abandonment<br>Family support | School fees |

| THEMES               | Group 6                                             | Group 7                            | Group 8 | Group 9 |
|----------------------|-----------------------------------------------------|------------------------------------|---------|---------|
| Communication        | Peri-op death<br>Prehabilitation                    | Metastectomies                     |         |         |
| Recovery             |                                                     | Disabled<br>Hair loss<br>Fractures |         |         |
| Psychological impact | Motivational goals<br>Accountability<br>Peri-op PPE |                                    |         |         |
| Relationships        | Protection of children                              |                                    |         |         |
| Lifestyle            |                                                     |                                    |         |         |
| Support              |                                                     |                                    |         |         |

## APPENDIX I: Unit responders

| Institution                                                   | Perform PE | Use Literature                      | Copy of literature |
|---------------------------------------------------------------|------------|-------------------------------------|--------------------|
| Swansea                                                       | Yes        | Yes                                 | Yes                |
| St Mark's Hospital, London                                    | Yes        | Yes                                 | Yes                |
| Royal Prince Alfred Hospital, Camperdown, New South Wales     | Yes        | Yes                                 | Yes                |
| imperial                                                      | Yes        | Yes                                 | Yes                |
| Christie                                                      | Yes        | Yes                                 | Yes                |
| Glasgow Royal Infirmary                                       | Yes        | Macmillan                           | No                 |
| Norfolk and Norwich University Hospital                       | Yes        | clinic letter                       | No                 |
| Royal Devon and Exeter Hospital                               | Yes        | clinic letter                       | No                 |
| Addenbrooke's Hospital, Cambridge                             | Yes        | clinic letter                       | No                 |
| St Vincent's University Hospital, Dublin,                     | Yes        | internet based cases                | No                 |
| Southampton General Hospital                                  | Yes        | Yes- intraoperative<br>radiotherapy | Yes                |
| Leeds General Infirmary                                       | Yes        | No                                  | No                 |
| Guy's and St Thomas' Hospital, London                         | Yes        | No                                  | No                 |
| Peter MacCallum Cancer Centre, Melbourne, Victoria, Australia | Yes        | No                                  | No                 |
| Christchurch Hospital, Christchurch, New Zealand              | Yes        | No                                  | No                 |
| Leicester Royal Infirmary                                     | Yes        | No                                  | No                 |
| Royal Infirmary Edinburgh                                     | Yes        | No                                  | No                 |
| The Royal Victoria Infirmary, Newcastle                       | Yes        | No                                  | No                 |
| Raigmore Hospital, Inverness                                  | Yes        | No                                  | No                 |
| The Heart of England Foundation Trust                         | Yes        | No                                  | No                 |
| Queen Elizabeth Hospital, Birmingham                          | Yes        | No                                  | No                 |
| Manchester Royal Infirmary, Manchester                        | Yes        | No                                  | No                 |
| Frimley Health NHS Foundation Trust                           | Yes        | No                                  | No                 |
| Countess of Chester                                           | No         | No                                  | No                 |
| Arrowe Park, Liverpool                                        | No         | No                                  | No                 |
| Royal Victoria hospital, Dundee                               | No         | No                                  | No                 |
| University Hospital of Wales, Cardiff                         | No         | No                                  | No                 |
| University Hospital Monklands, Airdrie                        | No         | No                                  | No                 |
| The Royal Free, London                                        | No         | No                                  | No                 |
| 27 units                                                      |            |                                     |                    |
| <b>Non-responders</b>                                         |            |                                     |                    |
| Royal Marsden Hospital, London                                |            |                                     |                    |

|                                        |  |  |  |
|----------------------------------------|--|--|--|
| Cleveland Clinic, Cleveland, Ohio      |  |  |  |
| St Bartholomew's Hospital, London      |  |  |  |
| Royal Preston Hospital                 |  |  |  |
| Queen's Medical Centre, Nottingham     |  |  |  |
| Aintree University Hospital, Liverpool |  |  |  |
| Royal Derby Hospital                   |  |  |  |

## **APPENDIX J: Semi-structured cognitive interview guide for Agile development of the PtDA**

### **Standard interview questions**

1. Structure and Design
  - a. Is it visually appealing?
  - b. Is it well-structured and easy to follow?
  - c. Is there anything that needs to be changed?
2. Content
  - a. Do you think the content is relevant to patients undergoing PE? Is it acceptable to all patients undergoing PE?
  - b. Is there any important information missing?
3. Acceptability
  - a. Do you think this tool will be useful in clinical consultations to aid decision making?
  - b. Do you think this tool will promote shared decision making?
  - c. (PATIENTS) Do you think this tool will be useful in addition to talking to health care professionals and standard leaflets?
  - d. (MEDICS) What are the challenges/barriers of using this tool in clinic?
4. Comprehensibility
  - a. Do you think this tool is easy to understand?
  - b. Are there any parts of the tool which are confusing or need further clarification?
5. Desirability
  - a. Are there any changes you would like to make to the tool?

## **APPENDIX K: Standardised semi-structured cognitive interview guide for alpha testing**

(adapted from Kelly-Blake's 'Refining a brief decision aid in stable CAD: cognitive interviews')

### **Question 1**

“Please look over the first couple of pages. Take as much time as you would like to look over the pages. As you are doing this, tell me out loud any thoughts that go through your mind as you read every 1–2 pages.”

- . What is new or different about the information presented here from what you already know? Is there any information presented here that you question?
- What have you read here that other patients might find confusing?
- After reading over each section in the booklet:
- What is this section or part of the booklet telling you? Did it hold your attention? Why or why not?

### **Question 2**

“What other thoughts came to mind while you were looking over the booklet that you haven’t shared?”

- What do you think is missing from the booklet?
- What concerns do you think other patients would have that we have not covered?
- What concerns do you think other patients would have that we have covered?
- What do you think the main message was?



## APPENDIX L: QQ-10 questionnaire

QQ-10 Please circle the answers below each of the following 10 statements that best fit your feelings about the questionnaire that you recently completed Please use the boxes at the bottom of the next page to make additional comments

---

### **The PtDA helped me to communicate about my condition**

---

|                   |                 |                               |                    |                      |
|-------------------|-----------------|-------------------------------|--------------------|----------------------|
| Strongly<br>agree | Mostly<br>agree | Neither agree<br>nor disagree | Mostly<br>disagree | Strongly<br>disagree |
|-------------------|-----------------|-------------------------------|--------------------|----------------------|

---

### **The PtDA was relevant to my condition**

---

|                   |                 |                               |                    |                      |
|-------------------|-----------------|-------------------------------|--------------------|----------------------|
| Strongly<br>agree | Mostly<br>agree | Neither agree<br>nor disagree | Mostly<br>disagree | Strongly<br>disagree |
|-------------------|-----------------|-------------------------------|--------------------|----------------------|

---

### **The PtDA was easy to complete**

---

|                   |                 |                               |                    |                      |
|-------------------|-----------------|-------------------------------|--------------------|----------------------|
| Strongly<br>agree | Mostly<br>agree | Neither agree<br>nor disagree | Mostly<br>disagree | Strongly<br>disagree |
|-------------------|-----------------|-------------------------------|--------------------|----------------------|

---

### **The PtDA included all the aspects of my condition that I am concerned about**

---

|                   |                 |                               |                    |                      |
|-------------------|-----------------|-------------------------------|--------------------|----------------------|
| Strongly<br>agree | Mostly<br>agree | Neither agree<br>nor disagree | Mostly<br>disagree | Strongly<br>disagree |
|-------------------|-----------------|-------------------------------|--------------------|----------------------|

---

### **I enjoyed reading the PtDA**

---

|                   |                 |                               |                    |                      |
|-------------------|-----------------|-------------------------------|--------------------|----------------------|
| Strongly<br>agree | Mostly<br>agree | Neither agree<br>nor disagree | Mostly<br>disagree | Strongly<br>disagree |
|-------------------|-----------------|-------------------------------|--------------------|----------------------|

---

### **I would be happy to use the PtDA again in the future as part of my routine care**

---



**Were any of your important symptoms, problems or concerns missed out by the PtDA you used?**

---

**Do you feel that any areas or problems in the PtDA you used were over-represented?**

---

## APPENDIX M: Individual alpha testing feedback

|                        | 1 (F)                                                                                                                                                                                                | 2 (M)                                                                                           | 3 (F)                                                                                 | 4 (M)                                                                                                                                                                                                                 |
|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Content                | <p>Clarify long and short-term symptoms</p> <p>Too much info- Survival 3&amp;5yr</p>                                                                                                                 | <p>Individualise info</p> <p>Add in – perineal numbness<br/>use impotent aids for impotence</p> | <p>Add in – surgeons’ choice what kind of flap<br/>you MAY experience emotions...</p> |                                                                                                                                                                                                                       |
| Layout/design          |                                                                                                                                                                                                      |                                                                                                 |                                                                                       | <p>Front page not appealing – needs to be softened</p> <p>Add questions page at end</p>                                                                                                                               |
| Specific items missing | <p>New info – mention pathological CR maximising recovery</p> <p>More info – LRRC/LARC in flow chart<br/>Menopausal symptoms<br/>IGAP uni or bilateral<br/>CNS support<br/>Central line/catheter</p> |                                                                                                 |                                                                                       | <p>Add in – OOH contact<br/>physios in support<br/>cold extremities ctx<br/>skin soreness rx<br/>permanent stoma<br/>infrequent long-term urostomy leakage<br/>sperm collection prior to surgery<br/>ITU delirium</p> |
| Readability            | <p>Grammar</p> <p>Spelling</p>                                                                                                                                                                       |                                                                                                 |                                                                                       | <p>Clarify ELSIE</p>                                                                                                                                                                                                  |

|           |  |                                                                                                |                                                 |  |
|-----------|--|------------------------------------------------------------------------------------------------|-------------------------------------------------|--|
| Usability |  | I don't think it would be a good document to give to someone without having had a consultation | Needs be clear at what point will this be used? |  |
|-----------|--|------------------------------------------------------------------------------------------------|-------------------------------------------------|--|

|                        |                                                                        |                                                                     |                                               |                           |
|------------------------|------------------------------------------------------------------------|---------------------------------------------------------------------|-----------------------------------------------|---------------------------|
|                        | 5 (M)                                                                  | 6 (F)                                                               | 7 (F)                                         | 8 F (HCP)                 |
| Content                |                                                                        |                                                                     |                                               |                           |
| Layout/design          | Flow chart after discussion of options<br><br>Real life stoma pictures |                                                                     |                                               |                           |
| Specific items missing | Add in –<br>Prehab<br>Aftercare<br>TPN/diet<br>Foot drop aids          | Explain about the space after all the organs have come out          | Add in you may need CT's XR whilst in patient |                           |
| Readability            |                                                                        | Clarify fistula further<br>Clarify collection in pelvis?<br>abscess | Clarify postmenopausal                        | Clarify complete response |
| Usability              |                                                                        |                                                                     |                                               |                           |

|                        | 9 F (HCP)                                                                                    | 10 F | 11 F                        | 12 F                                                               |
|------------------------|----------------------------------------------------------------------------------------------|------|-----------------------------|--------------------------------------------------------------------|
| Content                | Adjuvant chemo 8-12 weeks<br>CNS are funded by Macmillan<br>– no sperate nurse. Remove on p7 |      |                             | Concerns- new diarrhoea –<br>change to change in stoma<br>activity |
| Layout/design          |                                                                                              |      |                             |                                                                    |
| Specific items missing | Explain nursed side to side<br>with flap                                                     |      | Side effects adjuvant chemo | Help at home                                                       |
| Readability            |                                                                                              |      |                             | ELSIE doesn't mean anything<br>to patients                         |
| Usability              |                                                                                              |      |                             |                                                                    |

|                           | 13 M (HCP)                                                                                                             | 14 M                               | 15 F | 16 F (HCP)                                                                              |
|---------------------------|------------------------------------------------------------------------------------------------------------------------|------------------------------------|------|-----------------------------------------------------------------------------------------|
| Content                   | Remove cystoprostatectomy –<br>not for rectal and add in TPE<br>and sacrectomy illustration                            |                                    |      | National trials – clinical trials                                                       |
| Layout/design             | Scale the stoma bag                                                                                                    |                                    |      | Table of options – rotate 180<br>degrees                                                |
| Specific items<br>missing | Reasons for not choosing<br>surgery 'not fit for major<br>surgery'<br><br>Sacrectomy – chronic wound,<br>wound healing |                                    |      | Reasons for not choosing<br>surgery 'don't find the idea of<br>major surgery appealing' |
| Readability               | % should read x in y                                                                                                   | Qualify long and short term<br>QoL |      |                                                                                         |

|           |                                                                                                                                                                        |  |  |  |
|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|
|           | <p>Supportive rx will help to control sx</p> <p>Bag sticks to the skin</p> <p>Flap may die – lose blood supply</p> <p>Disfigured from donor site – look different?</p> |  |  |  |
| Usability |                                                                                                                                                                        |  |  |  |

|         |                                                                                                                                                                                                                                                                                                                                                     |                                                                                              |      |                                                                                       |
|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|------|---------------------------------------------------------------------------------------|
|         | 17 M (HCP)                                                                                                                                                                                                                                                                                                                                          | 18 M (HCP)                                                                                   | 19 M | 20 F                                                                                  |
| Content | <p>Palliative chemorad is a treatment – maybe do they want treatment where curative, or palliative is the qu in flow chart?</p> <p>Poor response can still have surgery</p> <p>Palliative surgery is an option in some cases</p> <p>Phrase it to use at neoadjuvant chemorad phase. Oncological treatment to include neoadjuvant and palliative</p> | <p>P 17 regardless of menopause should read ‘you will no longer be able to get pregnant’</p> |      | <p>Highlight that you may experience emotional changes not necessarily experience</p> |

|                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                  |                                                               |                                                   |
|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|---------------------------------------------------|
| Layout/design          | <p>P12 and p30 repetitive. Info p30 needs to read earlier with p12</p> <p>Remove ELSIE – separate vessels, nerves, lymph nodes</p>                                                                                                                                                                                                                                                                                                                                                   | <p>Timescale short and long term QoL and rephrase to ‘consequences’</p> <p>Navigate sections of organ removal to further info e.g. vagina to sexual changes, recon surgery to recon section</p>                                  |                                                               |                                                   |
| Specific items missing | <p>Pain is normal after major surgery</p> <p>Physical changes – n&amp;V, poor sleep, delirium, wt loss need for nutrition in short term</p> <p>Need to clarify that the surgeon will decide if a flap is appropriate</p> <p>Explain mechanical aids for ED in men in sexual changes</p> <p>TPN</p> <p>Sate stoma is usually permanent</p> <p>Risks – anastomotic leak and add in urostomy</p> <p>Highlight different flaps but the surgeon will choose which one will be offered</p> | <p>Bones missing in male version for organs</p> <p>Highlight that the tumour, prev rtx and surgery will affect your ability and desire to have sex</p> <p>Highlight you MAY experience a change in relationships with people</p> | Explain that some men feel less of a man in emotional changes | Urine will look and smell different with urostomy |



|             |                                                                                                                                   |                                                                                   |                                 |                                                                                                       |
|-------------|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|---------------------------------|-------------------------------------------------------------------------------------------------------|
|             | Risks of complications will depend on age, other medical conditions and the type of operation                                     |                                                                                   |                                 |                                                                                                       |
| Readability | <p>‘every person’ not every man/woman</p> <p>Return to baseline 12 months</p> <p>Having an acceptable rather than certain QoL</p> | Sexual changes - unable to get an erection naturally. State they will be impotent | P 22 – infusing to ‘giving you’ | In support – more positivity – highlight that your team will support you, will do everything possible |
| Usability   |                                                                                                                                   |                                                                                   |                                 |                                                                                                       |

|                        |     |                                                                                                                                                                                                             |                                                                                     |                                                              |
|------------------------|-----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------------|
|                        | 21M | 22 F                                                                                                                                                                                                        | 23 F (HCP)                                                                          | 24 M (HCP)                                                   |
| Content                |     |                                                                                                                                                                                                             |                                                                                     |                                                              |
| Layout/design          |     |                                                                                                                                                                                                             | <p>Rarely remove introitus</p> <p>Add penis to illustrations to avoid confusion</p> |                                                              |
| Specific items missing |     | <p>Physio in support for surgery</p> <p>Clothing support</p> <p>Bladder – long term infrequent leaking</p> <p>Feel swollen which can change sitting following flap</p> <p>Leakage of fluid through flap</p> |                                                                                     | Name different flaps otherwise doesn’t mean much to patients |

|             |  |                           |  |  |
|-------------|--|---------------------------|--|--|
|             |  | Helping your own recovery |  |  |
| Readability |  |                           |  |  |
| Usability   |  |                           |  |  |

|                        |                                |      |      |      |
|------------------------|--------------------------------|------|------|------|
|                        | 25 F (HCP)                     | 26 M | 27 F | 28 M |
| Content                |                                |      |      |      |
| Layout/design          |                                |      |      |      |
| Specific items missing |                                |      |      |      |
| Readability            | Abdomen p 12 should have tummy |      |      |      |
| Usability              |                                |      |      |      |

**APPENDIX N: QQ-10 individual responses (green= value domains, red = burden domains)**

| <b>Patient</b> | <b>Help<br/>communicate</b> | <b>Relevant<br/>to my<br/>condition</b> | <b>Easy<br/>to<br/>read</b> | <b>Included all<br/>aspects that I<br/>am<br/>concerned<br/>about</b> | <b>Enjoyed<br/>reading</b> | <b>Happy<br/>to use<br/>again</b> | <b>Too<br/>long</b> | <b>Too<br/>embarrassing</b> | <b>Too<br/>complicated</b> | <b>Upset<br/>me</b> |
|----------------|-----------------------------|-----------------------------------------|-----------------------------|-----------------------------------------------------------------------|----------------------------|-----------------------------------|---------------------|-----------------------------|----------------------------|---------------------|
| <b>1</b>       | 4                           | 4                                       | 4                           | 4                                                                     | 4                          | 4                                 | 0                   | 0                           | 0                          | 0                   |
| <b>2</b>       | 3                           | 4                                       | 2                           | 2                                                                     | 2                          | 4                                 | 0                   | 0                           | 0                          | 2                   |
| <b>3</b>       | 4                           | 4                                       | 4                           | 3                                                                     | 3                          | 4                                 | 1                   | 0                           | 0                          | 0                   |
| <b>4</b>       | 4                           | 4                                       | 4                           | 4                                                                     | 4                          | 4                                 | 0                   | 0                           | 0                          | 0                   |
| <b>5</b>       | 3                           | 4                                       | 3                           | 3                                                                     | 3                          | 4                                 | 0                   | 0                           | 0                          | 1                   |
| <b>6</b>       | 4                           | 4                                       | 4                           | 4                                                                     | 3                          | 4                                 | 2                   | 0                           | 1                          | 0                   |
| <b>7</b>       | 4                           | 4                                       | 4                           | 4                                                                     | 4                          | 4                                 | 0                   | 0                           | 0                          | 0                   |
| <b>8</b>       | 4                           | 4                                       | 4                           | 3                                                                     | 3                          | 4                                 | 1                   | 1                           | 0                          | 0                   |
| <b>9</b>       | 3                           | 3                                       | 3                           | 2                                                                     | 2                          | 2                                 | 0                   | 0                           | 0                          | 0                   |
| <b>10</b>      | 4                           | 4                                       | 4                           | 4                                                                     | 4                          | 4                                 | 3                   | 0                           | 0                          | 3                   |
| <b>11</b>      | 4                           | 4                                       | 4                           | 4                                                                     | 4                          | 4                                 | 0                   | 0                           | 0                          | 0                   |
| <b>12</b>      | 2                           | 4                                       | 4                           | 3                                                                     | 3                          | 4                                 | 2                   | 0                           | 0                          | 0                   |
| <b>13</b>      | 4                           | 4                                       | 4                           | 4                                                                     | 2                          | 4                                 | 0                   | 0                           | 0                          | 2                   |
| <b>14</b>      | 4                           | 4                                       | 4                           | 4                                                                     | 5                          | 4                                 | 0                   | 0                           | 0                          | 0                   |
| <b>15</b>      | 3                           | 4                                       | 3                           | 3                                                                     | 1                          | 2                                 | 2                   | 1                           | 1                          | 3                   |
| <b>16</b>      | 4                           | 4                                       | 4                           | 4                                                                     | 4                          | 4                                 | 0                   | 0                           | 0                          | 0                   |
| <b>17</b>      | 2                           | 4                                       | 4                           | 4                                                                     | 2                          | 4                                 | 0                   | 0                           | 0                          | 1                   |
| <b>18</b>      | 3                           | 4                                       | 3                           | 3                                                                     | 2                          | 4                                 | 0                   | 0                           | 0                          | 0                   |
| <b>19</b>      | 4                           | 4                                       | 4                           | 3                                                                     | 3                          | 4                                 | 1                   | 0                           | 0                          | 0                   |
| <b>MEDIAN</b>  | 4                           | 4                                       | 4                           | 4                                                                     | 3                          | 4                                 | 0                   | 0                           | 0                          | 0                   |

## APPENDIX O: EORTC PATSAT-C33 questionnaire

ENGLISH



### **EORTC PATSAT-C33**

We are interested in your MOST RECENT experience of the care received in this hospital service or clinic. Please answer all the questions yourself by circling the number that best applies to you. There are no 'right' or 'wrong' answers. The information that you provide will remain strictly confidential.

Please indicate the hospital service or clinic you are assessing (select only one of them):

If inpatient care: ☐

If outpatient care: ☐

| In this hospital, how would you rate <u>doctors</u> in terms of:                                             | Poor | Fair | Good | Very good | Excellent |     |
|--------------------------------------------------------------------------------------------------------------|------|------|------|-----------|-----------|-----|
| 1. Their awareness of the care and treatment you received previously?                                        | 1    | 2    | 3    | 4         | 5         |     |
| 2. The attention they gave to your physical symptoms?                                                        | 1    | 2    | 3    | 4         | 5         | N/A |
| 3. Their thoroughness in treating your physical symptoms?                                                    | 1    | 2    | 3    | 4         | 5         | N/A |
| 4. The information they gave you about your illness?                                                         | 1    | 2    | 3    | 4         | 5         | N/A |
| 5. The information they gave you about your medical tests and treatment?                                     | 1    | 2    | 3    | 4         | 5         | N/A |
| 6. The attention they gave to your opinion about the choice of your treatment (in case of possible choices)? | 1    | 2    | 3    | 4         | 5         | N/A |
| 7. The interest they showed in you as a person?                                                              | 1    | 2    | 3    | 4         | 5         |     |
| 8. The comfort and support they gave you?                                                                    | 1    | 2    | 3    | 4         | 5         |     |
| 9. The frequency of their visits/consultations?                                                              | 1    | 2    | 3    | 4         | 5         |     |
| 10. The time they devoted to you?                                                                            | 1    | 2    | 3    | 4         | 5         |     |

Please go on to the next page

**In this hospital, how would you rate nurses or radiotherapy technicians in terms of:**

Poor Fair Good Very good Excellent

Please indicate the professional(s) you evaluate:

- ☐ Nurse(s)  
☐ Radiotherapy technician(s)

|                                                                  |   |   |   |   |   |     |
|------------------------------------------------------------------|---|---|---|---|---|-----|
| 11. The attention they gave to your physical comfort?            | 1 | 2 | 3 | 4 | 5 | N/A |
| 12. The information they gave you about your care and treatment? | 1 | 2 | 3 | 4 | 5 | N/A |
| 13. The advice they gave you on managing your physical symptoms? | 1 | 2 | 3 | 4 | 5 | N/A |
| 14. The interest they showed in you as a person?                 | 1 | 2 | 3 | 4 | 5 | N/A |
| 15. The comfort and support they gave you?                       | 1 | 2 | 3 | 4 | 5 | N/A |
| 16. Their promptness in answering your specific requests?        | 1 | 2 | 3 | 4 | 5 | N/A |
| 17. The time they devoted to you?                                | 1 | 2 | 3 | 4 | 5 | N/A |

**In this hospital, how would you rate services & care organisation, in terms of:**

Poor Fair Good Very good Excellent

|                                                                                                                                                                        |   |   |   |   |   |     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|---|---|---|---|-----|
| 18. The ease of recognizing the roles and responsibilities of the different caregivers (doctors, nurses, physiotherapists, psychologists, etc.) involved in your care? | 1 | 2 | 3 | 4 | 5 |     |
| 19. The exchange of information between the different caregivers (doctors, nurses, physiotherapists, psychologists, etc.)?                                             | 1 | 2 | 3 | 4 | 5 |     |
| 20. The way doctors, nurses and other caregivers involved in your care seem to work together as a team?                                                                | 1 | 2 | 3 | 4 | 5 |     |
| 21. The exchange of information with other care services in the community (general practitioner, home care, nursing house, social services, etc.)?                     | 1 | 2 | 3 | 4 | 5 | N/A |
| 22. The kindness and helpfulness of the technical, reception, laboratory personnel, etc.?                                                                              | 1 | 2 | 3 | 4 | 5 |     |
| 23. The information provided on the scheduling of medical tests, treatment or care?                                                                                    | 1 | 2 | 3 | 4 | 5 |     |

Please go on to the next page

| <b>In this hospital, how would you<br/>rate <u>services &amp; care organisation</u>, in terms of:</b>                                                      | <b>Poor</b> | <b>Fair</b> | <b>Good</b> | <b>Very<br/>good</b> | <b>Excellent</b> |     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|-------------|-------------|----------------------|------------------|-----|
| 24. The information provided on the overall supportive services available (social, psychological, physiotherapy, dietitian services, support group, etc.)? | 1           | 2           | 3           | 4                    | 5                |     |
| 25. The information provided by doctors, nurses and other caregivers on things you could do to improve your health or prevent illness?                     | 1           | 2           | 3           | 4                    | 5                |     |
| 26. The waiting time for obtaining results of medical tests?                                                                                               | 1           | 2           | 3           | 4                    | 5                | N/A |
| 27. The waiting time for undergoing medical tests and/or treatments?                                                                                       | 1           | 2           | 3           | 4                    | 5                |     |
| 28. The privacy given when you were examined or treated?                                                                                                   | 1           | 2           | 3           | 4                    | 5                |     |
| 29. The opportunity for your family or those close to you to be involved in your care (talking to doctors, receiving disease and care information, etc.)?  | 1           | 2           | 3           | 4                    | 5                | N/A |
| 30. The ease of access (parking, means of transport, etc.)?                                                                                                | 1           | 2           | 3           | 4                    | 5                |     |
| 31. The ease of finding your way to the different departments in the hospital?                                                                             | 1           | 2           | 3           | 4                    | 5                |     |
| 32. The environment of the building (cleanness, spaciousness, calmness, etc.)?                                                                             | 1           | 2           | 3           | 4                    | 5                |     |
| <b>In general,</b>                                                                                                                                         |             |             |             |                      |                  |     |
| 33. How would you rate the care you received in this hospital?                                                                                             | 1           | 2           | 3           | 4                    | 5                |     |

## APPENDIX P: Prep-DM questionnaire

### Preparation for Decision Making Scale

Please indicate your opinion about the effect of the educational material by circling the appropriate number to show the extent to which you agree with each statement.

| Did this educational material . . . |                                                                      | Not at all | A little | Some-<br>what | Quite a<br>bit | A great<br>deal |
|-------------------------------------|----------------------------------------------------------------------|------------|----------|---------------|----------------|-----------------|
| 1.                                  | Help you recognize that a decision needs to be made?                 | 1          | 2        | 3             | 4              | 5               |
| 2.                                  | Prepare you to make a better decision?                               | 1          | 2        | 3             | 4              | 5               |
| 3.                                  | Help you think about the pros and cons of each option?               | 1          | 2        | 3             | 4              | 5               |
| 4.                                  | Help you think about which pros and cons are most important?         | 1          | 2        | 3             | 4              | 5               |
| 5.                                  | Help you know that the decision depends on what matters most to you? | 1          | 2        | 3             | 4              | 5               |
| 6.                                  | Help you organize your own thoughts about the decision?              | 1          | 2        | 3             | 4              | 5               |
| 7.                                  | Help you think about how involved you want to be in this decision?   | 1          | 2        | 3             | 4              | 5               |
| 8.                                  | Help you identify questions you want to ask your doctor?             | 1          | 2        | 3             | 4              | 5               |
| 9.                                  | Prepare you to talk to your doctor about what matters most to you?   | 1          | 2        | 3             | 4              | 5               |
| 10.                                 | Prepare you for a follow-up visit with your doctor?                  | 1          | 2        | 3             | 4              | 5               |

Preparation for Decision Making Scale © ID Graham, AM O'Connor 1996, revised 2005 University of Ottawa

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## APPENDIX Q: NoMAD questionnaire



### Survey Instructions

**This survey is designed to help get a better understanding of how to apply and integrate new technologies and complex interventions in health care.**

This survey asks questions about the implementation of **[the intervention]**. We understand that people involved with **[the intervention]** have different roles, and that people may have more than one role.

From the statements below please choose an option that best describes ***your main role*** in relation to **[the intervention]**:

- **I am involved in managing or overseeing [the intervention]** ☐
- **I am involved in delivering [the intervention]** ☐

For this survey, please answer all the statements from the perspective of this role. Depending on your role or responsibilities in [the intervention], some statements may be more relevant than others.

The survey is in 3 parts. Part A asks some brief questions about yourself and your role. Part B includes three general questions about **[the intervention]**. Part C contains a set of more detailed questions about **[the intervention]**. For each statement in Part C, there is the option to agree or disagree with what is being asked **(OPTION A)**. However, if you feel that the statement is not relevant to you, there are also options to tell us why **(OPTION B)**.

Please take the time to decide which answer **best suits your experience for each statement and tick the appropriate circle.**

Copyright © Newcastle University 2014. Please reference as: Finch et al., 2013. Improving the normalization of complex interventions: measure development based on normalization process theory (NoMAD): study protocol. Implementation Science 2013, 8:43. Development of this survey was funded by the Economic and Social Research Council: Study Grant RFS-062-23-3274.



**Part A: About yourself**

**1. How many years have you worked for this Trust? (If your Trust has merged with another or changed its name, please include in your answer all the time you have worked with this Trust and its predecessors)**

- ☐ Less than one year    ☐ 1-2 years    ☐ 3-5 years    ☐ 6-10 years    ☐ 11-15 years    ☐ More than 15 years

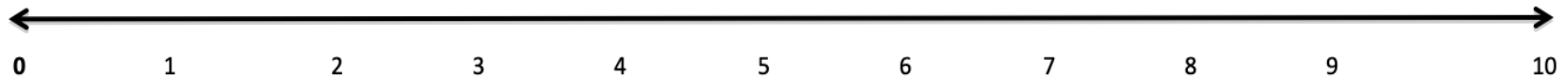
**2. How would you describe your professional job category?**

## Part B: General questions about the intervention

When you use [the intervention], how familiar does it feel?

Still feels very new

Feels completely familiar

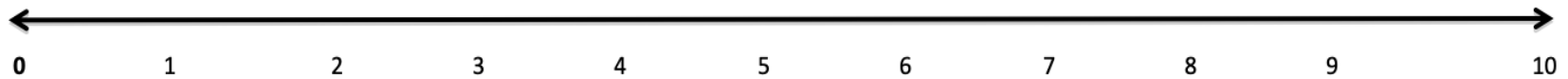


Do you feel [the intervention] is currently a normal part of your work?

Not at all

Somewhat

Completely

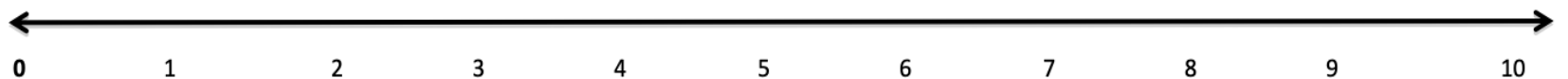


Do you feel [the intervention] will become a normal part of your work?

Not at all

Somewhat

Completely



## Part C: Detailed questions about the intervention

For each statement please select an answer that best suits your experience using Option A. If the statement is not relevant to you please select an answer from Option B.



| Section 1 |                                                                                             | Option A              |                       |                            |                       |                       | Option B                |                            |                                  |
|-----------|---------------------------------------------------------------------------------------------|-----------------------|-----------------------|----------------------------|-----------------------|-----------------------|-------------------------|----------------------------|----------------------------------|
|           |                                                                                             | Strongly Agree        | Agree                 | Neither agree nor disagree | Disagree              | Strongly disagree     | Not relevant to my role | Not relevant at this stage | Not relevant to the intervention |
| 1.        | I can see how [the intervention] differs from usual ways of working                         | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/>      | <input type="radio"/>            |
| 2.        | Staff in this organisation have a shared understanding of the purpose of [the intervention] | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/>      | <input type="radio"/>            |
| 3.        | I understand how [the intervention] affects the nature of my own work                       | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/>      | <input type="radio"/>            |
| 4.        | I can see the potential value of [the intervention] for my work                             | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/>      | <input type="radio"/>            |



For each statement please select an answer that best suits your experience using Option A. If the statement is not relevant to you please select an answer from Option B.

| Section 2 |                                                                                    | Option A              |                       |                            |                       |                       | Option B                |                            |                                  |
|-----------|------------------------------------------------------------------------------------|-----------------------|-----------------------|----------------------------|-----------------------|-----------------------|-------------------------|----------------------------|----------------------------------|
|           |                                                                                    | Strongly Agree        | Agree                 | Neither agree nor disagree | Disagree              | Strongly disagree     | Not relevant to my role | Not relevant at this stage | Not relevant to the intervention |
| 1.        | There are key people who drive [the intervention] forward and get others involved  | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/>      | <input type="radio"/>            |
| 2.        | I believe that participating in [the intervention] is a legitimate part of my role | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/>      | <input type="radio"/>            |
| 3.        | I'm open to working with colleagues in new ways to use [the intervention]          | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/>      | <input type="radio"/>            |
| 4.        | I will continue to support [the intervention]                                      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/>      | <input type="radio"/>            |

For each statement please select an answer that best suits your experience using Option A. If the statement is not relevant to you please select an answer from Option B.

| Section 4 |                                                                           | Option A              |                       |                            |                       |                       | Option B                |                            |                                  |
|-----------|---------------------------------------------------------------------------|-----------------------|-----------------------|----------------------------|-----------------------|-----------------------|-------------------------|----------------------------|----------------------------------|
|           |                                                                           | Strongly Agree        | Agree                 | Neither agree nor disagree | Disagree              | Strongly disagree     | Not relevant to my role | Not relevant at this stage | Not relevant to the intervention |
| 1.        | I am aware of reports about the effects of [the intervention]             | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/>      | <input type="radio"/>            |
| 2.        | The staff agree that [the intervention] is worthwhile                     | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/>      | <input type="radio"/>            |
| 3.        | I value the effects that [the intervention] has had on my work            | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/>      | <input type="radio"/>            |
| 4.        | Feedback about [the intervention] can be used to improve it in the future | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/>      | <input type="radio"/>            |
| 5.        | I can modify how I work with [the intervention]                           | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/>      | <input type="radio"/>            |

For each statement please select an answer that best suits your experience using Option A. If the statement is not relevant to you please select an answer from Option B.

| Section 3 |                                                                                 | Option A              |                       |                            |                       |                       | Option B                |                            |                                  |
|-----------|---------------------------------------------------------------------------------|-----------------------|-----------------------|----------------------------|-----------------------|-----------------------|-------------------------|----------------------------|----------------------------------|
|           |                                                                                 | Strongly Agree        | Agree                 | Neither agree nor disagree | Disagree              | Strongly disagree     | Not relevant to my role | Not relevant at this stage | Not relevant to the intervention |
| 1.        | I can easily integrate [the intervention] into my existing work                 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/>      | <input type="radio"/>            |
| 2.        | [The intervention] disrupts working relationships                               | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/>      | <input type="radio"/>            |
| 3.        | I have confidence in other people's ability to use [the intervention]           | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/>      | <input type="radio"/>            |
| 4.        | Work is assigned to those with skills appropriate to [the intervention]         | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/>      | <input type="radio"/>            |
| 5.        | Sufficient training is provided to enable staff to implement [the intervention] | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/>      | <input type="radio"/>            |
| 6.        | Sufficient resources are available to support [the intervention]                | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/>      | <input type="radio"/>            |
| 7.        | Management adequately supports [the intervention]                               | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/>   | <input type="radio"/>      | <input type="radio"/>            |

# **APPENDIX R: Pre-implementation PATSAT-C33 responses**

| <b>Variables N=24 (%)</b>                                                     | <b>Poor</b> | <b>Fair</b> | <b>Good</b> | <b>Very good</b> | <b>Excellent</b> |
|-------------------------------------------------------------------------------|-------------|-------------|-------------|------------------|------------------|
| Doctors' technical skills (items 1–3)                                         | 0 (0)       | 0 (0)       | 9 (13)      | 18 (25)          | 45 (62)          |
| Doctors' information exchange (items 4–6)                                     | 0 (0)       | 0 (0)       | 3 (4)       | 27 (37)          | 42 (59)          |
| Doctors' affective behaviour (items 7–10)                                     | 0 (0)       | 5 (5)       | 19 (20)     | 19 (20)          | 53 (55)          |
| Overall satisfaction with nurses' service (items 11–17)                       | 0 (0)       | 0 (0)       | 15 (9)      | 46 (28)          | 107 (63)         |
| Coordination (items 18–21)                                                    | 0 (0)       | 1 (1)       | 15 (15)     | 44 (46)          | 36 (38)          |
| Interaction with health-care teams (items 22–28)                              | 2 (2)       | 10 (6)      | 37 (22)     | 59 (35)          | 60 (35)          |
| <b>Single items</b>                                                           |             |             |             |                  |                  |
| Opportunity to be involved in their care (item 29)                            | 4 (17)      | 1 (4)       | 0 (0)       | 9 (37)           | 10 (42)          |
| Ease of access to the hospital (item 30)                                      | 0           | 5 (21)      | 7 (29)      | 10 (42)          | 2 (8)            |
| Ease of finding different departments (item 31)                               | 4 (17)      | 0           | 5 (21)      | 10 (42)          | 5 (21)           |
| Environment of the building (item 32)                                         | 0           | 0           | 5 (21)      | 13 (54)          | 6 (25)           |
| In general, how do you rate the care you received from the hospital (item 33) | 0           | 0           | 3 (13)      | 9 (37)           | 12 (50)          |

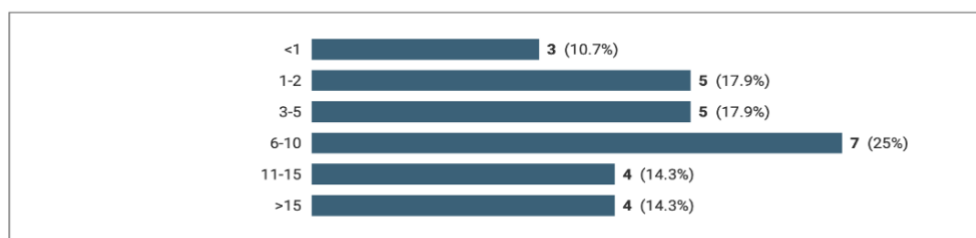
# **APPENDIX S: Post implementation PATSAT-C33 responses**

| <b>Variables N=22 (%)</b>                                                     | <b>Poor</b> | <b>Fair</b> | <b>Good</b> | <b>Very good</b> | <b>Excellent</b> |
|-------------------------------------------------------------------------------|-------------|-------------|-------------|------------------|------------------|
| Doctors' technical skills (items 1–3)                                         | 0 (0)       | 0 (0)       | 0 (0)       | 12 (18)          | 54 (82)          |
| Doctors' information exchange (items 4–6)                                     | 0 (0)       | 0 (0)       | 0 (0)       | 4 (6)            | 62 (94)          |
| Doctors' affective behaviour (items 7–10)                                     | 0 (0)       | 0 (0)       | 0 (0)       | 9 (10)           | 78 (90)          |
| Overall satisfaction with nurses' service (items 11–17)                       | 0 (0)       | 0 (0)       | 2 (1)       | 21(14)           | 131 (85)         |
| Coordination (items 18–21)                                                    | 0 (0)       | 0 (0)       | 3 (4)       | 14 (16)          | 71 (80)          |
| Interaction with health-care teams (items 22–28)                              | 0 (0)       | 0 (0)       | 1 (1)       | 18 (12)          | 135 (87)         |
| <b>Single items</b>                                                           |             |             |             |                  |                  |
| Opportunity to be involved in their care (item 29)                            | 0 (0)       | 0 (0)       | 0 (0)       | 1 (5)            | 21 (95)          |
| Ease of access to the hospital (item 30)                                      | 0 (0)       | 0 (0)       | 0 (0)       | 6 (27)           | 16 (73)          |
| Ease of finding different departments (item 31)                               | 0 (0)       | 0 (0)       | 2 (9)       | 4 (17)           | 16 (73)          |
| Environment of the building (item 32)                                         | 0 (0)       | 0 (0)       | 0 (0)       | 6 (27)           | 16 (73)          |
| In general, how do you rate the care you received from the hospital (item 33) | 0 (0)       | 0 (0)       | 0 (0)       | 1 (5)            | 21 (95)          |



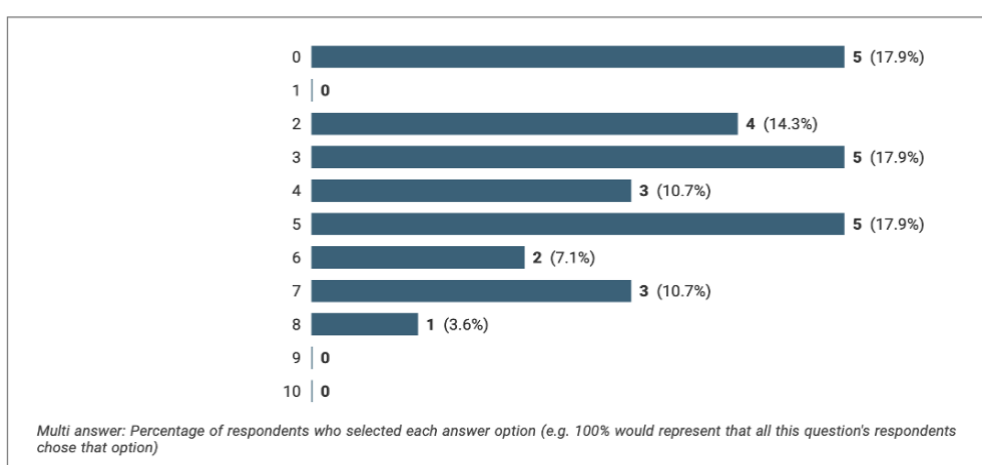
## APPENDIX T: NoMAD Responses

- 1** How many years have you worked for your organisation? (If your Trust has merged with another or changed its name, please include in your answer all the time you have worked for this Trust and its predecessors)



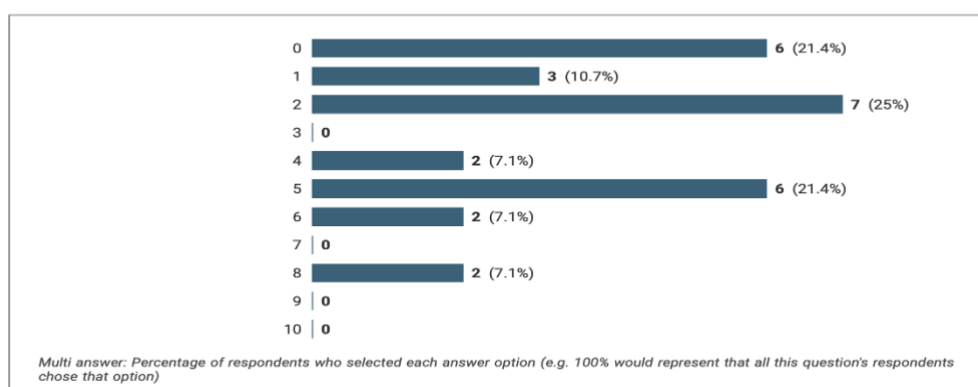
- 2** When you use the PtDA how familiar does it feel?

### 2.1 Still very new vs Feels completely familiar

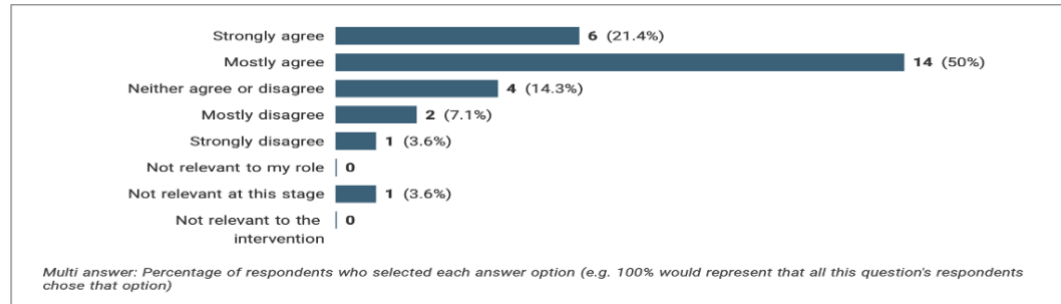


- 3** Do you feel the PtDA is currently a normal part of your work?

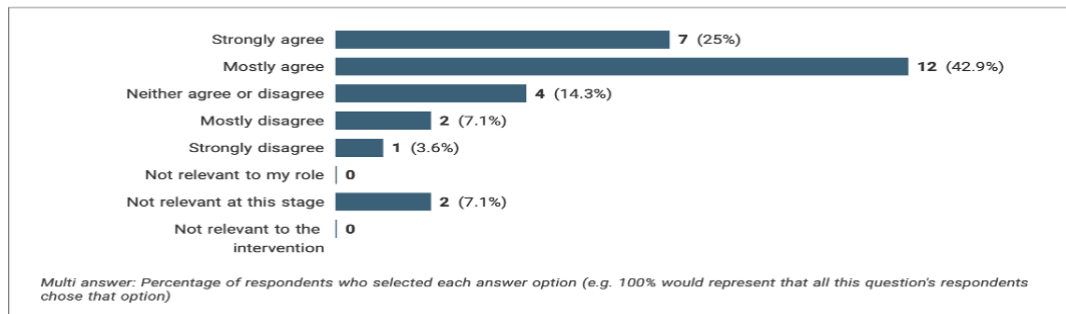
### 3.1 Not at all vs Completely



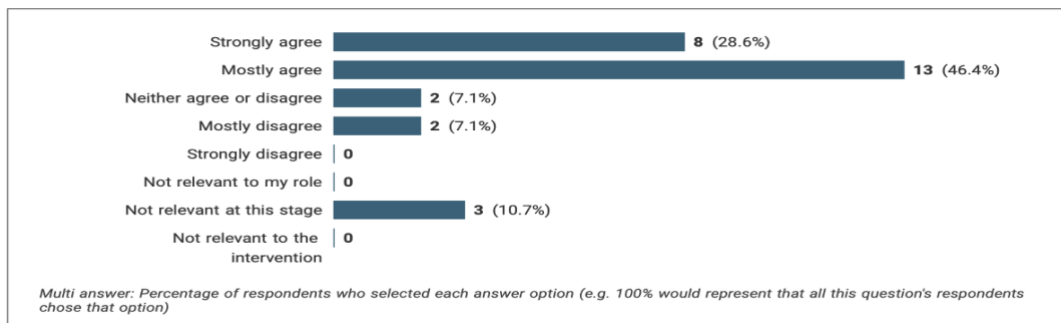
5.1 I can see how the PtDA differs from usual ways of working



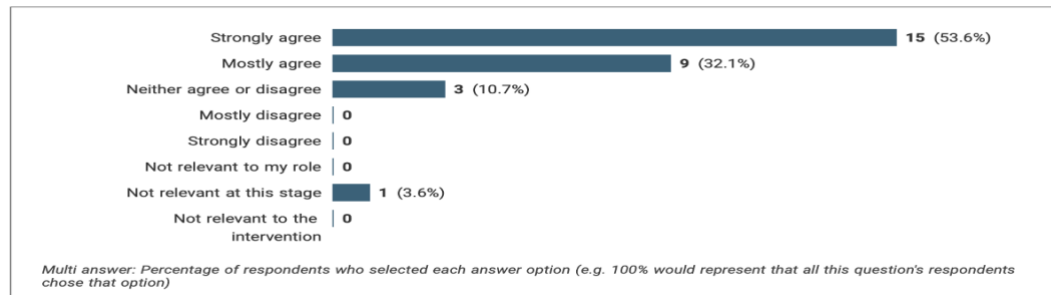
5.2 Staff in this organisation have a shared understanding of the purpose of the PtDA



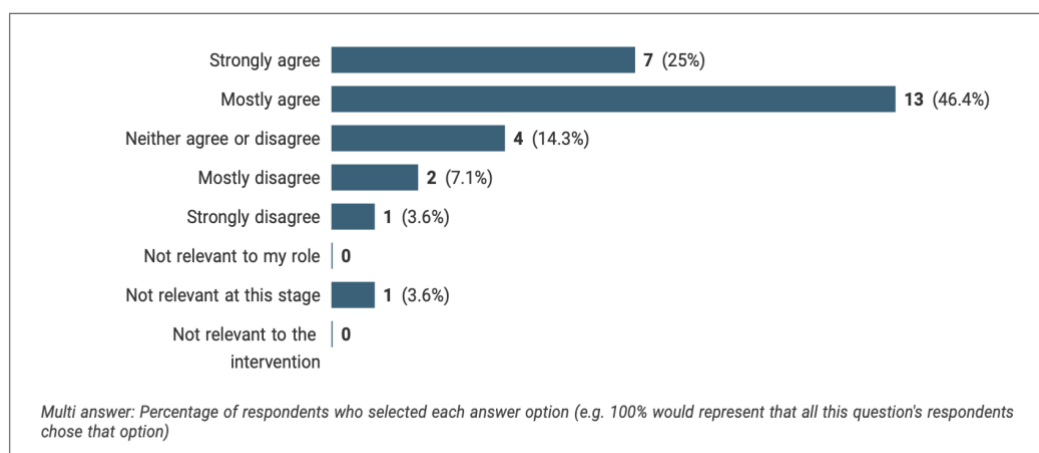
5.3 I understand how the PtDA affects the nature of my own work



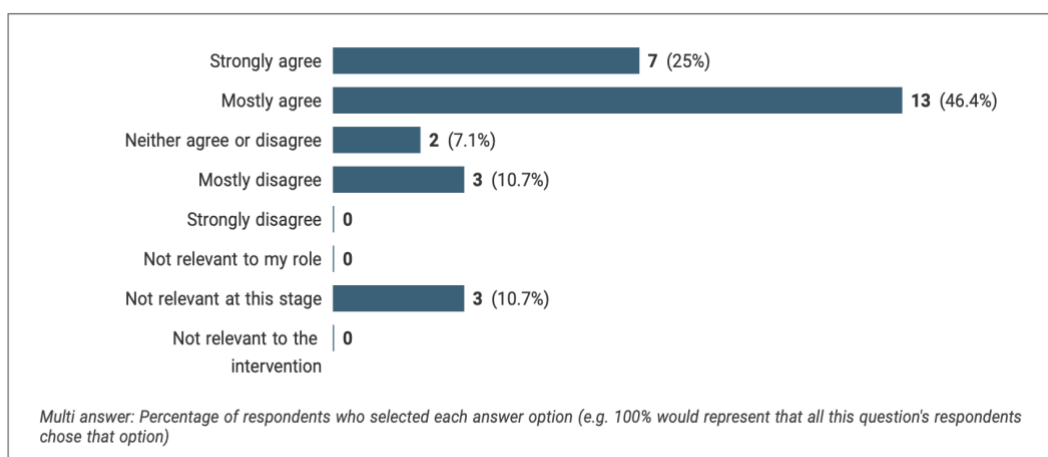
5.4 I can see the potential value of the PtDA for my work



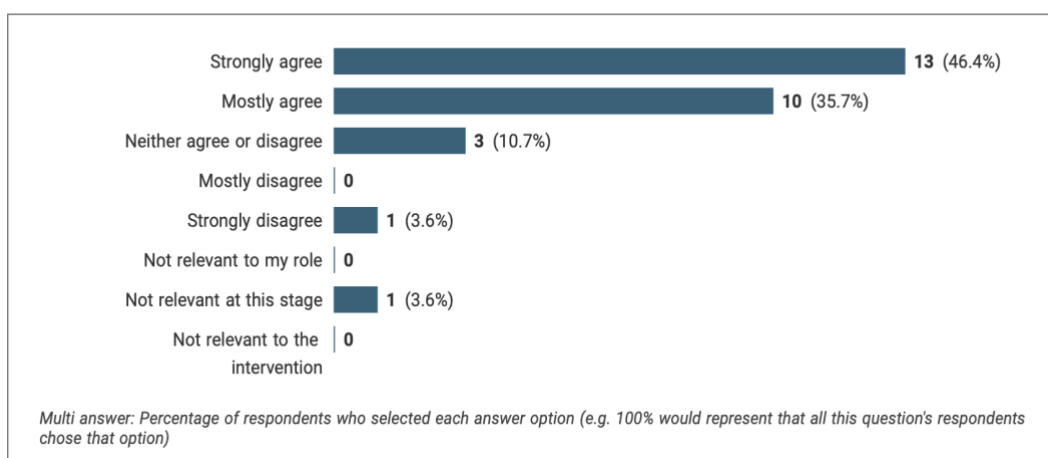
6.1 I can see how the PtDA differs from usual ways of working



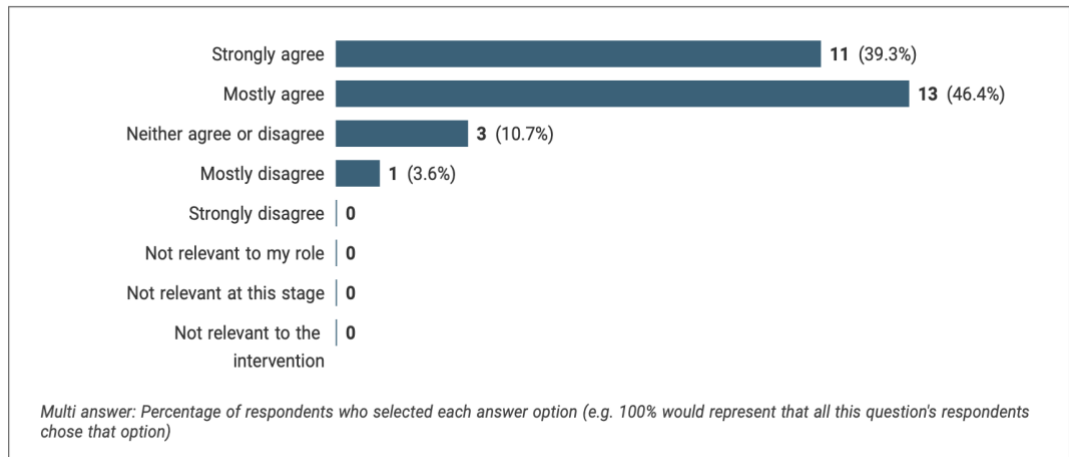
6.3 I understand how thePtDA affects the nature of my own work



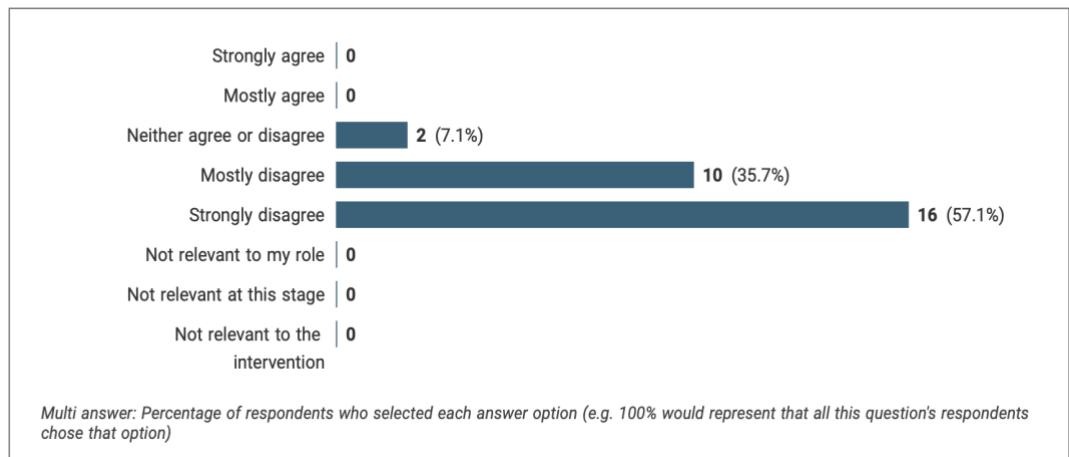
6.4 I can see the potential value of the PtDA for my work



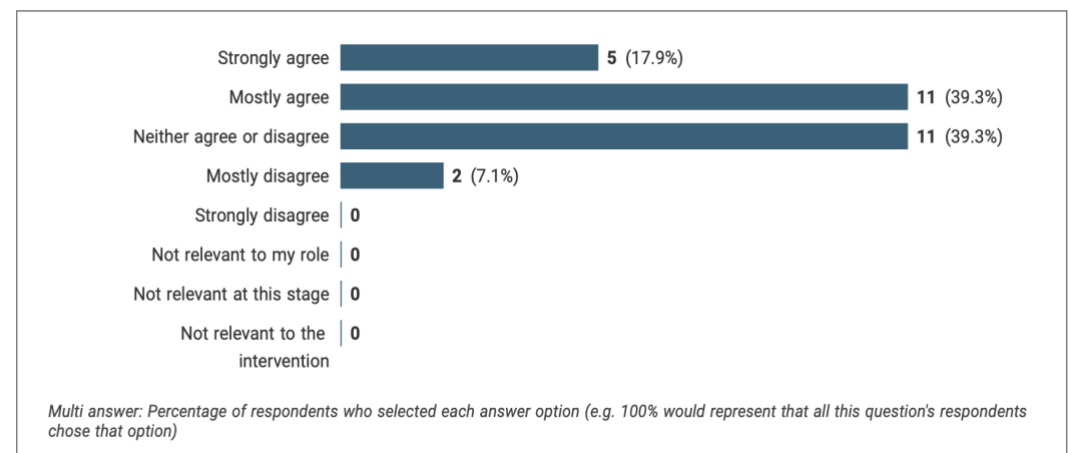
7.1 I can easily integrate the PtDA into my existing work



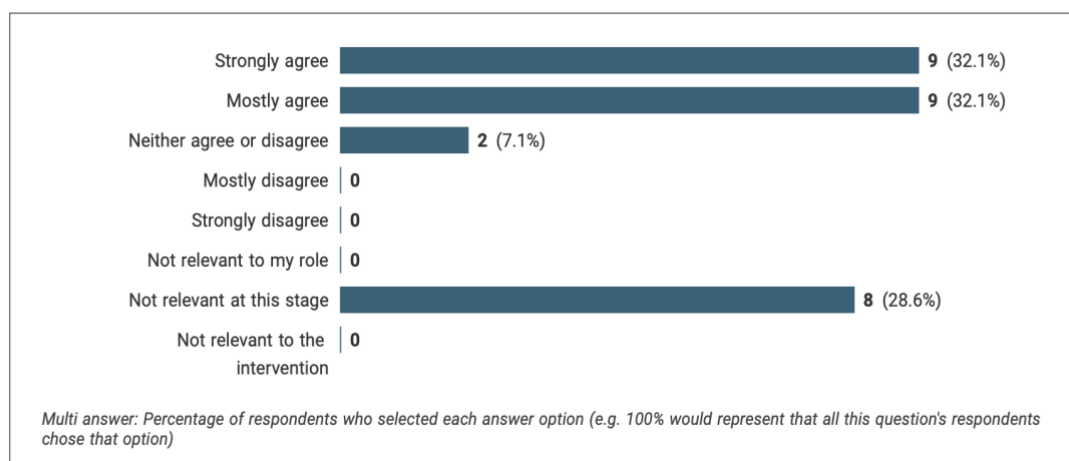
7.2 The PtDA disrupts working relationships



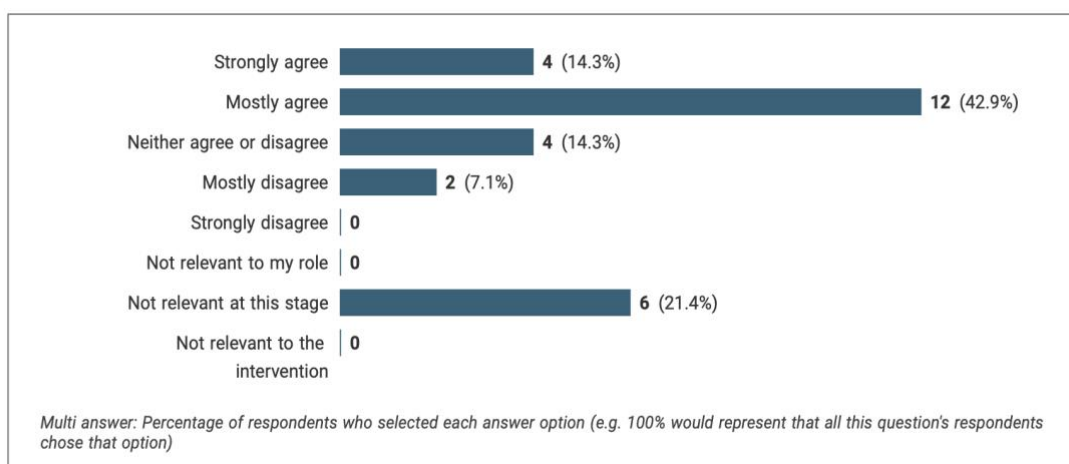
7.3 I have confidence in other people's ability to use the PtDA



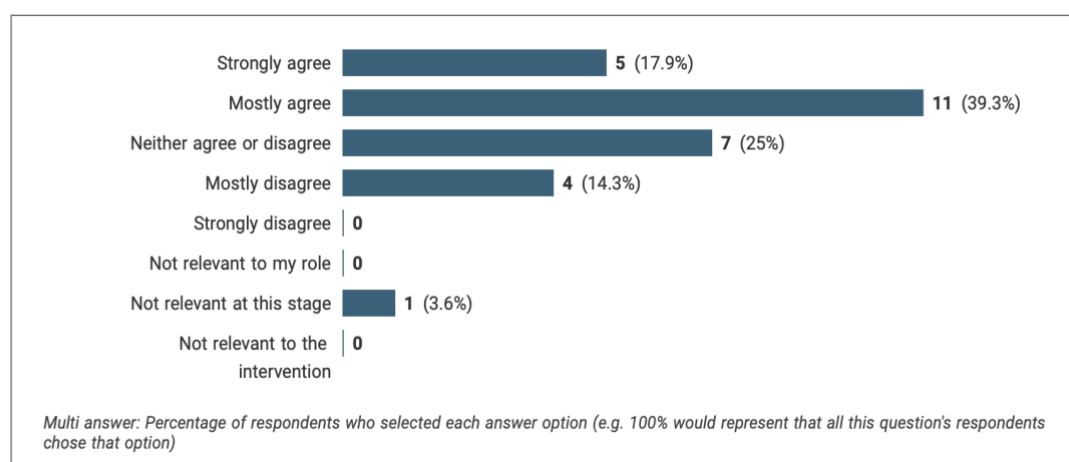
7.4 Work is assigned to those with skills appropriate to the PtDA



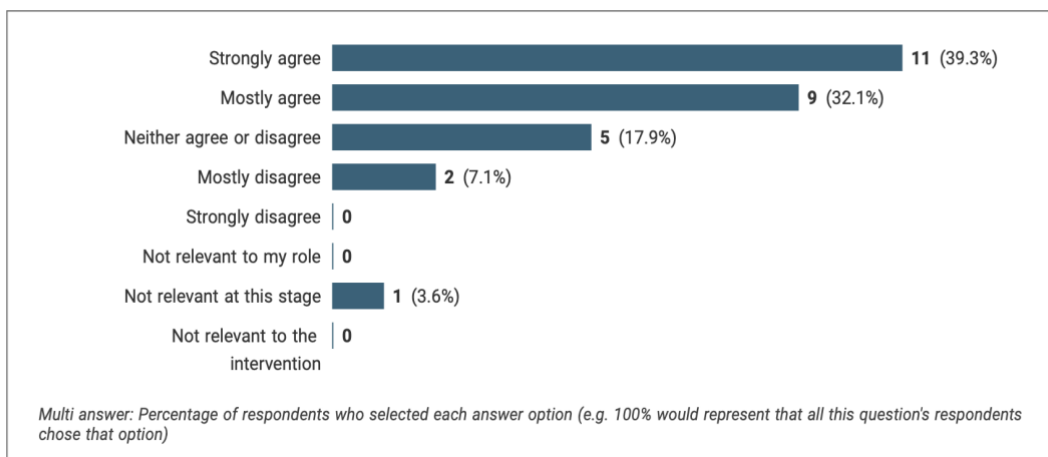
7.5 Sufficient training is provided to enable staff to implement the PtDA



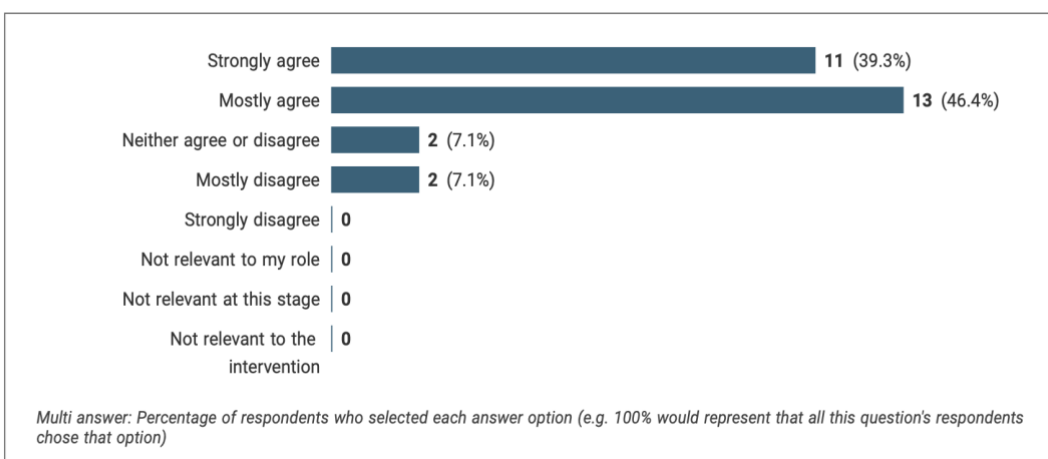
8.1 I am aware of reports about the effects of the PtDA



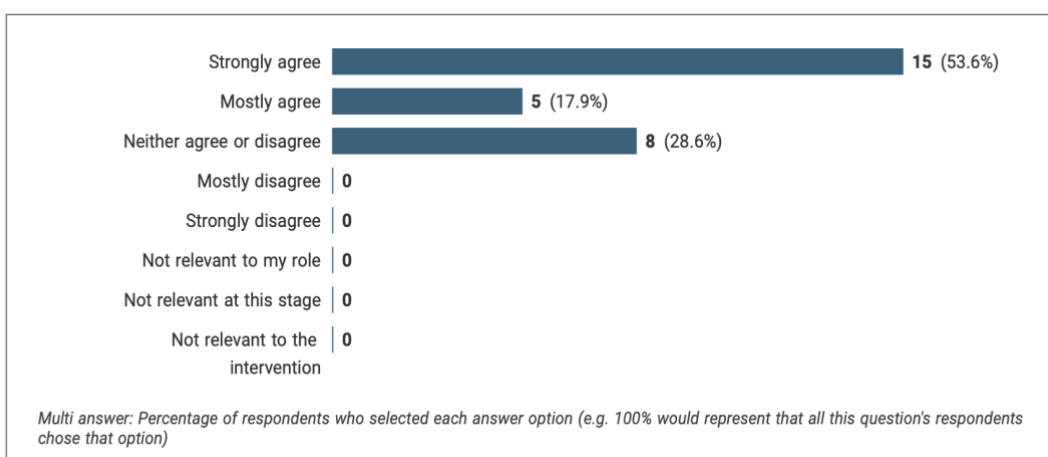
#### 8.2 The staff agree that the PtDA is worthwhile



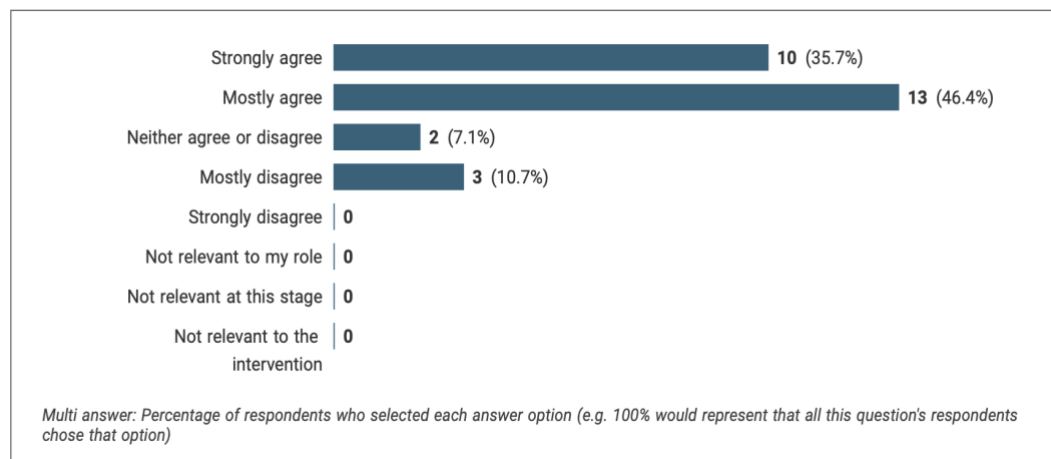
#### 8.3 I value the effects that the PtDA has had on my work



#### 8.4 Feedback about the PtDA can be used to improve it in the future



8.5 I can modify how I work with the PtDA



# **DECISION MAKING IN LOCALLY ADVANCED AND LOCALLY RECURRENT RECTAL CANCER – A PATIENT AND CLINICIAN PERSPECTIVE**

## **Volume 2**

**MISS ANWEN WILLIAMS  
MBBCh, BSc, MRCS**

**Submitted to Swansea University in fulfilment of the requirements for the  
Degree of Doctorate of Philosophy 2024**



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# Locally Advanced or Recurrent Pelvic Cancer Treatment Options for Women

*Patient Decision Aid*



## What is locally advanced or recurrent pelvic cancer?

The cancer in your pelvis may have grown outside of the part of your body that it started in (locally advanced) or the cancer may have returned after previous treatment (locally recurrent).

This decision aid can help you and your surgeon decide together which type of treatment is best for you. **It is important to make the choice that you feel is right for you.**

This will depend on your individual circumstances and how you feel about the surgery.

**Every woman is different so this decision aid is only a guide.**

## What are my choices?

- 1. To have surgery
- 2. To have chemotherapy and or radiotherapy alone
- 3. To have no medical treatment

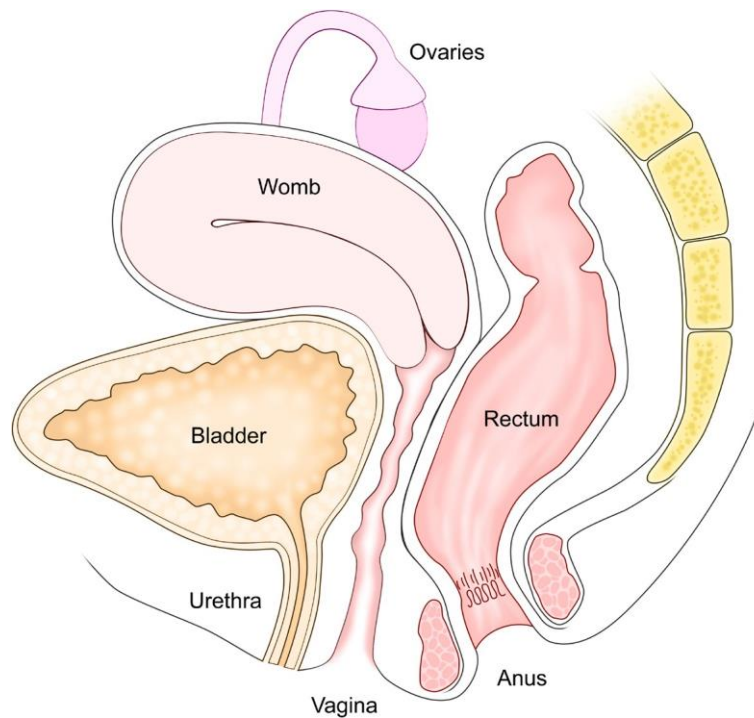


| SURGERY                                                        | CHEMORADIO THERAPY                                                                         | SUPPORTIVE TREATMENT                                              |
|----------------------------------------------------------------|--------------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| This decision aid explains more about the surgery to treat you | You may decide you do not want surgery & want chemo and/ or radiotherapy as an alternative | You may decide you do not want any surgery or chemo/ radiotherapy |

|                                                | SURGERY                                                                                                                                                                                                                                                                                                                                                                                                                                       | CHEMO & RADIOTHERAPY ALONE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | SUPPORTIVE TREATMENT                                                                                                                                                                                              |
|------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Will this option cure me of cancer?            | Yes.<br>This is the best chance of cure. You are only offered this surgery if there is a good chance of cure                                                                                                                                                                                                                                                                                                                                  | Rarely.<br>Up to 15% of patients can get a complete response (cure) to chemoradiotherapy for locally advanced rectal cancer with 8% achieving a complete response in locally recurrent rectal cancer                                                                                                                                                                                                                                                                                                                                                                                                                                                     | No                                                                                                                                                                                                                |
| What are my chances of survival?               | Half of patients will be alive at 5 years                                                                                                                                                                                                                                                                                                                                                                                                     | If you have complete response the overall survival is comparable to having surgery. If you do not get a complete response with chemo and radiotherapy it can prolong your survival. Less than 20% of patients will be alive at 5 years                                                                                                                                                                                                                                                                                                                                                                                                                   | Patients don't usually survive beyond 12 months with less than 5% being alive in 5 years                                                                                                                          |
| Will this option relieve my current symptoms?  | Yes but you may have different symptoms following surgery                                                                                                                                                                                                                                                                                                                                                                                     | Short term it can relieve or improve symptoms but without a complete response these symptoms may return and you could develop more symptoms as the cancer starts to grow                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | No. Without surgery your cancer will grow and any symptoms you have may get worse                                                                                                                                 |
| What are the benefits?                         | Majority of patients are cured of cancer                                                                                                                                                                                                                                                                                                                                                                                                      | Minority are cured of cancer. Treatment can prolong life compared to no treatment. Not having side effects or long-term symptoms of surgery                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Not having side effects or long term symptoms of surgery                                                                                                                                                          |
| What are the risks?                            | <p>Potentially you will experience short and long term side effects:</p> <ul style="list-style-type: none"> <li>• Pain</li> <li>• Urinary &amp; bowel symptoms</li> <li>• Reduced mobility/weakness</li> <li>• Long term tiredness</li> <li>• Psychological and emotional changes</li> <li>• Sexual dysfunction</li> </ul> <p>Complications:</p> <ul style="list-style-type: none"> <li>• Major</li> <li>• Minor (discussed later)</li> </ul> | <p>Potentially you may experience side effects of treatment:</p> <ul style="list-style-type: none"> <li>• Pins and needles</li> <li>• Numbness/pain in feet</li> <li>• Skin redness</li> <li>• Sickness</li> <li>• Fatigue (tiredness that doesn't go away)</li> <li>• Loss of appetite</li> <li>• Recurrent infections</li> <li>• Tummy pain</li> <li>• Diarrhoea or constipation</li> <li>• Sexual and urinary dysfunction</li> </ul> <p>Cancer may grow causing symptoms:</p> <ul style="list-style-type: none"> <li>• Blockage of the bowel</li> <li>• Pain</li> <li>• Bleeding</li> <li>• Growth can grow externally</li> <li>• Sickness</li> </ul> | <p>Cancer will grow causing symptoms:</p> <ul style="list-style-type: none"> <li>• Blockage of the bowel</li> <li>• Pain</li> <li>• Bleeding</li> <li>• Growth can grow externally</li> <li>• Sickness</li> </ul> |
| How will each treatment option affect my life? | <p>Surgery can affect your:</p> <ul style="list-style-type: none"> <li>• Physical health</li> <li>• Psychological health</li> <li>• Relationships</li> <li>• Lifestyle</li> </ul>                                                                                                                                                                                                                                                             | <p>Chemoradiotherapy can affect your:</p> <ul style="list-style-type: none"> <li>• Physical health</li> <li>• Psychological health</li> <li>• Relationships</li> <li>• Lifestyle</li> </ul> <p>Eventually you may get more symptoms requiring medication to keep you comfortable.</p>                                                                                                                                                                                                                                                                                                                                                                    | You are likely to get more symptoms requiring medication to keep you comfortable                                                                                                                                  |
| What kind of support will I have?              | <ul style="list-style-type: none"> <li>• Medical team – surgeons, junior doctors, ward nurses, clinical nurse specialist</li> <li>• Oncologist (cancer doctor)</li> <li>• Stoma nurses</li> <li>• District nurses</li> <li>• Clinical Nurse Specialist</li> <li>• GP's</li> <li>• Support charities</li> <li>• Friends and family</li> </ul>                                                                                                  | <ul style="list-style-type: none"> <li>• GP's</li> <li>• Macmillan nurses</li> <li>• Oncologist (cancer doctor)</li> <li>• Clinical Nurse Specialist</li> <li>• Support charities</li> <li>• Palliative care team when appropriate</li> <li>• Access to hospice care when appropriate</li> <li>• Friends and family</li> </ul>                                                                                                                                                                                                                                                                                                                           | <ul style="list-style-type: none"> <li>• Macmillan nurses</li> <li>• GP's</li> <li>• Support charities</li> <li>• Palliative care team</li> <li>• Access to hospice care</li> <li>• Friends and family</li> </ul> |

## What does surgery involve?

Pelvic Exenteration is a complex operation which requires removing all or part of your pelvic organs of which there are a number of different types.



***Normal anatomy - side view***

Your team will highlight what type of surgery you are having and what is relevant for you.

Several surgeons from different specialties are involved. The operation is a major undertaking and one of the most complex surgeries performed.

There are different types of pelvic exenteration. Depending on your cancer removal of all or some of the following may be necessary:

- Part of the bowel (the colon, rectum and anus)
- The urinary system (the bladder and ureters)
- Your gynaecological organs (your uterus (womb), your ovaries, your fallopian tubes and/or your vagina)
- Your lower spine (sacrum).

## What does the operation involve?

You will be asleep during the operation under general anaesthetic. A cut will be made from above the belly button to the bottom of your abdomen. It may also be necessary to make a second cut around the back passage and vagina.

It is likely you will go to intensive care or high dependency for observation following your surgery and after a few days you will go to the ward. You will wake up with some tubes, drains and drips. You will be allowed to drink initially, then you will be allowed food when your body can tolerate it. Your mobility will be limited in the early post-operative period.

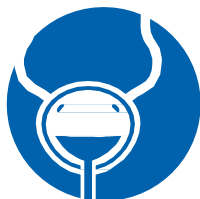
The hospital stay after surgery is variable. Typically if there are no post-operative setbacks patients are in hospital between 10-14 days. However, if you were to experience complications it can be much longer.

## How long will it take to recover?

These operations are a considerable undertaking and your body will go through lots of changes, so it is important that you are prepared for a long recovery. Initial recovery can take between 6 weeks and 3 months. Complete, longer term recovery can take up to 12 months.

## Will everything in my pelvis need to be removed?

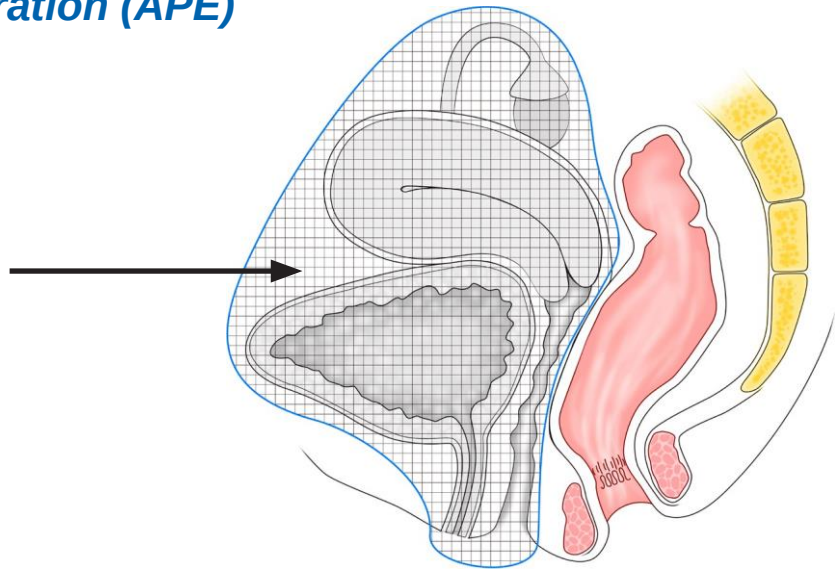
Not necessarily. There are different types of this operation depending on the location of your cancer. Anterior means the front organs, posterior means the organs towards the back and central everything in the middle.



## Parts to be removed in different variations of the surgery:

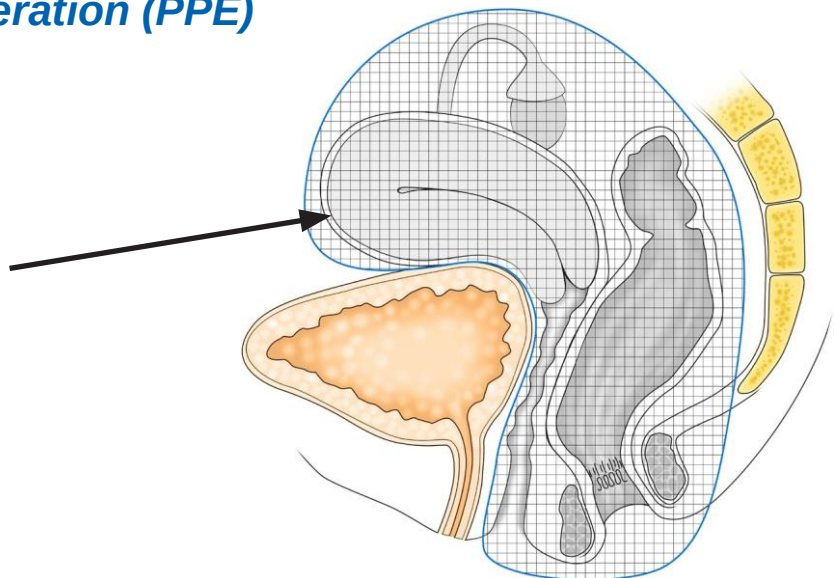
### *Anterior Pelvic Exenteration (APE)*

*Bladder, ureter, womb, tubes, vagina & ovaries removed*



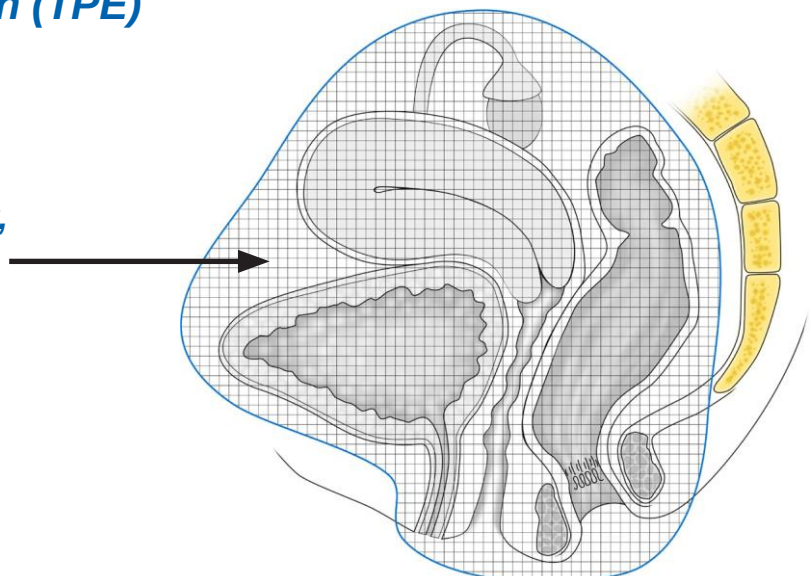
### *Posterior Pelvic Exenteration (PPE)*

*Rectum & anus.  
Occasionally womb, tubes, ovaries, vagina & sacrum removed*



### *Total Pelvic Exenteration (TPE)*

*Rectum, anus, bladder, ureter, womb, ovaries, tubes.  
Occasionally sacrum*



## Option 1

| ORGAN BEING REMOVED                     | TOTAL PELVIC EXENTERATION (TPE) | ANTERIOR PELVIC EXENTERATION (APE) | CENTRAL EXENTERATION | POSTERIOR PELVIC EXENTERATION (PPE) |
|-----------------------------------------|---------------------------------|------------------------------------|----------------------|-------------------------------------|
| Rectum (lower part bowel)               | Yes                             | No                                 | Occasionally         | Yes                                 |
| Anus (bottom)                           | Yes                             | No                                 | Occasionally         | Yes                                 |
| Bladder & end ureter (tube from kidney) | Yes                             | Yes                                | Occasionally         | No                                  |
| Womb, ovaries and tubes                 | Yes                             | Yes                                | Yes                  | Occasionally                        |
| Vagina                                  | Yes                             | Yes                                | Yes                  | Occasionally                        |
| Sacrum (lower spine)                    | Occasionally                    | No                                 | No                   | Occasionally                        |
| Hip bones (ilium, ischium)              | No                              | No                                 | No                   | No                                  |
| Nerves and vessels                      | Occasionally                    | No                                 | Occasionally         | No                                  |
| Plastic surgery reconstruction          | Yes                             | Occasionally                       | Occasionally         | Yes                                 |
| <b>STOMA</b>                            |                                 |                                    |                      |                                     |
| Permanent colostomy                     | Yes                             | No                                 | Maybe                | Yes                                 |
| Permanent urostomy                      | Yes                             | Yes                                | Maybe                | No                                  |



## Option 2

| ORGAN BEING REMOVED                     | TOTAL PELVIC EXENTERATION (TPE) | ANTERIOR PELVIC EXENTERATION (APE) | CENTRAL EXENTERATION | POSTERIOR PELVIC EXENTERATION (PPE) |
|-----------------------------------------|---------------------------------|------------------------------------|----------------------|-------------------------------------|
| Rectum (lower part bowel)               | ●                               |                                    | Occasionally         | ●                                   |
| Anus (bottom)                           | ●                               |                                    | Occasionally         | ●                                   |
| Bladder & end ureter (tube from kidney) | ●                               | ●                                  | Occasionally         |                                     |
| Womb, ovaries and tubes                 | ●                               | ●                                  | ●                    | Occasionally                        |
| Vagina                                  | ●                               | ●                                  | ●                    | Occasionally                        |
| Sacrum (lower spine)                    | Occasionally                    |                                    |                      | Occasionally                        |
| Hip bones (ilium, ischium)              |                                 |                                    |                      |                                     |
| Nerves and vessels                      | Occasionally                    |                                    | Occasionally         |                                     |
| Plastic surgery reconstruction          | ●                               | Occasionally                       | Occasionally         | ●                                   |
| <b>STOMA</b>                            |                                 |                                    |                      |                                     |
| Permanent colostomy                     | ●                               |                                    | Maybe                | ●                                   |
| Permanent urostomy                      | ●                               | ●                                  | Maybe                |                                     |

### Option 3

| ORGAN REMOVED<br>ORGAN SAVED            | ✓<br>✗ | TOTAL PELVIC<br>EXENTERATION (TPE) | ANTERIOR PELVIC<br>EXENTERATION (APE) | CENTRAL<br>EXENTERATION | POSTERIOR PELVIC<br>EXENTERATION (PPE) |
|-----------------------------------------|--------|------------------------------------|---------------------------------------|-------------------------|----------------------------------------|
| Rectum (lower part bowel)               | ✓      | ✓                                  | ✗                                     | Occasionally            | ✓                                      |
| Anus (bottom)                           | ✓      | ✓                                  | ✗                                     | Occasionally            | ✓                                      |
| Bladder & end ureter (tube from kidney) | ✓      | ✓                                  | ✓                                     | Occasionally            | ✗                                      |
| Womb, ovaries and tubes                 | ✓      | ✓                                  | ✓                                     | ✓                       | Occasionally                           |
| Vagina                                  | ✓      | ✓                                  | ✓                                     | ✓                       | Occasionally                           |
| Sacrum (lower spine)                    |        | Occasionally                       | ✗                                     | ✗                       | Occasionally                           |
| Hip bones (ilium, ischium)              | ✗      | ✗                                  | ✗                                     | ✗                       | ✗                                      |
| Nerves and vessels                      |        | Occasionally                       | ✗                                     | Occasionally            | ✗                                      |
| Plastic surgery reconstruction          | ✓      | ✓                                  | Occasionally                          | Occasionally            | ✓                                      |
| <b>STOMA</b>                            |        |                                    |                                       |                         |                                        |
| Permanent Colostomy                     | ✓      | ✓                                  | ✗                                     | Maybe                   | ✓                                      |
| Permanent urostomy                      | ✓      | ✓                                  | ✓                                     | Maybe                   | ✗                                      |

## Will I have a stoma bag?

It is likely you will have a stoma bag.

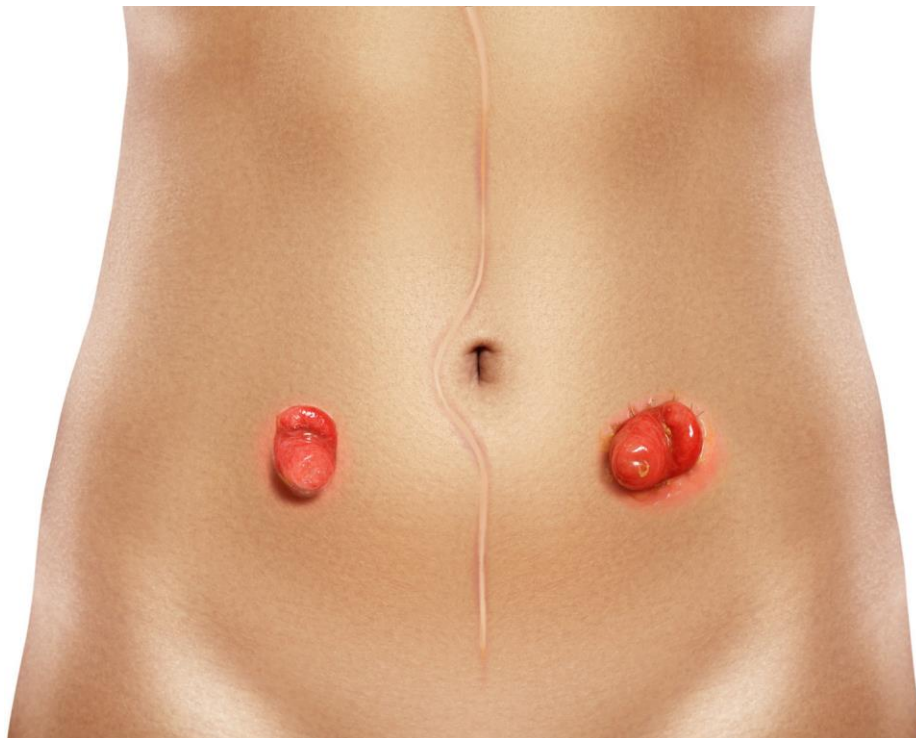
If your lower bowel (rectum) and/or bladder are removed you will no longer be able to go to the toilet in the usual way. Therefore a stoma will be made to create a new way for waste products to leave your body.

A colostomy passes faeces. This is usually created to the left-hand side of your belly button. A specially designed stoma bag sticks over it.

If your surgery requires bladder removal a stoma (urostomy) is formed usually on the right-hand side of your belly button. A watertight drainable bag with a tap sticks over it to collect your urine. This can then be emptied regularly.

Sometimes your back passage (anus) needs to be removed, and if so it will be stitched closed. If this is not necessary the remaining bowel will be closed off, leaving your back passage in place.

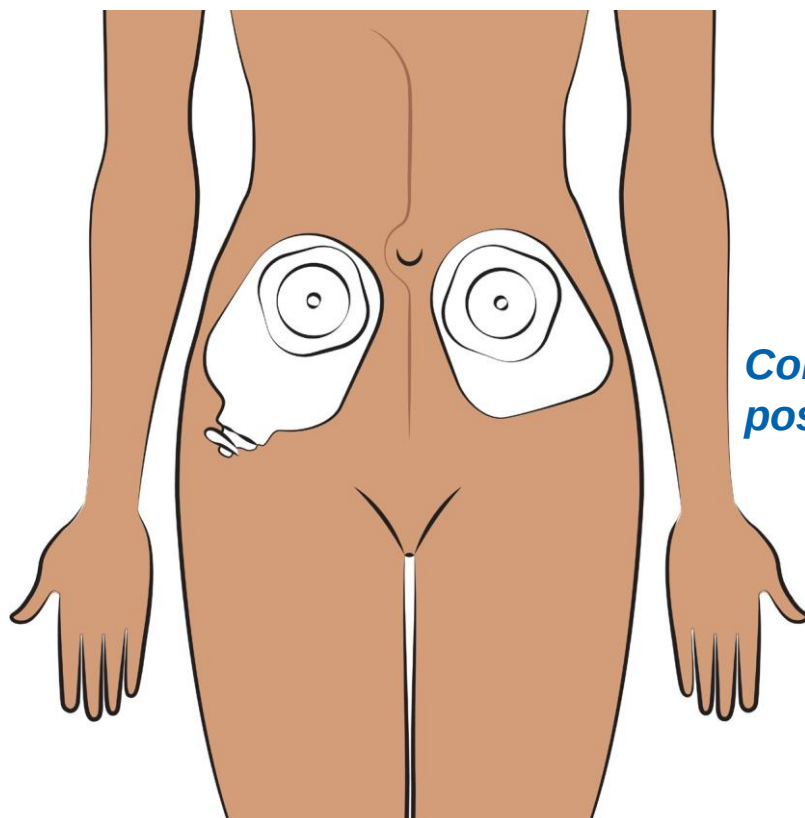
## What do stomas look like?



*Urostomy*

*Colostomy*

***Urostomy bag position***



***Colostomy bag position***



***Typical urostomy bag***



***Typical colostomy bag***

## Sometimes more specialised operations are also performed during the surgery.

|                                                              | SACRECTOMY                                                                                                                                                                                                                                                                                                                                | ELSIE<br>(EXTENDED LATERAL SIDE-WALL<br>RESECTION)                                                                                                                                                                                                                                                                                                                         |
|--------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| WHAT DOES THIS PROCEDURE INVOLVE?                            | When the cancer is stuck to the back of the back bone, it may be necessary to remove a part of your lower spine (sacrum and coccyx)                                                                                                                                                                                                       | If your cancer has grown into the side of your pelvis, it may be necessary to remove blood vessels, nerves and some of your pelvic bones                                                                                                                                                                                                                                   |
| WHAT ARE THE RISKS?                                          | <p>Nerve damage which can result in:</p> <ul style="list-style-type: none"> <li>• Altered leg control</li> <li>• Leg weakness</li> <li>• Leg numbness</li> <li>• Leg pain</li> <li>• Difficulty walking</li> <li>• Foot drop</li> <li>• Problems passing water (urine) if bladder is not removed</li> <li>• Sexual dysfunction</li> </ul> | <p>Nerve damage (including to the sciatic nerve) which can result in:</p> <ul style="list-style-type: none"> <li>• Altered leg control</li> <li>• Leg weakness</li> <li>• Leg numbness</li> <li>• Leg pain</li> <li>• Difficulty walking</li> <li>• Foot drop</li> <li>• Problems passing water (urine) if bladder is not removed</li> <li>• Sexual dysfunction</li> </ul> |
| WHAT ARE THE BENEFITS?                                       | If a sacrectomy is recommended this is because the team treating you feel this is required to completely remove your cancer. Complete removal greatly improves your chance of cure                                                                                                                                                        | If an ELSIE is recommended this is because the team treating you feel this is required to completely remove your cancer. Complete removal greatly improves your chance of cure                                                                                                                                                                                             |
| HOW WILL THIS AFFECT ME?                                     | <p>You may experience:</p> <ul style="list-style-type: none"> <li>• Long-term pain</li> <li>• Reduced mobility</li> <li>• Inability to walk without stick</li> <li>• Inability to walk long distances</li> <li>• Need to catheterise to pass water (urine)</li> </ul>                                                                     | <p>You may experience:</p> <ul style="list-style-type: none"> <li>• Long-term pain</li> <li>• Reduced mobility</li> <li>• Inability to walk without stick</li> <li>• Inability to walk long distances</li> <li>• Inability to run</li> <li>• Need to catheterise to pass water (urine)</li> <li>• Need to modify your car to drive</li> </ul>                              |
| WHAT IS THE RECOVERY SPECIFIC TO THIS PART OF THE OPERATION? | <p>Potentially:</p> <ul style="list-style-type: none"> <li>• Longer physiotherapy</li> <li>• Permanent walking aid</li> <li>• Need for permanent ankle support</li> <li>• Limited mobility (only walk short distances)</li> </ul>                                                                                                         | <p>Potentially:</p> <ul style="list-style-type: none"> <li>• Longer physiotherapy</li> <li>• Permanent walking aid</li> <li>• Need for permanent ankle support</li> <li>• Limited mobility (only walk short distances)</li> </ul>                                                                                                                                          |

## Will I have plastic surgery reconstruction?

After complex pelvic cancer surgery there is often a sizable defect (hole) in the area where the anus (back passage) and vagina used to be. It is therefore often necessary to use plastic surgery to fill the gap. Skin and muscle from a different area of the body are taken as a 'flap' to fill this space.

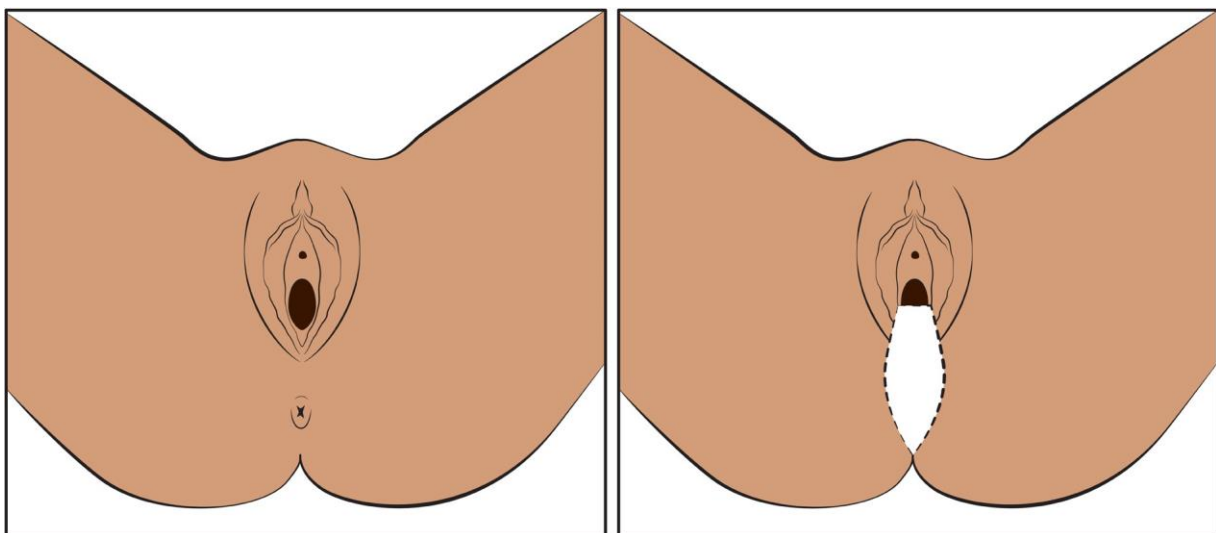
In patients who's vagina is taken away this can be reconstructed at the same time.

There is no agreement on which is the best type of flap, therefore different flaps are used in different centres across the world depending on surgeon preference and the patients' body shape.

## Will it be obvious that I have had surgery on my bottom after plastic surgery?

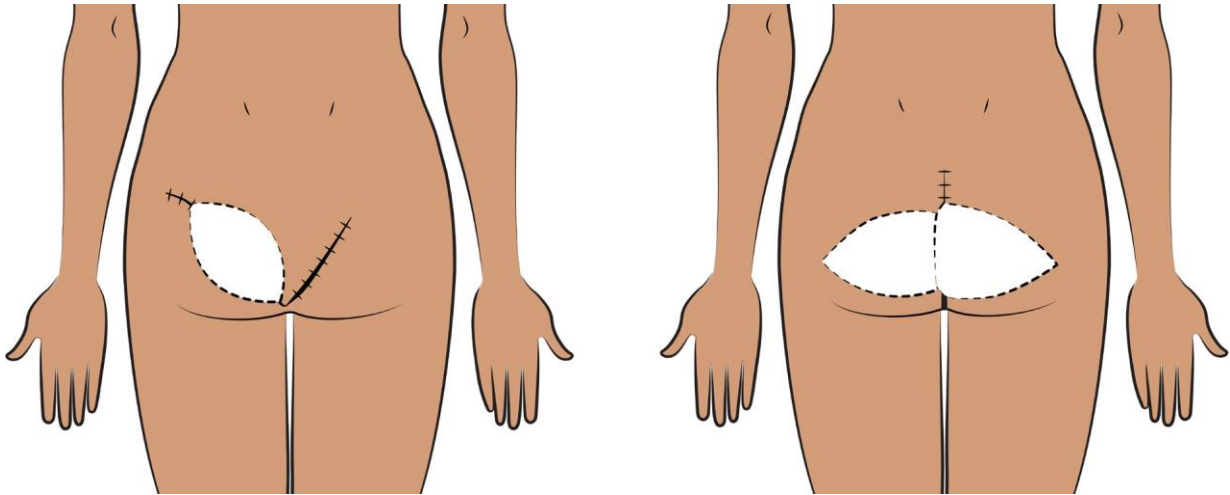
In normal clothes it will not be obvious that you have undergone surgery. However, without clothes on, following plastic surgery, your bottom will look and feel different. You may experience some numbness in this area that is normal.

## What do flaps look like?

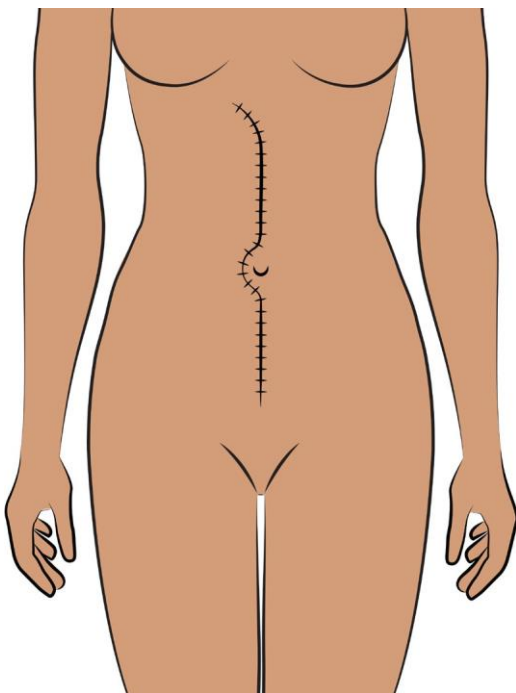


***Normal vagina & anus***

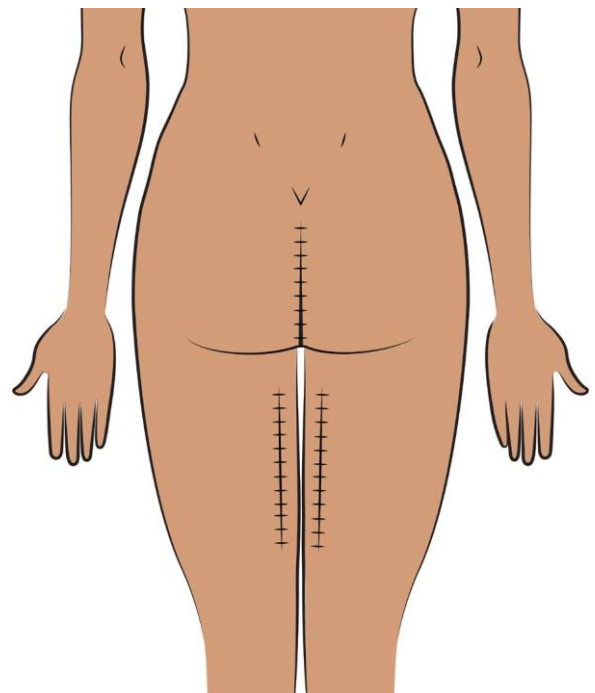
***Flap in position***



**Buttock flaps**



**Abdomen scar**



**Thigh scar**

## **Will I be able to sit on a skin flap?**

All flaps need careful monitoring to ensure healing. In order to allow a flap to heal it is important that pressure is not applied to the area.

Usually, after a week you will be able to sit for five minutes, three to four times a day and this will be increased slowly.

Sitting can be a problem for many weeks or months because of discomfort and a pressure-relieving cushion when sitting is recommended.





**(Photos as alternative option instead of line diagrams)**



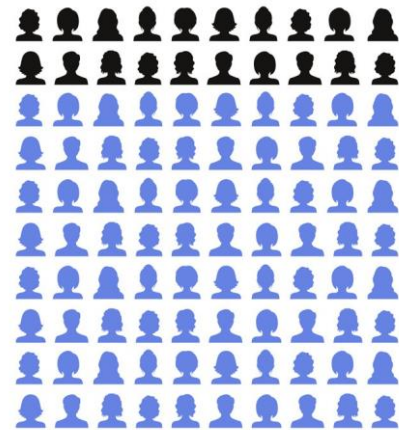
## What are the potential complications?

The risks depend on the complexity of the operation you need.

Around 20% (one in five) patients will experience a major complication from the surgery.

### Major risks of surgery include:

- Bleeding (haemorrhage)
  - Heart attack (myocardial infarction)
  - Blood clot in the chest (pulmonary embolism)
  - Risk of the wound including muscle fully opening up
  - Risk of the plastic surgical flap dying
  - Injury to the bowel
  - Injury to the urinary tract
  - Kidney failure
  - Bowel obstruction
- 
- Formation of an abnormal passage between two places (fistula)
  - Incomplete removal of the cancer or it not being possible to proceed with cancer removal during the operation

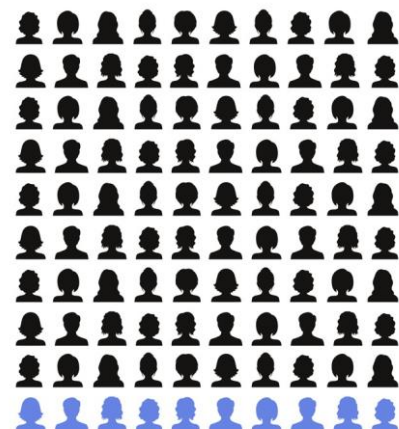


20 out of 100 experience  
major complications

Most patients experience some **minor complications** after surgery. This happens in 90% (9 out of 10) patients.

### Minor risks of surgery include:

- Infection (chest/wound/urine)
- Risk of skin wound opening up
- Collection inside the abdomen
- Bleeding and the need for a blood transfusion
- Blood clot in the legs (Deep Vein Thrombosis or DVT)
- Frequently the bowels can be slow to start working again but usually resolves in time (ileus).

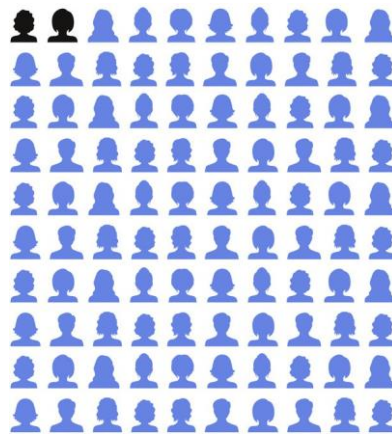


90 out of 100 experience  
minor complications

To minimise the risks of clots we give you elastic stockings to wear and give you blood-thinning injections to prevent clots. These injections are usually continued for 28 days after your operation.

## Can I die as a result of surgery?

The risk of dying within 30 days of the operation is less than 2%, meaning the chances of dying during the operation are low.



*2 out of 100 die after the operation*

## What do I expect after the surgery?

Following your surgery it will be necessary to keep a close eye on you. Depending where you have your surgery, this may be called high dependency, critical care or intensive care. Typically you will stay in this area for 2-5 days.

When you wake from surgery, you will have a number of things attached to you:

- Oxygen tubes in your nose or through a mask on your face
- Drips to keep you hydrated
- Drains (tubes) inside your tummy and bottom to drain excess fluid
- Tube placed in your stomach via your nose to drain any fluid in your stomach
- Staples or stitches in the wounds

## What are the other potential things to expect after surgery? Early Issues

|                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| PAIN MANAGEMENT         | <p>You may be offered different pain-relief options which will change during your stay. These include:</p> <ul style="list-style-type: none"> <li>• Epidural (fine tube inserted into your back infusing painkiller)</li> <li>• Patient controlled analgesia (PCA) (painkiller via a drip into your vein on demand with a button)</li> <li>• Spinal (injection into your back before the operation)</li> <li>• Rectus sheath catheters (local anaesthetic being dripped into your six pack muscles)</li> <li>• Tablets/liquids</li> </ul>                                                                                                                                          |
| MOBILITY                | <ul style="list-style-type: none"> <li>• Daily physiotherapy to get you walking as early as possible after your operation</li> <li>• Muscle weakness</li> <li>• Need to use a walking aid (frame/crutch/stick)</li> <li>• Problems with mobility should gradually improve</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                               |
| BOWEL/URINE CHANGES     | <p><b>Bowel</b></p> <ul style="list-style-type: none"> <li>• Episodes of accidents with controlling your bowels (incontinence)</li> <li>• Leaking stoma bags if colostomy formed</li> </ul> <p><b>Urine</b></p> <p>If your bladder is not removed you will have a catheter for around a week to drain urine away from your bladder via a tube which empties into a bag. Issues after removal can be:</p> <ul style="list-style-type: none"> <li>• Episodes of wetting yourself (incontinence)</li> <li>• Inability to empty your bladder without inserting an 'in and out' catheter to drain the bladder</li> <li>• Leaking bags if urostomy formed and bladder removed</li> </ul> |
| FUNCTIONAL IMPACT       | <ul style="list-style-type: none"> <li>• Weakness</li> <li>• Tiredness</li> <li>• Inability to do normal tasks – washing, dressing</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| PSYCHOLOGICAL IMPACT    | <ul style="list-style-type: none"> <li>• You are likely to experience a range of emotions which may or may not disappear with time (anxiety, anger, regret, fear, depression)</li> <li>• Body function. Your body will be very different in function following the surgery. You may have stoma bags. You will have a big scar. You may no longer have a back passage and may have a skin flap in its place. Your body will feel different.</li> </ul>                                                                                                                                                                                                                              |
| IMPACT ON RELATIONSHIPS | <ul style="list-style-type: none"> <li>• Altered relationships with partner, family and friends</li> <li>• Dependence on others for normal activities – washing, dressing, cleaning</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

## Later issues

|                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| PAIN                    | <ul style="list-style-type: none"> <li>• Long term painkilling medication may be necessary</li> <li>• Doses and types will change over time as your body starts to heal</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| MOBILITY                | <ul style="list-style-type: none"> <li>• Long-term physiotherapy</li> <li>• Walking aid (frame/crutch/stick)</li> <li>• Unable to walk more than a short distance</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| BOWEL/URINE CHANGES     | <ul style="list-style-type: none"> <li>• Ongoing bowel and urine symptoms</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| FUNCTIONAL IMPACT       | <p>Fatigue (tiredness that doesn't go away with rest) lasting longer than 12 months</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| IMPACT ON RELATIONSHIPS | <ul style="list-style-type: none"> <li>• Altered relationships with partner, family and friends</li> <li>• Dependence on others</li> <li>• Altered sexual relationship</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| PSYCHOLOGICAL IMPACT    | <ul style="list-style-type: none"> <li>• Range of emotions which may or may not disappear with time (anxiety, anger, regret, fear, depression &amp; despondency)</li> <li>• Body image: Body changes can affect the way you think and feel about your body which can affect your self-confidence. You might also worry that people will treat you differently because of the change to your body</li> <li>• Low self-esteem or lack of confidence</li> </ul> <p>It is normal to find these changes difficult to adapt to physically and mentally. Different patients adapt in different ways. Some patients have reported:</p> <ul style="list-style-type: none"> <li>• Being too embarrassed to leave home</li> <li>• Withdrawing from social activities</li> <li>• Avoiding intimacy with a partner</li> <li>• Low mood</li> </ul> |

## Later issues continued

|                 |                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| SEXUAL ACTIVITY | <ul style="list-style-type: none"><li>• Vaginal dryness which can be treated with lubricants</li><li>• If the vagina is reconstructed it will look and feel different</li><li>• You may not be able to climax in the same way</li><li>• As the new tissue starts to heal it may become scarred and tight so it will be important to use dilators to keep it open</li><li>• The reconstruction may not work for you</li></ul> |
| WORK            | <ul style="list-style-type: none"><li>• It is unlikely that you will be able to work for at least three months dependent on your job role</li><li>• You may wish to consider lighter duties or reduced hours</li><li>• Your employer should understand the extent of surgery you are undertaking and be prepared for a sickness of up to a year</li></ul>                                                                    |
| FINANCE         | <ul style="list-style-type: none"><li>• Support charities can signpost you to places for help with finances</li><li>• Benefits to help you through financial difficulties. These are means tested but can help you with loss of income as well as directing you towards extra entitlements during your period of recovery and adjustment</li></ul>                                                                           |
| EXERCISE        | <ul style="list-style-type: none"><li>• You may be unable to do the same exercises as you did pre-operatively</li><li>• Your team may advise you not to do excessive exercise or prolonged amounts of sitting</li><li>• Swimming and cycling may not be possible until the wound has completely healed</li></ul>                                                                                                             |



If you decide to have the surgery you will be followed-up for five years afterwards. Two to three weeks after your operation the results of the pathological examination (what your tumour looked like under the microscope) will be available. The team looking after you will communicate the results to you. They may suggest that you consider chemotherapy treatment.

Your follow-up will consist of clinic visits, surveillance CT scans and blood tests at different intervals for the 5 year period.

If you have any questions at any time, please ask any member of your team. They will be pleased to explain anything that concerns you or your family. Another good tip is to write your thoughts and questions down so that you do not forget when you meet your team.

## **Support - Who are we?**

We are a specialist team dealing with pelvic cancers. The team includes surgeons, doctors, surgical nurse practitioners and other specialist nurses including stoma care nurse specialists.

### ***Your Consultant is***

.....

***Contact number (Secretary)***

.....

***Your specialist nurse is***

.....

***Contact number***

.....

***Your stoma care nurse is***

.....

***Contact number***

.....

## Who do I contact with concerns after my operation?

If you have concerns after you have gone home then you can contact your specialist nurse or stoma care nurse or consultant via the secretary on the numbers above.

If you experience any of the following:

- persistent nausea (feeling sick) or vomiting (being sick)
- fever or a high temperature (37.5°C/101.5°F or above)
- oozing or increasing redness around either of the wound sites
- new pain
- new diarrhoea

Please get in contact with any of the team above or your GP. If you are unable to access these contacts out of hours then please contact the GP out of hours service or attend the A&E department of your nearest hospital.



## Useful Links

Individual patients will have different additional needs. There are charities and support groups that can help with money worries and advice on what you're entitled to and help with things like parking permits and extra money you can claim. There are online communities and support groups to help you find ways to have difficult conversations and support you as you come to terms with changes in your life. Families and friends may need support in adapting in a new role as a carer or emotional support in coming to terms with what their relative is going through. You can be put in touch with a support group where you can meet people in a similar situation and get information first-hand about your type of cancer.

You are not alone and we can signpost you to various additional support you require.

## Financial & Practical Support



Macmillan Cancer Support: [www.macmillan.org.uk](http://www.macmillan.org.uk) Tel:  
0808 808 0000

Maggie's: [www.maggies.org](http://www.maggies.org) Tel:  
0300 123 1801

Bowel Cancer UK: [www.bowelcanceruk.org.uk](http://www.bowelcanceruk.org.uk) Tel:  
020 7940 1760

## Psychological and Emotional Support

Maggie's: [www.maggies.org](http://www.maggies.org) Tel:  
0300 123 1801

Macmillan Cancer Support: [www.macmillan.org.uk](http://www.macmillan.org.uk) Tel:  
0808 808 0000

Bowel Cancer UK: [www.bowelcanceruk.org.uk](http://www.bowelcanceruk.org.uk) Tel:  
020 7940 1760

Beating Bowel Cancer: [www.beatingbowelcancer.org](http://www.beatingbowelcancer.org)  
Tel: 020 8973 0011

Bladder and Bowel Foundation: [www.bladderandbowelfoundation](http://www.bladderandbowelfoundation) Tel:  
0845 345 0165

## Relationship support

College of Sexual Relationship Therapists: [www.cosrt.org.uk](http://www.cosrt.org.uk) Tel:  
020 8543 2707

Macmillan Cancer Support: [www.macmillan.org.uk](http://www.macmillan.org.uk) Tel:  
0808 808 0000

Maggie's: [www.maggies.org](http://www.maggies.org) Tel:  
0300 123 1801



## Stoma support

Urostomy Association [www.urostomyassociation.org.uk](http://www.urostomyassociation.org.uk)  
Tel: 01889 563191

Colostomy Association [www.colostomyassociation.org.uk](http://www.colostomyassociation.org.uk)  
Tel: 0800 328 4257

Macmillan Cancer Support: [www.macmillan.org.uk](http://www.macmillan.org.uk) Tel:  
0808 808 0000

Bowel Cancer UK: [www.bowelcanceruk.org.uk](http://www.bowelcanceruk.org.uk) Tel:  
020 7940 1760

Beating Bowel Cancer: [www.beatingbowelcancer.org](http://www.beatingbowelcancer.org)  
Tel: 020 8973 0011

Bladder and Bowel Foundation: [www.bladderandbowelfoundation](http://www.bladderandbowelfoundation) Tel:  
0845 345 0165

## Sources

Patient Decision Aid for Women. Produced  
as part of study IRAS 257890.  
First published: February 2021. Review date: February 2023.

# Locally Advanced or Recurrent Pelvic Cancer Treatment Options for Men

## *Patient Decision Aid*



# What is locally advanced or recurrent pelvic cancer?

The cancer in your pelvis may have grown outside of the part of your body that is started in (locally advanced) or the cancer may have returned after previous treatment (locally recurrent).

This decision aid can help you and your surgeon decide together which type of treatment is best for you. **It is important to make the choice that you feel is right for you.**

This will depend on your individual circumstances and how you feel about the surgery.

**Every man is different so this decision aid in only a guide.**

## What are my choices?

- 1. To have surgery
- 2. To have chemotherapy and or radiotherapy alone
- 3. To have no medical treatment



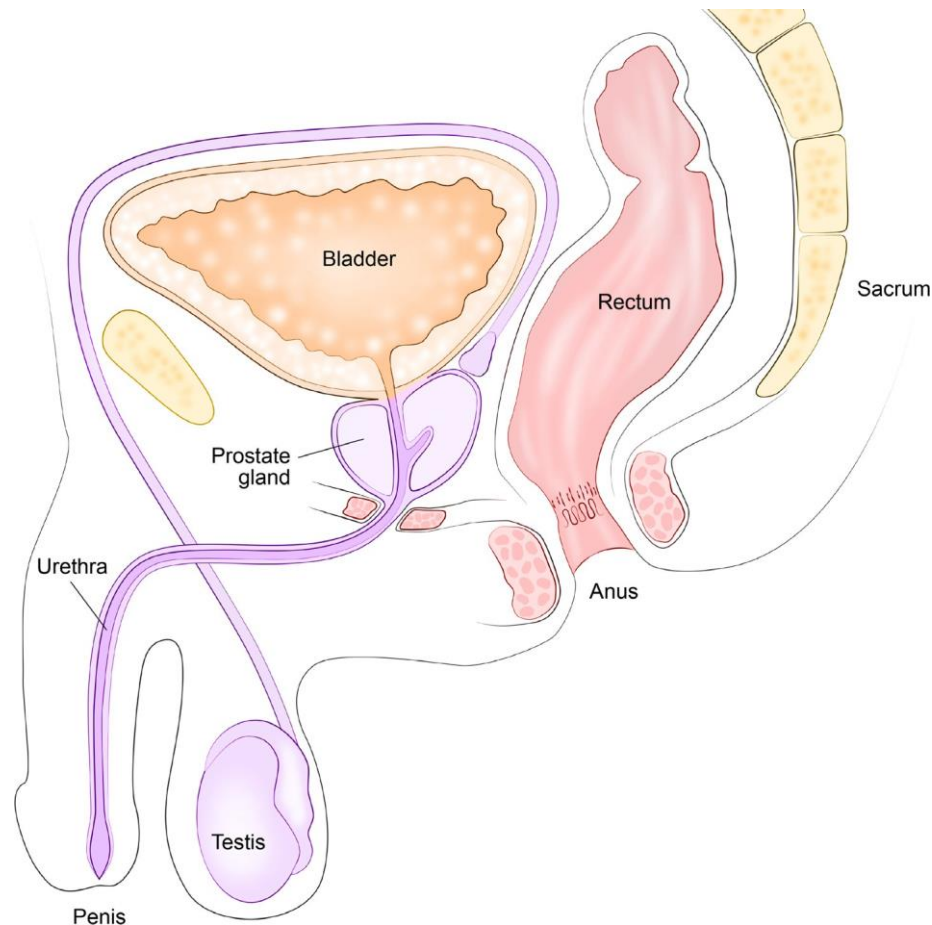
| SURGERY                                                        | CHEMORADIO THERAPY                                                                         | SUPPORTIVE TREATMENT                                              |
|----------------------------------------------------------------|--------------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| This decision aid explains more about the surgery to treat you | You may decide you do not want surgery & want chemo and/ or radiotherapy as an alternative | You may decide you do not want any surgery or chemo/ radiotherapy |

|                                                | SURGERY                                                                                                                                                                                                                                                                                                                                                                                                                                       | CHEMO & RADIOTHERAPY ALONE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | SUPPORTIVE TREATMENT                                                                                                                                                                                              |
|------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Will this option cure me of cancer?            | Yes.<br>This is the best chance of cure. You are only offered this surgery if there is a good chance of cure                                                                                                                                                                                                                                                                                                                                  | Rarely.<br>Up to 15% of patients can get a complete response (cure) to chemoradiotherapy for locally advanced rectal cancer with 8% achieving a complete response in locally recurrent rectal cancer                                                                                                                                                                                                                                                                                                                                                                                                                                                     | No                                                                                                                                                                                                                |
| What are my chances of survival?               | Half of patients will be alive at 5 years                                                                                                                                                                                                                                                                                                                                                                                                     | If you have complete response the overall survival is comparable to having surgery. If you do not get a complete response with chemo and radiotherapy it can prolong your survival. Less than 20% of patients will be alive at 5 years                                                                                                                                                                                                                                                                                                                                                                                                                   | Patients don't usually survive beyond 12 months with less than 5% being alive in 5 years                                                                                                                          |
| Will this option relieve my current symptoms?  | Yes but you may have different symptoms following surgery                                                                                                                                                                                                                                                                                                                                                                                     | Short term it can relieve or improve symptoms but without a complete response these symptoms may return and you could develop more symptoms as the cancer starts to grow                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | No. Without surgery your cancer will grow and any symptoms you have may get worse                                                                                                                                 |
| What are the benefits?                         | Majority of patients are cured of cancer                                                                                                                                                                                                                                                                                                                                                                                                      | Minority are cured of cancer. Treatment can prolong life compared to no treatment. Not having side effects or long-term symptoms of surgery                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Not having side effects or long term symptoms of surgery                                                                                                                                                          |
| What are the risks?                            | <p>Potentially you will experience short and long term side effects:</p> <ul style="list-style-type: none"> <li>• Pain</li> <li>• Urinary &amp; bowel symptoms</li> <li>• Reduced mobility/weakness</li> <li>• Long term tiredness</li> <li>• Psychological and emotional changes</li> <li>• Sexual dysfunction</li> </ul> <p>Complications:</p> <ul style="list-style-type: none"> <li>• Major</li> <li>• Minor (discussed later)</li> </ul> | <p>Potentially you may experience side effects of treatment:</p> <ul style="list-style-type: none"> <li>• Pins and needles</li> <li>• Numbness/pain in feet</li> <li>• Skin redness</li> <li>• Sickness</li> <li>• Fatigue (tiredness that doesn't go away)</li> <li>• Loss of appetite</li> <li>• Recurrent infections</li> <li>• Tummy pain</li> <li>• Diarrhoea or constipation</li> <li>• Sexual and urinary dysfunction</li> </ul> <p>Cancer may grow causing symptoms:</p> <ul style="list-style-type: none"> <li>• Blockage of the bowel</li> <li>• Pain</li> <li>• Bleeding</li> <li>• Growth can grow externally</li> <li>• Sickness</li> </ul> | <p>Cancer will grow causing symptoms:</p> <ul style="list-style-type: none"> <li>• Blockage of the bowel</li> <li>• Pain</li> <li>• Bleeding</li> <li>• Growth can grow externally</li> <li>• Sickness</li> </ul> |
| How will each treatment option affect my life? | <p>Surgery can affect your:</p> <ul style="list-style-type: none"> <li>• Physical health</li> <li>• Psychological health</li> <li>• Relationships</li> <li>• Lifestyle</li> </ul>                                                                                                                                                                                                                                                             | <p>Chemoradiotherapy can affect your:</p> <ul style="list-style-type: none"> <li>• Physical health</li> <li>• Psychological health</li> <li>• Relationships</li> <li>• Lifestyle</li> </ul> <p>Eventually you may get more symptoms requiring medication to keep you comfortable.</p>                                                                                                                                                                                                                                                                                                                                                                    | You are likely to get more symptoms requiring medication to keep you comfortable.                                                                                                                                 |

|                                          |                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                   |
|------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>What kind of support will I have?</p> | <ul style="list-style-type: none"> <li>• Medical team – surgeons, junior doctors, ward nurses, clinical nurse specialist</li> <li>• Oncologist (cancer doctor)</li> <li>• Stoma nurses</li> <li>• District nurses</li> <li>• Clinical Nurse Specialist</li> <li>• GP's</li> <li>• Support charities</li> <li>• Friends and family</li> </ul> | <ul style="list-style-type: none"> <li>• GP's</li> <li>• Macmillan nurses</li> <li>• Oncologist (cancer doctor)</li> <li>• Clinical Nurse Specialist</li> <li>• Support charities</li> <li>• Palliative care team when appropriate</li> <li>• Access to hospice care when appropriate</li> <li>• Friends and family</li> </ul> | <ul style="list-style-type: none"> <li>• Macmillan nurses</li> <li>• GP's</li> <li>• Support charities</li> <li>• Palliative care team</li> <li>• Access to hospice care</li> <li>• Friends and family</li> </ul> |
|------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## What does surgery involve?

Pelvic Exenteration is a complex operation which requires removing all or part of your pelvic organs of which there are a number of different types.



### *Normal anatomy - side view*

Your team will highlight what type of surgery you are having and what is relevant for you.

Several surgeons from different specialties are involved. The operation is a major undertaking and one of the most complex surgeries performed.

There are different types of pelvic exenteration. Depending on your cancer removal of all or some of the following may be necessary:

- Part of the bowel (the colon, rectum and anus)
- The urinary system (the bladder and ureters)
- Your reproductive organs (prostate, seminal vesicles)
- Your lower spine (sacrum)

## What does the operation involve?

You will be asleep during the operation under general anaesthetic. A cut will be made from above the belly button to the bottom of your abdomen. It may also be necessary to make a second cut around the back passage.

It is likely you will go to intensive care or high dependency for observation following your surgery and after a few days you will go to the ward. You will wake up with some tubes, drains and drips. You will be allowed to drink initially, then you will be allowed food when your body can tolerate it. Your mobility will be limited in the early post-operative period.

The hospital stay after surgery is variable. Typically if there are no post-operative setbacks patients are in hospital between 10-14 days. However, if you were to experience complications it can be much longer.

## How long will it take to recover?

These operations are a considerable undertaking and your body will go through lots of changes, so it is important that you are prepared for a long recovery. Initial recovery can take between 6 weeks and 3 months. Complete, longer term recovery can take up to 12 months.

## Will everything in my pelvis need to be removed?

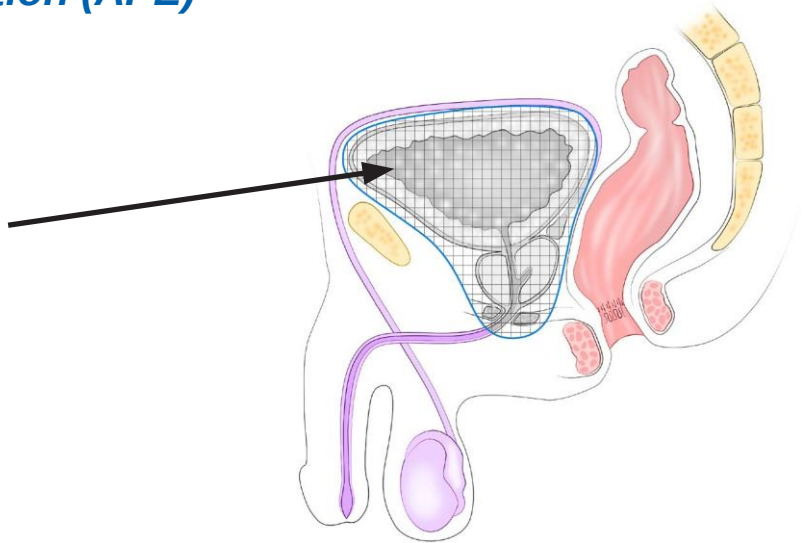
Not necessarily. There are different types of this operation depending on the location of your cancer. Anterior means the front organs, posterior means the organs towards the back and central everything in the middle.



## Parts to be removed in different variations of the surgery:

### *Anterior Pelvic Exenteration (APE)*

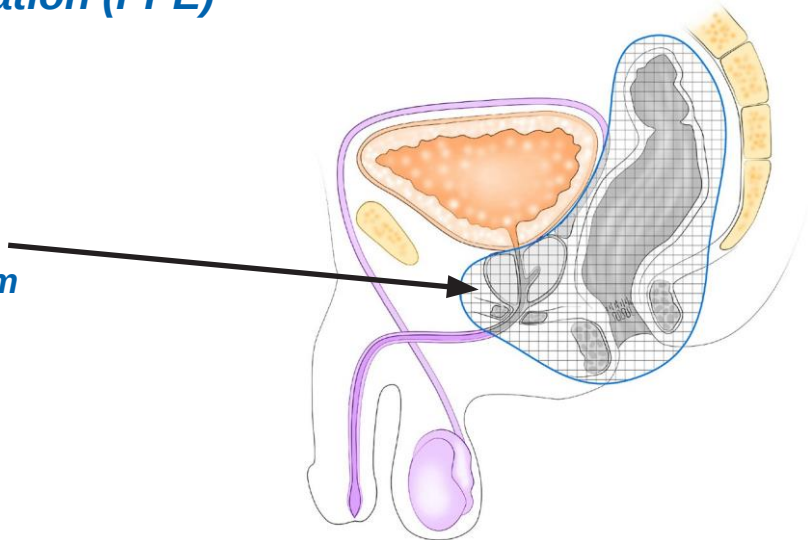
*Bladder, ureter, prostate, seminal vesicles*



### *Posterior Pelvic Exenteration (PPE)*

*Rectum & anus.*

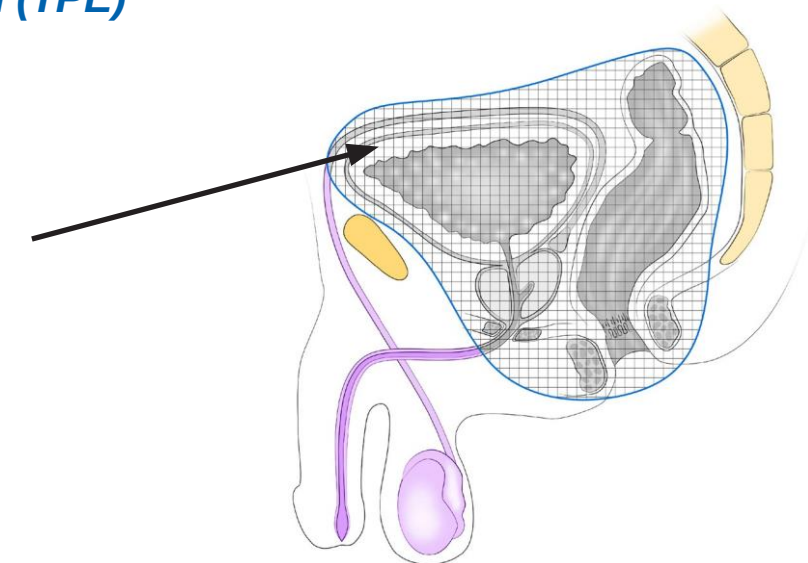
*Occasionally prostate & sacrum removed*



### *Total Pelvic Exenteration (TPE)*

*Rectum, anus, bladder, ureter, prostate, seminal vesicles.*

*Occasionally sacrum*





## Option 1

| ORGAN BEING REMOVED                     | TOTAL PELVIC EXENTERATION (TPE) | ANTERIOR PELVIC EXENTERATION (APE) | POSTERIOR PELVIC EXENTERATION (PPE) |
|-----------------------------------------|---------------------------------|------------------------------------|-------------------------------------|
| Rectum (lower part bowel)               | Yes                             | No                                 | Yes                                 |
| Anus (bottom)                           | Yes                             | No                                 | Yes                                 |
| Bladder & end ureter (tube from kidney) | Yes                             | Yes                                | No                                  |
| Prostate, seminal vesicles              | Yes                             | Yes                                | Occasionally                        |
| Sacrum (lower spine)                    | Occasionally                    | No                                 | Occasionally                        |
| Hip bones (ilium, ischium)              | No                              | No                                 | No                                  |
| Nerves and vessels                      | Occasionally                    | No                                 | No                                  |
| Plastic surgery reconstruction          | Yes                             | Occasionally                       | Yes                                 |
| <b>STOMA</b>                            |                                 |                                    |                                     |
| Permanent colostomy                     | Yes                             | No                                 | Yes                                 |
| Permanent urostomy                      | Yes                             | Yes                                | No                                  |

## Option 2

| ORGAN BEING REMOVED                     | TOTAL PELVIC EXENTERATION (TPE) | ANTERIOR PELVIC EXENTERATION (APE) | POSTERIOR PELVIC EXENTERATION (PPE) |
|-----------------------------------------|---------------------------------|------------------------------------|-------------------------------------|
| Rectum (lower part bowel)               |                                 |                                    |                                     |
| Anus (bottom)                           |                                 |                                    |                                     |
| Bladder & end ureter (tube from kidney) |                                 |                                    |                                     |
| Prostate, seminal vesicles              |                                 |                                    | Occasionally                        |
| Sacrum (lower spine)                    | Occasionally                    |                                    | Occasionally                        |
| Hip bones (ilium, ischium)              |                                 |                                    |                                     |
| Nerves and vessels                      | Occasionally                    |                                    |                                     |
| Plastic surgery reconstruction          |                                 | Occasionally                       |                                     |
| STOMA                                   |                                 |                                    |                                     |
| Permanent colostomy                     |                                 |                                    |                                     |
| Permanent urostomy                      |                                 |                                    |                                     |

## Option 3

| ORGAN REMOVED<br>ORGAN SAVED            | ✓<br>✗ | TOTAL PELVIC<br>EXENTERATION (TPE) | ANTERIOR PELVIC<br>EXENTERATION (APE) | POSTERIOR PELVIC<br>EXENTERATION (PPE) |
|-----------------------------------------|--------|------------------------------------|---------------------------------------|----------------------------------------|
| Rectum (lower part bowel)               |        | ✓                                  | ✗                                     | ✓                                      |
| Anus (bottom)                           |        | ✓                                  | ✗                                     | ✓                                      |
| Bladder & end ureter (tube from kidney) |        | ✓                                  | ✓                                     | ✗                                      |
| Womb, ovaries and tubes                 |        | ✓                                  | ✓                                     | Occasionally                           |
| Vagina                                  |        | ✓                                  | ✓                                     | Occasionally                           |
| Sacrum (lower spine)                    |        | Occasionally                       | ✗                                     | Occasionally                           |
| Hip bones (ilium, ischium)              |        | ✗                                  | ✗                                     | ✗                                      |
| Nerves and vessels                      |        | Occasionally                       | ✗                                     | ✗                                      |
| Plastic surgery reconstruction          |        | ✓                                  | Occasionally                          | ✓                                      |
| STOMA                                   |        |                                    |                                       |                                        |
| Permanent Colostomy                     |        | ✓                                  | ✗                                     | ✓                                      |
| Permanent urostomy                      |        | ✓                                  | ✓                                     | ✗                                      |

## Will I have a stoma bag?

It is likely you will have a stoma bag.

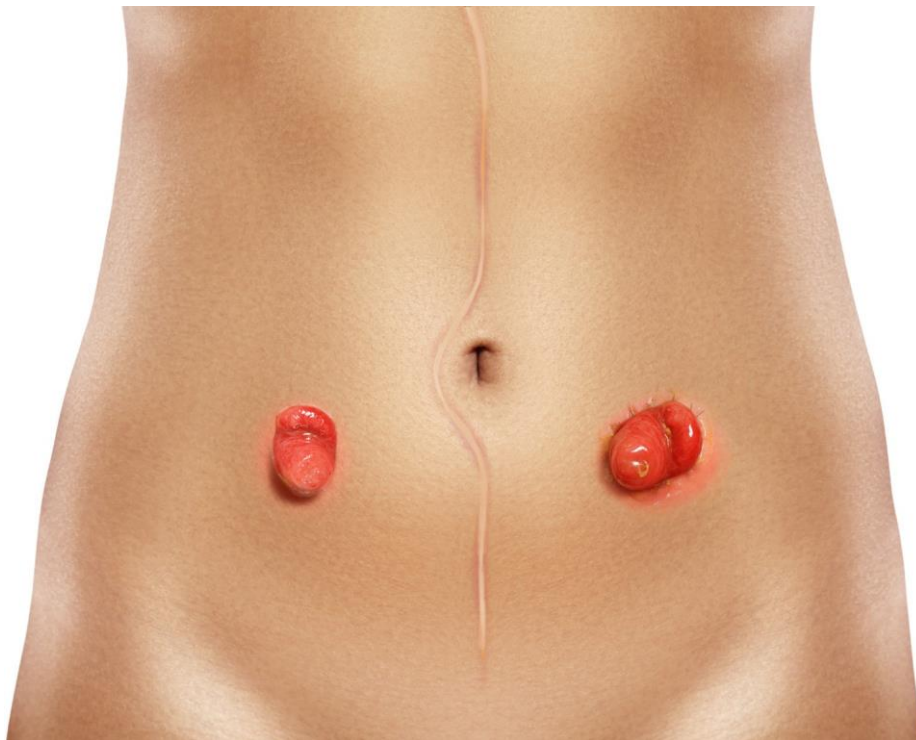
If your lower bowel (rectum) and/or bladder are removed you will no longer be able to go to the toilet in the usual way. Therefore a stoma will be made to create a new way for waste products to leave your body.

A colostomy passes faeces. This is usually created to the left-hand side of your belly button. A specially designed stoma bag sticks over it.

If your surgery requires bladder removal a stoma (urostomy) is formed usually on the right-hand side of your belly button. A watertight drainable bag with a tap sticks over it to collect your urine. This can then be emptied regularly.

Sometimes your back passage (anus) needs to be removed, and if so it will be stitched closed. If this is not necessary the remaining bowel will be closed off, leaving your back passage in place.

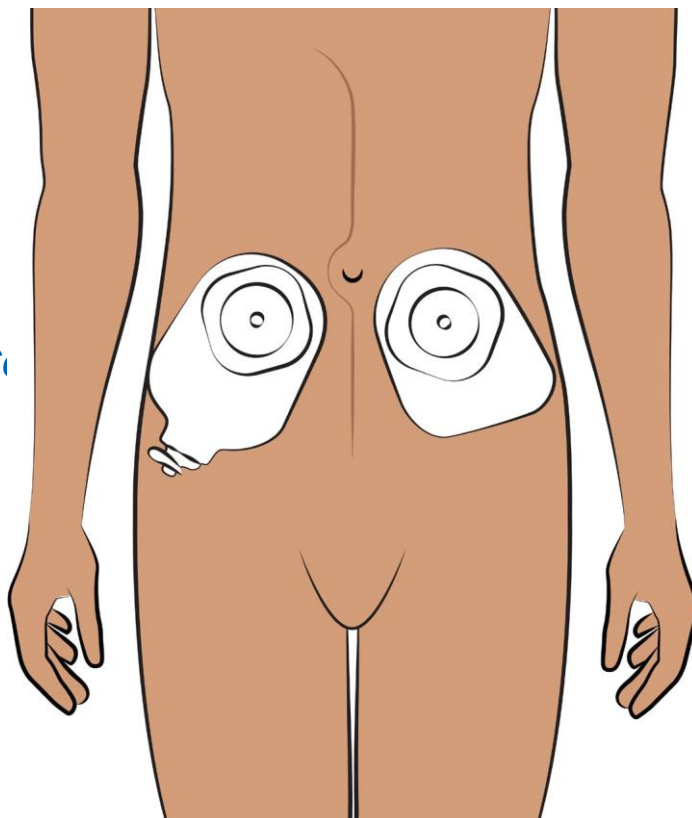
## What do stomas look like?



*Urostomy*

*Colostomy*

**Urostomy bag position**



**Typical urostomy bag**



**Typical colostomy bag**

## Sometimes more specialised operations are also performed during the surgery.

|                                                              | SACRECTOMY                                                                                                                                                                                                                                                                                                                                | ELSIE<br>(EXTENDED LATERAL SIDE-WALL RESECTION)                                                                                                                                                                                                                                                                                                                            |
|--------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| WHAT DOES THIS PROCEDURE INVOLVE?                            | When the cancer is stuck to the back of the back bone, it may be necessary to remove a part of your lower spine (sacrum and coccyx)                                                                                                                                                                                                       | If your cancer has grown into the side of your pelvis, it may be necessary to remove blood vessels, nerves and some of your pelvic bones                                                                                                                                                                                                                                   |
| WHAT ARE THE RISKS?                                          | <p>Nerve damage which can result in:</p> <ul style="list-style-type: none"> <li>• Altered leg control</li> <li>• Leg weakness</li> <li>• Leg numbness</li> <li>• Leg pain</li> <li>• Difficulty walking</li> <li>• Foot drop</li> <li>• Problems passing water (urine) if bladder is not removed</li> <li>• Sexual dysfunction</li> </ul> | <p>Nerve damage (including to the sciatic nerve) which can result in:</p> <ul style="list-style-type: none"> <li>• Altered leg control</li> <li>• Leg weakness</li> <li>• Leg numbness</li> <li>• Leg pain</li> <li>• Difficulty walking</li> <li>• Foot drop</li> <li>• Problems passing water (urine) if bladder is not removed</li> <li>• Sexual dysfunction</li> </ul> |
| WHAT ARE THE BENEFITS?                                       | If a sacrectomy is recommended this is because the team treating you feel this is required to completely remove your cancer. Complete removal greatly improves your chance of cure                                                                                                                                                        | If an ELSIE is recommended this is because the team treating you feel this is required to completely remove your cancer. Complete removal greatly improves your chance of cure                                                                                                                                                                                             |
| HOW WILL THIS AFFECT ME?                                     | <p>You may experience:</p> <ul style="list-style-type: none"> <li>• Long-term pain</li> <li>• Reduced mobility</li> <li>• Inability to walk without stick</li> <li>• Inability to walk long distances</li> <li>• Need to catheterise to pass water (urine)</li> </ul>                                                                     | <p>You may experience:</p> <ul style="list-style-type: none"> <li>• Long-term pain</li> <li>• Reduced mobility</li> <li>• Inability to walk without stick</li> <li>• Inability to walk long distances</li> <li>• Inability to run</li> <li>• Need to catheterise to pass water (urine)</li> <li>• Need to modify your car to drive</li> </ul>                              |
| WHAT IS THE RECOVERY SPECIFIC TO THIS PART OF THE OPERATION? | <p>Potentially:</p> <ul style="list-style-type: none"> <li>• Longer physiotherapy</li> <li>• Permanent walking aid</li> <li>• Need for permanent ankle support</li> <li>• Limited mobility (only walk short distances)</li> </ul>                                                                                                         | <p>Potentially:</p> <ul style="list-style-type: none"> <li>• Longer physiotherapy</li> <li>• Permanent walking aid.</li> <li>• Need for permanent ankle support</li> <li>• Limited mobility (only walk short distances)</li> </ul>                                                                                                                                         |

## Will I have plastic surgery reconstruction?

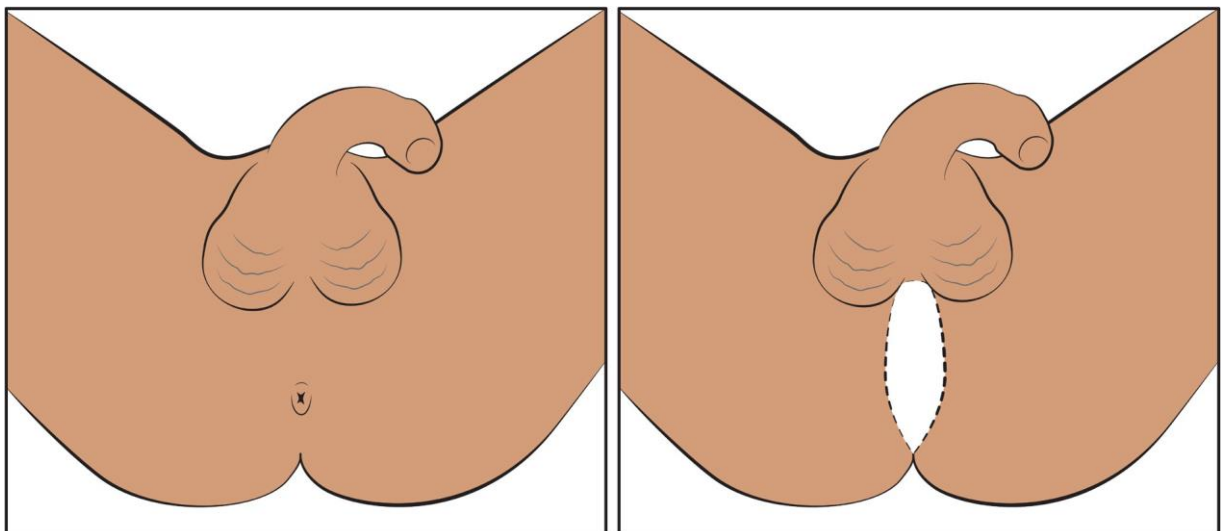
After complex pelvic cancer surgery there is often a sizable defect (hole) in the area where the anus (back passage) used to be. It is therefore often necessary to use plastic surgery to fill the gap. Skin and muscle from a different area of the body are taken as a 'flap' to fill this space.

There is no agreement on which is the best type of flap, therefore different flaps are used in different centers across the world depending on surgeon preference and the patients' body shape.

## Will it be obvious that I have had surgery on my bottom after plastic surgery?

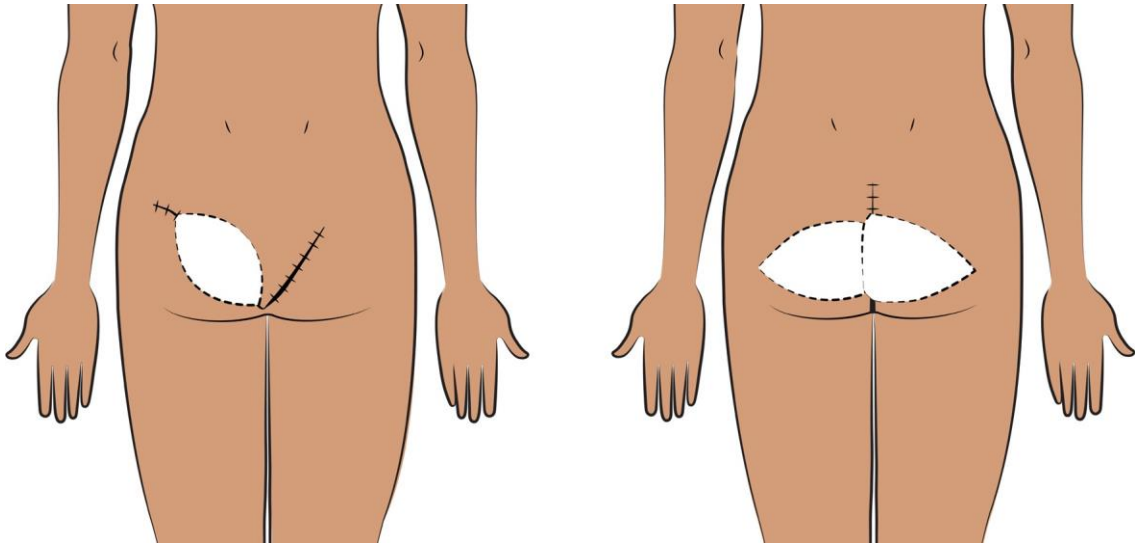
In normal clothes it will not be obvious that you have undergone surgery. However, without clothes on, following plastic surgery, your bottom will look and feel different. You may experience some numbness in this area that is normal.

## What do flaps look like?

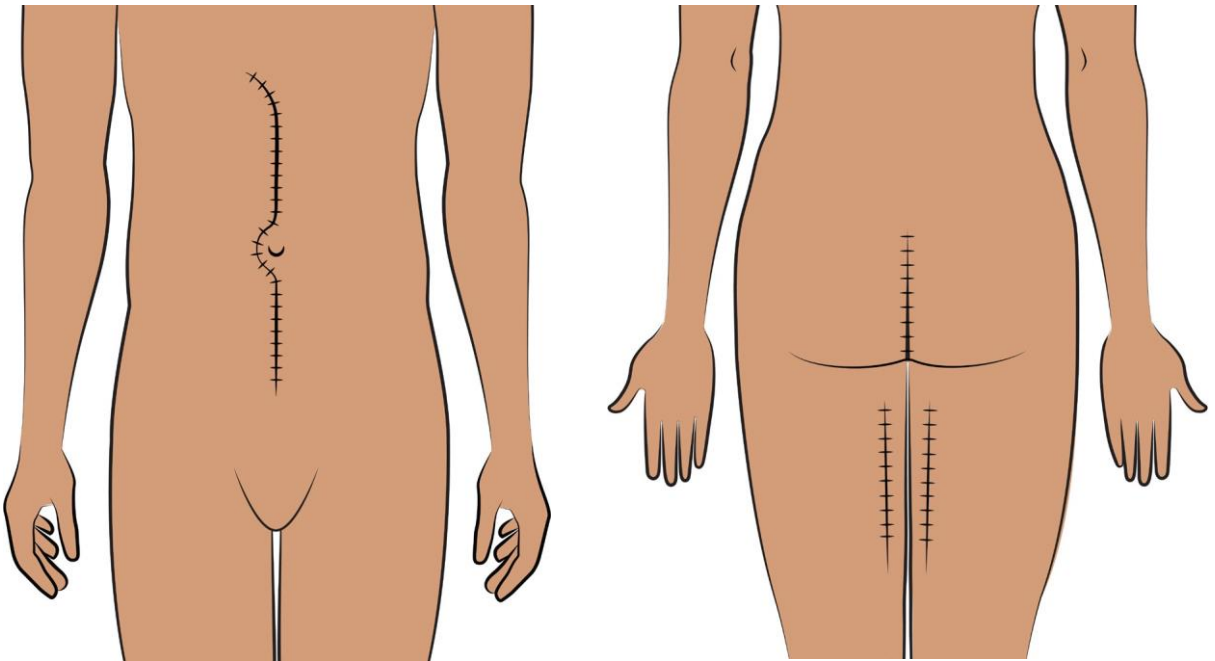


***Normal penis & anus position***

***Flap from the tummy in***



***Buttock flaps***



***Abdomen scar***

***Thigh scar***

## **Will I be able to sit on a skin flap?**

All flaps need careful monitoring to ensure healing. In order to allow a flap to heal it is important that pressure is not applied to the area.

Usually, after a week you will be able to sit for five minutes, three to four times a day and this will be increased slowly.

Sitting can be a problem for many weeks or months because of discomfort and a pressure-relieving cushion when sitting is recommended.





**(Photos as alternative option instead of line diagrams)**

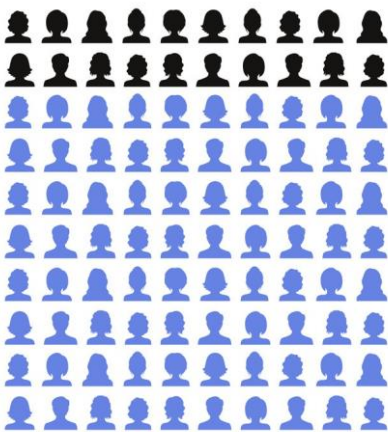
## What are the potential complications?

The risks depend on the complexity of the operation you need.

Around 20% (one in five) patients will experience a major complication from the surgery.

### Major risks of surgery include:

- Bleeding (haemorrhage)
- Heart attack (myocardial infarction)
- Blood clot in the chest (pulmonary embolism)
- Risk of the wound including muscle fully opening up
- Risk of the plastic surgical flap dying
- Injury to the bowel
- Injury to the urinary tract
- Kidney failure
- Bowel obstruction
- Formation of an abnormal passage between two places (fistula)
- Incomplete removal of the cancer or it not being possible to proceed with cancer removal during the operation.

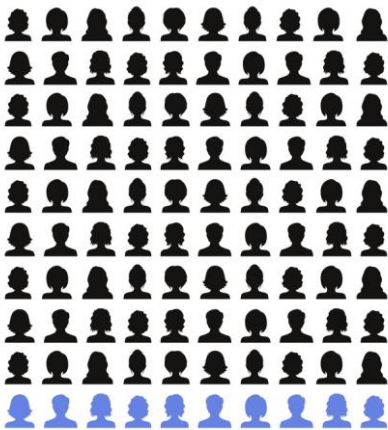


20 out of 100 experience major complications

Most patients experience some minor complications after surgery. This happens in 90% (9 out of 10) patients.

### Minor risks of surgery include:

- Infection (chest/wound/urine)
- Risk of skin wound opening up
- Collection inside the abdomen
- Bleeding and the need for a blood transfusion
- Blood clot in the legs (Deep Vein Thrombosis or DVT)
- Frequently the bowels can be slow to start working again but usually resolves in time (ileus).

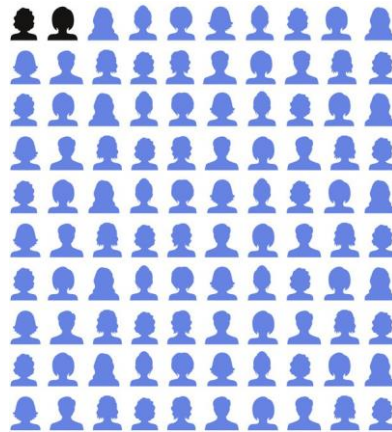


90 out of 100 experience minor complications

To minimise the risks of clots we give you elastic stockings to wear and give you blood-thinning injections to prevent clots. These injections are usually continued for 28 days after your operation.

## Can I die as a result of surgery?

The risk of dying within 30 days of the operation is less than 2%, meaning the chances of dying during the operation are low.



*2 out of 100 die after the operation*

## What do I expect after the surgery?

Following your surgery it will be necessary to keep a close eye on you. Depending where you have your surgery, this may be called high dependency, critical care or intensive care. Typically you will stay in this area for 2-5 days.

When you wake from surgery, you will have a number of things attached to you:

- Oxygen tubes in your nose or through a mask on your face.
- Drips to keep you hydrated.
- Drains (tubes) inside your tummy and bottom to drain excess fluid.
- Tube placed in your stomach via your nose to drain any fluid in your stomach.
- Staples or stitches in the wounds.

## What are the other potential things to expect? Early Issues

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|--------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>PAIN MANAGEMENT</b>         | <p>You may be offered different pain-relief options which will change during your stay. These include:</p> <ul style="list-style-type: none"> <li>• Epidural (fine tube inserted into your back infusing painkiller)</li> <li>• Patient controlled analgesia (PCA) (painkiller via a drip into your vein on demand with a button)</li> <li>• Spinal (injection into your back before the operation)</li> <li>• Rectus sheath catheters (local anaesthetic being dripped into your six pack muscles)</li> <li>• Tablets/liquids</li> </ul>                                                                                                                                          |
| <b>MOBILITY</b>                | <ul style="list-style-type: none"> <li>• Daily physiotherapy to get you walking as early as possible after your operation</li> <li>• Muscle weakness</li> <li>• Need to use a walking aid (frame/crutch/stick)</li> <li>• Problems with mobility should gradually improve</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>BOWEL/URINE CHANGES</b>     | <p><b>Bowel</b></p> <ul style="list-style-type: none"> <li>• Episodes of accidents with controlling your bowels (incontinence)</li> <li>• Leaking stoma bags if colostomy formed</li> </ul> <p><b>Urine</b></p> <p>If your bladder is not removed you will have a catheter for around a week to drain urine away from your bladder via a tube which empties into a bag. Issues after removal can be:</p> <ul style="list-style-type: none"> <li>• Episodes of wetting yourself (incontinence)</li> <li>• Inability to empty your bladder without inserting an 'in and out' catheter to drain the bladder</li> <li>• Leaking bags if urostomy formed and bladder removed</li> </ul> |
| <b>FUNCTIONAL IMPACT</b>       | <ul style="list-style-type: none"> <li>• Weakness</li> <li>• Tiredness</li> <li>• Inability to do normal tasks – washing, dressing</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>PSYCHOLOGICAL IMPACT</b>    | <ul style="list-style-type: none"> <li>• You are likely to experience a range of emotions which may or may not disappear with time (anxiety, anger, regret, fear, depression)</li> <li>• Body function. Your body will be very different in function following the surgery. You may have stoma bags. You will have a big scar. You may no longer have a back passage and may have a skin flap in its place. Your body will feel different</li> </ul>                                                                                                                                                                                                                               |
| <b>IMPACT ON RELATIONSHIPS</b> | <ul style="list-style-type: none"> <li>• Altered relationships with partner, family and friends</li> <li>• Dependence on others for normal activities – washing, dressing, cleaning</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

## Later Issues

|                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| PAIN                    | <ul style="list-style-type: none"> <li>• Long term painkilling medication may be necessary</li> <li>• Doses and types will change over time as your body starts to heal</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| MOBILITY                | <ul style="list-style-type: none"> <li>• Long-term physiotherapy</li> <li>• Walking aid (frame/crutch/stick)</li> <li>• Unable to walk more than a short distance</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| BOWEL/URINE CHANGES     | <ul style="list-style-type: none"> <li>• Ongoing bowel and urine symptoms</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| FUNCTIONAL IMPACT       | <p>Fatigue (tiredness that doesn't go away with rest) lasting longer than 12 months</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| IMPACT ON RELATIONSHIPS | <ul style="list-style-type: none"> <li>• Altered relationships with partner, family and friends.</li> <li>• Dependence on others</li> <li>• Altered sexual relationship</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| PSYCHOLOGICAL IMPACT    | <ul style="list-style-type: none"> <li>• Range of emotions which may or may not disappear with time (anxiety, anger, regret, fear, depression &amp; despondency)</li> <li>• Body image: Body changes can affect the way you think and feel about your body which can affect your self-confidence. You might also worry that people will treat you differently because of the change to your body</li> <li>• Low self-esteem or lack of confidence</li> </ul> <p>It is normal to find these changes difficult to adapt to physically and mentally. Different patients adapt in different ways. Some patients have reported:</p> <ul style="list-style-type: none"> <li>• Being too embarrassed to leave home</li> <li>• Withdrawing from social activities</li> <li>• Avoiding intimacy with a partner</li> <li>• Low mood</li> </ul> |

## Later Issues

|                 |                                                                                                                                                                                                                                                                                                                                                     |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| SEXUAL ACTIVITY | <ul style="list-style-type: none"><li>You will not be able to achieve an erection or ejaculate following this type of surgery</li></ul>                                                                                                                                                                                                             |
| WORK            | <ul style="list-style-type: none"><li>It is unlikely that you will be able to work for at least three months dependent on your job role</li><li>You may wish to consider lighter duties or reduced hours</li><li>Your employer should understand the extent of surgery you are undertaking and be prepared for a sickness of up to a year</li></ul> |
| FINANCE         | <ul style="list-style-type: none"><li>Support charities can signpost you to places for help with finances</li><li>Benefits to help you through financial difficulties. These are means tested but can help you with loss of income as well as directing you towards extra entitlements during your period of recovery and adjustment</li></ul>      |
| EXERCISE        | <ul style="list-style-type: none"><li>You may be unable to do the same exercises as you did pre-operatively</li><li>Your team may advise you not to do excessive exercise or prolonged amounts of sitting</li><li>Swimming and cycling may not be possible until the wound has completely healed</li></ul>                                          |



If you decide to have the surgery you will be followed-up for five years afterwards. Two to three weeks after your operation the results of the pathological examination (what your tumour looked like under the microscope) will be available. The team looking after you will communicate the results to you. They may suggest that you consider chemotherapy treatment.

Your follow- up will consist of clinic visits, surveillance CT scans and blood tests at different intervals for the 5 year period.

If you have any questions at any time, please ask any member of your team. They will be pleased to explain anything that concerns you or your family. Another good tip is to write your thoughts and questions down so that you do not forget when you meet your team.

## **Support - Who are we?**

We are a specialist team dealing with pelvic cancers. The team includes surgeons, doctors, surgical nurse practitioners and other specialist nurses including stoma care nurse specialists.

### ***Your Consultant is***

.....

### ***Contact number (Secretary)***

.....

### ***Your specialist nurse is***

.....

### ***Contact number***

.....

### ***Your stoma care nurse is***

.....

### ***Contact number***

.....

## Who do I contact with concerns after my operation?

If you have concerns after you have gone home then you can contact your specialist nurse or stoma care nurse or consultant via the secretary on the numbers above.

If you experience any of the following:

- persistent nausea (feeling sick) or vomiting (being sick)
- fever or a high temperature (37.5°C/101.5°F or above)
- (oozing) or increasing redness around either of the wound sites
- new pain
- new diarrhoea

Please get in contact with any of the team above or your GP. If you are unable to access these contacts out of hours then please contact the GP out of hours service or attend the A&E department of your nearest hospital.

## Useful Links



Individual patients will have different additional needs. There are charities and support groups that can help with money worries and advice on what you're entitled to and help with things like parking permits and extra money you can claim. There are online communities and support groups to help you find ways to have difficult conversations and support you as you come to terms with changes in your life. Families and friends may need support in adapting in a new role as a carer or emotional support in coming to terms with what their relative is going through. You can be put in touch with a support group where you can meet people in a similar situation and get information first- hand about your type of cancer.

You are not alone and we can signpost you to various additional support you require.



## Financial & Practical Support

Macmillan Cancer Support: [www.macmillan.org.uk](http://www.macmillan.org.uk) Tel: 0808 808 0000



Maggie's: [www.maggies.org](http://www.maggies.org) Tel: 0300 123 1801

Bowel Cancer UK: [www.bowelcanceruk.org.uk](http://www.bowelcanceruk.org.uk) Tel: 020 7940 1760

## Psychological and Emotional Support

Maggie's: [www.maggies.org](http://www.maggies.org) Tel: 0300 123 1801

Macmillan Cancer Support: [www.macmillan.org.uk](http://www.macmillan.org.uk) Tel: 0808 808 0000

Bowel Cancer UK: [www.bowelcanceruk.org.uk](http://www.bowelcanceruk.org.uk) Tel: 020 7940 1760

Beating Bowel Cancer: [www.beatingbowelcancer.org](http://www.beatingbowelcancer.org)  
Tel: 020 8973 0011

Bladder and Bowel Foundation: [www.bladderandbowelfoundation](http://www.bladderandbowelfoundation) Tel: 0845 345 0165

## Relationship support

College of Sexual Relationship Therapists: [www.cosrt.org.uk](http://www.cosrt.org.uk) Tel: 020 8543 2707

Macmillan Cancer Support: [www.macmillan.org.uk](http://www.macmillan.org.uk) Tel: 0808 808 0000

Maggie's: [www.maggies.org](http://www.maggies.org) Tel: 0300 123 1801

## Stoma support

Urostomy Association [www.urostomyassociation.org.uk](http://www.urostomyassociation.org.uk)  
Tel: 01889 563191

Colostomy Association [www.colostomyassociation.org.uk](http://www.colostomyassociation.org.uk)  
Tel: 0800 328 4257

Macmillan Cancer Support: [www.macmillan.org.uk](http://www.macmillan.org.uk) Tel:  
0808 808 0000

Bowel Cancer UK: [www.bowelcanceruk.org.uk](http://www.bowelcanceruk.org.uk) Tel:  
020 7940 1760

Beating Bowel Cancer: [www.beatingbowelcancer.org](http://www.beatingbowelcancer.org) Tel:  
020 8973 0011

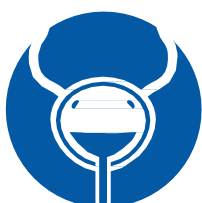
Bladder and Bowel Foundation: [www.bladderandbowelfoundation](http://www.bladderandbowelfoundation) Tel:  
0845 345 0165

## Sources

Patient Decision Aid for Men. Produced as part of study IRAS 257890.  
First published: February 2021. Review date: February 2023.

# Complex Rectal Cancer Treatment Options for Women

## *Patient Decision Aid*



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## What is complex rectal cancer?

The cancer in your pelvis that started in your bowel (rectum) may have spread to other organs nearby (locally advanced) or the cancer may have returned after previous treatment (locally recurrent).

You have been given this decision aid because surgery is a potential option for you. This decision aid aims to help you and your surgeon decide together which type of treatment is best for you. **It is important to make the choice that you feel is right for you.**

The decision will depend on your individual circumstances and how you feel about surgery. Surgery is not everyone's choice and there are different options that may not cure you but will support you through this illness.

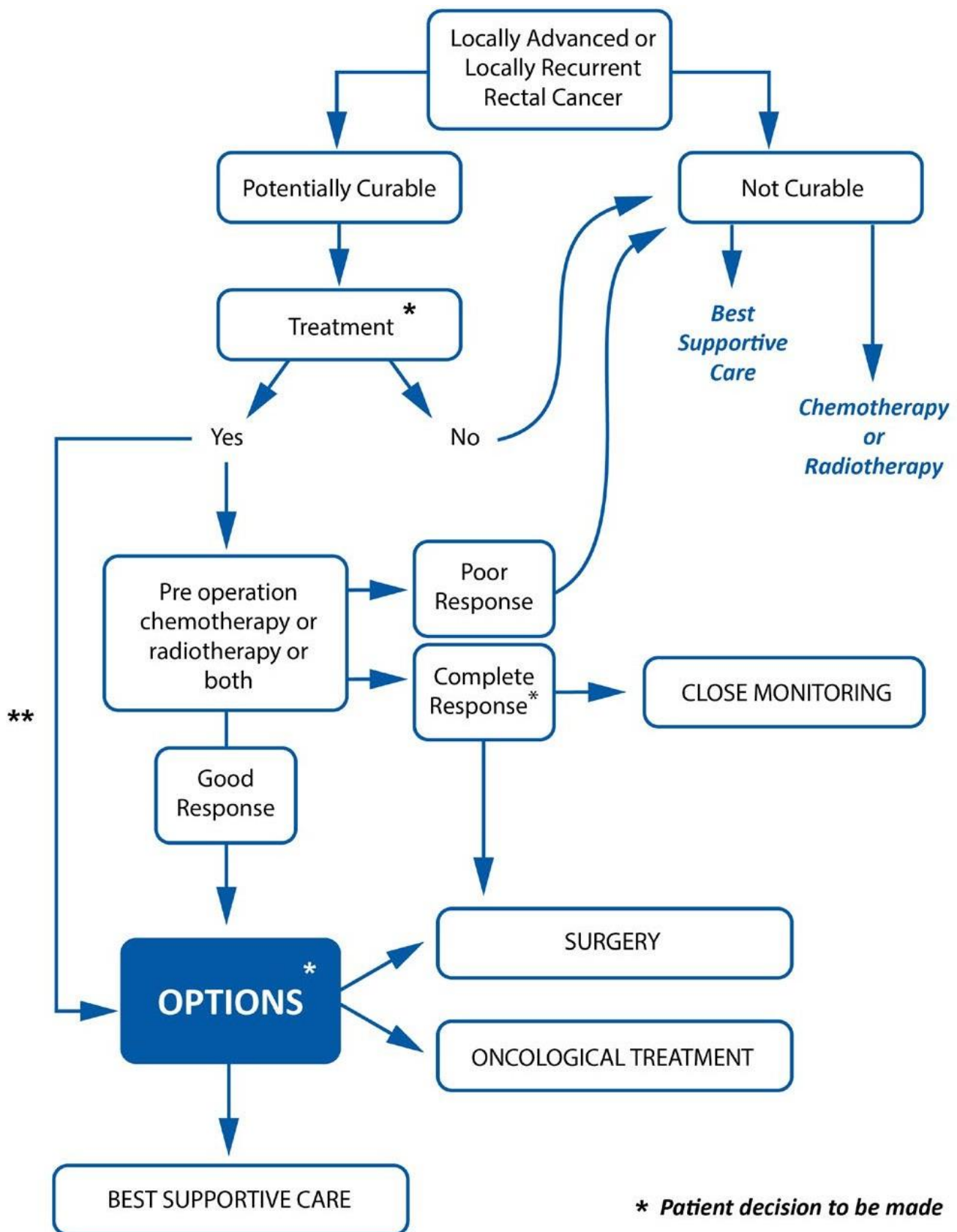
**Every woman is different so this decision aid is only a guide.** Different options will be appropriate for different patients.

You may have already had oncological treatment - chemotherapy, radiotherapy or both before you get to the option of surgery called pelvic exenteration.

You and your team may decide after having your oncological treatment that surgery is not something you want or need (complete response).

There are a number of things to consider when you are about to make a decision about treatment. It is good to think about the possible benefits and disadvantages of treatment to help you make the right decision for you. There are no right or wrong answers. People make different choices for different reasons.

This flow diagram gives you an idea where you have been on your cancer journey and the choices you now face.



Follow-up will be individualised for each patient regardless of the pathway they chose.

\* Patient decision to be made  
 \*\* In some recurrent cases, there may be a choice to proceed straight to surgery

Treatment options:

When being offered surgery there are three main options for you to consider:

- 1. To have surgery.
- 2. To have chemotherapy and/or radiotherapy alone.
- 3. To have no further active cancer treatment (best supportive care).



| SURGERY                                                 | ONCOLOGICAL TREATMENT                                                                                                                                                                                                                                                  | BEST SUPPORTIVE CARE                                                         |
|---------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| <p>Surgery is the only potential option for a cure.</p> | <p>Further oncological treatments (chemotherapy and radiotherapy) are possible dependent on what you have previously received. These treatments will be guided by your symptoms and would be used in a non-curative way. Your oncologist can discuss this further.</p> | <p>You may decide you do not want any surgical or oncological treatment.</p> |

Some patients may decide that they do not want any treatment in the form of surgery or chemotherapy and/or radiotherapy. There are reasons people choose best supportive care which may be:

- They do not want the symptoms associated with chemotherapy and radiotherapy
- They want to maximise their quality of life
- They couldn't cope psychologically with having a stoma(s)

Best supportive care is the care given to improve the quality of life of people living with cancer. The goal of supportive care is to improve the quality of life of patients and their families facing the problems associated with life-threatening illness, through treating any symptoms as early as possible and treating the psychological, social, and spiritual problems related to the cancer. This can include psychological therapy, complementary therapies and, national trials.

You will be followed up with your palliative care team of nurses and doctors who will monitor you. You may not have symptoms or need any support right now but you will be able to access all support when you need it. Your local team will be able to discuss this further.

## **Your cancer treatment goals**

Your cancer treatment goals depend on many factors:

- Being cancer free
- Living longer, even with cancer
- Having fewer symptoms from cancer and side effects from its treatment
- Maintaining physical and emotional strength
- Having a certain quality of life



## This table explains your treatment options:

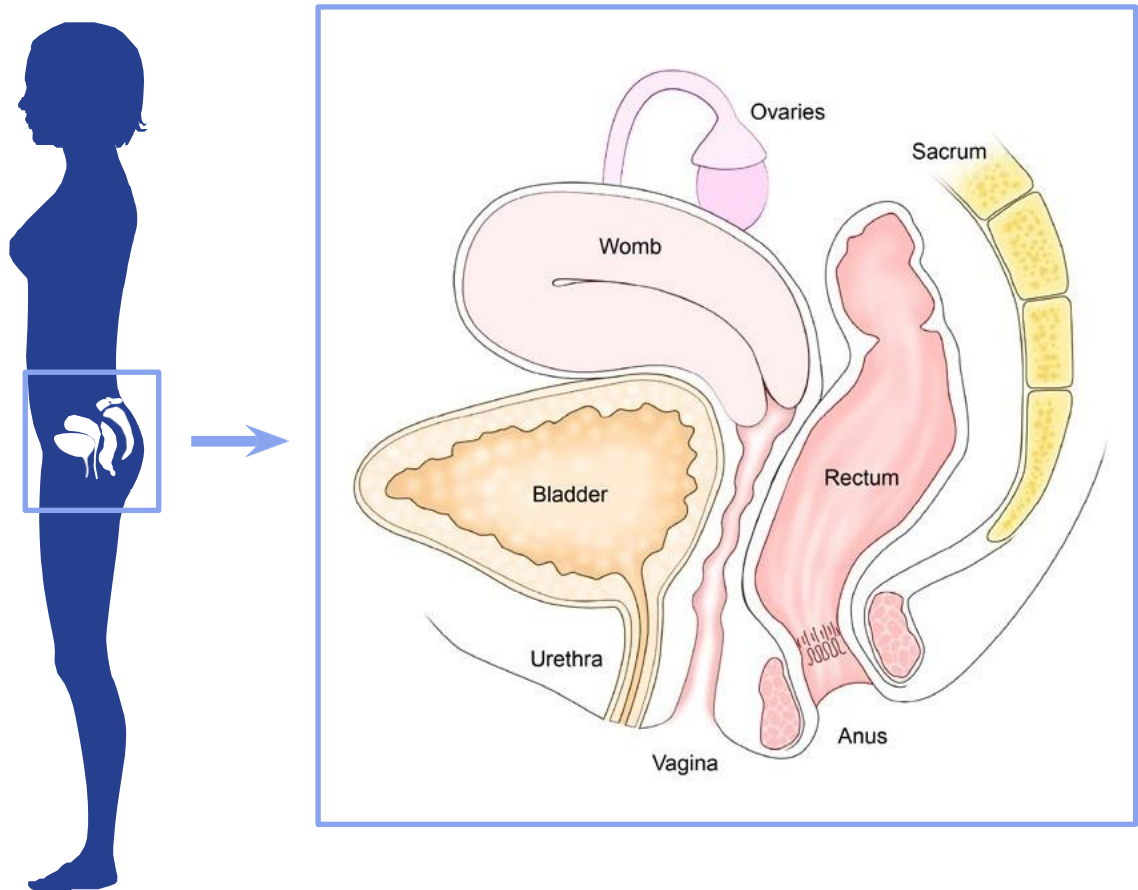
|                                                | SURGERY                                                                                                                                                                                                                                                                                                                                      | ONCOLOGICAL TREATMENT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | SUPPORTIVE TREATMENT                                                                                                                                                                                                                                                                                                        |
|------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Will this option cure me of cancer?            | <p>Surgery potentially can cure your cancer.</p> <p>This is your best chance of cure. You are only offered this surgery if there is a good chance of a cure.</p>                                                                                                                                                                             | <p>Very rarely can chemotherapy and/or radiotherapy alone cure your cancer.</p> <p>This option would not be used as curative treatment but rather palliative treatment to help control your symptoms. Your oncologist will discuss what is available to you.</p> <p>Whilst cure is not usually possible, up to 15% of patients can get a complete response (cure) to chemoradiotherapy for locally advanced rectal cancer with 8% achieving a complete response in locally recurrent rectal cancer.</p> | <p>Supportive treatment will not cure your cancer but it will treat your symptoms.</p> <p>Supportive treatment prevents or treats as early as possible the symptoms of the cancer. It also addresses the physical, psychological, social and spiritual needs tailored to your needs to give you a good quality of life.</p> |
| How will each treatment option affect my life? | <p>Surgery can affect your:</p> <ul style="list-style-type: none"> <li>• Physical health</li> <li>• Psychological health</li> <li>• Relationships</li> <li>• Lifestyle</li> </ul>                                                                                                                                                            | <p>Chemoradiotherapy can affect your:</p> <ul style="list-style-type: none"> <li>• Physical health</li> <li>• Psychological health</li> <li>• Relationships</li> <li>• Lifestyle</li> </ul> <p>Eventually you may get more symptoms which we will treat to keep you as comfortable as possible.</p>                                                                                                                                                                                                     | <p>You are likely to get more symptoms with time. You will have access to support teams in order to help you manage your symptoms and feel as comfortable as possible.</p>                                                                                                                                                  |
| What kind of support will I have?              | <ul style="list-style-type: none"> <li>• Medical team – surgeons, junior doctors, ward nurses, clinical nurse specialist</li> <li>• Oncologist (cancer doctor)</li> <li>• Stoma nurses</li> <li>• District nurses</li> <li>• Clinical Nurse Specialist</li> <li>• GP's</li> <li>• Support charities</li> <li>• Friends and family</li> </ul> | <ul style="list-style-type: none"> <li>• GP's</li> <li>• Macmillan nurses</li> <li>• Oncologist (cancer doctor)</li> <li>• Clinical Nurse Specialist</li> <li>• Support charities</li> <li>• Palliative care team when appropriate</li> <li>• Access to hospice care when appropriate</li> <li>• Friends and family</li> </ul>                                                                                                                                                                          | <ul style="list-style-type: none"> <li>• Macmillan nurses</li> <li>• GP's</li> <li>• Support charities</li> <li>• Palliative care team</li> <li>• Access to hospice care</li> <li>• Friends and family</li> </ul>                                                                                                           |

|                                               | SURGERY                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | ONCOLOGICAL TREATMENT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | SUPPORTIVE TREATMENT                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Will this option relieve my current symptoms? | Yes but you may have different symptoms following surgery.                                                                                                                                                                                                                                                                                                                                                                                                                | Short term it can relieve or improve symptoms but these symptoms may return and you could develop more symptoms as the cancer starts to grow.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Supportive treatment will control your symptoms. Without surgery your cancer will grow & any symptoms you have may get worse. There are ways of managing pain and other symptoms using both medicines and other therapies such as physiotherapy and complementary therapies.                                                                                                             |
| What are the benefits?                        | Increased chance of survival. Improved pre-operative symptoms.                                                                                                                                                                                                                                                                                                                                                                                                            | Treatment can prolong life compared to no treatment.<br><br>Not having side effects or long-term symptoms of surgery.<br><br>Rarely cures cancer.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Potentially an improved quality of life.<br><br>Not having side effects or long-term symptoms of surgery or oncological treatments.                                                                                                                                                                                                                                                      |
| What are the risks?                           | <p>You are likely to experience short and long term side effects:</p> <ul style="list-style-type: none"> <li>• Pain</li> <li>• Urinary &amp; bowel symptoms</li> <li>• Reduced mobility/weakness</li> <li>• Long term fatigue (tiredness that doesn't go away)</li> <li>• Psychological and emotional changes</li> <li>• Sexual dysfunction</li> </ul> <p>Complications:</p> <ul style="list-style-type: none"> <li>• Major</li> <li>• Minor (discussed later)</li> </ul> | <p>Symptoms are different for different people but can include the following:</p> <p>Symptoms from chemotherapy:</p> <ul style="list-style-type: none"> <li>• Pins and needles</li> <li>• Numbness/pain in feet</li> <li>• Sickness</li> <li>• Fatigue</li> <li>• Loss of appetite</li> <li>• Recurrent infections</li> <li>• Tummy pain</li> <li>• Diarrhoea or constipation</li> </ul> <p>Symptoms from radiotherapy:</p> <ul style="list-style-type: none"> <li>• Skin redness</li> <li>• Sickness</li> <li>• Fatigue</li> <li>• Diarrhoea or constipation</li> <li>• Sexual &amp; urinary dysfunction</li> </ul> <p>You will also experience psychological and emotional changes.</p> | <p>You may develop more symptoms as the cancer begins to grow which we will support you with to ensure you are as comfortable as possible. Symptoms may include:</p> <ul style="list-style-type: none"> <li>• Blockage of the bowel</li> <li>• Pain</li> <li>• Bleeding</li> <li>• Tumour can grow externally</li> <li>• Sickness</li> <li>• Fatigue</li> <li>• Poor appetite</li> </ul> |

|                                  | SURGERY                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | ONCOLOGICAL TREATMENT                                                                                                                                                                                                                                                                                                                                                                                                               | SUPPORTIVE TREATMENT                                                                                                                                                                                             |
|----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| What are my chances of survival? | <p>Survival is a very general statistic based on historical large groups of patients. <b>They can't tell you what will happen in your individual case.</b></p> <p>The terms 3-year survival and 5-year survival don't mean that you will only live for 3 or 5 years. Some people live much longer than 5 years.</p> <p><b>Ask your team about information more specific to what we know about your disease.</b></p> <p>In general, 98% of patients will be alive at 30 days after surgery.</p> <p>The <b>average survival</b> following surgery for:</p> <p><b>Locally Advanced Rectal Cancer:</b> 3 year survival: 6 in 10 patients will be alive</p>  <p>5 year survival: 4 in 10 patients will be alive</p>  <p><b>Locally Recurrent Rectal Cancer:</b> 3 year survival: 5 in 10 patients will be alive</p>  <p>5 year survival: 3 in 10 patients will be alive</p>  | <p>Oncological treatment will prolong survival and this will be different in every person.</p> <p><b>Locally Advanced Rectal Cancer:</b> Chemotherapy with, or without radiotherapy can provide palliation, and extends survival on average by 10-17 months.</p> <p><b>Locally Recurrent Rectal Cancer:</b> Chemotherapy with, or without radiotherapy can provide palliation, and extends survival on average by 10–15 months.</p> | <p><b>Locally Advanced Rectal Cancer:</b> Without treatment, most patients live for 12 months after diagnosis.</p> <p><b>Locally Recurrent Rectal Cancer:</b> Untreated patients usually survive 6-8 months.</p> |

## What does surgery involve?

Pelvic Exenteration is an operation that requires removal of all, some or part of your pelvic organs of which there are a number of different types.



### *Normal anatomy - side view*

Your team will highlight what type of surgery you are having and what is relevant for you.

Several surgeons from different specialties are involved. The operation is a major undertaking and one of the most complex surgeries performed.

There are different types of pelvic exenteration. Depending on your cancer removal of all or some of the following may be necessary:

- Part of the bowel (the colon, rectum and anus)
- The urinary system (the bladder and ureters)
- Your gynaecological organs (your uterus (womb), your ovaries, your fallopian tubes and/or your vagina)
- Your lower spine (sacrum).

**If you are considering surgery, this booklet will now provide more detail about what this will involve in the short and longer term.**

## **What does the operation involve?**

You will be asleep (under general anaesthetic) during the operation. A cut will be made from above the belly button to the bottom of your abdomen. It may also be necessary to make a second cut around the back passage (anus) and vagina. In a very small number of cases it may be possible to carry out the procedure in a minimally invasive way i.e. keyhole or robotically.

It is likely you will go to intensive care or high dependency to be looked after following your surgery and after a few days you will go to the ward. You will wake up with some tubes, drains and drips. You will be allowed to drink initially, then you will be allowed food when your body can tolerate it. Your ability to move around, out of your bed, will be reduced for up to a week.

The hospital stay after surgery is variable. Typically if there are no post-operative setbacks patients are in hospital between 14 days to 3 months. However, if you were to experience complications it can be much longer.

## **How long will it take to recover?**

These operations are a considerable undertaking and your body will go through lots of changes, so it is important that you are prepared for a long recovery. Initial recovery can take between 6 weeks and 3 months. Complete, longer term recovery can take up to 12 months.

## **Will everything in my pelvis need to be removed?**

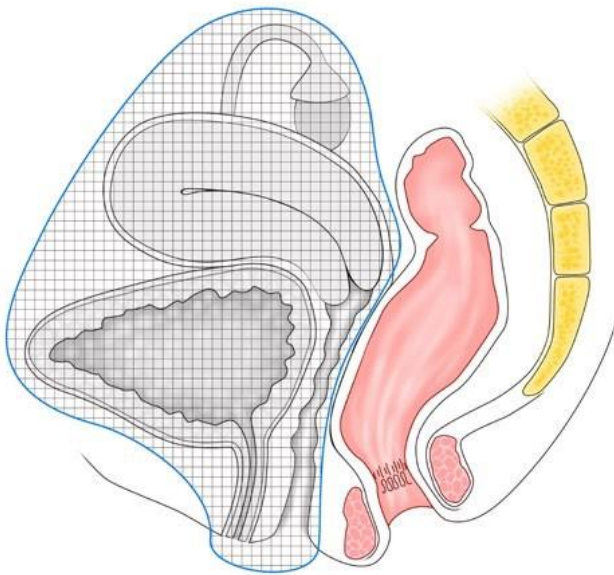
Not necessarily. There are different types of this operation depending on the location of your cancer.



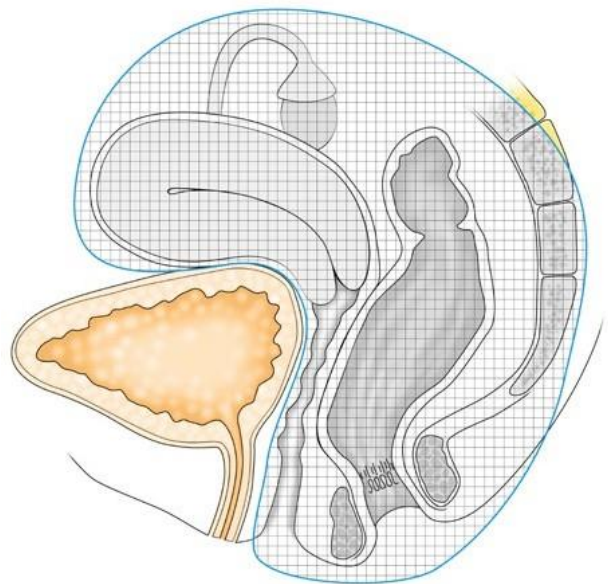
## Some variations of the surgery:

These are some possible options, depending where your tumour is.

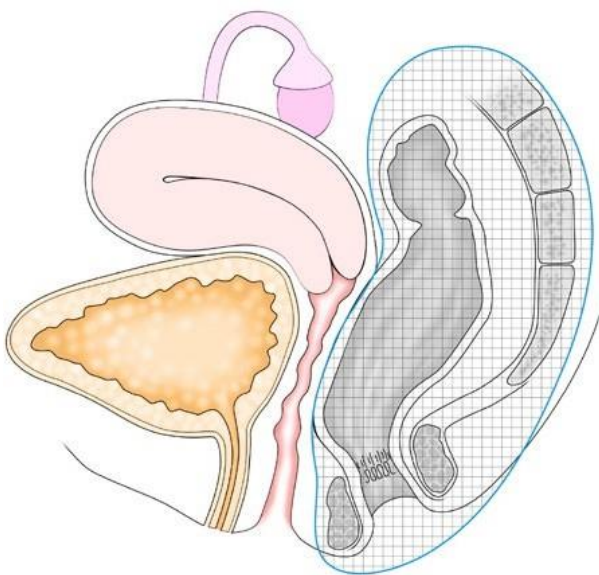
*Shaded area = what will be removed*



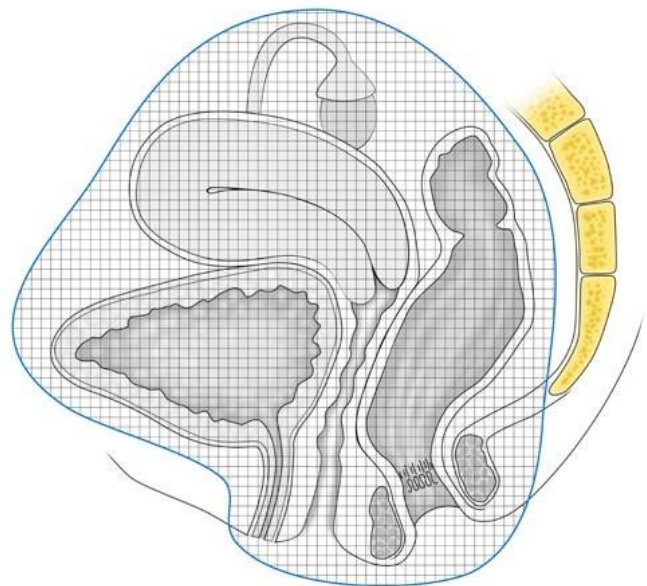
**Bladder, ureter, womb, tubes, vagina & ovaries removed**



**Rectum & anus. Occasionally womb, tubes, ovaries, vagina & sacrum removed**



**Rectum, anus & sacrum**



**Rectum, anus, bladder, ureter, womb, ovaries, tubes. Occasionally sacrum**



## Will I have a stoma bag?

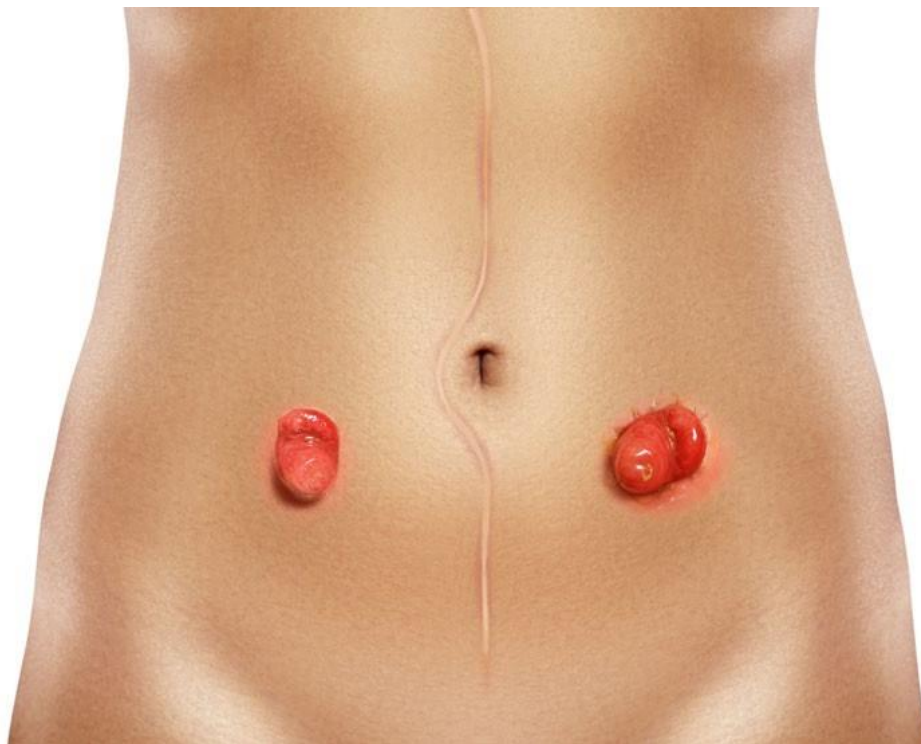
It is likely you will have a stoma bag as part of your operation.

The 'bag' is the appliance that actually sits on top of the stoma to collect your body's waste (wee/poo). A stoma is made when part of your bowel is pulled through your tummy wall onto the skin.

If your back passage (anus) is removed then the bowel will redirect waste products (poo/faeces) through a piece of bowel brought through the skin on your tummy. This is usually created to the left-hand side of your belly button. A specially designed bag sticks over the stoma to collect the faeces.

If your bladder is removed then the bowel will redirect waste products (wee/urine) through the new piece of bowel through the skin on your tummy. This is called a urostomy or ileal conduit. This is usually created to the right-hand side of your belly button. A specially designed bag sticks over the stoma to collect the urine.

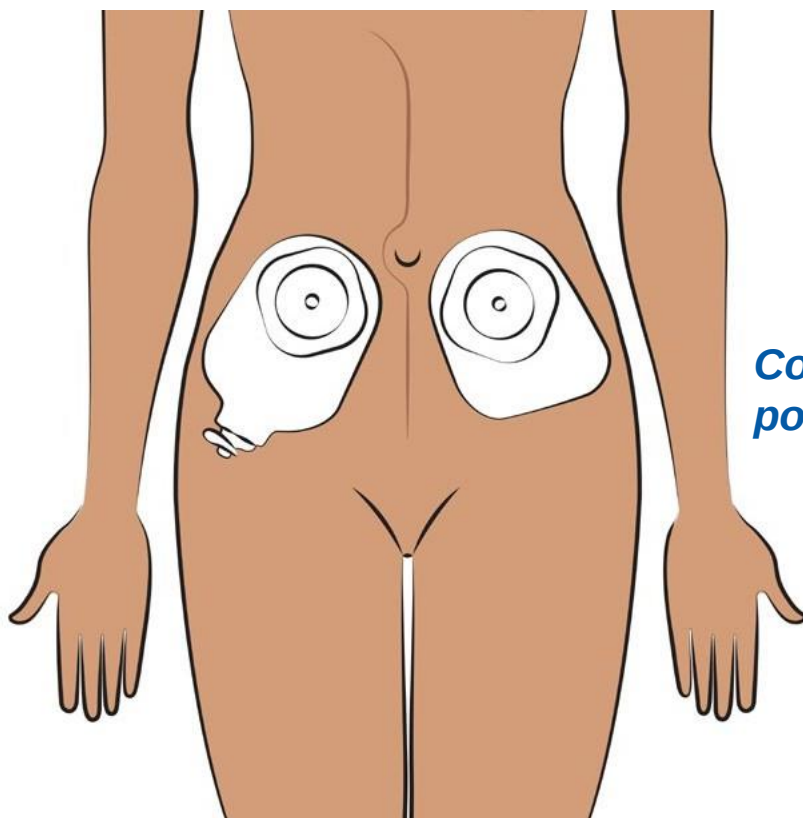
## What do stomas look like?



*Urostomy/ileal conduit*

*Colostomy*

***Urostomy bag position***



***Colostomy bag position***



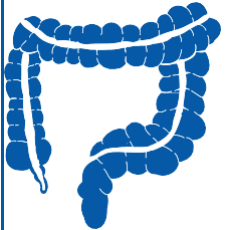
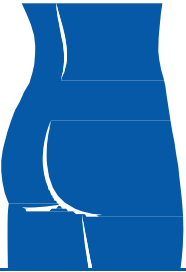
***Typical urostomy bag***

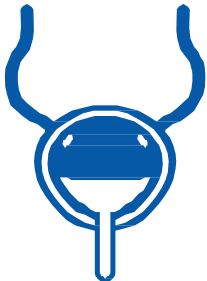


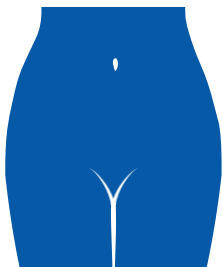
***Typical colostomy bag***



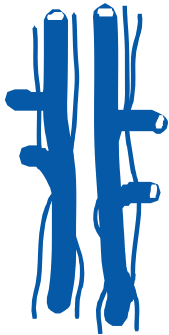
## What will I have removed & what does that potentially mean for me?

| TICK IF APPLICABLE TO ME | ORGAN                                                                                                                 | IMPLICATION                                                                                                                                                                        | SHORT TERM QUALITY OF LIFE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | LONG TERM QUALITY OF LIFE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|--------------------------|-----------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          | <b>Rectum</b> (lower part bowel)<br> | <p>It may or not be possible to join your bowel back together.</p> <p>You may need a permanent or temporary stoma.</p>                                                             | <p><b>If joined:</b></p> <ul style="list-style-type: none"> <li>• 5-15% chance of the join leaking</li> <li>• Inability to control opening your bowel (incontinence)</li> <li>• Urgency to open bowels</li> <li>• Need to open bowels often</li> <li>• Difficulty emptying your bowel despite visiting the toilet and passing soft motions often</li> </ul> <p><b>If you have a stoma:</b></p> <ul style="list-style-type: none"> <li>• Episodes of stoma leaking</li> <li>• Stoma can 'prolapse' meaning more bowel can protrude through the tummy wall than planned</li> </ul> | <p><b>If joined:</b></p> <ul style="list-style-type: none"> <li>• Inability to control opening your bowel (incontinence)</li> <li>• Urgency to open bowels</li> <li>• Need to open bowels often</li> <li>• Difficulty emptying your bowel despite visiting the toilet and passing soft motions often</li> <li>• Long term medication to regulate bowel motion</li> </ul> <p><b>If you have a stoma:</b></p> <ul style="list-style-type: none"> <li>• Infrequent episodes of stoma leaking</li> <li>• Hernia* around stoma</li> <li>• Body image</li> <li>• Emotional impact</li> <li>• Relationships affected</li> </ul> <p>(* the visible part of your stoma bulges out further from your body)</p> |
|                          | <b>Anus</b> (back passage)<br>     | <p>You will have a permanent stoma (colostomy) – this means you will poo through the stoma on your tummy.</p> <p>You will no longer have an anus as it will have been sewn up.</p> | <ul style="list-style-type: none"> <li>• Episodes of leaking stoma bags</li> <li>• Emotional impact</li> <li>• Wound issues</li> <li>• Altered sensation</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                              | <ul style="list-style-type: none"> <li>• Infrequent episodes of leaking stoma bags</li> <li>• Delayed wound healing</li> <li>• Emotional impact</li> <li>• Body image</li> <li>• Altered sensation</li> <li>• Phantom back passage pain</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

| TICK IF APPLICABLE TO ME | ORGAN                                                                                                                   | IMPLICATION                                                                                                                                                                                                                                                                                         | SHORT TERM QUALITY OF LIFE                                                                                                                                                                                                     | LONG TERM QUALITY OF LIFE                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|--------------------------|-------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          | <b>Bladder</b><br>                     | <p>You will have a permanent stoma (urostomy/ileal conduit) – urine will drain through a stoma on your abdomen into a stoma bag.</p> <p>There will be fine tubes (stents) that are visible within the stoma and are usually removed a few weeks post surgery. These help the new joins to heal.</p> | <ul style="list-style-type: none"> <li>• Frequent episodes of leaking urostomy bag</li> <li>• Urine/stent infections</li> <li>• Stents can block</li> <li>• Stents can move</li> </ul>                                         | <ul style="list-style-type: none"> <li>• Frequent episodes of leaking urostomy bag</li> <li>• Hernia around stoma – urostomy becomes difficult to manage</li> <li>• Kidney failure</li> <li>• Stoma narrowing</li> </ul>                                                                                                                                                                                                                                       |
|                          | <b>Uterus, ovaries and tubes</b><br> | <p>If you have not been through the menopause, you will no longer be able to get pregnant.</p> <p>If you have not been through the menopause, you will go through the menopause.</p> <p>You will no longer have a cervix (no further smear tests if within screening age).</p>                      | <p>Menopausal symptoms if pre-menopausal:</p> <ul style="list-style-type: none"> <li>• Flushes</li> <li>• Night sweats</li> <li>• Irritability</li> <li>• Infertility</li> <li>• Reduced libido and vaginal dryness</li> </ul> | <p>If pre-menopausal before surgery:</p> <ul style="list-style-type: none"> <li>• Infertility. If you have wishes of having a child then there are options for egg collection and IVF with surrogate</li> <li>• Longer term early menopausal management of bone health/ supplements</li> <li>• Need for hormone replacement therapy (HRT)</li> </ul> <p>General</p> <ul style="list-style-type: none"> <li>• Emotional impact</li> <li>• Body image</li> </ul> |

| TICK IF APPLICABLE TO ME | ORGAN                                                                                                                    | IMPLICATION                                                                                                                     | SHORT TERM QUALITY OF LIFE                                                                                    | LONG TERM QUALITY OF LIFE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|--------------------------|--------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          | <b>Vagina</b>                           | <p>You may or may not be able to engage in sexual intercourse involving penetration of the vagina (more information below).</p> | <ul style="list-style-type: none"> <li>Emotional impact</li> <li>Sexual dysfunction</li> </ul>                | <p>If the vagina is not reconstructed, you will not be able to engage in penetration.</p> <p>If the vagina is reconstructed:</p> <ul style="list-style-type: none"> <li>It will look and feel different</li> <li>The 'lie'/angle of the vagina may change which can cause pain on intercourse.</li> <li>The vagina will be dry and will need lubrication with non-hormonal lubricants for both dilation and sexual purposes</li> <li>You may not be able to climax in the same way</li> <li>As the new tissue starts to heal it may become scarred &amp; tight so it will be important to use dilators to keep it open.</li> <li>The reconstruction may not work for you</li> <li>Psychological impact</li> <li>Body image</li> </ul> |
|                          | <b>Hip bones</b><br>(ilium, ischium)  | <p>It can affect your mobility.</p>                                                                                             | <ul style="list-style-type: none"> <li>Altered leg control</li> <li>Leg weakness</li> <li>Hip pain</li> </ul> | <ul style="list-style-type: none"> <li>Altered leg control</li> <li>Leg weakness</li> <li>Hip pain</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

| TICK IF APPLICABLE TO ME | ORGAN                                                                                                                                                                                                               | IMPLICATION                                                                                                                                                                                                                                                                                                                                                                | SHORT TERM QUALITY OF LIFE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | LONG TERM QUALITY OF LIFE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|--------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          | <p><b>Sacrum</b><br/>(lower spine)</p>  <p>The sacrum can be divided at a high or low level depending on where your cancer is.</p> | <p><b>Low/All Sacrectomy</b><br/>You may experience pain.</p> <p><b>High Sacrectomy</b></p> <ul style="list-style-type: none"> <li>• It can affect your bladder control (if no urostomy)</li> <li>• It can affect your mobility</li> <li>• You may experience pain</li> <li>• Your legs can be effected with weakness, numbness/pins and needles, poor mobility</li> </ul> | <p><b>Low/All Sacrectomy</b><br/>Nerve pain - shooting pains, pins and needles.</p> <p><b>High Sacrectomy</b></p> <ul style="list-style-type: none"> <li>• Episodes of wetting yourself (incontinence)</li> <li>• Inability to empty the bladder without inserting an 'in and out' catheter to drain the bladder</li> <li>• Foot drop (at rest, foot remains pointing to the floor and you are unable to lift it to a normal position)</li> <li>• Muscle weakness</li> <li>• Need to use a walking aid (frame/crutch/stick)</li> <li>• Numbness to feet/legs</li> <li>• Problems with mobility may or may not gradually improve</li> </ul> | <p><b>Low/All Sacrectomy</b><br/>Long term pain.</p> <p><b>High Sacrectomy</b></p> <ul style="list-style-type: none"> <li>• Episodes of wetting yourself (incontinence)</li> <li>• Inability to empty the bladder without inserting an 'in and out' catheter to drain the bladder</li> <li>• Long-term physiotherapy</li> <li>• Foot drop (need for permanent ankle support)</li> <li>• Dependence on walking aid (frame/crutch/stick)</li> <li>• Short distance mobility only</li> <li>• Unable to walk more than a short distance</li> <li>• Modified car to drive</li> </ul> |
|                          | <p><b>Reconstructive surgery</b></p>                                                                                             | <p>New area of skin will look and feel different.</p>                                                                                                                                                                                                                                                                                                                      | <ul style="list-style-type: none"> <li>• Inability to sit for more than short periods</li> <li>• Numbness</li> <li>• Flap may die leading to issues with wound breakdown and prolonged wound healing (further detailed information later in document)</li> </ul>                                                                                                                                                                                                                                                                                                                                                                           | <ul style="list-style-type: none"> <li>• Altered sensation and appearance</li> </ul> <p>Potentially you may experience a hernia</p>                                                                                                                                                                                                                                                                                                                                                                                                                                             |

| TICK IF APPLICABLE TO ME | ORGAN                                                                                                                                                | IMPLICATION                                                                                                                                                                                                                               | SHORT TERM QUALITY OF LIFE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | LONG TERM QUALITY OF LIFE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|--------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          | <b>Nerves &amp; vessels</b><br><br>                                 | <p><b>Depending on what nerves are cut:</b></p> <p>It can affect your bladder control.</p> <p>It can affect your bowel control.</p> <p>It can affect your legs – mobility, weakness, numbness.</p> <p>Long term pain can be an issue.</p> | <ul style="list-style-type: none"> <li>• Need to catheterise to pass water (urine) if no urostomy</li> <li>• Altered leg control</li> <li>• Leg weakness</li> <li>• Leg numbness</li> <li>• Leg pain</li> <li>• Difficulty walking</li> <li>• Foot drop (at rest, foot remains pointing to the floor and you are unable to lift it to a normal position)</li> <li>• Reduced mobility</li> <li>• Inability to walk without frame/ crutch/stick</li> <li>• Able to walk short distance only</li> </ul>                                                | <ul style="list-style-type: none"> <li>• Need to catheterise to pass water (urine) if no urostomy</li> <li>• Altered leg control</li> <li>• Leg weakness</li> <li>• Leg numbness</li> <li>• Leg pain</li> <li>• Difficulty walking</li> <li>• Foot drop (need for long term ankle support)</li> <li>• Reduced mobility</li> <li>• Inability to walk without stick</li> <li>• Able to walk short distance only</li> <li>• Inability to run</li> <li>• Modified car to drive</li> </ul>                       |
|                          | <p><b>ELSIE</b><br/>(extended lateral side wall excision)</p><br> | <p>It can affect your mobility.</p> <p>You may experience pain.</p> <p>Your legs can be effected with weakness, numbness/ pins and needles, poor mobility.</p> <p>It may affect your bladder control (if no urostomy).</p>                | <ul style="list-style-type: none"> <li>• Altered leg control</li> <li>• Leg weakness</li> <li>• Buttock, leg or foot numbness</li> <li>• Foot drop (at rest, foot remains pointing to the floor and you are unable to lift it to a normal position)</li> <li>• Need to use a walking aid (frame/ crutch/stick)</li> <li>• Nerve pain – shooting pains, pins and needles</li> <li>• Episodes of wetting yourself (incontinence)</li> <li>• Inability to empty the bladder without inserting an 'in and out' catheter to drain the bladder</li> </ul> | <ul style="list-style-type: none"> <li>• Long-term physiotherapy</li> <li>• Foot drop (need for long term ankle support)</li> <li>• Inability to walk without a stick</li> <li>• Inability to walk more than a short distance</li> <li>• Inability to run</li> <li>• Long-term pain</li> <li>• Need to modify your car to drive</li> <li>• Episodes of wetting yourself (incontinence)</li> <li>• Inability to empty the bladder without inserting an 'in and out' catheter to drain the bladder</li> </ul> |

## What are the other potential things to expect after surgery?

| Impact                  | Short Term                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Long Term                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Pain</b>             | <p>You may be offered different pain-relief options which will change during your hospital stay. These include:</p> <ul style="list-style-type: none"> <li>• Epidural (fine tube inserted into your back infusing painkiller)</li> <li>• Patient controlled analgesia (PCA) (painkiller via a drip into your vein on demand with a button)</li> <li>• Spinal (injection into your back before the operation)</li> <li>• Rectus sheath catheters (local anaesthetic being dripped into your six-pack muscles)</li> <li>• Tablets/liquids/patches</li> </ul> <p>The pain relief appropriate for you will be discussed with the anaesthetist</p> | <p>Long term painkilling medication may be necessary. Doses and types will change over time as your body starts to heal.</p>                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Physical Changes</b> | <p><b>Functional</b></p> <ul style="list-style-type: none"> <li>• Weakness</li> <li>• Tiredness</li> <li>• Inability to do normal tasks – for example washing, dressing</li> </ul> <p><b>Hormonal (if pre-menopausal before surgery) **</b></p> <ul style="list-style-type: none"> <li>• Hot flushes</li> <li>• Night sweats</li> <li>• Difficulty sleeping</li> <li>• Low mood or anxiety</li> <li>• Problems with memory and concentration</li> </ul>                                                                                                                                                                                       | <p><b>Functional</b></p> <ul style="list-style-type: none"> <li>• Fatigue (tiredness that does not go away with rest) lasting longer than 12 months</li> </ul> <p><b>Hormonal (if pre-menopausal before surgery) **</b></p> <ul style="list-style-type: none"> <li>• Reduced sex drive</li> <li>• Vaginal dryness and discomfort during sex</li> <li>• Difficulty sleeping</li> <li>• Low mood or anxiety</li> <li>• Problems with memory and concentration</li> <li>• Loss of bone strength</li> <li>• Weight gain</li> </ul> |

**\*\* There are various medications you can have to improve these symptoms – please discuss further with your doctor if applicable to you**

| Impact                   | Short and Long Term                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|--------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Physical Changes</b>  | <p><b>Body changes:</b></p> <ul style="list-style-type: none"> <li>• Your body will be very different following the surgery</li> <li>• You may have one or two stomas</li> <li>• You will have scars</li> <li>• You may no longer have a back passage (anus)</li> <li>• You may have a skin flap which has altered or no sensation with another area where the flap was taken from which may be slightly disfigured</li> <li>• Your body will feel different</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Emotional changes</b> | <p><b>Emotions:</b><br/>Anxiety, Anger, Regret, Fear, Depression, Sadness.</p> <p>These emotions will change with time. You will get good days as well as bad days. These emotions may or may not disappear with time. Experience of other patients suggests you will adapt. There are support mechanisms to help you through it.</p> <p><b>Long Term</b></p> <p><b>Infertility:</b> If cancer treatment results in your inability to get pregnant this can affect you psychologically. There is the option of egg collection and a surrogate.</p> <p><b>Body image:</b> Body changes can affect the way you think and feel about your body which can affect your self- confidence. You might also worry that people will treat you differently because of the change to your body.</p> <p>Low self-esteem or lack of confidence.</p> <p>It is normal to find these changes difficult to adapt to physically and mentally. Different patients adapt in different ways. Some patients have reported:</p> <ul style="list-style-type: none"> <li>• Being too embarrassed to leave home</li> <li>• Withdrawing from social activities</li> <li>• Avoiding intimacy with a partner</li> <li>• Low mood</li> </ul> |

| Impact                | Long Term                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Sexual changes</b> | <p>Pre-existing sexual status will determine recovery of your sex life. If you do not have sexual intercourse now (before surgery) then this may not be relevant to you. If you do engage in sexual relations then sex will never be the same following this surgery.</p> <p>You should discuss with your partner the changes that will happen to your body and that sexual relations may resume in the long term however it may be very different to its current state.</p> <p>If your vagina is fully or partially removed and you decide not to have a reconstruction the space will be stitched up leaving little or no vagina and sexual intercourse will not be possible (the rest of this section will not be relevant to you).</p> <p><b>General changes</b></p> <ul style="list-style-type: none"> <li>• The vagina may change shape following surgery and radiotherapy</li> <li>• The 'lie'/angle of the vagina may alter which might make penetration less comfortable and require you to adopt a different sexual position for penetration</li> <li>• Sex may not be the same. The vagina will be dry needing lubrication in order to use it</li> <li>• You may not be able to climax in the same way</li> <li>• You may feel a loss of desire</li> <li>• It may feel different inside and outside</li> <li>• You will need to use vaginal moisturisers and lubricants and / or oestrogen creams (if no reconstruction)</li> </ul> <p><b>Vaginal reconstruction</b></p> <ul style="list-style-type: none"> <li>• It will look and feel different.</li> <li>• You may not have any feeling inside</li> <li>• Other organs – labia and clitoris may feel different and some patients have described unpleasant sensations in the genital area</li> <li>• You will need to use dilators to keep it open</li> <li>• You will need to use non-hormonal lubricants for dilation and sexual purposes</li> </ul> <p>Your vulva (clitoris, labia, mons pubis - see picture below) usually would not be removed in your operation. The operation may affect the way this area feels and can change the way you are able to orgasm.</p> <p>There is a choice to pursue penetrative sex – some may accept not to.</p> |



| Impact               | Short Term                                                                                                                                                                                                           | Long Term                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Relationships</b> | <p>Altered relationships with partner.</p> <p>Altered relationships with family and friends.</p> <p>Dependence on others for normal activities – washing, dressing, cleaning.</p>                                    | <p><b>Altered relationship with partner</b><br/>Although physical penetration may change, there will be other ways of being intimate. Sex is more than just penetration. There is a psychological aspect to sex. How you feel sexually is about how you feel both physically and psychologically. You may still express desire and arousal but this may be shown differently.</p> <p><b>Altered relationships with family and friends</b><br/>You may feel differently after this surgery and that may or may not impact your relationships with others.</p> |
| <b>Work</b>          | <p>You are unlikely to work short term unless you can work from home and this doesn't require you to sit for long periods. Your employer should understand that you would need some flexibility within your day.</p> | <p>Your employer should understand the extent of surgery you are undertaking and prepared for a sickness of up to a year.</p> <p>You may never be able to return to the same job you performed before.</p>                                                                                                                                                                                                                                                                                                                                                   |
| <b>Finance</b>       | <p>Potential loss of income.</p>                                                                                                                                                                                     | <p>Financial difficulty can be addressed by support charities who can direct you to places for help with money problems. Benefits can help you through financial difficulties. These are means tested but can help you with loss of income as well as directing you towards extra entitlements during your period of recovery and adjustment.</p>                                                                                                                                                                                                            |
| <b>Exercise</b>      | <p>Short term pain.</p> <p>Lack of energy.</p> <p>Change in routine that effect exercise.</p>                                                                                                                        | <p>You may or may not be able to do the same exercises as you did pre-operatively. Your team may advise you not to do excessive exercise or prolonged amounts of sitting. Swimming and cycling may not be possible until the wound has completely healed. Returning to 'normal' activity is the goal and this expected in the majority of patients.</p>                                                                                                                                                                                                      |

## Will I have reconstructive surgery?

After organs affected by the cancer have been removed, some patients may benefit from reconstructive surgery. This is usually done at the same operation as the pelvic exenteration, by a Plastic Surgeon working with the surgical team. It involves moving tissue from elsewhere in the body into the pelvis and bottom end.

The tissue that is moved is known as a flap. It usually consists of skin, fat and muscle. Flaps can be moved from several places, including the tummy (abdomen), buttocks or thighs. Which of these is most suitable for you will depend mainly on the type and extent of the surgery you are having. For a flap to work well it must have a good blood supply. This is usually not a problem but if it is, part or all of the flap may die and need to be removed.

The benefits of reconstructive surgery are:

- To fill up the space left when organs in the pelvis are removed
- To prevent long term problems, such as a pelvic hernia or chronic infection
- To help wounds to heal quickly
- To reconstruct the vagina if necessary

The risks of reconstructive surgery are:

- Adding time on to a long operation
- It may fail resulting in prolonged wound problems, hernia, occasionally need for re-operation
- It may leave a deformity in the area the flap is taken from

Reconstructive surgery cannot make things totally normal again. For instance, it cannot recreate a back passage (anus) that works.



## **Do I have to have reconstructive surgery if it is offered to me?**

Vaginal reconstruction is your choice. However, if a 'flap' has been discussed with you it is usually necessary in order to fill the space following the removal of your cancer.

It is important that you discuss this with your Plastic Surgeon.

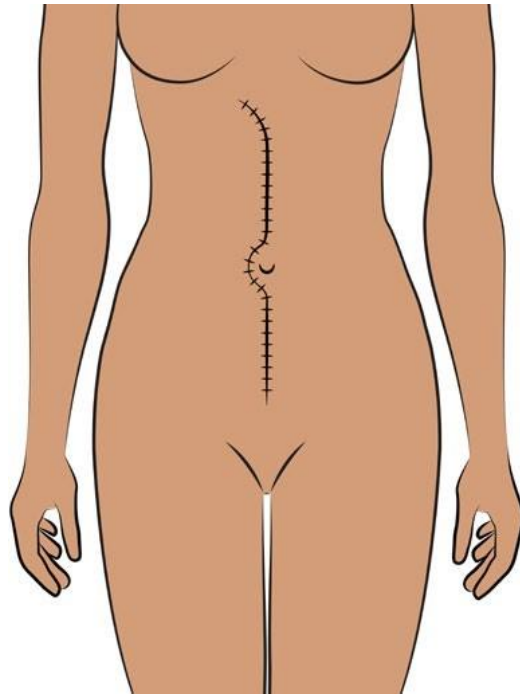
## **Will I be able to sit after the surgery?**

It is sometimes best for patients who have had reconstructive surgery, not to sit normally for 1 to 2 weeks. This is to avoid putting pressure on the flap tissue. For the same reason, these patients are also encouraged to lie on their side while they are in bed. Once sitting is allowed, a pressure-relieving air cushion is recommended. A graduated sitting programme is introduced to help you adjust to sitting.

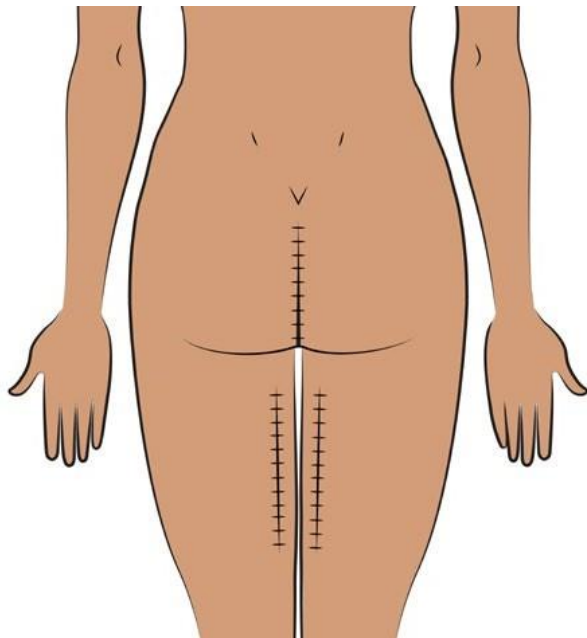
## **What will things look like after my surgery?**

Surgery always leaves scars. In normal clothes these will not be visible, but without clothes on you will be able to see scars on your (tummy) abdomen and elsewhere. Your stoma (or stomas) will also be visible and the shape of your abdomen, buttocks or thighs may also have changed if a flap from these areas has been used. This may be visible even in clothes. Following surgery, your bottom end (perineum) may also feel numb.

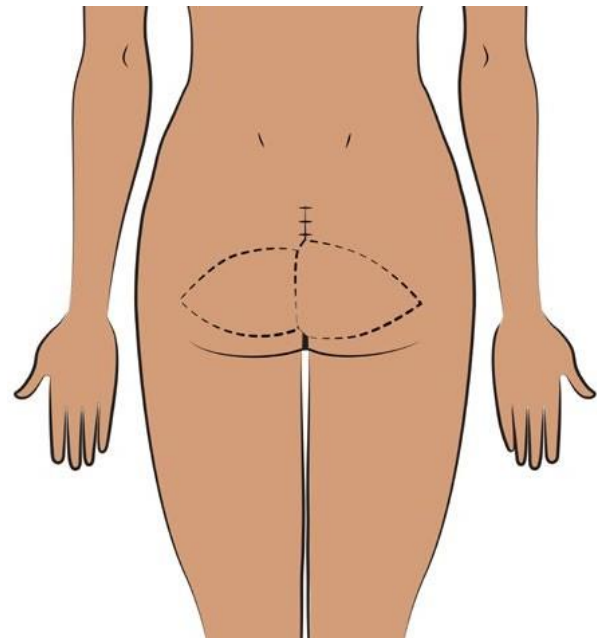
When a flap from the tummy (abdomen) is used, the scars are as shown in diagram A. Scars from thigh and buttock flaps are shown in diagrams B & C.



**A** Abdomen scar



**B** Thigh scar



**C** Buttock flaps

## If I need Vaginal Reconstruction, can I have sex?

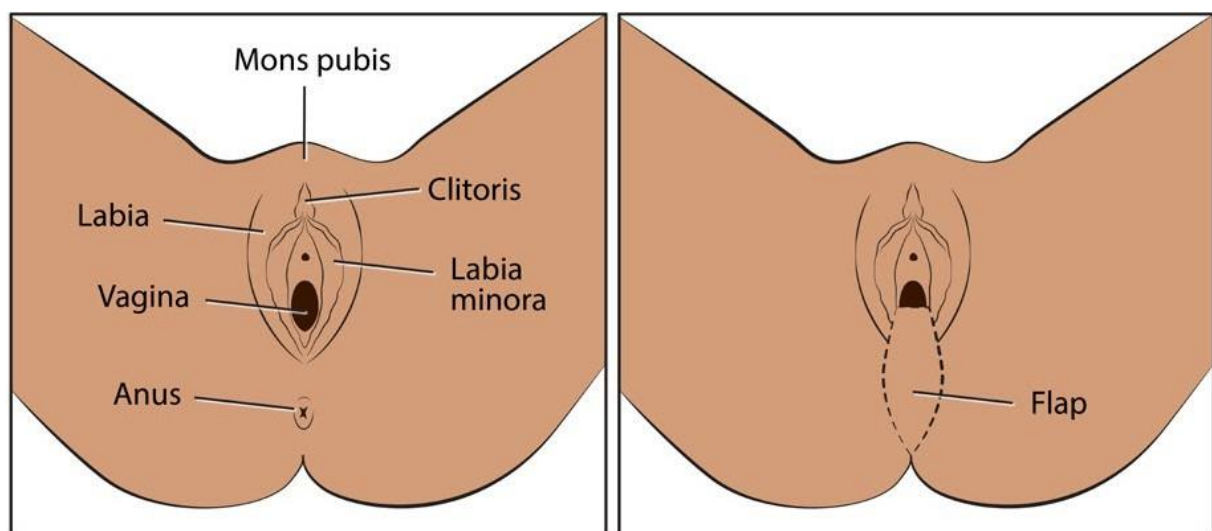
Yes. Once your wounds have healed well you will be able to resume having penetrative sexual intercourse. Healing time is different in all patients.

A reconstructed vagina cannot make things totally normal again. It will provide you with a hole in the same position as your old vagina but it will be a different shape and size. It may lie in a different angle to before.

Scars inside the vagina can sometimes feel tight and you may need to use dilators to keep the new vagina open. Your Specialist Nurse can show you how to do this and how often.

Sex will never be the same again following this surgery. Your new vagina will feel different. You may not have any feeling inside. You may experience pain when using it. You will still have your clitoris and this may still be able to give you an orgasm. However, initially, it may be uncomfortable or painful to touch.

At first you will need to use lubricants for dilation and sex, to build up your confidence and they are likely to be needed long term. You can also speak to your team about starting on HRT to help with libido if you were pre-menopausal before treatment.



***Normal vagina & anus***

***Flap in position***

## What are the potential complications?

The risks depend on the complexity of the operation you need.

Around 20% (one in five) patients will experience a major complication from the surgery.

### Major risks of surgery include:

- Excessive bleeding (return to theatre, major blood transfusion)
- Heart attack (myocardial infarction)
- Blood clot in the chest (pulmonary embolism)
- Risk of the wound including muscle fully opening up
- Risk of the plastic surgical flap dying
- Collection in the pelvis (x-ray guided drain insertion)
- Injury to the bowel
- Injury to the urinary tract
- Kidney failure
- Bowel obstruction
- Formation of an abnormal passage between two places (fistula)
- Incomplete removal of the cancer or it not being possible to proceed with cancer removal during the operation
- Need for reoperation 10%

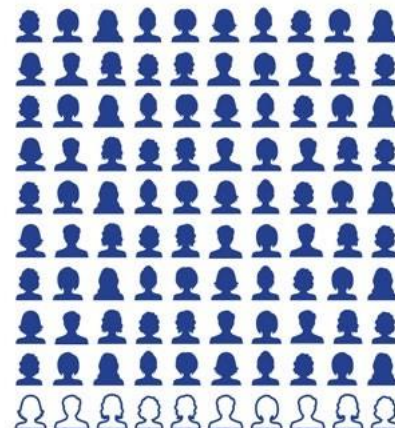


*20 out of 100 experience  
major complications*

Most patients experience some minor complications after surgery. This happens in 90% (9 out of 10) patients.

### Minor risks of surgery include:

- Infection (chest/wound/urine)
- Risk of skin wound opening up
- Blood clot in the legs (Deep Vein Thrombosis or DVT)
- Bowels slow to start working again but usually resolves in time (ileus)



*90 out of 100 experience minor complications*



To minimise the risks of clots we give you elastic stockings to wear and give you blood-thinning injections to prevent clots. These injections are usually continued for 28 days after your operation.

## Can I die as a result of surgery?

The risk of dying within 30 days of the surgery is less than 2%, meaning the chances of dying during the operation are low.



*2 out of 100 die after the operation*

Your chances of surviving 90 days after surgery are 95% (95 out of 100).

## What do I expect after the surgery?

Following your surgery it will be necessary to keep a close eye on you. Depending where you have your surgery, this may be called high dependency, critical care or intensive care. Typically you will stay in this area for 2-5 days.

When you wake from surgery, you will have a number of things attached to you:

- Oxygen tubes in your nose or through a mask on your face
- Drips to keep you hydrated.
- Drains (tubes) inside your tummy and bottom to drain excess fluid
- Tube placed in your stomach via your nose to drain any fluid in your stomach
- Staples or stitches in the wounds



If you decide to have the surgery you will be followed-up for five years afterwards. Two to three weeks after your operation the results of the pathological examination (what your tumour looked like under the microscope) will be available. The team looking after you will communicate the results to you. They may suggest that you consider chemotherapy treatment.

## **Do I have to have chemotherapy if it's offered?**

You will have a discussion with your oncologists regarding the risk and benefit for you as an individual. If it is offered as an option, it is usually only beneficial within 3 to 6 months after surgery.

You may have lots of questions regarding more chemotherapy. These can be discussed with your oncologist. If you decide to have chemotherapy and cannot tolerate it, then you can stop treatment.

## **What is my follow-up?**

Your follow-up will consist of clinic visits, surveillance CT scans and blood tests at different intervals for the 5 year period. If you have any questions at any time, please ask any member of your team. They will be pleased to explain anything that concerns you or your family. Another good tip is to write your thoughts and questions down so that you do not forget when you meet your team.



## Support - Who are we?

We are a specialist team dealing with pelvic cancers. The team includes surgeons, doctors, surgical nurse practitioners and other specialist nurses including stoma care nurse specialists.

**Your Consultant is** .....

**Contact number (Secretary)** .....

**Your specialist nurse is** .....

**Contact number** .....

**Your stoma care nurse is** .....

**Contact number** .....

## Who do I contact with concerns after my operation?

If you have concerns after you have gone home then you can contact your specialist nurse or stoma care nurse or consultant via the secretary on the numbers above.

If you experience any of the following:

- persistent nausea (feeling sick) or vomiting (being sick)
- fever or a high temperature (37.5°C/101.5°F or above)
- oozing or increasing redness around either of the wound sites
- new pain
- new diarrhoea

Please get in contact with any of the team above or your GP. If you are unable to access these contacts out of hours then please contact the GP out of hours service or attend the A&E department of your nearest hospital.

## Support

You may want to discuss your options further. There are charities and support groups that can help. There are also online communities and support groups that you can talk to. You will need to discuss things with your family and/or friends which may mean some difficult conversations.

It is important that you get the right support for you as you come to terms with the decision you face. It is important that you understand the implications of what life may look like by surviving the disease. Families and friends may need support with the idea of adapting in a new role as a carer or emotional support in coming to terms with what their relative is going through. You can be put in touch with a support group where you can meet people in a similar situation and get information first-hand about your type of cancer. You are not alone and we can signpost you to various additional support you require. You may also want to re-discuss things with your team and it is important that you get in touch if you feel this is something you need to do.

### **For additional support services or further discussions (outside your medical team), we recommend:**

Macmillan Cancer Support: [www.macmillan.org.uk](http://www.macmillan.org.uk)  
Tel: 0808 808 0000

Maggie's: [www.maggies.org](http://www.maggies.org)  
Tel: 0300 123 1801

Bowel Cancer UK: [www.bowelcanceruk.org.uk](http://www.bowelcanceruk.org.uk)  
Tel: 020 7940 1760

Beating Bowel Cancer: [www.beatingbowelcancer.org](http://www.beatingbowelcancer.org)  
Tel: 020 8973 0011

Bladder and Bowel Foundation: [www.bladderandbowelfoundation.org](http://www.bladderandbowelfoundation.org)  
Tel: 0845 345 0165

Urostomy Association [www.urostomyassociation.org.uk](http://www.urostomyassociation.org.uk)  
Tel: 01889 563191



Colostomy Association [www.colostomyassociation.org.uk](http://www.colostomyassociation.org.uk)  
Tel: 0800 328 4257

It is important to get as emotionally prepared as possible before you decide to have this operation. There are NHS psychological support services available to help you adjust to the losses in your body as well as the permanent changes of how your body will function. You may feel you are getting enough support from your family, GP and hospital team including your CNS, however, sometimes more specialist input is needed.

## **Psychosexual issues**

College of Sexual Relationship Therapists: [www.cosrt.org.uk](http://www.cosrt.org.uk)  
Tel: 020 8543 2707

RELATE. Low cost relationship & sexual therapy services across the UK: [www.relate.org.uk](http://www.relate.org.uk)

## **Psychological issues**

NHS psycho-oncology services and psychological support services are available in specialist centres. However, additional psychological counselling can be found:

British Psychological Society  
<https://www.bps.org.uk/public/find-psychologist>

British Association for Counselling & Psychotherapy  
<https://www.bacp.co.uk/search/Therapists>

UK Council for Psychotherapy: <https://www.psychotherapy.org.uk/>

## **Sexual issues**

CNS or pelvic floor physiotherapists will provide specialist practical support.

## Menopausal issues

Support in dealing with menopause following this surgery can be found:  
Manage my Menopause - [www.managemymenopause.co.uk](http://www.managemymenopause.co.uk) Menopause

matters - [www.menopausematters.co.uk](http://www.menopausematters.co.uk)

Daisy Network (aimed at young women with premature ovarian failure)  
[www.daisynetwork.org](http://www.daisynetwork.org)

## Do not identify as heterosexual / cisgender?

LGBTQI Cancer Charity for those individuals who do not identify as  
heterosexual / cisgender: [www.livethroughthis.co.uk](http://www.livethroughthis.co.uk)

**If you decide to have surgery you may want to revisit this document  
after surgery to remind you of the adjustments you may face.**

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First published: May 2021. Review date: May 2023.

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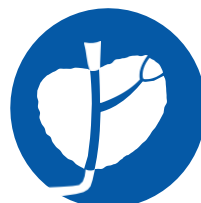
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# Complex Rectal Cancer Treatment Options for Men

## *Patient Decision Aid*



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## What is complex rectal cancer?

The cancer in your pelvis that started in your bowel (rectum) may have spread to other organs nearby (locally advanced) or the cancer may have returned after previous treatment (locally recurrent).

You have been given this decision aid because surgery is a potential option for you. This decision aid aims to help you and your surgeon decide together which type of treatment is best for you. **It is important to make the choice that you feel is right.**

The decision will depend on your individual circumstances and how you feel about surgery. Surgery is not everyone's choice and there are different options that may not cure you but will support you through this illness.

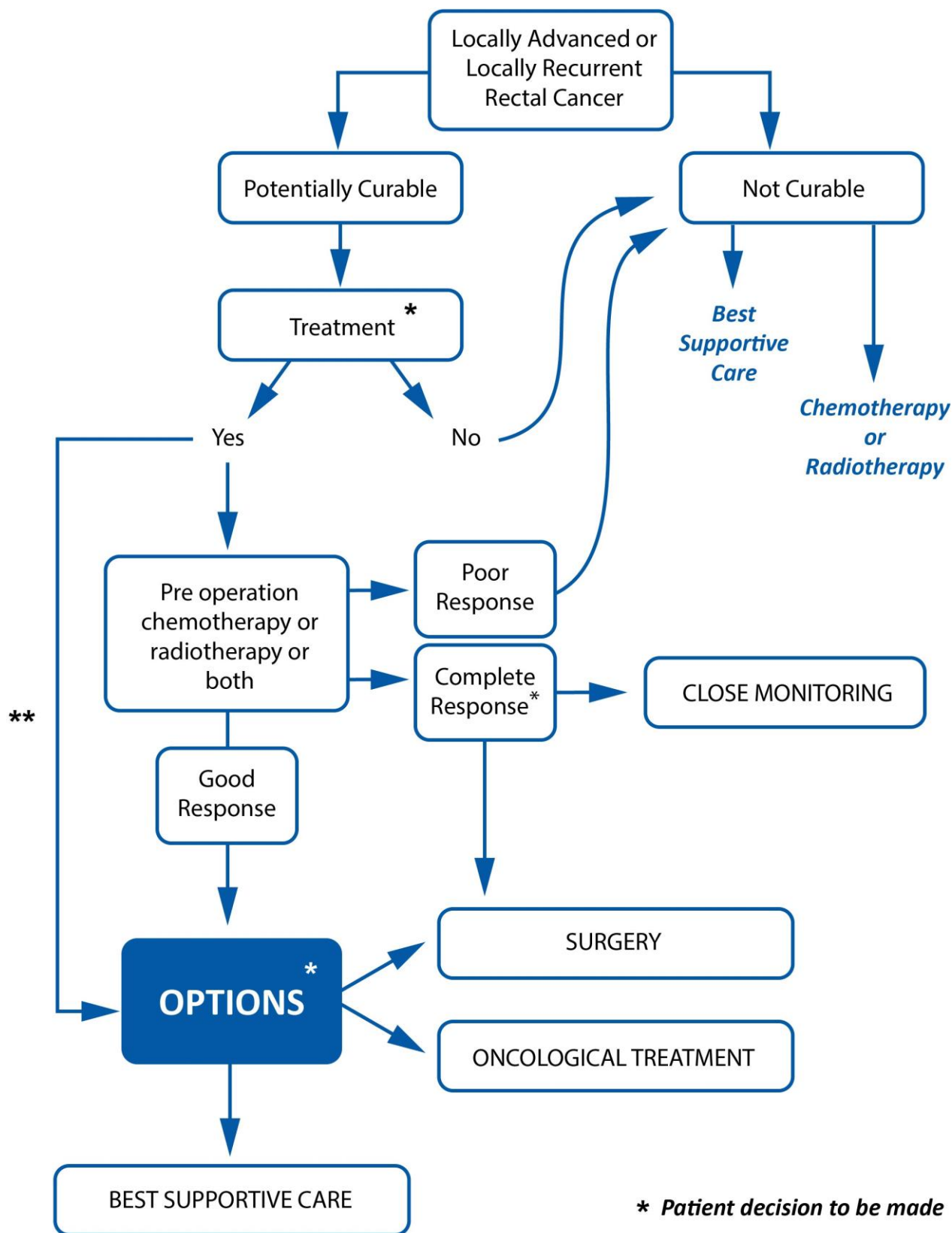
**Every man is different so this decision aid is only a guide.** Different options will be appropriate for different patients.

You may have already had oncological treatment (chemotherapy, radiotherapy or both) before you get to the option of surgery called pelvic exenteration.

You and your team may decide after having your oncological treatment that surgery is not something you want or need (complete response).

There are a number of things to consider when you are about to make a decision about treatment. It is good to think about the possible benefits and disadvantages of treatment to help you make the right decision for you. There are no right or wrong answers. People make different choices for different reasons.

This flow diagram gives you an idea where you have been on your cancer journey and the choices you now face.



Follow-up will be individualised for each patient regardless of the pathway they chose.

**\* Patient decision to be made**  
**\*\* In some recurrent cases, there may be a choice to proceed straight to surgery**



# Treatment options

When being offered surgery there are three main options for you to consider:

- 1. To have surgery.
- 2. To have chemotherapy and/or radiotherapy.
- 3. To have no further active cancer treatment (best supportive care).



| SURGERY                                                 | ONCOLOGICAL TREATMENT                                                                                                                                                                                                                                                   | BEST SUPPORTIVE TREATMENT                                                    |
|---------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| <p>Surgery is the only potentially option for cure.</p> | <p>Further oncological treatments (chemotherapy and radiotherapy) are possible dependent on what you have previously received. These treatments will be guided by your symptoms and would be used in a non- curative way. Your oncologist can discuss this further.</p> | <p>You may decide you do not want any surgical or oncological treatment.</p> |

Some patients may decide that they do not want any treatment in the form of surgery or chemotherapy and/or radiotherapy. There are reasons people choose best supportive care which may be:

- They do not want the symptoms associated with chemotherapy and radiotherapy
- They want to maximise their quality of life
- They couldn't cope psychologically with having a stoma(s)

Best supportive care is the care given to improve the quality of life of people living with cancer. The goal of supportive care is to improve the quality of life of patients and their families facing the problems associated with life-threatening illness, through treating any symptoms as early as possible and treating the psychological, social, and spiritual problems related to the cancer. This can include psychological therapy, complementary therapies and, national trials.

You will be followed up with your palliative care team of nurses and doctors who will monitor you. You may not have symptoms or need any support right now but you will be able to access all support when you need it. Your local team will be able to discuss this further.

## **Your cancer treatment goals**

Your cancer treatment goals depend on many factors:

- Being cancer free
- Living longer, even with cancer
- Having fewer symptoms from cancer and side effects from its treatment
- Maintaining physical and emotional strength
- Having a certain quality of life

## This table explains your treatment options:

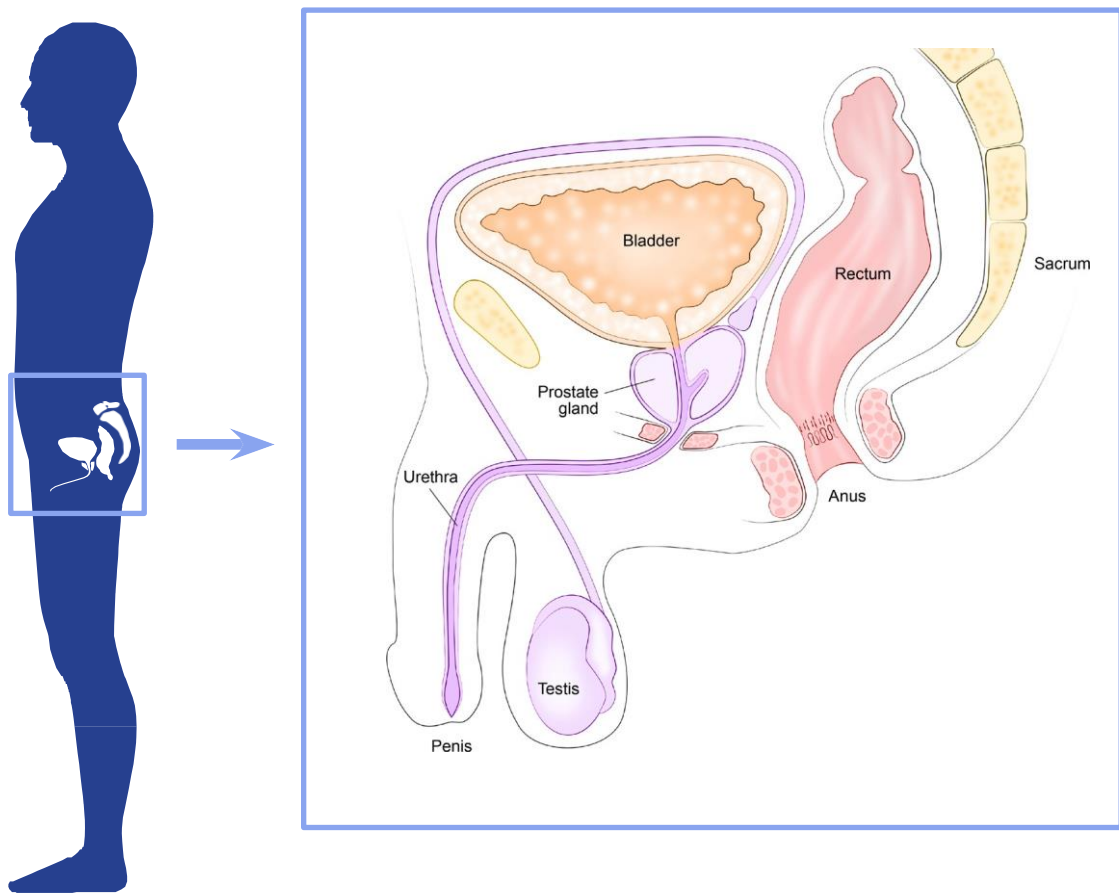
|                                                | SURGERY                                                                                                                                                                                                                                                                                                                                      | ONCOLOGICAL TREATMENT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | SUPPORTIVE TREATMENT                                                                                                                                                                                                                                                                                                        |
|------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Will this option cure me of cancer?            | <p>Surgery potentially can cure your cancer.</p> <p>This is your best chance of cure. You are only offered this surgery if there is a good chance of a cure.</p>                                                                                                                                                                             | <p>Very rarely can chemotherapy and/or radiotherapy alone cure your cancer.</p> <p>This option would not be used as curative treatment but rather palliative treatment to help control your symptoms. Your oncologist will discuss what is available to you.</p> <p>Whilst a cure is not usually possible, up to 15% of patients can get a complete response (cure) to chemoradiotherapy for locally advanced rectal cancer with 8% achieving a complete response in locally recurrent rectal cancer.</p> | <p>Supportive treatment will not cure your cancer but it will treat your symptoms.</p> <p>Supportive treatment prevents or treats as early as possible the symptoms of the cancer. It also addresses the physical, psychological, social and spiritual needs tailored to your needs to give you a good quality of life.</p> |
| How will each treatment option affect my life? | <p>Surgery can affect your:</p> <ul style="list-style-type: none"> <li>• Physical health</li> <li>• Psychological health</li> <li>• Relationships</li> <li>• Lifestyle</li> </ul>                                                                                                                                                            | <p>Chemoradiotherapy can affect your:</p> <ul style="list-style-type: none"> <li>• Physical health</li> <li>• Psychological health</li> <li>• Relationships</li> <li>• Lifestyle</li> </ul> <p>Eventually you may get more symptoms which we will treat to keep you as comfortable as possible.</p>                                                                                                                                                                                                       | <p>You are likely to get more symptoms with time. You will have access to support teams in order to help you manage your symptoms and feel as comfortable as possible.</p>                                                                                                                                                  |
| What kind of support will I have?              | <ul style="list-style-type: none"> <li>• Medical team – surgeons, junior doctors, ward nurses, clinical nurse specialist</li> <li>• Oncologist (cancer doctor)</li> <li>• Stoma nurses</li> <li>• District nurses</li> <li>• Clinical Nurse Specialist</li> <li>• GP's</li> <li>• Support charities</li> <li>• Friends and family</li> </ul> | <ul style="list-style-type: none"> <li>• GP's</li> <li>• Macmillan nurses</li> <li>• Oncologist (cancer doctor)</li> <li>• Clinical Nurse Specialist</li> <li>• Support charities</li> <li>• Palliative care team when appropriate</li> <li>• Access to hospice care when appropriate</li> <li>• Friends and family</li> </ul>                                                                                                                                                                            | <ul style="list-style-type: none"> <li>• Macmillan nurses</li> <li>• GP's</li> <li>• Support charities</li> <li>• Palliative care team</li> <li>• Access to hospice care</li> <li>• Friends and family</li> </ul>                                                                                                           |

|                                               | SURGERY                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | ONCOLOGICAL TREATMENT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | SUPPORTIVE TREATMENT                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Will this option relieve my current symptoms? | Yes but you may have different symptoms following surgery.                                                                                                                                                                                                                                                                                                                                                                                                                | Short term it can relieve or improve symptoms but these symptoms may return and you could develop more symptoms as the cancer starts to grow.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Supportive treatment will control your symptoms. Without surgery your cancer will grow & any symptoms you have may get worse. There are ways of managing pain and other symptoms using both medicines and other therapies such as physiotherapy and complementary therapies.                                                                                                             |
| What are the benefits?                        | Increased chance of survival. Improved pre-operative symptoms.                                                                                                                                                                                                                                                                                                                                                                                                            | Treatment can prolong life compared to no treatment.<br><br>Not having side effects or long-term symptoms of surgery.<br><br>Rarely can cure cancer.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Potentially an improved quality of life.<br><br>Not having side effects or long-term symptoms of surgery or oncological treatments.                                                                                                                                                                                                                                                      |
| What are the risks?                           | <p>You are likely to experience short and long term side effects:</p> <ul style="list-style-type: none"> <li>• Pain</li> <li>• Urinary &amp; bowel symptoms</li> <li>• Reduced mobility/weakness</li> <li>• Long term fatigue (tiredness that doesn't go away)</li> <li>• Psychological and emotional changes</li> <li>• Sexual dysfunction</li> </ul> <p>Complications:</p> <ul style="list-style-type: none"> <li>• Major</li> <li>• Minor (discussed later)</li> </ul> | <p>Symptoms are different for different people but can include the following:</p> <p>Symptoms from chemotherapy:</p> <ul style="list-style-type: none"> <li>• Pins and needles</li> <li>• Numbness/pain in feet</li> <li>• Sickness</li> <li>• Fatigue</li> <li>• Loss of appetite</li> <li>• Recurrent infections</li> <li>• Tummy pain</li> <li>• Diarrhoea or constipation</li> </ul> <p>Symptoms from radiotherapy:</p> <ul style="list-style-type: none"> <li>• Skin redness</li> <li>• Sickness</li> <li>• Fatigue</li> <li>• Diarrhoea or constipation</li> <li>• Sexual &amp; urinary dysfunction</li> </ul> <p>You will also experience psychological and emotional changes</p> | <p>You may develop more symptoms as the cancer begins to grow which we will support you with to ensure you are as comfortable as possible. Symptoms may include:</p> <ul style="list-style-type: none"> <li>• Blockage of the bowel</li> <li>• Pain</li> <li>• Bleeding</li> <li>• Tumour can grow externally</li> <li>• Sickness</li> <li>• Fatigue</li> <li>• Poor appetite</li> </ul> |

|                                  | SURGERY                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | ONCOLOGICAL TREATMENT                                                                                                                                                                                                                                                                                                                                                                                                                       | SUPPORTIVE TREATMENT                                                                                                                                                                                             |
|----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| What are my chances of survival? | <p>Survival is a very general statistic based on historical large groups of patients. <b>They can't tell you what will happen in your individual case.</b></p> <p>The terms 3-year survival and 5-year survival don't mean that you will only live for 3 or 5 years. Some people live much longer than 5 years.</p> <p><b>Ask your team about information more specific to what we know about your disease.</b></p> <p>In general, 98% of patients will be alive at 30 days after surgery.</p> <p>The <b>average survival</b> following surgery for:</p> <p><b>Locally Advanced Rectal Cancer:</b> 3 year survival: 6 in 10 patients will be alive</p>  <p>5 year survival: 4 in 10 patients will be alive.</p>  <p><b>Locally Recurrent Rectal Cancer:</b> 3 year survival: 5 in 10 patients will be alive.</p>  <p>5 years survival: 3 in 10 patients will be alive.</p>  | <p>Oncological treatment will prolong survival and this will be different in every person.</p> <p><b>Locally Advanced Rectal Cancer:</b><br/>Chemotherapy with, or without radiotherapy can provide palliation, and extends survival on average by 10-17 months.</p> <p><b>Locally Recurrent Rectal Cancer:</b><br/>Chemotherapy with, or without radiotherapy can provide palliation, and extends survival on average by 10-15 months.</p> | <p><b>Locally Advanced Rectal Cancer:</b> Without treatment, most patients live for 12 months after diagnosis.</p> <p><b>Locally Recurrent Rectal Cancer:</b> Untreated patients usually survive 6-8 months.</p> |

## What does surgery involve?

Pelvic exenteration is an operation that requires removal of all, some or part of your pelvic organs of which there are a number of different types.



### *Normal anatomy - side view*

Your team will highlight what type of surgery you are having and what is relevant for you.

Several surgeons from different specialties are involved. The operation is a major undertaking and one of the most complex surgeries performed.

There are different types of pelvic exenteration. Depending on your cancer removal of all or some of the following may be necessary:

- Part of the bowel (the colon, rectum and anus)
- The urinary system (the bladder and ureters)
- Your reproductive organs (prostate, seminal vesicles)
- Your lower spine (sacrum)

**If you are considering surgery, this booklet will now provide more detail about what this will involve in the short and longer term.**

## **What does the operation involve?**

You will be asleep (under general anaesthetic) during the operation. A cut will be made from above the belly button to the bottom of your abdomen. It may also be necessary to make a second cut around the back passage (anus). In a very small number of cases it may be possible to carry out the procedure in a minimally invasive way i.e. keyhole or robotically.

It is likely you will go to intensive care or high dependency to be looked after following your surgery and after a few days you will go to the ward. You will wake up with some tubes, drains and drips. You will be allowed to drink initially, then you will be allowed food when your body can tolerate it. Your ability to move around, out of your bed, will be reduced for up to a week.

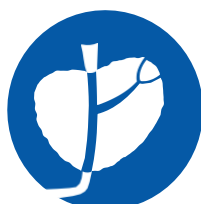
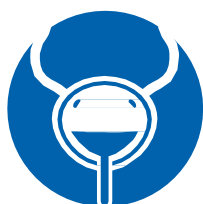
The hospital stay after surgery is variable. Typically if there are no post-operative setbacks patients are in hospital between 14 days to 3 months. However, if you were to experience complications it can be much longer.

## **How long will it take to recover?**

These operations are a considerable undertaking and your body will go through lots of changes, so it is important that you are prepared for a long recovery. Initial recovery can take between 6 weeks and 3 months. Complete, longer term recovery can take up to 12 months.

## **Will everything in my pelvis need to be removed?**

Not necessarily. There are different types of this operation depending on the location of your cancer.

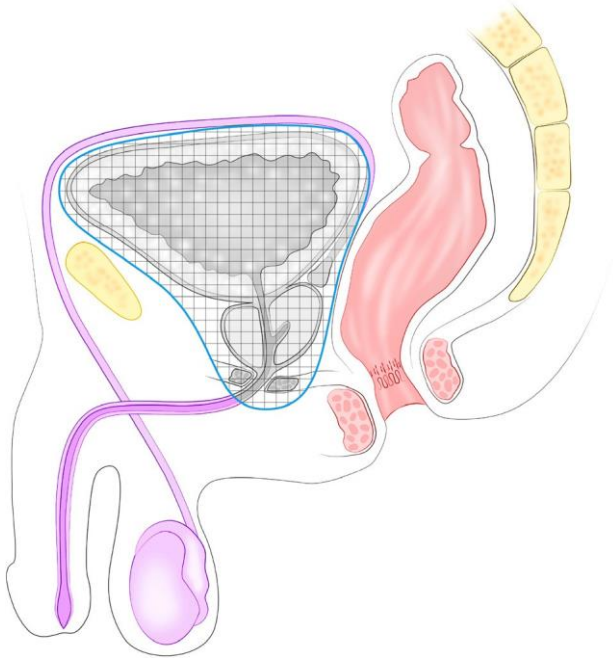




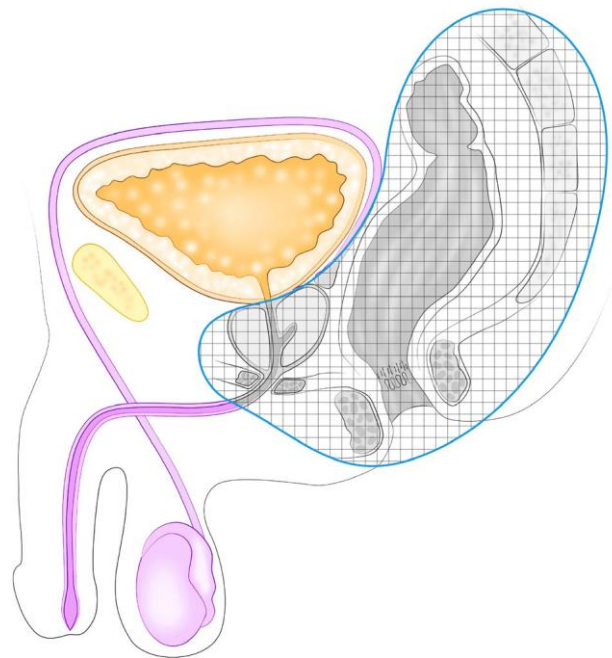
## Some variations of the surgery:

These are some possible options, depending where your tumour is.

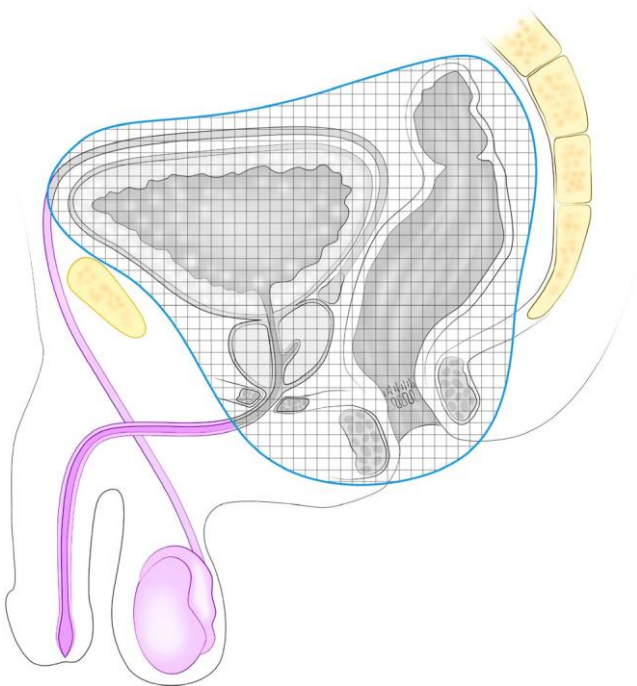
*Shaded area = what will be removed*



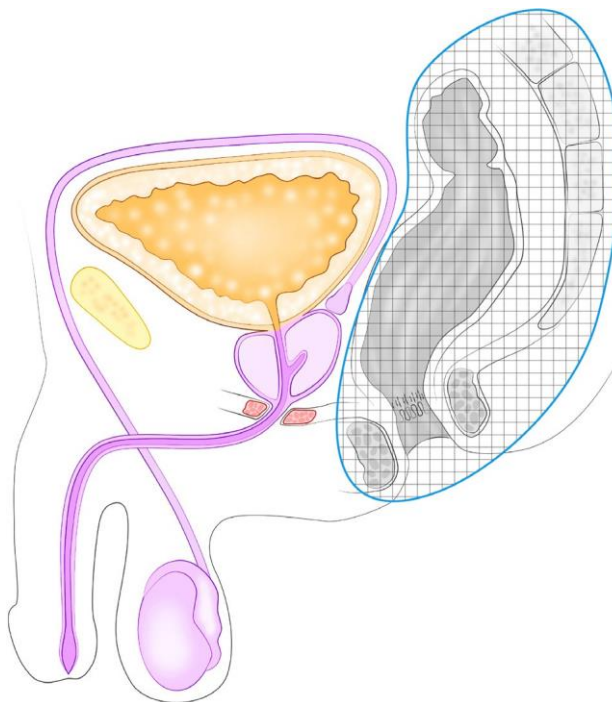
**Bladder, ureter, prostate, seminal vesicles**



**Rectum & anus, prostate, occasionally sacrum**



**Rectum, anus, bladder, ureter, prostate, seminal vesicles.  
Occasionally sacrum**



**Rectum, anus & sacrum removed**



## Will I have a stoma bag?

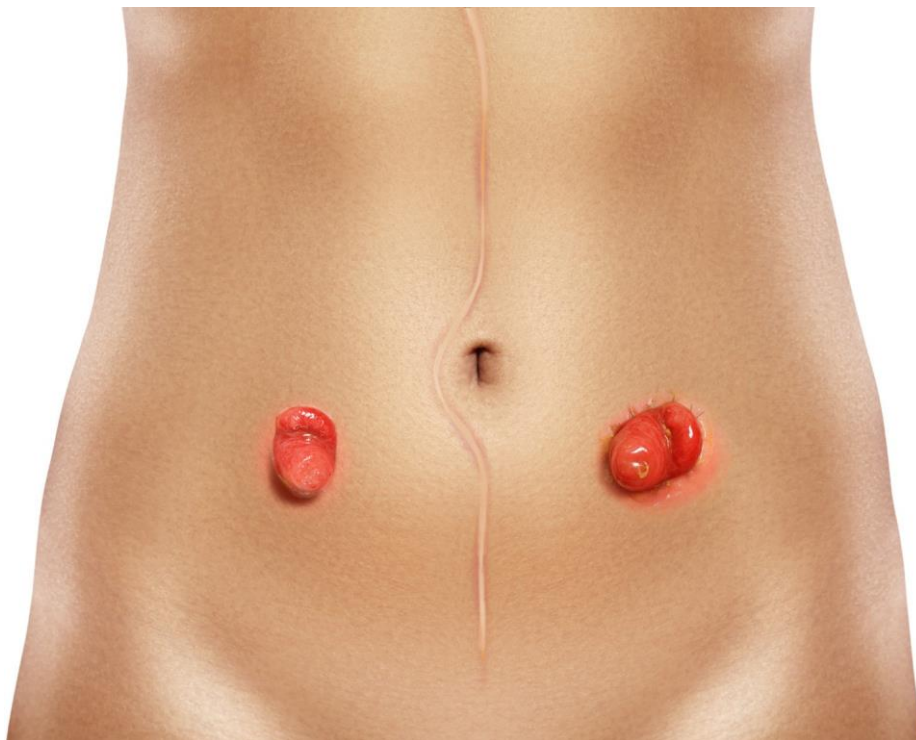
It is likely you will have a stoma bag as part of your operation.

The 'bag' is the appliance that actually sits on top of the stoma to collect the waste (wee/poo). A stoma is made when part of your bowel is pulled through your tummy wall onto the skin.

If your back passage (anus) is removed then the bowel will redirect waste products (poo/faeces) through a piece of bowel brought through the skin on your tummy. This is usually created to the left-hand side of your belly button. A specially designed bag sticks over the stoma to collect the faeces.

If your bladder is removed then the bowel will redirect waste products (wee/urine) through the new piece of bowel through the skin on your tummy. This is called a urostomy or ileal conduit. This is usually created to the right-hand side of your belly button. A specially designed bag sticks over the stoma to collect the urine.

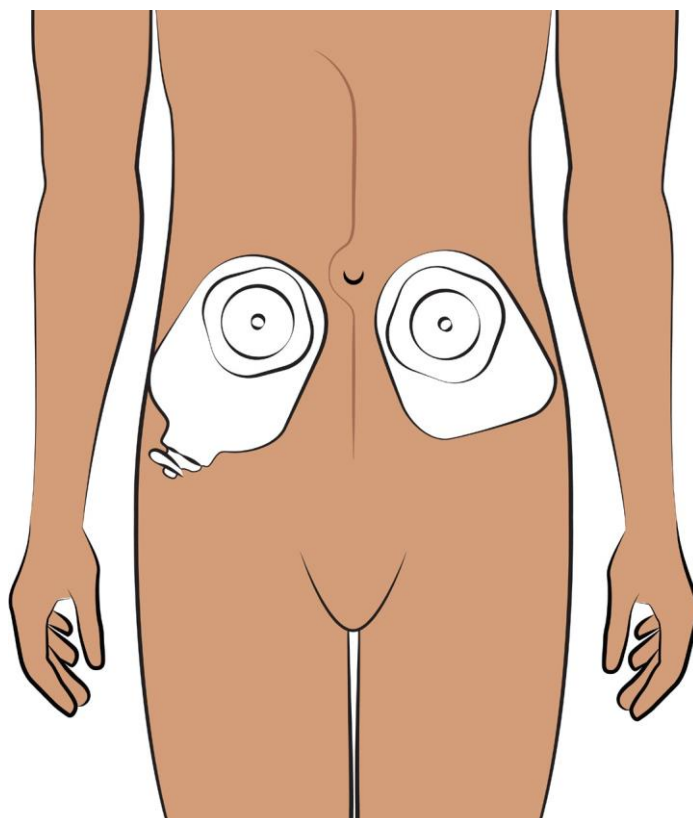
## What do stomas look like?



***Urostomy/ileal conduit***

***Colostomy***

***Urostomy bag position***



***Colostomy bag position***

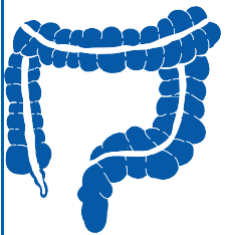
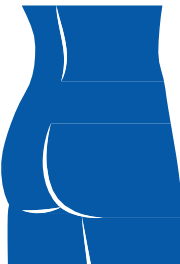


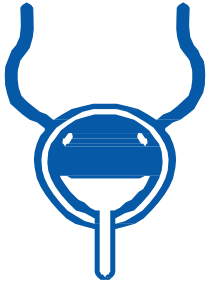
***Typical urostomy bag***



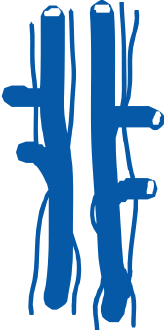
***Typical colostomy bag***

## What will I have removed & what does that potentially mean for me?

| TICK IF APPLICABLE TO ME | ORGAN                                                                                                                 | IMPLICATION                                                                                                                                                                        | SHORT TERM QUALITY OF LIFE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | LONG TERM QUALITY OF LIFE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|--------------------------|-----------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          | <b>Rectum</b> (lower part bowel)<br> | <p>It may or not be possible to join your bowel back together.</p> <p>You may need a permanent or temporary stoma.</p>                                                             | <p><b>If joined:</b></p> <ul style="list-style-type: none"> <li>• 5-15% chance of the join leaking</li> <li>• Inability to control opening your bowel (incontinence)</li> <li>• Urgency to open bowels</li> <li>• Need to open bowels often</li> <li>• Difficulty emptying your bowel despite visiting the toilet and passing soft motions often</li> </ul> <p><b>If you have a stoma:</b></p> <ul style="list-style-type: none"> <li>• Episodes of stoma leaking</li> <li>• Stoma can 'prolapse' meaning more bowel can protrude through the tummy wall than planned</li> </ul> | <p><b>If joined:</b></p> <ul style="list-style-type: none"> <li>• Inability to control opening your bowel (incontinence)</li> <li>• Urgency to open bowels</li> <li>• Need to open bowels often</li> <li>• Difficulty emptying your bowel despite visiting the toilet and passing soft motions often</li> <li>• Long term medication to regulate bowel motion</li> </ul> <p><b>If you have a stoma:</b></p> <ul style="list-style-type: none"> <li>• Infrequent episodes of stoma leaking</li> <li>• Hernia* around stoma</li> <li>• Body image</li> <li>• Emotional impact</li> <li>• Relationships affected</li> </ul> <p>(* the visible part of your stoma bulges out further from your body)</p> |
|                          | <b>Anus</b> (back passage)<br>     | <p>You will have a permanent stoma (colostomy) – this means you will poo through the stoma on your tummy.</p> <p>You will no longer have an anus as it will have been sewn up.</p> | <ul style="list-style-type: none"> <li>• Episodes of leaking stoma bags</li> <li>• Emotional impact</li> <li>• Wound issues</li> <li>• Altered sensation</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                              | <ul style="list-style-type: none"> <li>• Infrequent episodes of leaking stoma bags</li> <li>• Delayed wound healing</li> <li>• Emotional impact</li> <li>• Body image</li> <li>• Altered sensation</li> <li>• Phantom back passage pain</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

| TICK IF APPLICABLE TO ME | ORGAN                                                                                                          | IMPLICATION                                                                                                                                                                                                                                                                                             | SHORT TERM QUALITY OF LIFE                                                                                                                                                             | LONG TERM QUALITY OF LIFE                                                                                                                                                                                                                                    |
|--------------------------|----------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          | <b>Bladder</b><br>            | <p>You will have a permanent stoma (urostomy/ileal conduit) – you will pass urine through a stoma on your abdomen into a stoma bag.</p> <p>There will be fine tubes (stents) that are visible within the stoma and are usually removed a few weeks after surgery. These help the new joins to heal.</p> | <ul style="list-style-type: none"> <li>• Frequent episodes of leaking urostomy bag</li> <li>• Urine/stent infections</li> <li>• Stents can block</li> <li>• Stents can move</li> </ul> | <ul style="list-style-type: none"> <li>• Frequent episodes of leaking urostomy bag</li> <li>• Hernia around stoma – urostomy becomes difficult to manage</li> <li>• Kidney failure</li> <li>• Stoma narrowing</li> </ul>                                     |
|                          | <b>Prostate</b><br>          | <p>You will not be able to get an erection naturally or ejaculate.</p> <p>Your penis will get smaller and shorter.</p>                                                                                                                                                                                  | <ul style="list-style-type: none"> <li>• Emotional impact</li> <li>• Sexual dysfunction</li> <li>• Unable to conceive naturally</li> </ul>                                             | <ul style="list-style-type: none"> <li>• Emotional impact</li> <li>• Sexual dysfunction</li> <li>• Relationships affected</li> <li>• Infertility - If you have wishes of having a child then there are other options for sperm collection and IVF</li> </ul> |
|                          | <b>Seminal vesicles</b><br> | <p>You will not be able to ejaculate and will not be able to conceive naturally.</p>                                                                                                                                                                                                                    | <ul style="list-style-type: none"> <li>• Emotional impact</li> <li>• Sexual dysfunction</li> </ul>                                                                                     | <ul style="list-style-type: none"> <li>• Emotional impact</li> <li>• Sexual dysfunction</li> <li>• Relationships affected</li> </ul>                                                                                                                         |

| TICK IF APPLICABLE TO ME | ORGAN                                                                                                                                                                                                               | IMPLICATION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | SHORT TERM QUALITY OF LIFE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | LONG TERM QUALITY OF LIFE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
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|                          | <p><b>Sacrum</b><br/>(lower spine)</p>  <p>The sacrum can be divided at a high or low level depending on where your cancer is.</p> | <p><b>Low/All Sacrectomy</b></p> <ul style="list-style-type: none"> <li>- You may experience pain.</li> <li>- You may not be able to get an erection naturally or ejaculate.</li> </ul> <p><b>High Sacrectomy</b></p> <ul style="list-style-type: none"> <li>• It can affect your bladder control (if no urostomy)</li> <li>• It can affect your mobility</li> <li>• Your legs can be effected with weakness, numbness/pins and needles, poor mobility</li> <li>• You will not be able to get an erection naturally or ejaculate.</li> <li>• Your penis will get smaller and shorter</li> </ul> | <p><b>Low/All Sacrectomy</b></p> <ul style="list-style-type: none"> <li>- Nerve pain - shooting pains, pins and needles.</li> <li>- Sexual dysfunction</li> <li>- Infertility</li> <li>- Emotional Impact</li> </ul> <p><b>High Sacrectomy</b></p> <ul style="list-style-type: none"> <li>• Episodes of wetting yourself (incontinence)</li> <li>• Inability to empty the bladder without inserting an 'in and out' catheter to drain the bladder</li> <li>• Foot drop (at rest, foot remains pointing to the floor and you are unable to lift it to a normal position)</li> <li>• Muscle weakness</li> <li>• Need to use a walking aid (frame/crutch/stick)</li> <li>• Numbness to feet/legs</li> <li>• Problems with mobility may or may not gradually improve</li> </ul> | <p><b>Low/All Sacrectomy</b></p> <ul style="list-style-type: none"> <li>- Long term pain.</li> <li>- Sexual dysfunction</li> <li>- Infertility</li> <li>- Emotional Impact</li> </ul> <p><b>High Sacrectomy</b></p> <ul style="list-style-type: none"> <li>• Episodes of wetting yourself (incontinence)</li> <li>• Inability to empty the bladder without inserting an 'in and out' catheter to drain the bladder</li> <li>• Long-term physiotherapy</li> <li>• Foot drop (need for permanent ankle support)</li> <li>• Dependence on walking aid (frame/crutch/stick)</li> <li>• Short distance mobility only</li> <li>• Unable to walk more than a short distance</li> <li>• Modified car to drive</li> </ul> |

| TICK IF APPLICABLE TO ME | ORGAN                                                                                                             | IMPLICATION                                                                                                                                                                                                                                                                                            | SHORT TERM QUALITY OF LIFE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | LONG TERM QUALITY OF LIFE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|--------------------------|-------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          | <b>Nerves and vessels</b>        | <p><b>Depending on what nerves are cut:</b></p> <p>It can affect your bladder control.</p> <p>It can affect your bowel control.</p> <p>It can affect your legs – mobility, weakness, numbness.</p> <p>Long term pain can be an issue.</p> <p>You may not be able to have an erection or ejaculate.</p> | <ul style="list-style-type: none"> <li>• Need to catheterise to pass water (urine) if no urostomy</li> <li>• Altered leg control</li> <li>• Leg weakness</li> <li>• Leg numbness</li> <li>• Leg pain</li> <li>• Difficulty walking</li> <li>• Foot drop (at rest foot remains pointing to floor and you are unable to lift it to a normal position)</li> <li>• Reduced mobility</li> <li>• Inability to walk without frame/ crutch/stick</li> <li>• Able to walk short distance only</li> <li>• Inability to control bowel (incontinence)</li> <li>• Sexual dysfunction</li> <li>• Infertility</li> </ul> | <ul style="list-style-type: none"> <li>• Need to catheterise to pass water (urine) if no urostomy</li> <li>• Altered leg control</li> <li>• Leg weakness</li> <li>• Leg numbness</li> <li>• Leg pain</li> <li>• Difficulty walking</li> <li>• Foot drop (need for long term ankle support)</li> <li>• Reduced mobility</li> <li>• Inability to walk without stick</li> <li>• Able to walk short distance only</li> <li>• Inability to run</li> <li>• Modified car to drive</li> <li>• Inability to control bowel (incontinence)</li> <li>• Sexual dysfunction</li> <li>• Infertility</li> </ul> |
|                          | <b>Reconstructive Surgery</b>  | <p>New area of skin will look and feel different.</p>                                                                                                                                                                                                                                                  | <ul style="list-style-type: none"> <li>• Inability to sit for more than short periods</li> <li>• Numbness</li> <li>• Flap may die leading to issues with wound breakdown and prolonged wound healing (further detailed information later in document)</li> </ul>                                                                                                                                                                                                                                                                                                                                          | <ul style="list-style-type: none"> <li>• Altered sensation and appearance</li> </ul> <p>Potentially you may experience a hernia</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

| TICK IF APPLICABLE TO ME | ORGAN                                                                                                                                           | IMPLICATION                                                                                                                                                                                                                | SHORT TERM QUALITY OF LIFE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | LONG TERM QUALITY OF LIFE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|--------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          | <p><b>ELSIE</b><br/>(extended lateral side wall excision)</p>  | <p>It can affect your mobility.</p> <p>You may experience pain.</p> <p>Your legs can be effected with weakness, numbness/ pins and needles, poor mobility.</p> <p>It may affect your bladder control (if no urostomy).</p> | <ul style="list-style-type: none"> <li>• Altered leg control</li> <li>• Leg weakness</li> <li>• Buttock, leg or foot numbness</li> <li>• Foot drop (at rest foot remains pointing to floor and you are unable to lift it to a normal position)</li> <li>• Need to use a walking aid (frame/ crutch/stick)</li> <li>• Nerve pain – shooting pains, pins and needles</li> <li>• Episodes of wetting yourself (incontinence)</li> <li>• Inability to empty the bladder without inserting an ‘in and out’ catheter to drain the bladder</li> </ul> | <ul style="list-style-type: none"> <li>• Long-term physiotherapy</li> <li>• Foot drop (need for long term ankle support)</li> <li>• Inability to walk without a stick</li> <li>• Inability to walk more than a short distance</li> <li>• Inability to run</li> <li>• Long-term pain</li> <li>• Need to modify your car to drive</li> <li>• Episodes of wetting yourself (incontinence)</li> <li>• Inability to empty the bladder without inserting an ‘in and out’ catheter to drain the bladder</li> </ul> |

## What are the other potential things to expect after surgery?

| Impact                  | Short Term                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Long Term                                                                                                                                                      |
|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Pain</b>             | <p>You may be offered different pain-relief options which will change during your hospital stay. These include:</p> <ul style="list-style-type: none"> <li>• Epidural (fine tube inserted into your back infusing painkiller)</li> <li>• Patient controlled analgesia (PCA) (painkiller via a drip into your vein on demand with a button)</li> <li>• Spinal (injection into your back before the operation)</li> <li>• Rectus sheath catheters (local anaesthetic being dripped into your six-pack muscles)</li> <li>• Tablets/liquids/patches</li> </ul> <p>The pain relief appropriate for you will be discussed with the anaesthetist.</p> | <p>Long term painkilling medication may be necessary. Doses and types will change over time as your body starts to heal.</p>                                   |
| <b>Physical changes</b> | <p><b>Functional:</b></p> <ul style="list-style-type: none"> <li>• Weakness</li> <li>• Tiredness</li> <li>• Inability to do normal tasks – for example washing, dressing</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <p><b>Functional:</b></p> <ul style="list-style-type: none"> <li>• Fatigue (tiredness that doesn't go away with rest) lasting longer than 12 months</li> </ul> |
|                         | <p><b>Body changes:</b></p> <ul style="list-style-type: none"> <li>• Your body will be very different following the surgery</li> <li>• You may have one or two stomas</li> <li>• You will have scars</li> <li>• You may no longer have a back passage (anus)</li> <li>• You may have a skin flap which has altered or no sensation and you may have another area where the flap was taken from which may be slightly disfigured.</li> <li>• Your body will feel different</li> <li>• Your penis may get smaller and shorter with time</li> </ul>                                                                                               |                                                                                                                                                                |



| Impact            | Short and Long Term                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Emotional changes | <p><b>Emotions:</b><br/>Anxiety, Anger, Regret, Fear, Depression, Sadness.</p> <p>These emotions will change with time. You will get good days as well as bad days. These emotions may or may not disappear with time. Experience of other patients suggests you will adapt. There are support mechanisms to help you through it.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|                   | <p><b>Long Term</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|                   | <p><b>Infertility:</b><br/>If cancer treatment results in the inability to get your partner pregnant this can affect you psychologically. There is the option of sperm collection and freezing prior to treatment and subsequent IVF.</p> <p><b>Body image:</b><br/>Body changes can affect the way you think and feel about your body which can affect your self-confidence. You might also worry that people will treat you differently because of the change to your body.</p> <p>Low self-esteem or lack of confidence.</p> <p>It is normal to find these changes difficult to adapt to physically and mentally. Different patients adapt in different ways. Some patients have reported:</p> <ul style="list-style-type: none"> <li>• Being too embarrassed to leave home</li> <li>• Withdrawing from social activities</li> <li>• Avoiding intimacy with a partner</li> <li>• Low mood</li> </ul> |

| Impact                | Short Term                                                                                                                                                                     | Long Term                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Sexual changes</b> |                                                                                                                                                                                | <p>Pre-existing sexual status will determine recovery of your sex life. If you do not have sexual intercourse now (before surgery) then this may not be relevant to you. If you do engage in sexual relations then sex will never be the same following this surgery.</p> <p>You should discuss with your partner the changes that will happen to your body and that sexual relations may resume in the long term however it may be very different to its current state.</p> <p>Following surgery you may not be able to get an erection naturally. There are ways using both medication and physical aids to assist getting an erection. This may or may not be successful for you. If you are able to have an erection with aids, it may feel different to before. It may not be as pleasant as before the surgery. You may not be able to ejaculate.</p> <p>Your penis may change in appearance over time. It may get smaller and shorter.</p> <p>There is a choice to try to pursue penetrative sex - some may accept not to.</p> |
| <b>Relationships</b>  | <p>Altered relationships with partner</p> <p>Altered relationships with family and friends</p> <p>Dependence on others for normal activities – washing, dressing, cleaning</p> | <p><b>Altered relationship with partner</b><br/>Although physically sexual intercourse will change, you will find other ways of being intimate. There is more to sex than the physical part. There is an interrelationship between psychological and sexual aspects so how you feel sexually is not just how you feel physically but it's how you feel psychologically too. You can still express desire and arousal but this will be shown differently.</p> <p><b>Altered relationships with family and friends</b><br/>You may feel differently after this surgery and that may or may not impact your relationships with others.</p>                                                                                                                                                                                                                                                                                                                                                                                               |

| Impact          | Short Term                                                                                                                                                                                                    | Long Term                                                                                                                                                                                                                                                                                                                                  |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Work</b>     | You are unlikely to work short term unless you can work from home and this doesn't require you to sit for long periods. Your employer should understand that you would need some flexibility within your day. | <p>Your employer should understand the extent of surgery you are undertaking and be prepared for a sickness of up to a year.</p> <p>You may never be able to return to the same job you performed before.</p>                                                                                                                              |
| <b>Finance</b>  | Potential loss of income.                                                                                                                                                                                     | Financial difficulty can be addressed by support charities who can direct you to places for help with money problems. Benefits can help you through financial difficulties. These are means tested but can help you with loss of income as well as directing you towards extra entitlements during your period of recovery and adjustment. |
| <b>Exercise</b> | <p>Short term pain. Lack of energy.</p> <p>Change in routine that effect exercise.</p>                                                                                                                        | You may or may not be able to do the same exercises as you did pre-operatively. Your team may advise you not to do excessive exercise or prolonged amounts of sitting. Swimming and cycling may not be possible until the wound has completely healed. Returning to 'normal' activity is the goal and this is expected in most patients.   |

## Will I have reconstructive surgery?

After organs affected by the cancer have been removed, some patients may benefit from reconstructive surgery. This is usually done at the same operation as the pelvic exenteration, by a Plastic Surgeon working with the surgical team. It involves moving tissue from elsewhere in the body into the pelvis and bottom end.

The tissue that is moved is known as a flap. It usually consists of skin, fat and muscle. Flaps can be moved from several places, including the tummy (abdomen), buttocks or thighs. Which of these is most suitable for you will depend mainly on the type and extent of the surgery you are having. For a flap to work well it must have a good blood supply. This is usually not a problem but if it is, part or all of the flap may die and need to be removed.

The benefits of reconstructive surgery are:

- To fill up the space left when organs in the pelvis are removed
- To prevent long term problems, such as a pelvic hernia or chronic infection
- To help wounds to heal quickly

The risks of reconstructive surgery are:

- Adding time on to a long operation
- It may fail resulting in prolonged wound problems, hernia, occasionally need for re-operation
- It may leave a deformity in the area the flap is taken from

Reconstructive surgery cannot make things totally normal again. For instance, it cannot recreate a back passage (anus) that works.

## Do I have to have reconstructive surgery if it's offered to me?

If a 'flap' has been discussed with you it is usually necessary in order to fill the space following the removal of the cancer.

It is important that you speak to your Plastic Surgeon.

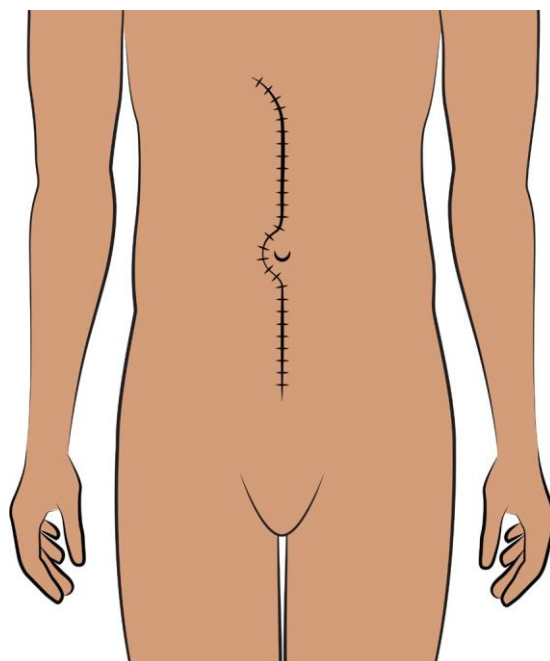
## Will I be able to sit after the surgery?

It is sometimes best for patients who have had reconstructive surgery, not to sit normally for 1 to 2 weeks. This is to avoid putting pressure on the flap tissue. For the same reason, these patients are also encouraged to lie on their side while they are in bed. Once sitting is allowed, a pressure-relieving air cushion is recommended. A graduated sitting programme is introduced to help you adjust to sitting.

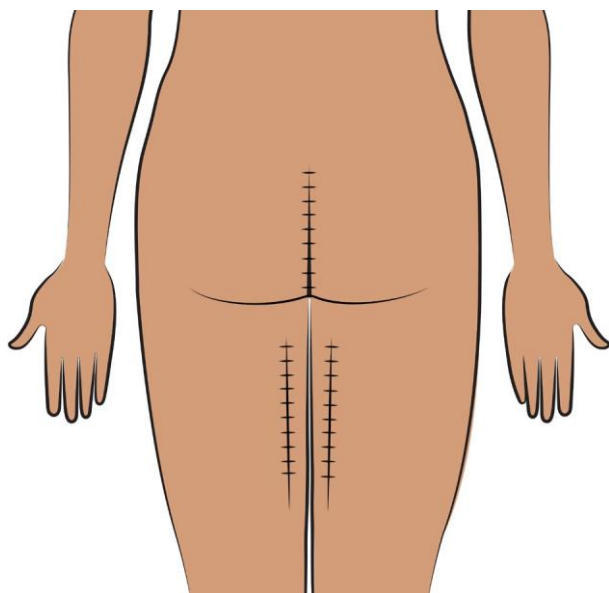
## What will things look like after my surgery?

Surgery always leaves scars. In normal clothes these will not be visible, but without clothes on you will be able to see scars on your tummy (abdomen) and elsewhere. Your stoma (or stomas) will also be visible and the shape of your abdomen, buttocks or thighs may also have changed if a flap from these areas has been used. Following surgery, your bottom end (perineum) may also feel numb.

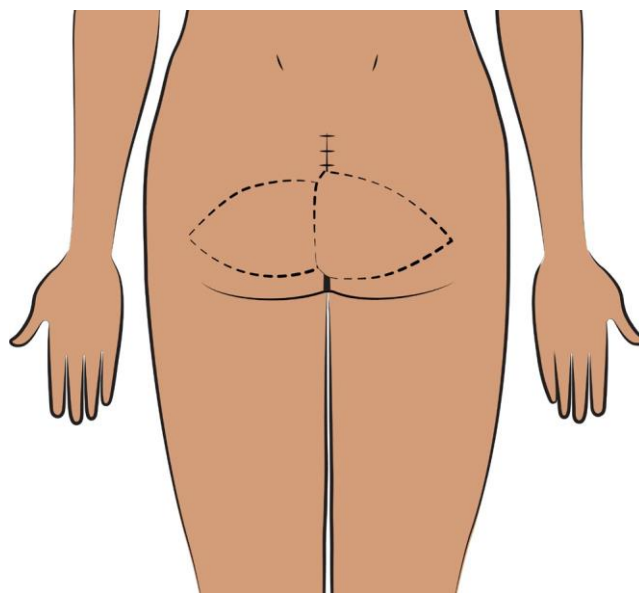
When a flap from the abdomen is used, the scars are as shown in diagram A. Scars from thigh and buttock flaps are shown in diagrams B & C.



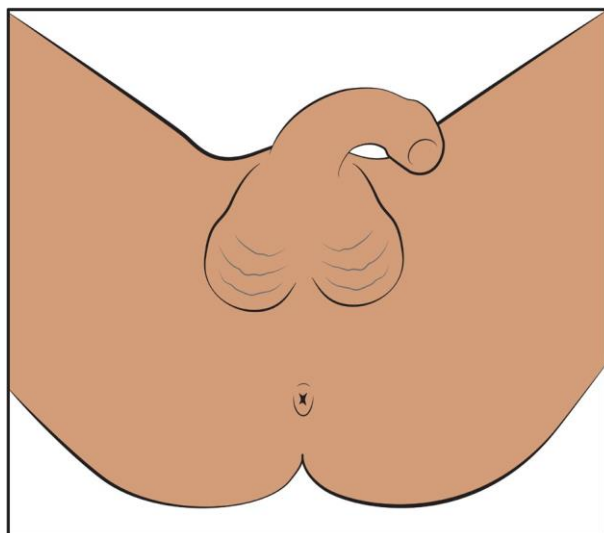
**A** Abdomen scar



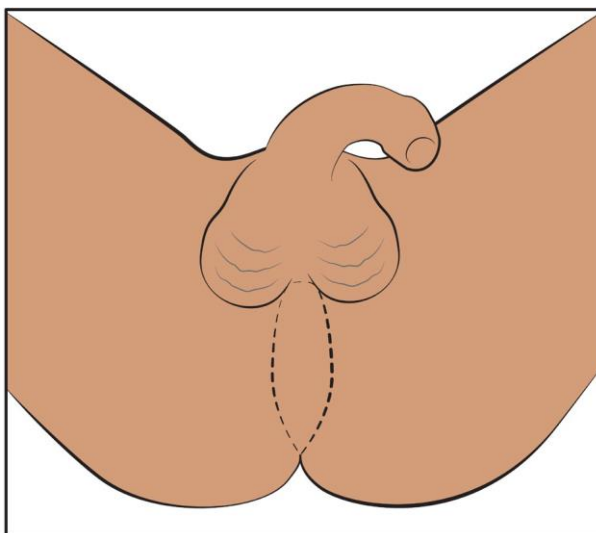
***B Thigh scar***



***C Buttock flaps***



***Normal penis & anus***



***Flap in position***

## What are the potential complications?

The risks depend on the complexity of the operation you need.

Around 20% (one in five) patients will experience a major complication from the surgery.

### Major risks of surgery include:

- Excessive bleeding (return to theatre, major blood transfusion)
- Heart attack (myocardial infarction)
- Blood clot in the chest (pulmonary embolism)
- Risk of the wound including muscle fully opening up
- Risk of the plastic surgical flap dying
- Collection in the pelvis (x-ray guided drain insertion)
- Injury to the bowel
- Injury to the urinary tract
- Kidney failure
- Bowel obstruction
- Formation of an abnormal passage between two places (fistula)
- Incomplete removal of the cancer or it not being possible to proceed with cancer removal during the operation
- Need for reoperation 10%

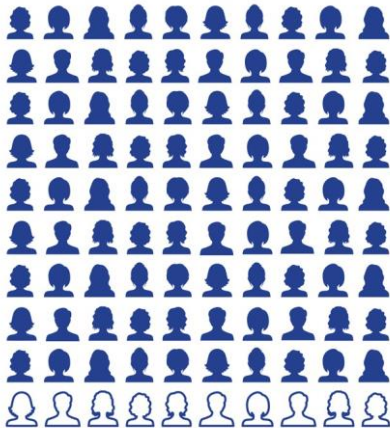


20 out of 100 experience major complications

Most patients experience some minor complications after surgery. This happens in 90% (9 out of 10) patients.

### Minor risks of surgery include:

- Infection (chest/wound/urine)
- Risk of skin wound opening up
- Blood clot in the legs (Deep Vein Thrombosis or DVT)
- Bowels slow to start working again but usually resolves in time (ileus)



90 out of 100 experience minor complications



To minimise the risks of clots we give you elastic stockings to wear and give you blood-thinning injections to prevent clots. These injections are usually continued for 28 days after your operation.

## Can I die as a result of surgery?

The risk of dying within 30 days of the surgery is less than 2%, meaning the chances of dying during the operation are low.



*2 out of 100 die after the operation*

Your chances of surviving 90 days after surgery are 95% (95 out of a 100).

## What do I expect after the surgery?

Following your surgery it will be necessary to keep a close eye on you. Depending where you have your surgery, this may be called high dependency, critical care or intensive care. Typically you will stay in this area for 2-5 days.

When you wake from surgery, you will have a number of things attached to you:

- Oxygen tubes in your nose or through a mask on your face
- Drips to keep you hydrated
- Drains (tubes) inside your tummy and bottom to drain excess fluid
- Tube placed in your stomach via your nose to drain any fluid in your stomach
- Staples or stitches in the wounds





If you decide to have the surgery you will be followed-up for five years afterwards. Two to three weeks after your operation the results of the pathological examination (what your tumour looked like under the microscope) will be available. The team looking after you will communicate the results to you. They may suggest that you consider chemotherapy treatment.

## **Do I have to have chemotherapy if it's offered?**

You will have a discussion with your oncologists regarding the risk and benefit for you as an individual. If it is offered as an option it is usually only beneficial within 3 to 6 months after surgery.

You may have lots of questions regarding more chemotherapy. These can be discussed with your oncologist. If you decide to have chemotherapy and cannot tolerate it, then you can stop treatment.

## **What is my follow-up?**

Your follow-up will consist of clinic visits, surveillance CT scans and blood tests at different intervals for the 5 year period. If you have any questions at any time, please ask any member of your team. They will be pleased to explain anything that concerns you or your family. Another good tip is to write your thoughts and questions down so that you do not forget when you meet your team.

## Support - Who are we?

We are a specialist team dealing with pelvic cancers. The team includes surgeons, doctors, surgical nurse practitioners and other specialist nurses including stoma care nurse specialists.

**Your Consultant is** .....

**Contact number (Secretary)** .....

**Your specialist nurse is** .....

**Contact number** .....

**Your stoma care nurse is** .....

**Contact number** .....

## Who do I contact with concerns after my operation?

If you have concerns after you have gone home then you can contact your specialist nurse or stoma care nurse or consultant via the secretary on the numbers above.

If you experience any of the following:

- persistent nausea (feeling sick) or vomiting (being sick)
- fever or a high temperature (37.5°C/101.5°F or above)
- (oozing) or increasing redness around either of the wound sites
- new pain
- new diarrhoea

Please get in contact with any of the team above or your GP. If you are unable to access these contacts out of hours then please contact the GP out of hours service or attend the A&E department of your nearest hospital.

## Support

You may want to discuss your options further. There are charities and support groups that can help. There are also online communities and support groups that you can talk to. You will need to discuss things with your family and/or friends which may mean some difficult conversations.

It is important that you get the right support for you as you come to terms with the decision you face. It is important that you understand the implications of what life may look like by surviving the disease. Families and friends may need support with the idea of adapting in a new role as a carer or emotional support in coming to terms with what their relative is going through. You can be put in touch with a support group where you can meet people in a similar situation and get information first-hand about your type of cancer. You are not alone and we can signpost you to various additional support you require. You may also want to re-discuss things with your team and it is important that you get in touch if you feel this is something you need to do.

**For additional support services or further discussions (outside your medical team), we recommend:**



Macmillan Cancer Support: [www.macmillan.org.uk](http://www.macmillan.org.uk)  
Tel: 0808 808 0000

Maggie's: [www.maggies.org](http://www.maggies.org)  
Tel: 0300 123 1801

Bowel Cancer UK: [www.bowelcanceruk.org.uk](http://www.bowelcanceruk.org.uk)  
Tel: 020 7940 1760

Beating Bowel Cancer: [www.beatingbowelcancer.org](http://www.beatingbowelcancer.org)  
Tel: 020 8973 0011

Bladder and Bowel Foundation: [www.bladderandbowelfoundation.org](http://www.bladderandbowelfoundation.org)  
Tel: 0845 345 0165

Urostomy Association: [www.urostomyassociation.org.uk](http://www.urostomyassociation.org.uk)  
Tel: 01889 563191

Colostomy Association: [www.colostomyassociation.org.uk](http://www.colostomyassociation.org.uk)  
Tel: 0800 328 4257

It is important to get as emotionally prepared as possible before you decide to have this operation. There are NHS psychological support services available to help you adjust to the losses in your body as well as the permanent changes of how your body will function. You may feel you are getting enough support from your family, GP and hospital team including your CNS, however, sometimes more specialist input is needed.

## Psychosexual issues

College of Sexual Relationship Therapists: [www.cosrt.org.uk](http://www.cosrt.org.uk)  
Tel: 020 8543 2707

RELATE. Low cost relationship & sexual therapy services across the UK.  
[www.relate.org.uk](http://www.relate.org.uk)

## Psychological issues

NHS psycho-oncology services and psychological support services are available in specialist centres. However, additional psychological counselling can be found:

British Psychological Society  
<https://www.bps.org.uk/public/find-psychologist>

British Association for Counselling & Psychotherapy  
<https://www.bacp.co.uk/search/Therapists>

UK Council for Psychotherapy <https://www.psychotherapy.org.uk/>

## Sexual issues

Your CNS or Urologist will provide specialist practical support.

## Do not identify as heterosexual / cisgender?

LGBTQI Cancer Charity for those individuals who do not identify as heterosexual / cisgender: [www.livethroughthis.co.uk](http://www.livethroughthis.co.uk)

**If you decide to have surgery you may want to revisit this document after surgery to remind you of the adjustments you may face.**

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Patient Decision Aid for Men.

Produced as part of study IRAS 257890.

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Solum AM, Riffenburgh RH, Johnstone PA. Survival of patients with untreated rectal cancer. J Surg Oncol. 2004; 87:157–161

# Treatment Options for Complex Rectal Cancer in Women

*Patient Decision Aid*  
*Helping you make your decision*



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## What is complex rectal cancer?

The cancer in your pelvis that started in your bowel (**rectum**) may have grown into other organs nearby (**locally advanced**) or the cancer may have returned after previous treatment (**locally recurrent**).

You have been given this decision aid because surgery is a potential option for you. This decision aid aims to help you and your surgeon decide together which type of treatment is best for you. **It is important to make the choice that you feel is right for you.**

The decision will depend on your individual circumstances and how you feel about surgery. Surgery is not everyone's choice and there are different options that may not cure you but will support you through this illness.

**Every patient is different so this decision aid is only a guide.** Different options will be appropriate for different patients.

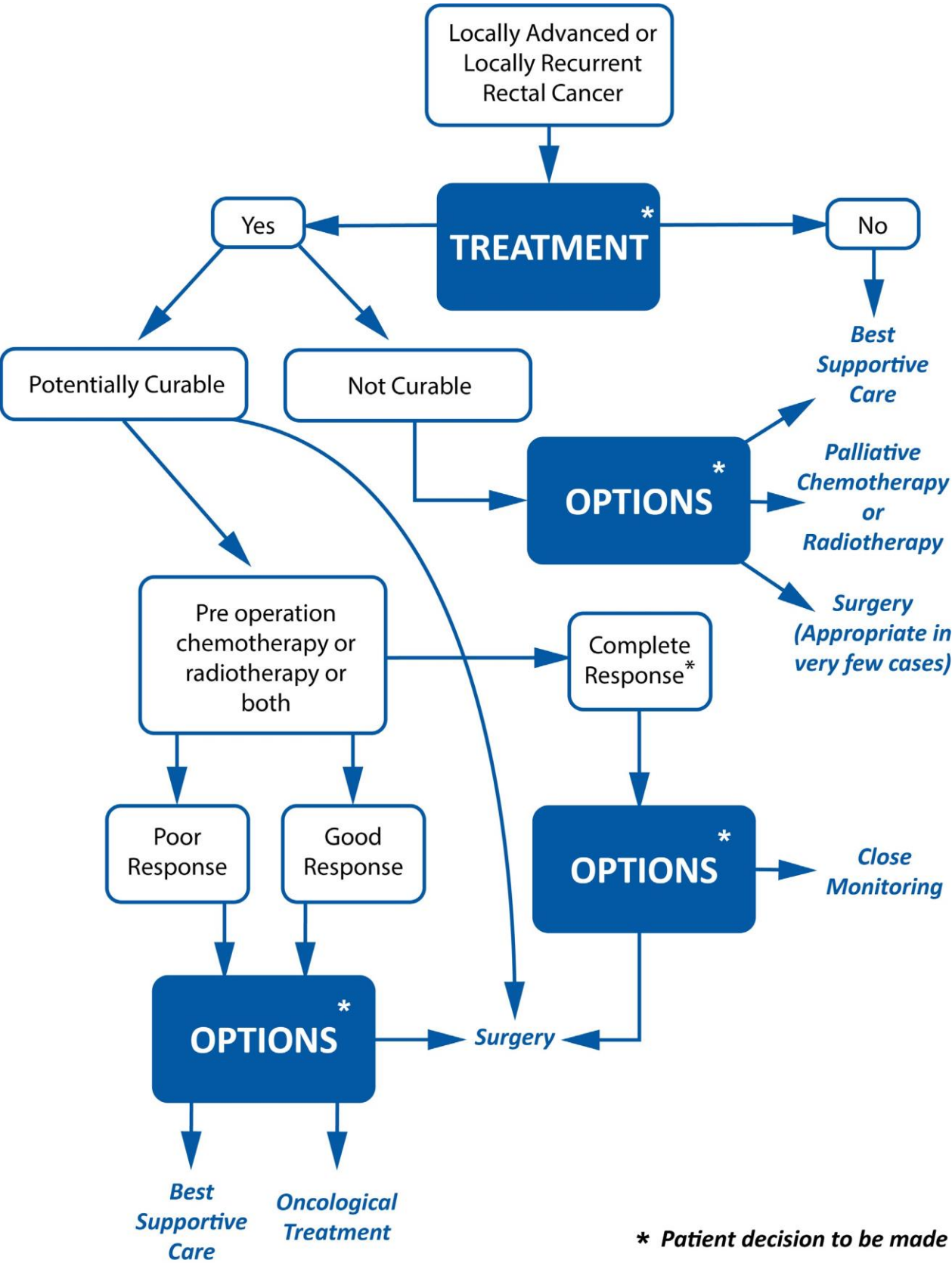
You may have already had oncological treatment - chemotherapy, radiotherapy or both before you get to the option of surgery called pelvic exenteration or pelvic clearance. Or you may be facing the decision of starting chemotherapy and/or radiotherapy with a view to having surgery later.

You and your team may decide after having your cancer treatment that surgery is not something you want or need (complete response).

There are a number of things to consider when you are about to make a decision about treatment. It is good to think about the possible benefits and disadvantages of treatment to help you make the right decision for you. There are **no right or wrong choices**. People make different choices for different reasons.



This flow diagram gives you an idea where you have been on your cancer journey and the choices you now face.



\* Patient decision to be made  
\*\* In some recurrent cases, there may be a choice to proceed straight to surgery

Follow-up will be individualised for each patient regardless of the pathway you choose.

# Treatment options:

When facing your diagnosis you have a decision to make whether you want treatment or not. There are three types of treatment that may be available to you.

- 1. To have surgery.
- 2. To have chemotherapy and/or radiotherapy.
- 3. To have no further active cancer treatment (best supportive care).



| SURGERY                                                                                                                                                                | ONCOLOGICAL TREATMENT                                                                                                                                                                                                                                                                                                | BEST SUPPORTIVE CARE                                                                                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|
| <p>Surgery is the only potential option for a cure.</p> <p>Occasionally it is offered to people who can not be cured. This will be made clear to you by your team.</p> | <p>Oncological treatments (chemotherapy and radiotherapy) is offered to try and shrink the cancer before surgery (curative) or it is offered to control your symptoms (not curative).</p> <p>What you will be offered will depend on any treatment you have had previously and any underlying health conditions.</p> | <p>You may decide you do not want any surgical or oncological (chemotherapy and/or radiotherapy) treatment.</p> |

Some patients may decide that they do not want any treatment in the form of surgery or chemotherapy and/or radiotherapy. There are reasons people choose best supportive care which may be:

- They do not want the symptoms from chemotherapy and radiotherapy
- They want to maximise their quality of life
- They could not cope psychologically with the result of surgery
- They do not find the idea of major surgery appealing
- They do not feel fit for surgery

Best supportive care is the care given to improve the quality of life of people living with cancer. The goal of supportive care is to improve the quality of life of patients and their families facing the problems associated with life-threatening illness, through treating any symptoms as early as possible and treating the psychological, social, and spiritual problems related to the cancer. This can include psychological therapy, complementary therapies (e.g yoga, reiki, massage, homeopathy, meditation, acupuncture) and clinical trials.

You will be followed up with your palliative care team of nurses and doctors who will monitor you. You may not have symptoms or need any support right now but you will be able to access all support when you need it. Your local team will be able to discuss this further.

## **Your cancer treatment goals**

Your cancer treatment goals depend on many factors:

- Being cancer free
- Living longer, even with cancer
- Having fewer symptoms from cancer and side effects from its treatment
- Maintaining physical and emotional strength
- Having an acceptable quality of life

## This table explains your treatment options:

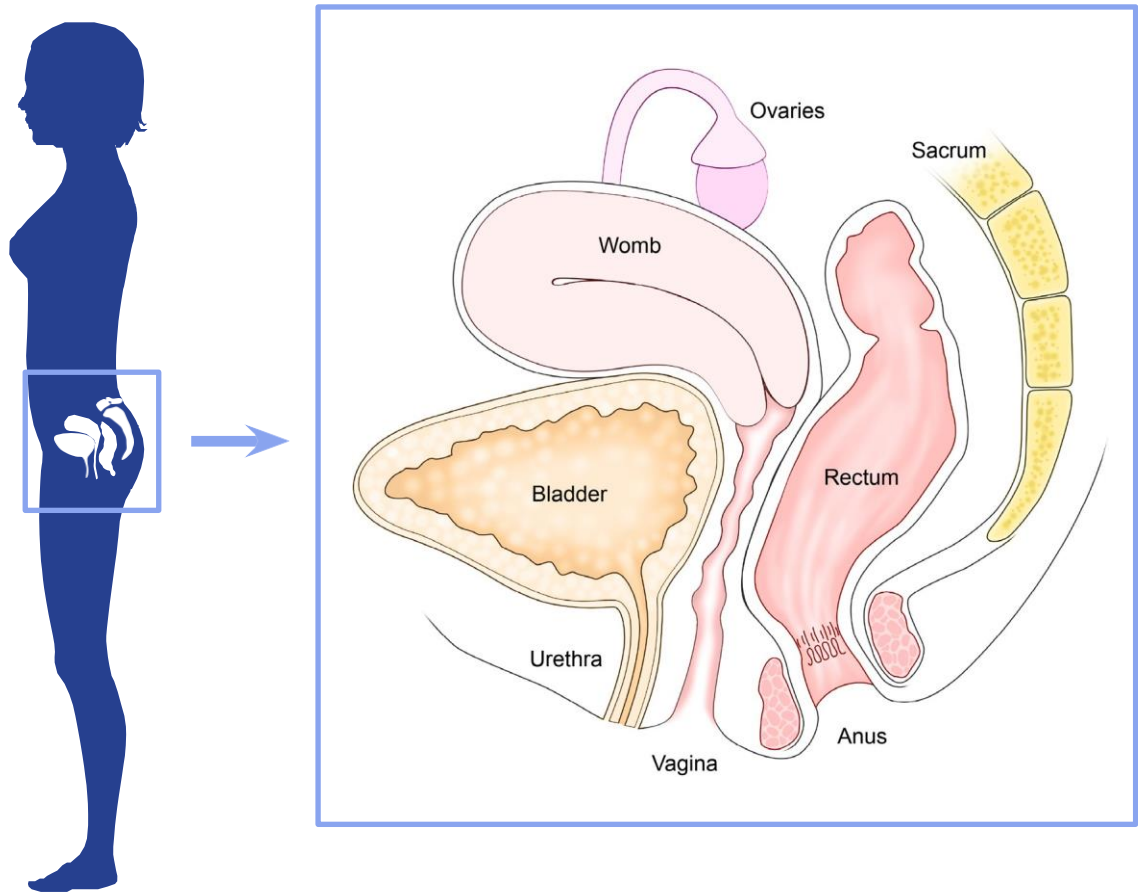
|                                                       | SURGERY                                                                                                                                                                                                                                                                                                                                                                 | ONCOLOGICAL TREATMENT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | SUPPORTIVE TREATMENT                                                                                                                                                                                                                                                                                                 |
|-------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Will this option cure me of cancer?</b>            | <p>It will improve your current symptoms but you will develop different symptoms following surgery</p> <p>Surgery potentially can cure your cancer.</p> <p>If surgery is being offered as a cure this is your best chance of cure.</p>                                                                                                                                  | <p>Very rarely can chemotherapy and/or radiotherapy alone cure your cancer.</p> <p>This often would be used as part of a curative approach before major surgery (to shrink your cancer) or this option would be used as palliative (non- curative) treatment to help control your symptoms. Your oncologist will discuss what is available to you.</p> <p>Whilst cure is not usually possible for treatment without surgery. When given with the intention to cure, up to 1 in 7 people (15%) of patients can get a complete response (cure) to chemoradiotherapy for locally advanced rectal cancer with 1 in 13 people (8%) achieving a complete response in locally recurrent rectal cancer.</p> | <p>Supportive treatment will not cure your cancer but it will treat your symptoms.</p> <p>Supportive treatment prevents or treats the symptoms of the cancer as early as possible. It also addresses the physical, mental, social and spiritual needs tailored to your needs to give you a good quality of life.</p> |
| <b>How will each treatment option affect my life?</b> | <p>Surgery can affect your:</p> <ul style="list-style-type: none"> <li>• Physical health</li> <li>• Mental health</li> <li>• Relationships</li> <li>• Lifestyle</li> </ul>                                                                                                                                                                                              | <p>Chemoradiotherapy can affect your:</p> <ul style="list-style-type: none"> <li>• Physical health</li> <li>• Mental health</li> <li>• Relationships</li> <li>• Lifestyle</li> </ul> <p>Without surgery, you may eventually get more symptoms which we will treat to keep you as comfortable as possible.</p>                                                                                                                                                                                                                                                                                                                                                                                       | <p>You are likely to get more symptoms with time. You will have access to support teams in order to help you manage your symptoms and feel as comfortable as possible.</p>                                                                                                                                           |
| <b>What kind of support will I have?</b>              | <ul style="list-style-type: none"> <li>• Medical team – surgeons, junior doctors, ward nurses, clinical nurse specialist</li> <li>• Oncologist (cancer doctor)</li> <li>• Stoma nurses</li> <li>• District nurses</li> <li>• Clinical Nurse Specialist</li> <li>• GP's</li> <li>• Support charities</li> <li>• Friends and family</li> <li>• Physiotherapist</li> </ul> | <ul style="list-style-type: none"> <li>• GP's</li> <li>• Macmillan nurses</li> <li>• Oncologist (cancer doctor)</li> <li>• Clinical Nurse Specialist</li> <li>• Support charities</li> <li>• Palliative care team when appropriate</li> <li>• Access to hospice support</li> <li>• Friends and family</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                    | <ul style="list-style-type: none"> <li>• Macmillan nurses</li> <li>• GP's</li> <li>• Support charities</li> <li>• Palliative care team</li> <li>• Access to hospice support</li> <li>• Friends and family</li> </ul>                                                                                                 |

|                                               | SURGERY                                                                                                                                                                                                                                                                                                                                                                                                                                                     | ONCOLOGICAL TREATMENT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | SUPPORTIVE TREATMENT                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Will this option relieve my current symptoms? | It will improve your current symptoms but you will develop different symptoms following surgery.                                                                                                                                                                                                                                                                                                                                                            | Short term it can relieve or improve symptoms but these symptoms may return and you could develop more symptoms without surgery.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Supportive treatment will control your symptoms. Without surgery your cancer will grow & any symptoms you have may get worse. There are ways of managing pain and other symptoms using both medicines and alternative therapies.                                                                                                                                                         |
| What are the benefits?                        | Increased chance of survival (curative) or improvements of the symptoms you had before having an operation (curative and non curative)                                                                                                                                                                                                                                                                                                                      | Curative (before surgery) <ul style="list-style-type: none"> <li>• Can shrink your cancer</li> <li>• Can rarely cure cancer without surgery</li> </ul> Palliative without surgery <ul style="list-style-type: none"> <li>• Can make you live longer</li> <li>• Not having side effects or longterm symptoms of surgery</li> <li>• Can rarely cure cancer without surgery</li> </ul>                                                                                                                                                                                                                                                                                                                                        | Potentially an improved quality of life.<br><br>Not having side effects or long-term symptoms of surgery or oncological treatments.                                                                                                                                                                                                                                                      |
| What are the risks?                           | You are likely to experience short and long term side effects: <ul style="list-style-type: none"> <li>• Pain</li> <li>• Urinary &amp; bowel symptoms</li> <li>• Reduced mobility/weakness</li> <li>• Long term fatigue (tiredness that doesn't go away)</li> <li>• Psychological and emotional changes</li> <li>• Sexual dysfunction</li> </ul> Complications: <ul style="list-style-type: none"> <li>• Major</li> <li>• Minor (discussed later)</li> </ul> | Symptoms are different for different people but can include the following:<br><br>Symptoms from chemotherapy <ul style="list-style-type: none"> <li>• Pins and needles</li> <li>• Numbness/pain in feet</li> <li>• Sickness</li> <li>• Fatigue</li> <li>• Loss of appetite</li> <li>• Recurrent infections</li> <li>• Tummy pain</li> <li>• Diarrhoea or constipation</li> <li>• Cold hands and feet</li> </ul> Symptoms from radiotherapy: <ul style="list-style-type: none"> <li>• Skin redness, tenderness and soreness</li> <li>• Sickness</li> <li>• Fatigue</li> <li>• Diarrhoea or constipation</li> <li>• Sexual &amp; urinary dysfunction</li> </ul> You can also experience psychological and emotional changes. | You may develop more symptoms as the cancer begins to grow which we will support you with to ensure you are as comfortable as possible.<br><br>Symptoms may include: <ul style="list-style-type: none"> <li>• Blockage of the bowel</li> <li>• Pain</li> <li>• Bleeding</li> <li>• Tumour can grow externally</li> <li>• Sickness</li> <li>• Fatigue</li> <li>• Poor appetite</li> </ul> |

|                                  | SURGERY                                                                                                                                                                                                                                                        | ONCOLOGICAL TREATMENT                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | SUPPORTIVE TREATMENT                                                                                                                                                                                             |
|----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| What are my chances of survival? | <p>Survival is a very general statistic based on historical large groups of patients. <b>They can't tell you what will happen in your individual case.</b></p> <p><b>Ask your team about information more specific to what we know about your disease.</b></p> | <p><b>Non-Curative (Palliative) Without Surgery:</b> Oncological treatment can allow people to live longer and this will be different in every person.</p> <p><b>Locally Advanced Rectal Cancer:</b> Chemotherapy with, or without radiotherapy can improve symptoms, and can extend survival on average by 10-17 months.</p> <p><b>Locally Recurrent Rectal Cancer:</b> Chemotherapy with, or without radiotherapy can improve symptoms, and can extend survival on average by 10–15 months.</p> | <p><b>Locally Advanced Rectal Cancer:</b> Without treatment, most patients live for 12 months after diagnosis.</p> <p><b>Locally Recurrent Rectal Cancer:</b> Untreated patients usually survive 6-8 months.</p> |

## What does surgery involve?

Pelvic Exenteration is an operation that requires removal of all, some or part of your pelvic organs of which there are a number of different types.



### *Normal anatomy - side view*

Your team will highlight what type of surgery you are having and what is relevant for you.

Several surgeons from different specialties are involved. The operation is a **major undertaking** and **one of the most complex surgeries performed**.

There are **different types of pelvic exenteration**. Depending on your cancer, removal of all or some of the following may be necessary:

- Part of the bowel (the colon, rectum and anus)
- The urinary system (the bladder and ureters)
- Your gynaecological organs (your uterus (womb), your ovaries, your fallopian tubes and/or your vagina)
- Your lower spine (sacrum).

**If you are considering surgery, this booklet will provide more detail about what this will involve in the short and longer term.**

**Further detail about oncological treatment (chemotherapy and or radiotherapy) can be discussed with your oncological team.**

## **What does the operation involve?**

You will be asleep (under general anaesthetic) during the operation. A cut will be made from above the belly button to the bottom of your tummy (abdomen). It may also be necessary to make a second cut around the back passage (anus) and vagina. In a very small number of cases it may be possible to carry out the procedure in a minimally invasive way i.e. keyhole or robotically.

## **What do I expect after the surgery?**

Following your surgery it will be necessary to keep a close eye on you. Depending where you have your surgery, this may be called high dependency, critical care or intensive care. Typically you will stay in this area for 2-5 days.

When you wake from surgery, you will have a number of things attached to you:

- Oxygen tubes in your nose or through a mask on your face.
- Drips to keep you hydrated.
- Drains (tubes) inside your tummy and bottom to drain excess fluid.
- Tube placed in your stomach via your nose to drain any fluid in your stomach.
- Staples or stitches in the wounds.
- Tube into your bladder (catheter) if you have not had your bladder removed.
- Sometimes a line in your neck is required for access to your veins (central line)

During your hospital stay it is normal to sometimes need x-rays and scans.



You will be allowed to drink initially, then you will be allowed food when your body can tolerate it. You will be nursed either on your side or your back for a few days. Your ability to move around, out of your bed, will be reduced for up to a week. If your bowels go on strike and stop working we may decide to feed you through your veins (TPN).

The hospital stay after surgery is variable. Typically if there are no post-operative setbacks patients are in hospital between 14 days to 3 months. However, if you were to experience complications it can be much longer.

## **How long will it take to recover?**

These operations are a considerable undertaking and your body will go through lots of changes, so it is important that you are prepared for a long recovery. Initial recovery can take between 6 weeks and 3 months. Complete, longer term recovery can take up to 12 months.

## **Will everything in my pelvis need to be removed?**

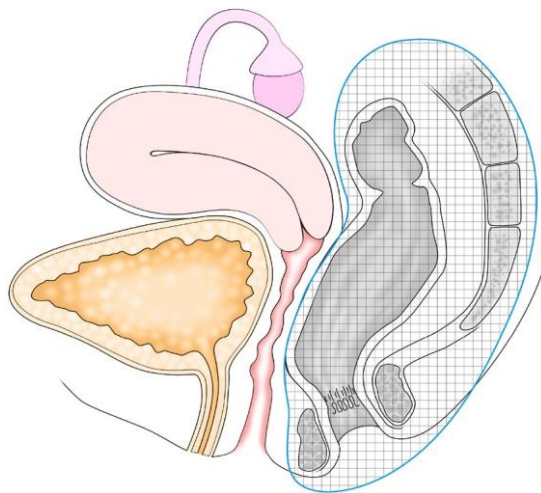
Not necessarily. There are different types of this operation depending on the location of your cancer.



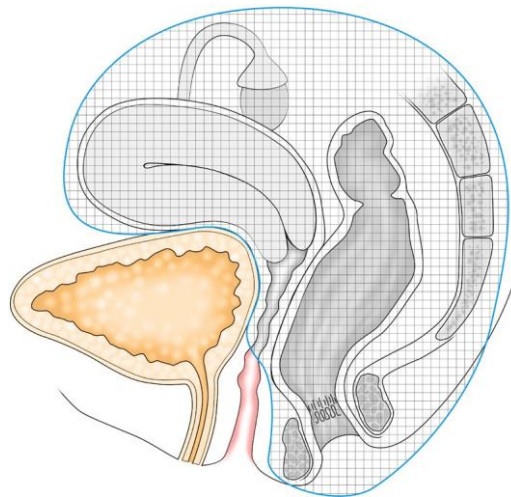
## Some variations of the surgery:

These are some possible options, depending where your tumour is.

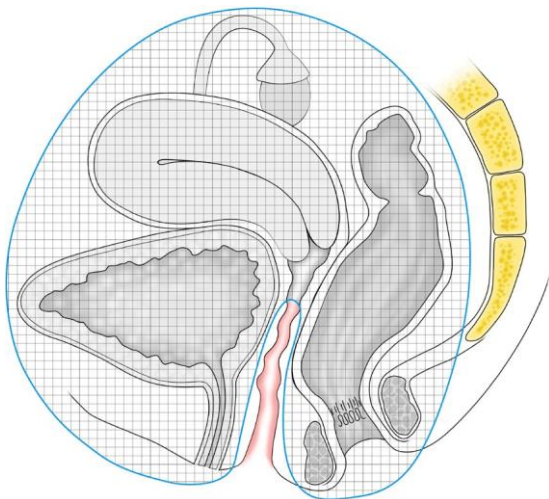
*Shaded area = what will be removed*



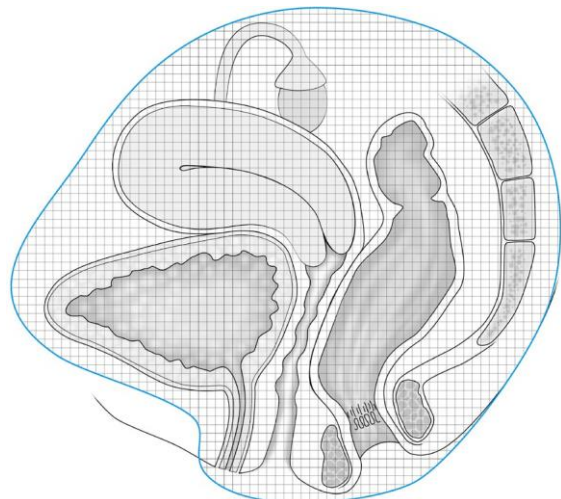
**Rectum, anus & sacrum**



**Rectum & anus. Occasionally womb, tubes, ovaries, part or all of vagina & sacrum removed**



**Bladder, womb, & rectum**



**Rectum, anus, bladder, ureter, womb, ovaries, tubes. Occasionally sacrum**

## Will I have a stoma bag?

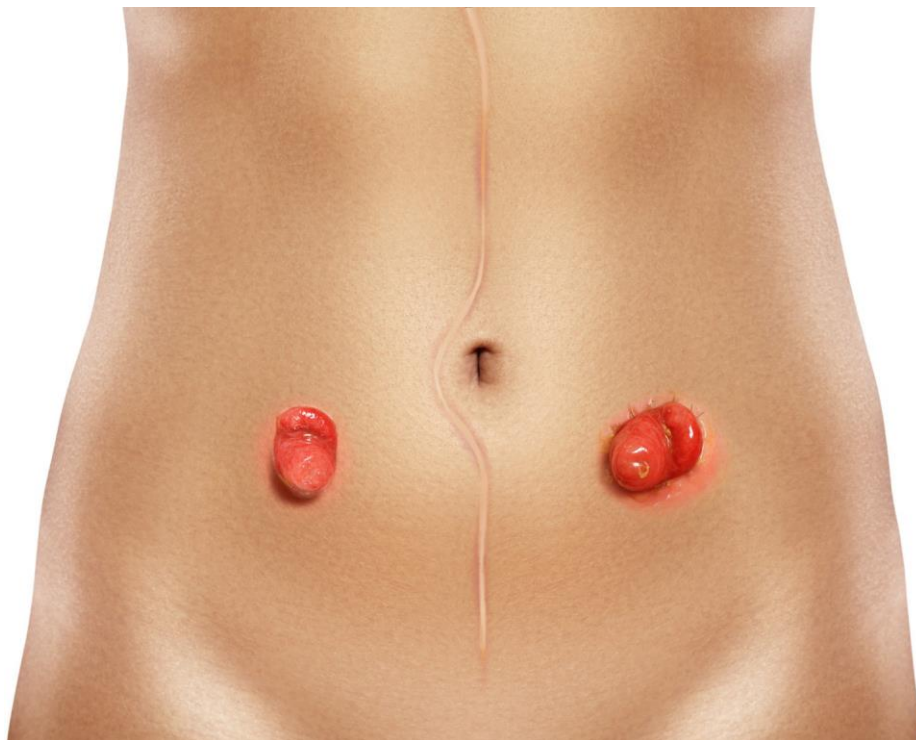
It is likely you will have a stoma bag as part of your operation. This is usually permanent.

The 'bag' is the appliance that sticks to the skin and sits on top of the stoma to collect your body's waste (wee/poo). A stoma is made when part of your bowel is pulled through your tummy wall onto the skin.

If your back passage (anus) is removed then the bowel will redirect waste products (poo/faeces) through a piece of bowel brought through the skin on your tummy. This is usually created to the left-hand side of your belly button. A specially designed bag sticks over the stoma to collect the faeces.

If your bladder is removed then the bowel will redirect waste products (wee/urine) through the new piece of bowel through the skin on your tummy. This is called a urostomy or ileal conduit. This is usually created to the right-hand side of your belly button. A specially designed bag sticks over the stoma to collect the urine.

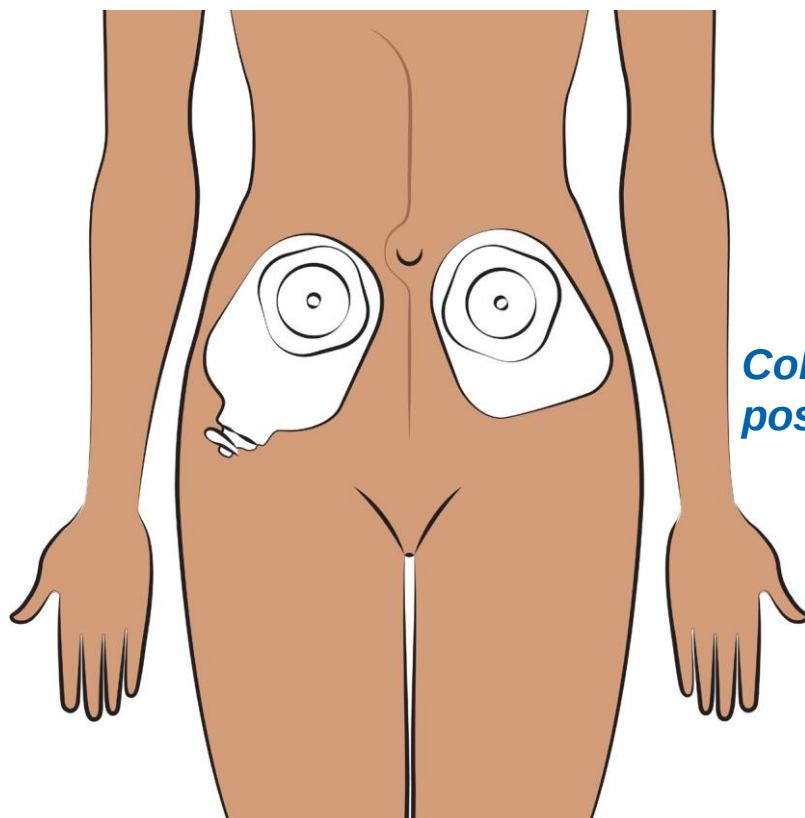
## What do stomas look like?



***Urostomy/ileal conduit***

***Colostomy***

*Urostomy bag position*



*Colostomy bag position*

*about  
15cm*



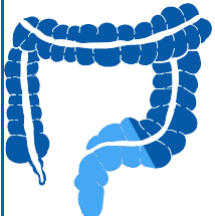
*Typical urostomy bag*



*Typical colostomy bag*

# What will I have removed & what does that POTENTIALLY mean for me?

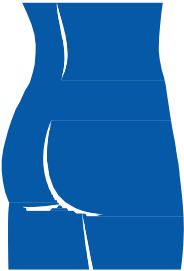
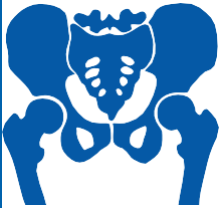
(It doesn't necessarily mean it will happen to you)

| TICK IF APPLICABLE TO ME | ORGAN                                                                                                                         | IMPLICATION                                                                                                                | POTENTIAL SHORT TERM CONSEQUENCES (0 - 3 MONTHS)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | POTENTIAL LONG TERM CONSEQUENCES (3 MONTHS + LONGER)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|--------------------------|-------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          | <p><b>Rectum</b><br/>(lower part bowel)</p>  | <p>It may or may not be possible to join your bowel back together.</p> <p>You may need a permanent or temporary stoma.</p> | <p><b>If joined:</b></p> <ul style="list-style-type: none"> <li>• The join may leak in 5 to 15 per 100 cases (5-15%)</li> <li>• Inability to control opening your bowels (incontinence)</li> <li>• Urgency to open bowels</li> <li>• Need to open bowels often</li> <li>• Difficulty emptying your bowel despite visiting the toilet and passing soft motions often</li> </ul> <p><b>If you have a stoma:</b></p> <ul style="list-style-type: none"> <li>• Episodes of stoma leaking</li> <li>• Stoma can 'prolapse' meaning more bowel can protrude through the tummy wall than planned</li> <li>• Dietary changes</li> <li>• Skin problems around stoma</li> </ul> | <p><b>If joined:</b></p> <ul style="list-style-type: none"> <li>• Inability to control opening your bowel (incontinence)</li> <li>• Urgency to open bowels</li> <li>• Need to open bowels often</li> <li>• Difficulty emptying your bowel despite visiting the toilet and passing soft motions often</li> <li>• Long term medication to regulate bowel motion</li> </ul> <p><b>If you have a stoma:</b></p> <ul style="list-style-type: none"> <li>• Infrequent episodes of stoma leaking</li> <li>• Hernia* around stoma</li> <li>• Body image</li> <li>• Emotional impact</li> <li>• Relationships affected</li> <li>• Dietary changes</li> <li>• Skin problems around stoma</li> </ul> <p>(* the visible part of your stoma bulges out further from your body)</p> |



## What will I have removed & what does that POTENTIALLY mean for me?

(It doesn't necessarily mean it will happen to you)

| TICK IF APPLICABLE TO ME | ORGAN                                                                                                                    | IMPLICATION                                                                                                                                                                        | POTENTIAL SHORT TERM CONSEQUENCES (0 - 3 MONTHS)                                                                                                                              | POTENTIAL LONG TERM CONSEQUENCES (3 MONTHS + LONGER)                                                                                                                                                                                               |
|--------------------------|--------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          | <b>Anus</b> (back passage)<br>          | <p>You will have a permanent stoma (colostomy) – this means you will poo through the stoma on your tummy.</p> <p>You will no longer have an anus as it will have been removed.</p> | <ul style="list-style-type: none"> <li>• Episodes of leaking stoma bags</li> <li>• Emotional impact</li> <li>• Wound issues</li> <li>• Altered sensation</li> </ul>           | <ul style="list-style-type: none"> <li>• Infrequent episodes of leaking stoma bags</li> <li>• Delayed wound healing</li> <li>• Emotional impact</li> <li>• Body image</li> <li>• Altered sensation</li> <li>• Phantom back passage pain</li> </ul> |
|                          | <b>Hip bones</b> (ilium, ischium)<br> | <p>It can affect your mobility.</p>                                                                                                                                                | <ul style="list-style-type: none"> <li>• Altered leg control</li> <li>• Leg weakness</li> <li>• Hip pain</li> <li>• Need to use a walking aid (frame/crutch/stick)</li> </ul> | <ul style="list-style-type: none"> <li>• Altered leg control</li> <li>• Leg weakness</li> <li>• Hip pain</li> <li>• Long term use of a walking aid (frame/crutch/stick)</li> <li>• Inability to run</li> </ul>                                     |

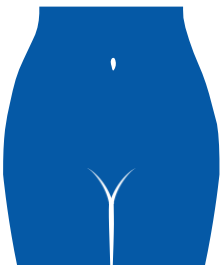
## What will I have removed & what does that POTENTIALLY mean for me?

(It doesn't necessarily mean it will happen to you)

| TICK IF APPLICABLE TO ME | ORGAN                                                                                                                     | IMPLICATION                                                                                                                                                                                                                        | POTENTIAL SHORT TERM CONSEQUENCES (0 - 3 MONTHS)                                                                                                                                                                                                                                                                                                                                                                                                                         | POTENTIAL LONG TERM CONSEQUENCES (3 MONTHS + LONGER)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|--------------------------|---------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          | <p><b>Uterus, ovaries and tubes</b></p>  | <p>You will no longer be able to get pregnant.</p> <p>If you have not been through the menopause, you will go through the menopause.</p> <p>You will no longer have a cervix (no further smear tests if within screening age).</p> | <p>Menopausal symptoms if you haven't already been through the menopause (pre-menopausal):</p> <ul style="list-style-type: none"> <li>• Flushes</li> <li>• Night sweats</li> <li>• Irritability</li> <li>• Infertility</li> <li>• Reduced libido and vaginal dryness</li> <li>• Poor sleep</li> <li>• Hair loss</li> </ul> <p>You will most probably need hormone replacement therapy (HRT) until at least the age you would expect to have completed the menopause.</p> | <p>If you haven't already been through the menopause before surgery (pre-menopausal):</p> <ul style="list-style-type: none"> <li>• Infertility. If you have wishes of having a child then there are options for egg collection and IVF with surrogate prior to chemoradiotherapy</li> <li>• Longer term early menopausal management of bone health/ supplements</li> <li>• Need for hormone replacement therapy (HRT)</li> </ul> <p>General</p> <ul style="list-style-type: none"> <li>• Emotional impact</li> <li>• Body image</li> </ul> |

## What will I have removed & what does that POTENTIALLY mean for me?

(It doesn't necessarily mean it will happen to you)

| TICK IF APPLICABLE TO ME | ORGAN                                                                                              | IMPLICATION                                                                                                          | POTENTIAL SHORT TERM CONSEQUENCES (0 - 3 MONTHS)                                                   | POTENTIAL LONG TERM CONSEQUENCES (3 MONTHS + LONGER)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------|----------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          | <b>Vagina</b><br> | <p>You may or may not be able to engage in sexual intercourse involving penetration of the vagina (see page 30).</p> | <ul style="list-style-type: none"> <li>• Emotional impact</li> <li>• Sexual dysfunction</li> </ul> | <p>If the vagina is not reconstructed, you will not be able to engage in penetration.</p> <p>If the vagina is reconstructed:</p> <ul style="list-style-type: none"> <li>• It will look and feel different</li> <li>• The 'lie'/angle and depth of the vagina may change which can cause pain on intercourse</li> <li>• The vagina will be dry and will need lubrication with non-hormonal lubricants for both dilation and sexual purposes</li> <li>• You may not be able to climax in the same way</li> <li>• As the new tissue starts to heal it may become scarred &amp; tight so it will be important to use dilators to keep it open</li> <li>• The reconstruction may not work for you</li> <li>• Psychological impact</li> <li>• Body image</li> </ul> |



## What will I have removed & what does that POTENTIALLY mean for me?

(It doesn't necessarily mean it will happen to you)

| TICK IF APPLICABLE TO ME | ORGAN                                                                                                                                                                                                               | IMPLICATION                                                                                                                                                                                                                                                                                                                                                               | POTENTIAL SHORT TERM CONSEQUENCES (0 - 3 MONTHS)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | POTENTIAL LONG TERM CONSEQUENCES (3 MONTHS + LONGER)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|--------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          | <p><b>Sacrum</b><br/>(lower spine)</p>  <p>The sacrum can be divided at a high or low level depending on where your cancer is.</p> | <p><b>Low/All Sacrectomy</b><br/>You may experience pain</p> <p><b>High Sacrectomy</b></p> <ul style="list-style-type: none"> <li>• It can affect your bladder control (if no urostomy)</li> <li>• It can affect your mobility</li> <li>• You may experience pain</li> <li>• Your legs can be effected with weakness, numbness/pins and needles, poor mobility</li> </ul> | <p><b>Low/All Sacrectomy</b><br/>Nerve pain - shooting pains, pins and needles.<br/>Wound healing problems - infection/slow healing.</p> <p><b>High Sacrectomy</b></p> <ul style="list-style-type: none"> <li>• Episodes of wetting yourself (incontinence)</li> <li>• Inability to empty the bladder without inserting an 'in and out' catheter to drain the bladder</li> <li>• Foot drop (at rest, foot remains pointing to the floor and you are unable to lift it to a normal position)</li> <li>• Muscle weakness</li> <li>• Need to use a walking aid (frame/crutch/stick)</li> <li>• Numbness to feet/legs</li> <li>• Problems with mobility may or may not gradually improve</li> </ul> | <p><b>Low/All Sacrectomy</b><br/>Long term pain</p> <p><b>High Sacrectomy</b></p> <ul style="list-style-type: none"> <li>• Episodes of wetting yourself (incontinence)</li> <li>• Inability to empty the bladder without inserting an 'in and out' catheter to drain the bladder</li> <li>• Long-term physiotherapy</li> <li>• Foot drop (need for permanent ankle support)</li> <li>• Dependence on walking aid (frame/crutch/stick)</li> <li>• Short distance mobility only</li> <li>• Unable to walk more than a short distance</li> <li>• Modified car to drive</li> </ul> |

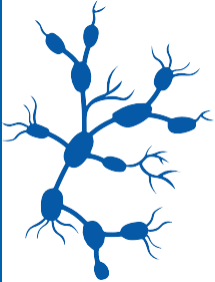
# What will I have removed & what does that POTENTIALLY mean for me?

(It doesn't necessarily mean it will happen to you)

| TICK IF APPLICABLE TO ME | ORGAN                                                                                           | IMPLICATION                                                                                                                                                                                                                                                                                                   | POTENTIAL SHORT TERM CONSEQUENCES (0 - 3 MONTHS)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | POTENTIAL LONG TERM CONSEQUENCES (3 MONTHS + LONGER)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|--------------------------|-------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          | <b>Nerves</b>  | <p><b>Depending on what nerves are cut:</b></p> <p>It can affect your bladder control (if it is not removed)</p> <p>It can affect your bowel control (if you have been joined up)</p> <p>It can affect your legs – mobility, weakness, numbness, pins and needles.</p> <p>Long term pain can be an issue.</p> | <ul style="list-style-type: none"> <li>• Need to catheterise to pass water (urine) if no urostomy</li> <li>• Altered leg control</li> <li>• Leg weakness</li> <li>• Leg numbness</li> <li>• Buttock, leg and foot numbness</li> <li>• Leg pain</li> <li>• Difficulty walking</li> <li>• Foot drop (at rest, foot remains pointing to the floor and you are unable to lift it to a normal position)</li> <li>• Reduced mobility</li> <li>• Inability to walk without frame/crutch/stick</li> <li>• Able to walk short distance only</li> <li>• Nerve pain - shooting pain, pins and needles</li> <li>• Episodes of wetting yourself (if you have a bladder)</li> </ul> | <ul style="list-style-type: none"> <li>• Need to catheterise to pass water (urine) if no urostomy</li> <li>• Altered leg control</li> <li>• Leg weakness</li> <li>• Leg numbness</li> <li>• Leg pain</li> <li>• Difficulty walking</li> <li>• Foot drop (need for long term ankle support)</li> <li>• Reduced mobility</li> <li>• Inability to walk without stick</li> <li>• Able to walk short distance only</li> <li>• Inability to run</li> <li>• Modified car to drive</li> <li>• Long term pain</li> <li>• Episodes of wetting yourself (if you have a bladder)</li> </ul> |

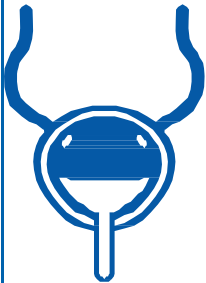
## What will I have removed & what does that POTENTIALLY mean for me?

(It doesn't necessarily mean it will happen to you)

| TICK IF APPLICABLE TO ME | ORGAN                                                                                                             | IMPLICATION                                                                    | POTENTIAL SHORT TERM CONSEQUENCES (0 - 3 MONTHS)                                                                                                                                                                                            | POTENTIAL LONG TERM CONSEQUENCES (3 MONTHS + LONGER)                                                                                                                                                                                                                                           |
|--------------------------|-------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          | <b>Lymph Nodes in Pelvis</b>     | It can affect the drainage of lymphatic fluid from your leg back to your body. | Build up of lymph fluid in your legs (lymphoedema)                                                                                                                                                                                          | <ul style="list-style-type: none"> <li>• Build up of lymph fluid in your legs (lymphoedema) leading to:</li> <li>• Aching, heavy</li> <li>• Difficulty with movement</li> <li>• Skin infections</li> <li>• Tight skin</li> <li>• Fluid leaking through skin</li> <li>• Skin growths</li> </ul> |
|                          | <b>Reconstructive surgery</b>  | New area of skin will look and feel different.                                 | <ul style="list-style-type: none"> <li>• Inability to sit for more than short periods</li> <li>• Numbness</li> <li>• Flap may lose blood supply leading to issues with wound breakdown and prolonged wound healing (see page 33)</li> </ul> | <ul style="list-style-type: none"> <li>• Altered sensation and appearance</li> </ul> <p>Potentially you may experience a hernia*</p> <p>(*The new area may bulge down further than surrounding tissue)</p>                                                                                     |

## What will I have removed & what does that POTENTIALLY mean for me?

(It doesn't necessarily mean it will happen to you)

| TICK IF APPLICABLE TO ME | ORGAN                                                                                                | IMPLICATION                                                                                                                                                                                                                                                                                       | POTENTIAL SHORT TERM CONSEQUENCES (0 - 3 MONTHS)                                                                                                                                                                                                  | POTENTIAL LONG TERM CONSEQUENCES (3 MONTHS + LONGER)                                                                                                                                                                                                                    |
|--------------------------|------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          | <b>Vessels</b><br>  | It can affect the blood supply to the affected leg.                                                                                                                                                                                                                                               | <ul style="list-style-type: none"> <li>• Leg swelling</li> <li>• Loss of blood supply to the leg</li> </ul>                                                                                                                                       | <ul style="list-style-type: none"> <li>• Leg pain</li> <li>• Leg swelling</li> <li>• Skin changes</li> <li>• Pain on walking</li> </ul>                                                                                                                                 |
|                          | <b>Bladder</b><br> | <p>You will have a permanent stoma (urostomy/ileal conduit) – urine will drain through a stoma on your tummy into a stoma bag.</p> <p>There will be fine tubes (stents) that are visible within the stoma and are usually removed a few weeks post surgery. These help the new joins to heal.</p> | <ul style="list-style-type: none"> <li>• Frequent episodes of leaking urostomy bag</li> <li>• Urine/stent infections</li> <li>• Stents can block</li> <li>• Stents can move</li> <li>• The join may leak in 2-10 per 100 cases (2-10%)</li> </ul> | <ul style="list-style-type: none"> <li>• Infrequent episodes of leaking urostomy bag</li> <li>• Hernia around stoma – urostomy becomes difficult to manage</li> <li>• Kidney failure</li> <li>• Stoma narrowing</li> <li>• Wee will smell and look different</li> </ul> |

## What are the other POTENTIAL things to expect after surgery?

| Impact                  | Short Term                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Long Term                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Pain</b>             | <p>Pain is normal after major surgery. We will use different ways to control your pain. These include:</p> <ul style="list-style-type: none"> <li>• Epidural (fine tube inserted into your back giving you painkiller)</li> <li>• Patient controlled analgesia (PCA) (painkiller via a drip into your vein on demand with a button)</li> <li>• Spinal (injection into your back before the operation)</li> <li>• Rectus sheath catheters (local anaesthetic being dripped into your six-pack muscles)</li> <li>• Tablets/liquids/patches</li> </ul> <p>The pain relief appropriate for you will be discussed with the anaesthetist</p> | <p>Long term painkilling medication may be necessary. Doses and types will change over time as your body starts to heal.</p>                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Physical Changes</b> | <p><b>Functional</b></p> <ul style="list-style-type: none"> <li>• Weakness</li> <li>• Tiredness</li> <li>• Inability to do normal tasks – for example washing, dressing</li> <li>• Poor sleep - bad dreams and night terrors</li> <li>• Weight loss</li> <li>• Nausea or vomiting</li> </ul> <p><b>Hormonal (if you haven't already been through the menopause) **</b></p> <ul style="list-style-type: none"> <li>• Hot flushes</li> <li>• Night sweats</li> <li>• Difficulty sleeping</li> <li>• Low mood or anxiety</li> <li>• Problems with memory &amp; concentration</li> </ul>                                                   | <p><b>Functional</b></p> <ul style="list-style-type: none"> <li>• Fatigue (tiredness that does not go away with rest) lasting longer than 12 months</li> </ul> <p><b>Hormonal (if you haven't already been through the menopause) **</b></p> <ul style="list-style-type: none"> <li>• Reduced sex drive</li> <li>• Vaginal dryness and discomfort during sex</li> <li>• Difficulty sleeping</li> <li>• Low mood or anxiety</li> <li>• Problems with memory and concentration</li> <li>• Loss of bone strength</li> <li>• Weight gain</li> </ul> |

**\*\* There are various medications you can have to improve these symptoms – please discuss further with your doctor if applicable to you**

| Impact                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|--------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Physical Changes</b>  | <p><b>Body changes:</b></p> <ul style="list-style-type: none"> <li>• Your body will be very different following the surgery</li> <li>• You may have one or two stomas</li> <li>• You will have scars</li> <li>• You may no longer have a back passage (anus)</li> <li>• You may have a skin flap which has altered or no sensation with another area where the flap was taken from which may be looks different</li> <li>• Your body will feel different</li> <li>• Your mobility may be different</li> <li>• You may experience emotional changes</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Emotional changes</b> | <p><b>Emotions:</b> Anxiety, Anger, Regret, Fear, Depression, Sadness.</p> <p>Some people describe an element of loss and bereavement for their body. These emotions will change with time. You will get good days as well as bad days. These emotions may or may not disappear with time. Experience of other patients suggests you will adapt. There are support mechanisms to help you through it.</p> <p><b>Infertility:</b> If cancer treatment results in your inability to get pregnant this can affect you psychologically. There is the option of egg collection and a surrogate.</p> <p><b>Body image:</b> Body changes can affect the way you think and feel about your body which can affect your self- confidence. You might also worry that people will treat you differently because of the change to your body.</p> <p><b>Low self-esteem or lack of confidence:</b></p> <p>It is normal to find these changes difficult to adapt to physically and mentally. Different patients adapt in different ways. Some patients have reported:</p> <ul style="list-style-type: none"> <li>• Being too embarrassed to leave home</li> <li>• Withdrawing from social activities</li> <li>• Avoiding intimacy with a partner</li> <li>• Low mood</li> <li>• Changing the way they dress</li> </ul> |

| Impact                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Sexual changes</b> | <p>Pre-existing sexual status will determine recovery of your sex life. The tumor, previous radiotherapy and surgery will affect your ability and desire to have sex. If you do not have sexual intercourse now (before surgery) then this may not be relevant to you. If you do engage in sexual relations then sex is unlikely to be the same following this surgery.</p> <p>You should discuss with your partner the changes that will happen to your body and that sexual relations may resume in the long term however it may be very different to its current state.</p> <p>If your vagina is fully or partially removed and you decide not to have a reconstruction the space will be stitched up leaving little or no vagina and sexual intercourse will not be possible (the rest of this section will not be relevant to you).</p> <p><b>General changes</b></p> <ul style="list-style-type: none"> <li>• The vagina may change shape following surgery and radiotherapy</li> <li>• The 'lie'/angle of the vagina may alter which might make penetration less comfortable and require you to adopt a different sexual position for penetration</li> <li>• Sex may not be the same. The vagina will be dry needing lubrication in order to use it</li> <li>• You may not be able to climax in the same way</li> <li>• You may feel a loss of desire</li> <li>• It may feel different inside and outside</li> <li>• You will need to use vaginal moisturisers and lubricants and / or oestrogen creams (if no reconstruction)</li> </ul> <p><b>Vaginal reconstruction</b></p> <ul style="list-style-type: none"> <li>• It will look and feel different.</li> <li>• You may not have any feeling inside</li> <li>• Other organs – labia and clitoris may feel different and some patients have described unpleasant sensations in the genital area</li> <li>• You will need to use dilators to keep it open</li> <li>• You will need to use non-hormonal lubricants for dilation and sexual purposes</li> </ul> <p>Your vulva (clitoris, labia, mons pubis - see page 30) usually would not be removed in your operation. The operation may affect the way this area feels and can change the way you are able to orgasm.</p> <p>There is a choice to pursue penetrative sex – some may accept not to.<br/>It is normal to feel nervous if you decide to have sex again - discuss this with your team.</p> |

| Impact               | Short Term                                                                                                                                                                                                                                                                                           | Long Term                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Relationships</b> | <p>You may experience a change in relationships with people:</p> <ul style="list-style-type: none"> <li>• Altered relationships with partner</li> <li>• Altered relationships with family and friends</li> <li>• Dependence on others for normal activities – washing, dressing, cleaning</li> </ul> | <p><b>Altered relationship with partner</b><br/>Although physical penetration may change, there will be other ways of being intimate. Sex is more than just penetration. There is a psychological and emotional aspect to sex. How you feel sexually is about how you feel both physically and mentally. You may still express desire and arousal but this may be shown differently.</p> <p><b>Altered relationships with family and friends</b><br/>You may feel differently after this surgery and that may or may not impact your relationships with others.</p> |
| <b>Work</b>          | You are unlikely to work short term unless you can work from home and this doesn't require you to sit for long periods. Your employer should understand that you would need some flexibility within your day.                                                                                        | <p>Your employer should understand the extent of surgery you are undertaking and prepared for a sickness of up to a year.</p> <p>You may not be able to return to the same job you performed before.</p>                                                                                                                                                                                                                                                                                                                                                            |
| <b>Finance</b>       | Potential loss of income                                                                                                                                                                                                                                                                             | Financial difficulty can be addressed by support charities who can direct you to places for help with money problems. Benefits can help you through financial difficulties. These are means tested but can help you with loss of income as well as directing you towards extra entitlements during your period of recovery and adjustment. Your nurse specialist can identify sources of financial support and help you through the process.                                                                                                                        |
| <b>Exercise</b>      | <ul style="list-style-type: none"> <li>• Short term pain</li> <li>• Lack of energy</li> <li>• Change in routine that affects exercise</li> </ul>                                                                                                                                                     | You may or may not be able to do the same exercises as you did pre-operatively. Your team may advise you not to do excessive exercise or prolonged amounts of sitting. Swimming and cycling may not be possible until the wound has completely healed. Returning to 'normal' activity is the goal and this is expected in the majority of patients.                                                                                                                                                                                                                 |



## Will I have reconstructive surgery?

After organs affected by the cancer have been removed, some patients may benefit from reconstructive surgery. This is usually done at the same operation as the pelvic exenteration, by a plastic surgeon working with the surgical team. It involves moving tissue from elsewhere in the body into the pelvis and bottom end. **Your surgeon will decide if this is appropriate for you.**

The tissue that is moved is known as a flap. It usually consists of skin, fat and muscle. Flaps can be moved from several places, including the tummy (abdomen), buttocks or thighs. For a flap to work well it must have a good blood supply. This is usually not a problem but if it is, part or all of the flap may lose its blood supply and may need to be removed.

The benefits of reconstructive surgery are:

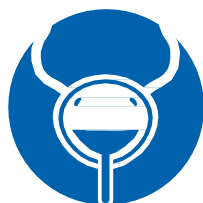
- To fill up the space left when organs in the pelvis are removed
- To prevent long term problems, such as a pelvic hernia or chronic infection
- To help wounds to heal quickly
- To reconstruct the vagina if necessary (optional)

The risks of reconstructive surgery are:

- Adding time on to a long operation
- It may fail resulting in prolonged wound problems, hernia, occasionally need for re-operation
- It may leave a deformity in the area the flap is taken from

Reconstructive surgery **cannot make things totally normal again**. For instance, it cannot recreate a back passage (anus) that works.

**There are different types of flaps (page 31) but your surgeon will decide which type they will offer you.**



## Do I have to have reconstructive surgery if it is offered to me?

**Vaginal reconstruction is your choice.** However, if a 'flap' has been discussed with you it is usually necessary in order to fill the space following the removal of your cancer.

It is important that you discuss this with your surgeon.

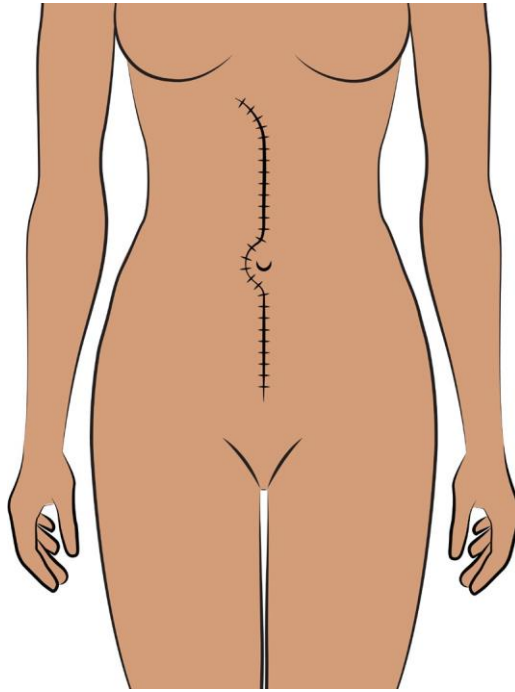
## Will I be able to sit after the surgery?

Patients who have had reconstructive surgery will be nursed from side to side in the bed for several days after surgery. This is to stop any pressure on the flap tissue. It is then sometimes best to not sit for 1 to 2 weeks. Once sitting is allowed, a pressure-relieving air cushion is recommended. This is usually for 10 minutes at a time. A graduated sitting programme is started to help you adjust to sitting which will be directed by your team.

## What will things look like after my surgery?

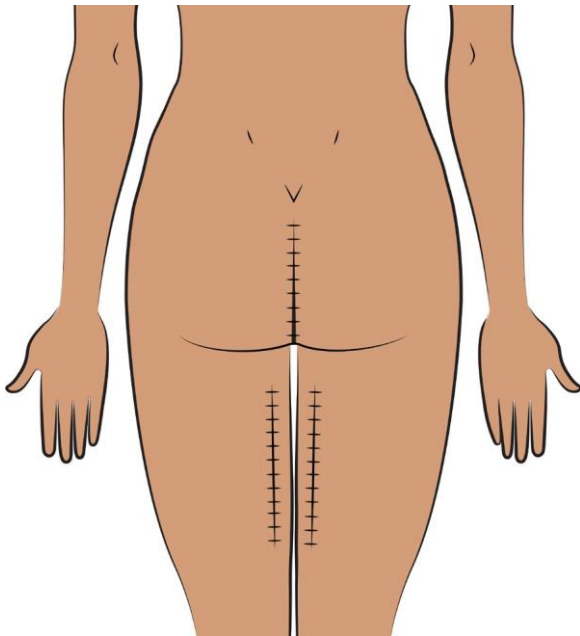
Surgery always leaves scars. In normal clothes these will not be visible, but without clothes on you will be able to see scars on your tummy (abdomen) and elsewhere. Your stoma (or stomas) will also be visible and the shape of your abdomen, buttocks or thighs may also have changed if a flap from these areas has been used. This may be visible even in clothes. Following surgery, your bottom end (perineum) may also feel numb and can also feel a bit swollen which can change the way you sit or balance sitting.

When a flap from the tummy (abdomen) is used, the scars are as shown in diagram A. Scars from thigh and buttock flaps are shown in diagrams B & C.



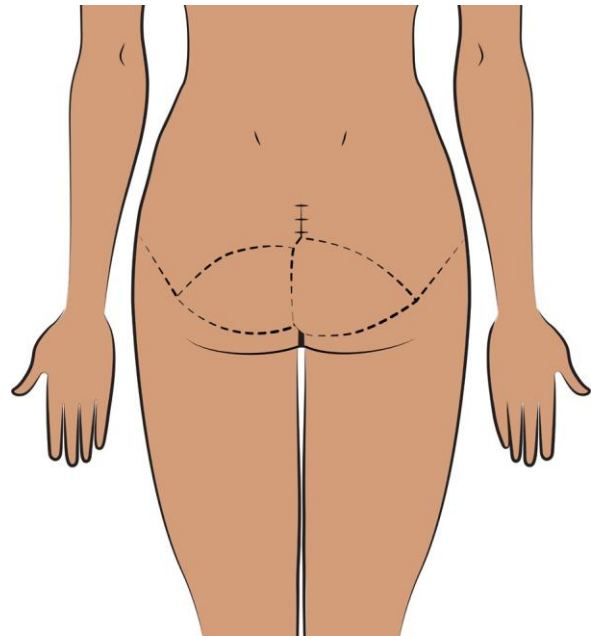
### **A** *Abdomen scar*

Your tummy will look similar to this if you have had an open operation (most often) or if you have had a flap taken from your six-pack (VRAM flap).



### **B** *Thigh scar (1 or 2)*

Your thighs will look like this if you have had your thigh muscle taken as a flap (gracilis flap).



### **C** *Buttock flaps (1 or 2)*

Your buttocks will look like this if you have had your buttocks muscle taken as a flap (IGAP flap).

## If I need Vaginal Reconstruction, can I have sex?

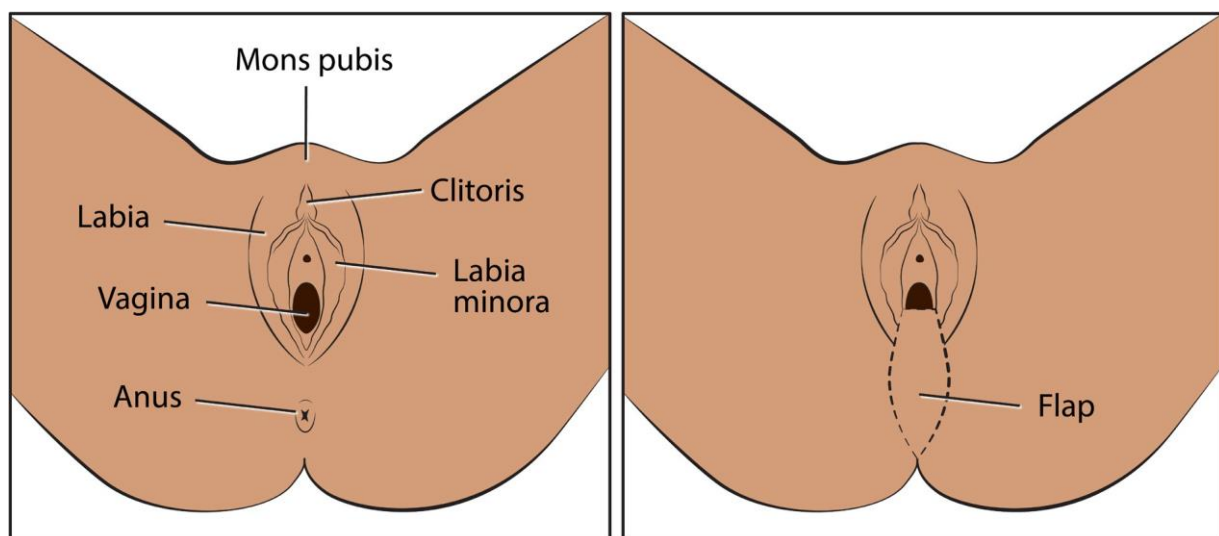
Yes. Once your wounds have healed well you will be able to resume having penetrative sexual intercourse. Healing time is different in all patients.

A reconstructed vagina cannot make things totally normal again. It will provide you with a hole in the same position as your vagina but it will be a different shape and size. It may lie in a different angle to before.

Scars inside the vagina can sometimes feel tight and you may need to use dilators to keep the new vagina open. Your specialist nurse can show you how to do this and how often.

This will greatly alter how sex will feel for you. Sex will never be the same again following this surgery. Your new vagina will feel different. You may not have any feeling inside. You may experience pain when using it. You will still have your clitoris and this may still be able to give you an orgasm. However, initially, it may be uncomfortable or painful to touch.

At first you will need to use lubricants for dilation and sex, to build up your confidence and they are likely to be needed long term. You can also speak to your team about starting on HRT to help with libido if you were pre-menopausal before treatment.



***Normal vagina & anus***

***Flap in position***

## What are the potential complications?

The risks depend on the complexity of the operation you need. The risk of complications will depend on your age, other medical conditions that you suffer with and the type of operation you require.

Around 1 in 5 patients (20%) will experience a major complication from the surgery.

### Major risks of surgery include:

- Excessive bleeding
- Heart attack
- Blood clot in the chest
- Risk of the wound including muscle fully opening up
- Risk of the plastic surgical flap losing its blood supply
- Collection of fluid in the pelvis
- Injury to the bowel & bowel join leaking
- Injury to the urinary tract
- Kidney failure
- Bowel blockage



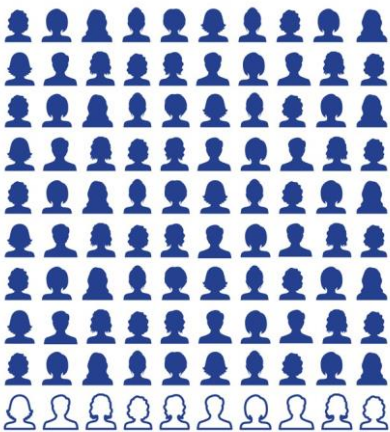
20 out of 100 experience major complications

- Formation of an abnormal connection between the bowel and skin
- Incomplete removal of the cancer or it not being possible to proceed with cancer removal during the operation
- Need for reoperation in around 1 in 10 patients (10%)

Most patients experience some minor complications after surgery. This happens in 9 out of 10 patients (90%).

### Minor risks of surgery include:

- Infection (chest/wound/urine)
- Risk of skin wound opening up
- Blood clot in the legs
- Bowels slow to start working again but usually resolves in time
- Leakage of fluid through the flap



90 out of 100 experience minor complications

To minimise the risks of clots we give you elastic stockings to wear and give you blood-thinning injections to prevent clots. These injections are usually continued for 28 days after your operation.

## Can I die as a result of surgery?

The risk of dying within 30 days of the surgery is low. 98 out of 100 patients (98%) will be alive 30 days after surgery.



***2 out of 100 die after the operation***

95 out of 100 patients (95%) will be alive after 90 days of surgery.

There are things you can do to get you through the recovery easier. The more you do before with regard to exercise, then the easier the recovery. Important things to maximise your recovery are;

- Exercise (getting fit)
- Healthy diet
- Get the right support
- Bring key people to your clinic appointments
- Have a positive state of mind

## Aftercare

You will need nursing care after going home. They will help you look after your wounds and stoma(s). District nurses will be arranged (sometimes they will need to visit daily). Stoma nurses will be available if required to support you.





If you decide to have the surgery you will be followed-up for five years afterwards. Two to three weeks after your operation the results of what your tumour looked like under the microscope will be available. The team looking after you will talk through the results to you. They may suggest that you consider chemotherapy treatment.

## **Do I have to have chemotherapy if it's offered?**

You will have a discussion with your oncologists regarding the risk and benefit for you as an individual. If it is offered as an option, it is usually only beneficial within 8 - 12 weeks after surgery.

You may have lots of questions regarding more chemotherapy. These can be discussed with your oncologist. If you decide to have chemotherapy and cannot tolerate it, then you can stop treatment.

## **What is my follow-up?**

Your follow-up will consist of clinic visits, surveillance CT scans and blood tests at different intervals for the 5 year period.

If you have any questions at any time, please ask any member of your team. They will be pleased to explain anything that concerns you or your family. Another good tip is to write your thoughts and questions down so that you do not forget when you meet your team.

## Support - Who are we?

We are a specialist team dealing with pelvic cancers. The team includes surgeons, doctors, surgical nurse practitioners and other specialist nurses including stoma care nurse specialists.

**Your Consultant is** .....

**Contact number (Secretary)** .....

**Your specialist nurse is** .....

**Contact number** .....

**Your stoma care nurse is** .....

**Contact number** .....

**Ward contact number 24/7** .....

## Who do I contact with concerns after my operation?

If you have concerns after you have gone home then you can contact your specialist nurse or stoma care nurse or consultant via the secretary on the numbers above. you can also contact the ward.

If you experience any of the following:

- persistent nausea (feeling sick) or vomiting (being sick)
- fever or a high temperature (37.5°C/101.5°F or above)
- oozing or increasing redness around either of the wound sites
- new pain
- Change in stoma activity (new loose stool/diarrhea via stoma)

Please get in contact with any of the team above or your GP. If you are unable to access these contacts out of hours then please contact the ward or the GP out of hours service or attend the A&E department of your nearest hospital.



## Support

**Your team will support you. They will do everything possible to support you and give you the best possible care. Do not be afraid to ask questions.**

You may want to discuss your options further. Your specialist nurse will always be available to discuss things and can help you direct you to charities and support groups that can sometimes help. There are also online communities and support groups that you can talk to. You will need to discuss things with your family and/or friends which may mean some difficult conversations.

It is important that you get the right support for you as you come to terms with the decision you face. It is important that you understand the implications of what life may look like by surviving the disease. Families and friends may need support with the idea of adapting in a new role as a carer or emotional support in coming to terms with what their relative is going through. You can be put in touch with a support group where you can meet people in a similar situation and get information first-hand about your type of cancer. You are not alone and we can signpost you to various additional support you require.

You may also want to re-discuss things with your team and it is important that you get in touch if you feel this is something you need to do.

### **For additional support services or further discussions (outside your medical team), we recommend:**

Macmillan Cancer Support: [www.macmillan.org.uk](http://www.macmillan.org.uk) Tel: 0808 808 0000

Maggie's: [www.maggies.org](http://www.maggies.org) Tel: 0300 123 1801

Bowel Cancer UK: [www.bowelcanceruk.org.uk](http://www.bowelcanceruk.org.uk) Tel: 020 7940 1760

Beating Bowel Cancer: [www.beatingbowelcancer.org](http://www.beatingbowelcancer.org) Tel: 020 8973 0011

Bladder and Bowel Foundation: [www.bladderandbowelfoundation.org](http://www.bladderandbowelfoundation.org) Tel: 0845 345 0165



Urostomy Association [www.urostomyassociation.org.uk](http://www.urostomyassociation.org.uk)  
Tel: 01889 563191

Colostomy Association [www.colostomyassociation.org.uk](http://www.colostomyassociation.org.uk)  
Tel: 0800 328 4257

It is important to get as emotionally prepared as possible before you decide to have this operation. There are NHS psychological support services available to help you adjust to the losses in your body as well as the permanent changes of how your body will function. You may feel you are getting enough support from your family, GP and hospital team including your CNS, however, sometimes more specialist input is needed.

## **Psychosexual issues**

College of Sexual Relationship Therapists: [www.cosrt.org.uk](http://www.cosrt.org.uk) Tel:  
020 8543 2707

RELATE, Low cost relationship & sexual therapy services across the UK:  
[www.relate.org.uk](http://www.relate.org.uk)

## **Psychological issues**

NHS psycho-oncology services and psychological support services are available in specialist centres. However, additional psychological counselling can be found:

British Psychological Society  
<https://www.bps.org.uk/public/find-psychologist>

British Association for Counselling & Psychotherapy  
<https://www.bacp.co.uk/search/Therapists>

UK Council for Psychotherapy: <https://www.psychotherapy.org.uk/>

## **Sexual issues**

CNS or pelvic floor physiotherapists will provide specialist practical support.

## **Clothing Support**

Vanilla Blush [www.vblush.com](http://www.vblush.com)

# Maximising Recovery

Book by Sarah Russell, The Bowel Cancer Recovery Toolkit

## Menopausal issues

Support in dealing with menopause following this surgery can be found:  
Manage my Menopause - [www.managemymenopause.co.uk](http://www.managemymenopause.co.uk)  
Menopause matters - [www.menopausematters.co.uk](http://www.menopausematters.co.uk)

Daisy Network (aimed at young women with premature ovarian failure)  
[www.daisynetwork.org](http://www.daisynetwork.org)

## Do not identify as heterosexual / cisgender?

LGBTQI Cancer Charity for those individuals who do not identify as heterosexual / cisgender: [www.livethroughthis.co.uk](http://www.livethroughthis.co.uk)

**If you decide to have surgery you may want to revisit this document after surgery to remind you of the adjustments you may face.**

## Sources

Patient Decision Aid for Women. Produced as part of study IRAS 257890.  
First published: March 2022. Review date: March 2024.

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Solum AM, Riffenburgh RH, Johnstone PA. Survival of patients with untreated rectal cancer. J Surg Oncol. 2004;87:157–161

# Questions

Many people will forget what they want to say or ask at the time of their consultation. You may find it helpful to write things down here and bring it to your appointments.

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## Questions

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## Questions

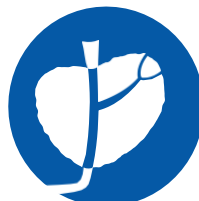
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## Questions

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# Treatment Options for Complex Rectal Cancer in Men

*Patient Decision Aid*  
*Helping you make your decision*





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## What is complex rectal cancer?

The cancer in your pelvis that started in your bowel (**rectum**) may have grown into other organs nearby (**locally advanced**) or the cancer may have returned after previous treatment (**locally recurrent**).

You have been given this decision aid because surgery is a potential option for you. This decision aid aims to help you and your surgeon decide together which type of treatment is best for you. **It is important to make the choice that you feel is right.**

The decision will depend on your individual circumstances and how you feel about surgery. Surgery is not everyone's choice and there are different options that may not cure you but will support you through this illness.

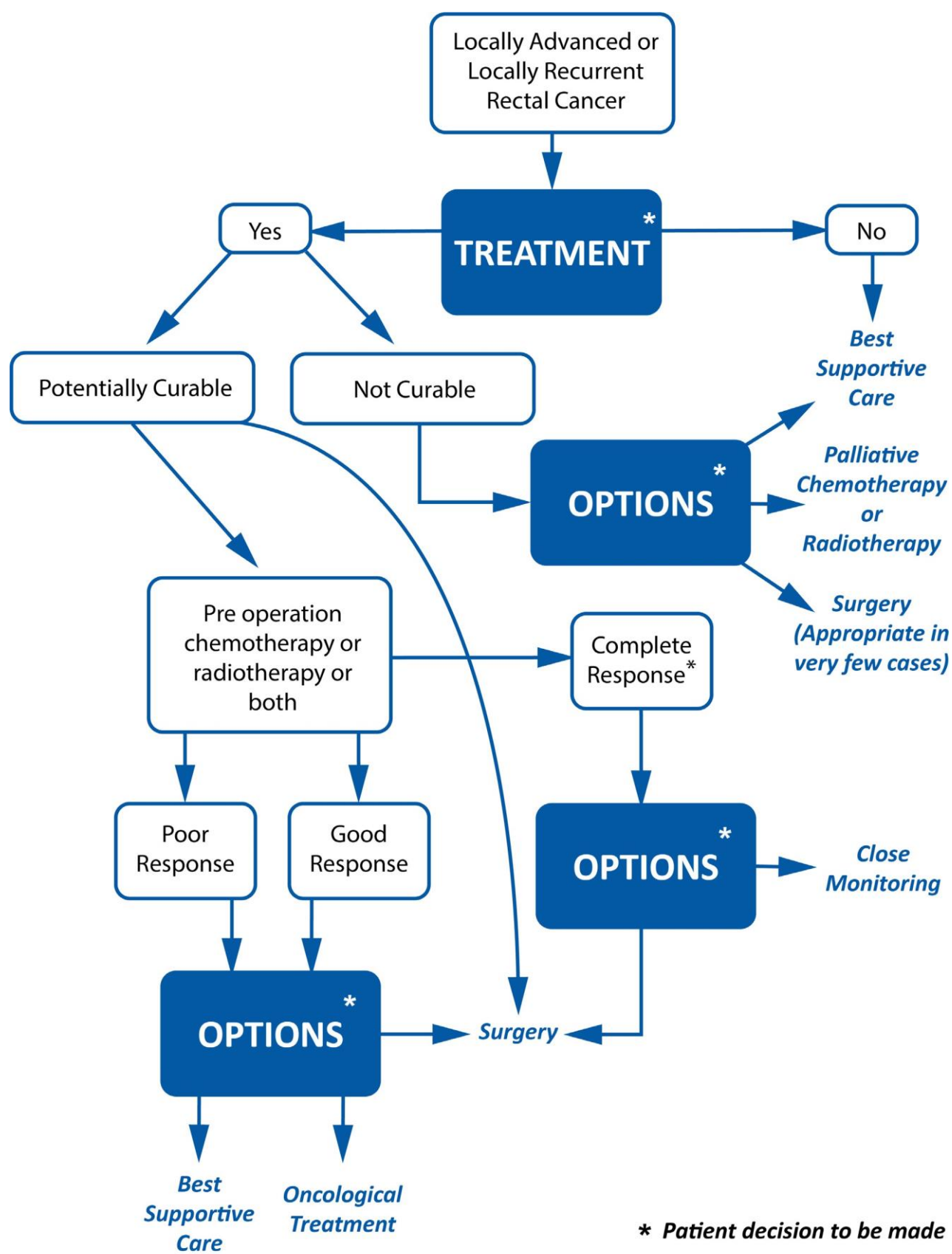
**Every patient is different so this decision aid is only a guide.** Different options will be appropriate for different patients.

You may have already had oncological treatment (chemotherapy, radiotherapy or both) before you get to the option of surgery called pelvic exenteration or pelvic clearance. Or you may be facing the decision of starting chemotherapy or radiotherapy with a view to having surgery later.

You and your team may decide after having your cancer treatment with chemotherapy and/or radiotherapy that surgery is not something you want or need (complete response).

There are a number of things to consider when you are about to make a decision about treatment. It is good to think about the possible benefits and disadvantages of treatment to help you make the right decision for you. There are **no right or wrong choices**. People make different choices for different reasons.

This flow diagram gives you an idea where you have been on your cancer journey and the choices you now face.



\* Patient decision to be made  
\*\* In some recurrent cases, there may be a choice to proceed straight to surgery

Follow-up will be individualised for each patient regardless of the pathway you choose.

# Treatment options

When facing your diagnosis you have a decision to make whether you want treatment or not. There are three types of treatment that may be available to you.

- 1. To have surgery.
- 2. To have chemotherapy and/or radiotherapy.
- 3. To have no further active cancer treatment (best supportive care).



| SURGERY                                                                                                                                                              | ONCOLOGICAL TREATMENT                                                                                                                                                                                                                                                                                                                                                    | BEST SUPPORTIVE TREATMENT                                                                                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|
| <p>Surgery is the only potential option for cure.</p> <p>Occasionally it is offered to people who can not be cured. This will be made clear to you by your team.</p> | <p>Oncological treatments (chemo and radiotherapy) are offered to try to shrink the cancer before surgery (curative), or it is offered to control your symptoms (not curative).</p> <p>What you will be offered will depend on any treatment you have previously had and any underlying health conditions. Your cancer doctor (oncologist) can discuss this further.</p> | <p>You may decide you do not want any surgical or oncological (chemotherapy and/or radiotherapy) treatment.</p> |

Some patients may decide that they do not want any treatment in the form of surgery or chemotherapy and/or radiotherapy. There are reasons people choose best supportive care which may be:

- They do not want the symptoms from chemotherapy and radiotherapy
- They want to maximise their quality of life
- They could not cope psychologically with the results of surgery
- They do not find the idea of major surgery appealing
- They do not feel fit for surgery

Best supportive care is the care given to improve the quality of life of people living with cancer. The goal of supportive care is to improve the quality of life of patients and their families facing the problems associated with life-threatening illness, through treating any symptoms as early as possible and treating the psychological, social, and spiritual problems related to the cancer. This can include psychological therapy, complementary therapies (e.g yoga, reiki, massage, homeopathy, meditation, acupuncture) and clinical trials.

You will be followed up with your palliative care team of nurses and doctors who will monitor you. You may not have symptoms or need any support right now but you will be able to access all support when you need it. Your local team will be able to discuss this further.

## **Your cancer treatment goals**

Your cancer treatment goals depend on many factors:

- Being cancer free
- Living longer, even with cancer
- Having fewer symptoms from cancer and side effects from its treatment
- Maintaining physical and emotional strength
- Having an acceptable quality of life

## This table explains your treatment options:

|                                                | SURGERY                                                                                                                                                                                                                                                                                                                                                                 | ONCOLOGICAL TREATMENT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | SUPPORTIVE TREATMENT                                                                                                                                                                                                                                                                                             |
|------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Will this option cure me of cancer?            | <p>It will improve your current symptoms but you will develop different symptoms following surgery.</p> <p>Surgery potentially can cure your cancer.</p> <p>If surgery is being offered as a cure this is your best chance of a cure.</p>                                                                                                                               | <p>Very rarely can chemotherapy and/or radiotherapy alone cure your cancer.</p> <p>This option would be used as part of a curative approach before major surgery (to shrink your cancer) or would be used as a palliative (non-curative) treatment to help control your symptoms. Your oncologist will discuss what is available to you.</p> <p>Whilst a cure is not usually possible for treatment without surgery, when given with the intention to cure, up to 1 in 7 people (15%) of patients can get a complete response (cure) to chemoradiotherapy for locally advanced rectal cancer with 1 in 13 people (8%) achieving a complete response in locally recurrent rectal cancer.</p> | <p>Supportive treatment will not cure your cancer but it will treat your symptoms.</p> <p>Supportive treatment prevents or treats the symptoms of cancer as early as possible. It also addresses the physical, mental, social and spiritual needs tailored to your needs to give you a good quality of life.</p> |
| How will each treatment option affect my life? | <p>Surgery can affect your:</p> <ul style="list-style-type: none"> <li>• Physical health</li> <li>• Mental health</li> <li>• Relationships</li> <li>• Lifestyle</li> </ul>                                                                                                                                                                                              | <p>Chemoradiotherapy can affect your:</p> <ul style="list-style-type: none"> <li>• Physical health</li> <li>• Mental health</li> <li>• Relationships</li> <li>• Lifestyle</li> </ul> <p>Without surgery, you may eventually get more symptoms which we will treat to keep you as comfortable as possible.</p>                                                                                                                                                                                                                                                                                                                                                                               | <p>You are likely to get more symptoms with time. You will have access to support teams in order to help you manage your symptoms and feel as comfortable as possible.</p>                                                                                                                                       |
| What kind of support will I have?              | <ul style="list-style-type: none"> <li>• Medical team – surgeons, junior doctors, ward nurses, clinical nurse specialist</li> <li>• Oncologist (cancer doctor)</li> <li>• Stoma nurses</li> <li>• District nurses</li> <li>• Clinical Nurse Specialist</li> <li>• GP's</li> <li>• Support charities</li> <li>• Friends and family</li> <li>• Physiotherapist</li> </ul> | <ul style="list-style-type: none"> <li>• GP's</li> <li>• Macmillan nurses</li> <li>• Oncologist (cancer doctor)</li> <li>• Clinical Nurse Specialist</li> <li>• Support charities</li> <li>• Palliative care team when appropriate</li> <li>• Access to hospice support</li> <li>• Friends and family</li> </ul>                                                                                                                                                                                                                                                                                                                                                                            | <ul style="list-style-type: none"> <li>• Macmillan nurses</li> <li>• GP's</li> <li>• Support charities</li> <li>• Palliative care team</li> <li>• Access to hospice support</li> <li>• Friends and family</li> </ul>                                                                                             |

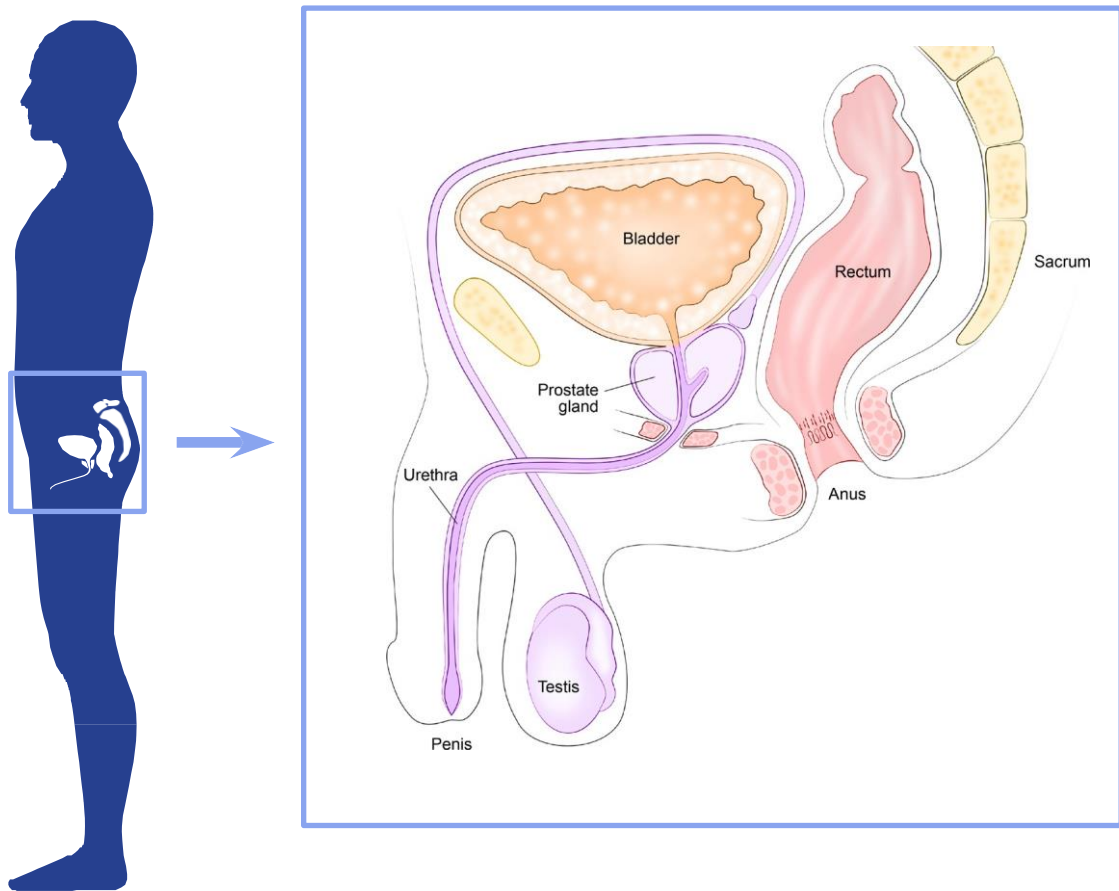
|                                               | SURGERY                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | ONCOLOGICAL TREATMENT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | SUPPORTIVE TREATMENT                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Will this option relieve my current symptoms? | It will improve your current symptoms but you will develop different symptoms following surgery                                                                                                                                                                                                                                                                                                                                                                           | Short term it can relieve or improve symptoms but these symptoms may return and you could develop more symptoms without.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Supportive treatment will control your symptoms. Without surgery your cancer will grow & any symptoms you have may get worse. There are ways of managing pain and other symptoms using both medicines and alternative therapies.                                                                                                                                                                |
| What are the benefits?                        | <p>Increased chance of survival (curative).</p> <p>Improvement of the symptoms you had before surgery (curative and non-curative)</p>                                                                                                                                                                                                                                                                                                                                     | <p>Curative (before surgery)</p> <ul style="list-style-type: none"> <li>• Can shrink your cancer</li> <li>• Can rarely cure cancer without surgery</li> </ul> <p>Palliative without surgery</p> <ul style="list-style-type: none"> <li>• Can make you live longer</li> <li>• Not having side effects or longterm symptoms of surgery</li> <li>• Can rarely cure cancer without surgery</li> </ul>                                                                                                                                                                                                                                                                                                                                               | <p>Potentially an improved quality of life.</p> <p>Not having side effects or long-term symptoms of surgery or oncological treatments.</p>                                                                                                                                                                                                                                                      |
| What are the risks?                           | <p>You are likely to experience short and long term side effects:</p> <ul style="list-style-type: none"> <li>• Pain</li> <li>• Urinary &amp; bowel symptoms</li> <li>• Reduced mobility/weakness</li> <li>• Long term fatigue (tiredness that doesn't go away)</li> <li>• Psychological and emotional changes</li> <li>• Sexual dysfunction</li> </ul> <p>Complications:</p> <ul style="list-style-type: none"> <li>• Major</li> <li>• Minor (discussed later)</li> </ul> | <p>Symptoms are different for different people but can include the following:</p> <p>Symptoms from chemotherapy:</p> <ul style="list-style-type: none"> <li>• Pins and needles</li> <li>• Numbness/pain in feet</li> <li>• Sickness</li> <li>• Fatigue</li> <li>• Loss of appetite</li> <li>• Recurrent infections</li> <li>• Tummy pain</li> <li>• Diarrhoea or constipation</li> <li>• Cold hands and feet</li> </ul> <p>Symptoms from radiotherapy:</p> <ul style="list-style-type: none"> <li>• Skin redness, tenderness and soreness</li> <li>• Sickness</li> <li>• Fatigue</li> <li>• Diarrhoea or constipation</li> <li>• Sexual &amp; urinary dysfunction</li> </ul> <p>You can also experience psychological and emotional changes</p> | <p>You may develop more symptoms as the cancer begins to grow which we will support you with to ensure you are as comfortable as possible.</p> <p>Symptoms may include:</p> <ul style="list-style-type: none"> <li>• Blockage of the bowel</li> <li>• Pain</li> <li>• Bleeding</li> <li>• Tumour can grow externally</li> <li>• Sickness</li> <li>• Fatigue</li> <li>• Poor appetite</li> </ul> |

|                                  | SURGERY                                                                                                                                                                                                                                                        | ONCOLOGICAL TREATMENT                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | SUPPORTIVE TREATMENT                                                                                                                                                                                                 |
|----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| What are my chances of survival? | <p>Survival is a very general statistic based on historical large groups of patients. <b>They can't tell you what will happen in your individual case.</b></p> <p><b>Ask your team about information more specific to what we know about your disease.</b></p> | <p>Non-curative (palliative) without surgery oncological treatment can allow people to live longer and this will be different in every person.</p> <p><b>Locally Advanced Rectal Cancer:</b><br/>Chemotherapy with, or without radiotherapy can improve symptoms, and can extend survival on average by 10-17 months.</p> <p><b>Locally Recurrent Rectal Cancer:</b><br/>Chemotherapy with, or without radiotherapy can improve symptoms, and can extend survival on average by 10-15 months.</p> | <p><b>Locally Advanced Rectal Cancer:</b> Without treatment, most patients live for 12 months after diagnosis.</p> <p><b>Locally Recurrent Rectal Cancer:</b><br/>Untreated patients usually survive 6-8 months.</p> |



## What does surgery involve?

Pelvic exenteration is an operation that requires removal of all, some or part of your pelvic organs of which there are a number of different types.



### *Normal anatomy - side view*

Your team will highlight what type of surgery you are having and what is relevant for you.

Several surgeons from different specialties are involved. The operation is a **major undertaking and one of the most complex surgeries performed.**

There are **different types of pelvic exenteration.** Depending on your cancer, removal of all or some of the following may be necessary:

- Part of the bowel (the colon, rectum and anus)
- The urinary system (the bladder and ureters)
- Your reproductive organs (prostate, seminal vesicles)
- Your lower spine (sacrum)

**If you are considering surgery, this booklet will provide more detail about what this will involve in the short and longer term.**

**Further detail about oncological treatment (chemotherapy and or radiotherapy) can be discussed with your oncological team**

## **What does the operation involve?**

You will be asleep (under general anaesthetic) during the operation. A cut will be made from above the belly button to the bottom of your tummy (abdomen). It may also be necessary to make a second cut around the back passage (anus). In a very small number of cases it may be possible to carry out the procedure in a minimally invasive way i.e. keyhole or robotically.

## **What do I expect after the surgery?**

Following your surgery it will be necessary to keep a close eye on you. Depending where you have your surgery, this may be called high dependency, critical care or intensive care. Typically you will stay in this area for 2-5 days.

When you wake from surgery, you will have a number of things attached to you:

- Oxygen tubes in your nose or through a mask on your face
- Drips to keep you hydrated
- Drains (tubes) inside your tummy and bottom to drain excess fluid
- Tube placed in your stomach via your nose to drain any fluid in your stomach
- Staples or stitches in the wounds
- Tube into your bladder (catheter) if you have not had your bladder removed.
- Sometimes a line in your neck is required for access to your veins (central line)

During your hospital stay it is normal to sometimes need x-rays and scans.

You will be allowed to drink initially, then you will be allowed food when your body can tolerate it. You will be nursed either on your side or your back for a few days. Your ability to move around, out of your bed, will be reduced for up to a week. If your bowels go on strike and stop working, we may decide to feed you through your veins (TPN).

The hospital stay after surgery is variable. Typically if there are no post-operative setbacks patients are in hospital between 14 days to 3 months.

However, if you were to experience complications it can be much longer.

## **How long will it take to recover?**

These operations are a considerable undertaking and your body will go through lots of changes, so it is important that you are prepared for a long recovery. Initial recovery can take between 6 weeks and 3 months. Complete, longer term recovery can take up to 12 months.

## **Will everything in my pelvis need to be removed?**

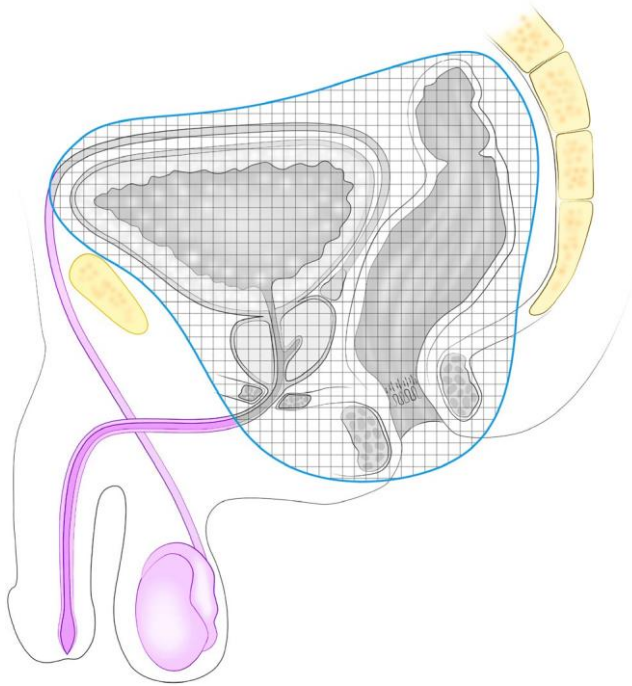
Not necessarily. There are different types of this operation depending on the location of your cancer.



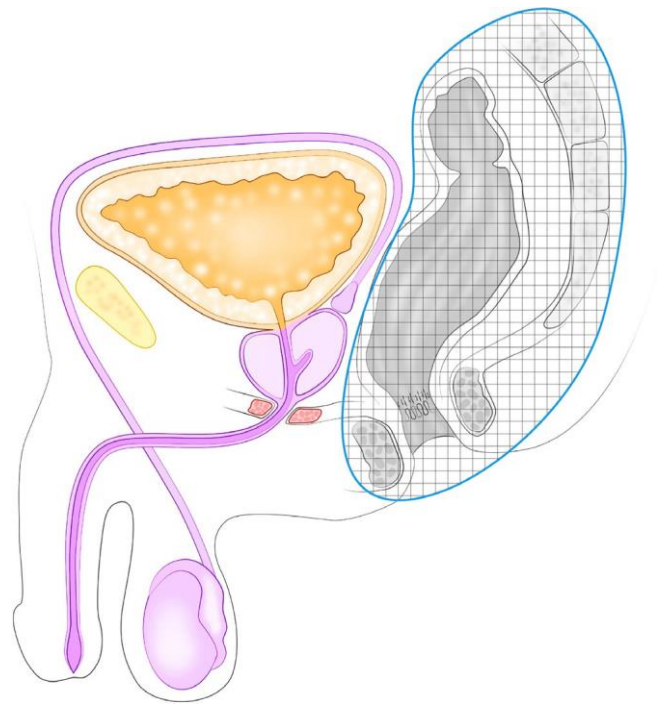
## Some variations of the surgery:

These are some possible options, depending where your tumour is.

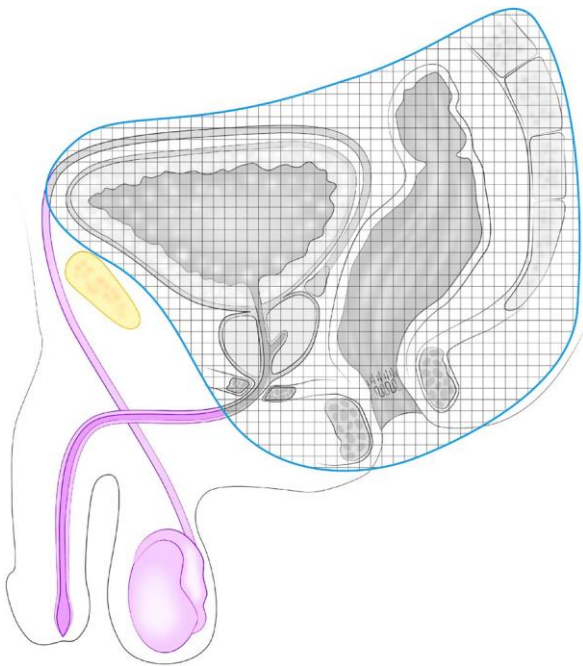
*Shaded area = what will be removed*



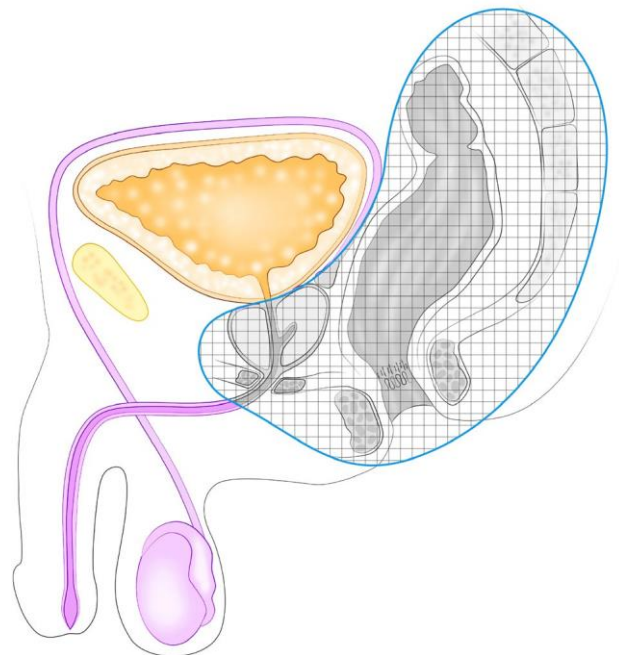
**Rectum, anus, bladder, ureter,  
prostate, seminal vesicles.  
Occasionally sacrum**



**Rectum, anus & sacrum removed**



**Total pelvic exenteration and  
sacrectomy**



**Rectum & anus, prostate,  
occasionally sacrum**

## Will I have a stoma bag?

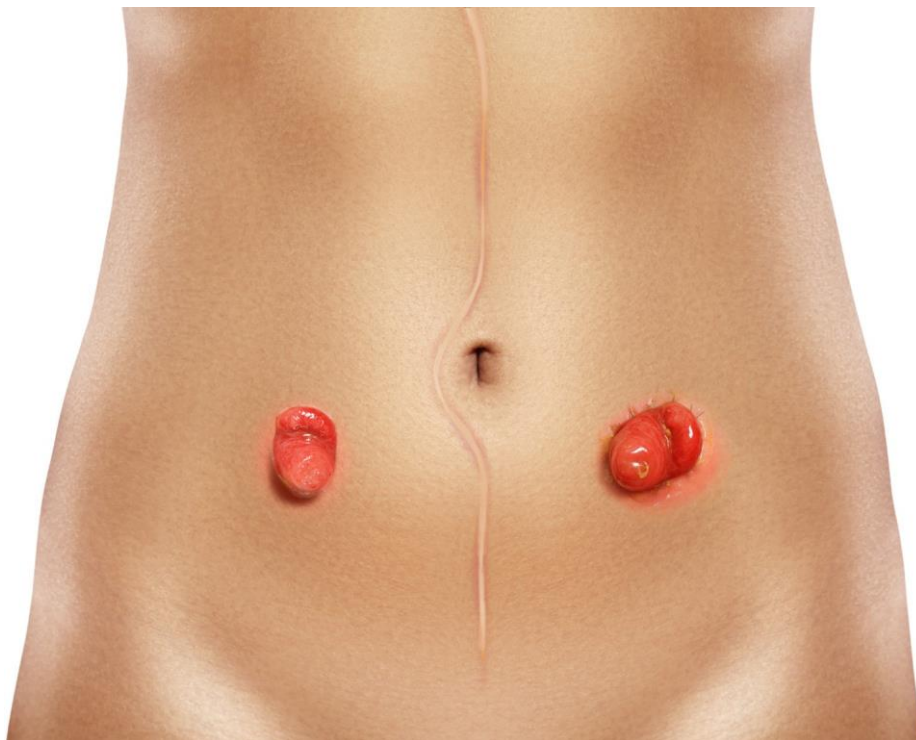
It is likely you will have a stoma bag as part of your operation. This is usually permanent.

The 'bag' is the appliance that sticks to the skin and sits on top of the stoma to collect the waste (wee or poo). A stoma is made when part of your bowel is pulled through your tummy wall onto the skin.

If your back passage (anus) is removed then the bowel will redirect waste products (poo/faeces) through a piece of bowel brought through the skin on your tummy. This is usually created to the left-hand side of your belly button. A specially designed bag sticks over the stoma to collect the faeces.

If your bladder is removed then the bowel will redirect waste products (wee/urine) through the new piece of bowel through the skin on your tummy. This is called a urostomy or ileal conduit. This is usually created to the right-hand side of your belly button. A specially designed bag sticks over the stoma to collect the urine.

## What do stomas look like?

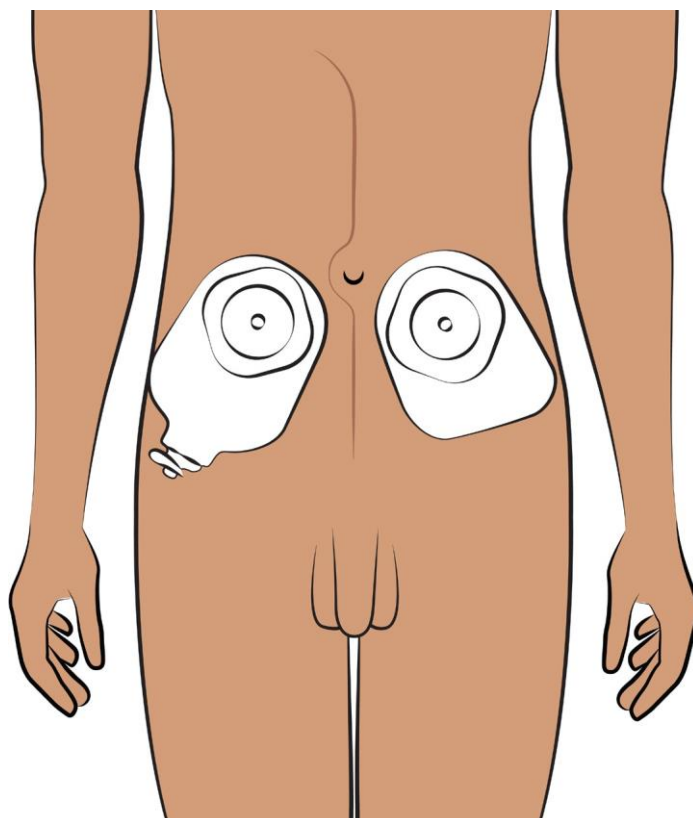


*Urostomy/ileal conduit*

*Colostomy*



*Urostomy bag position*



*Colostomy bag position*

*About  
15cm*



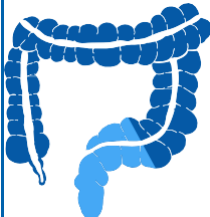
*Typical urostomy bag*



*Typical colostomy bag*

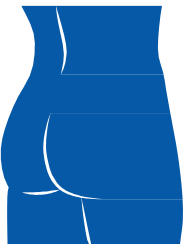
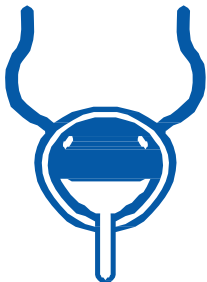
## What will I have removed & what does that POTENTIALLY mean for me?

(It doesn't necessarily mean it will happen to you)

| TICK IF APPLICABLE TO ME | ORGAN                                                                                                                         | IMPLICATION                                                                                                                | POTENTIAL SHORT TERM CONSEQUENCES (0 - 3 MONTHS)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | POTENTIAL LONG TERM CONSEQUENCES (3 MONTHS + LONGER)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|--------------------------|-------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          | <p><b>Rectum</b><br/>(lower part bowel)</p>  | <p>It may or may not be possible to join your bowel back together.</p> <p>You may need a permanent or temporary stoma.</p> | <p><b>If joined:</b></p> <ul style="list-style-type: none"> <li>• The join may leak in 5 to 15 per 100 cases (5-15%)</li> <li>• Inability to control opening your bowel (incontinence)</li> <li>• Urgency to open bowels</li> <li>• Need to open bowels often</li> <li>• Difficulty emptying your bowel despite visiting the toilet and passing soft motions often</li> </ul> <p><b>If you have a stoma:</b></p> <ul style="list-style-type: none"> <li>• Episodes of stoma leaking</li> <li>• Stoma can 'prolapse' meaning more bowel can protrude through the tummy wall than planned</li> <li>• Dietary changes</li> <li>• Skin problems around stoma</li> </ul> | <p><b>If joined:</b></p> <ul style="list-style-type: none"> <li>• Inability to control opening your bowel (incontinence)</li> <li>• Urgency to open bowels</li> <li>• Need to open bowels often</li> <li>• Difficulty emptying your bowel despite visiting the toilet and passing soft motions often</li> <li>• Long term medication to regulate bowel motion</li> </ul> <p><b>If you have a stoma:</b></p> <ul style="list-style-type: none"> <li>• Infrequent episodes of stoma leaking</li> <li>• Hernia* around stoma</li> <li>• Body image</li> <li>• Emotional impact</li> <li>• Relationships affected</li> <li>• Dietary changes</li> <li>• Skin problems around stoma</li> </ul> <p>(* the visible part of your stoma bulges out further from your body)</p> |

## What will I have removed & what does that POTENTIALLY mean for me?

(It doesn't necessarily mean it will happen to you)

| TICK IF APPLICABLE TO ME | ORGAN                                                                                                           | IMPLICATION                                                                                                                                                                                                                                                                                           | POTENTIAL SHORT TERM CONSEQUENCES (0 - 3 MONTHS)                                                                                                                                                                                                  | POTENTIAL LONG TERM CONSEQUENCES (3 MONTHS + LONGER)                                                                                                                                                                                                                    |
|--------------------------|-----------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          | <b>Anus</b> (back passage)<br> | <p>You will have a permanent stoma (colostomy) – this means you will poo through the stoma on your tummy.</p> <p>You will no longer have an anus as it will have been removed.</p>                                                                                                                    | <ul style="list-style-type: none"> <li>• Episodes of leaking stoma bags</li> <li>• Emotional impact</li> <li>• Wound issues</li> <li>• Altered sensation</li> </ul>                                                                               | <ul style="list-style-type: none"> <li>• Infrequent episodes of leaking stoma bags</li> <li>• Delayed wound healing</li> <li>• Emotional impact</li> <li>• Body image</li> <li>• Altered sensation</li> <li>• Phantom back passage pain</li> </ul>                      |
|                          | <b>Bladder</b><br>           | <p>You will have a permanent stoma (urostomy/ileal conduit) – you will pass urine through a stoma on your tummy into a stoma bag.</p> <p>There will be fine tubes (stents) that are visible within the stoma and are usually removed a few weeks after surgery. These help the new joins to heal.</p> | <ul style="list-style-type: none"> <li>• Frequent episodes of leaking urostomy bag</li> <li>• Urine/stent infections</li> <li>• Stents can block</li> <li>• Stents can move</li> <li>• The join may leak in 2-10 per 100 cases (2-10%)</li> </ul> | <ul style="list-style-type: none"> <li>• Infrequent episodes of leaking urostomy bag</li> <li>• Hernia around stoma – urostomy becomes difficult to manage</li> <li>• Kidney failure</li> <li>• Stoma narrowing</li> <li>• Wee will smell and look different</li> </ul> |



## What will I have removed & what does that POTENTIALLY mean for me?

(It doesn't necessarily mean it will happen to you)

| TICK IF APPLICABLE TO ME | ORGAN                                                                                                                       | IMPLICATION                                                                                                                                                         | POTENTIAL SHORT TERM CONSEQUENCES (0-3 MONTHS)                                                                                                                        | POTENTIAL LONG TERM CONSEQUENCES (3 MONTHS + LONGER)                                                                                                                                                                                                                               |
|--------------------------|-----------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          | <b>Prostate</b><br>                        | <p>You will not be able to get an erection naturally (impotent) or ejaculate (see page 24 for further details).</p> <p>Your penis will get smaller and shorter.</p> | <ul style="list-style-type: none"> <li>Emotional impact</li> <li>Sexual dysfunction</li> <li>Unable to conceive naturally</li> </ul>                                  | <ul style="list-style-type: none"> <li>Emotional impact</li> <li>Sexual dysfunction</li> <li>Relationships affected</li> <li>Infertility - If you have wishes of having a child then there are other options for sperm collection and IVF prior to chemotherapy/surgery</li> </ul> |
|                          | <b>Seminal vesicles</b><br>               | <p>You will not be able to ejaculate and will not be able to conceive naturally.</p>                                                                                | <ul style="list-style-type: none"> <li>Emotional impact</li> <li>Sexual dysfunction</li> </ul>                                                                        | <ul style="list-style-type: none"> <li>Emotional impact</li> <li>Sexual dysfunction</li> <li>Relationships affected</li> </ul>                                                                                                                                                     |
|                          | <b>Hip Bones</b><br>(ilium, ischium)<br> | <p>It can affect your mobility</p>                                                                                                                                  | <ul style="list-style-type: none"> <li>Altered leg control</li> <li>Leg weakness</li> <li>Hip pain</li> <li>Need to use a walking aid (frame/crutch/stick)</li> </ul> | <ul style="list-style-type: none"> <li>Altered leg control</li> <li>Leg weakness</li> <li>Hip pain</li> <li>Long term use of a walking aid (frame/crutch/stick)</li> <li>Inability to run</li> </ul>                                                                               |

## What will I have removed & what does that POTENTIALLY mean for me?

(It doesn't necessarily mean it will happen to you)

| TICK IF APPLICABLE TO ME | ORGAN                                                                                                                                                                                                               | IMPLICATION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | POTENTIAL SHORT TERM CONSEQUENCES (0-3 MONTHS)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | POTENTIAL LONG TERM CONSEQUENCES (3 MONTHS + LONGER)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|--------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          | <p><b>Sacrum</b><br/>(lower spine)</p>  <p>The sacrum can be divided at a high or low level depending on where your cancer is.</p> | <p><b>Low/All Sacrectomy</b></p> <p>You may experience pain.<br/>You may not be able to get an erection naturally or ejaculate</p> <p><b>High Sacrectomy</b></p> <ul style="list-style-type: none"> <li>• It can affect your bladder control (if no urostomy)</li> <li>• It can affect your mobility</li> <li>• Your legs can be effected with weakness, numbness/pins and needles, poor mobility</li> <li>• You will not be able to get an erection naturally or ejaculate</li> <li>• Your penis will get smaller and shorter</li> </ul> | <p><b>Low/All Sacrectomy</b></p> <ul style="list-style-type: none"> <li>- Nerve pain - shooting pains, pins &amp; needles.</li> <li>- Sexual dysfunction</li> <li>- Infertility</li> <li>- Emotional Impact</li> <li>- Wound healing problems</li> <li>- Infection/slow healing</li> </ul> <p><b>High Sacrectomy</b></p> <ul style="list-style-type: none"> <li>• Episodes of wetting yourself (incontinence)</li> <li>• Inability to empty the bladder without inserting an 'in and out' catheter to drain the bladder</li> <li>• Foot drop (at rest, foot remains pointing to the floor and you are unable to lift it to a normal position)</li> <li>• Muscle weakness</li> <li>• Need to use a walking aid (frame/crutch/stick)</li> <li>• Numbness to feet/legs</li> <li>• Problems with mobility may or may not gradually improve</li> </ul> | <p><b>Low/All Sacrectomy</b></p> <ul style="list-style-type: none"> <li>- Long term pain.</li> <li>- Sexual dysfunction</li> <li>- Infertility</li> <li>- Emotional Impact</li> </ul> <p><b>High Sacrectomy</b></p> <ul style="list-style-type: none"> <li>• Episodes of wetting yourself (incontinence)</li> <li>• Inability to empty the bladder without inserting an 'in and out' catheter to drain the bladder</li> <li>• Long-term physiotherapy</li> <li>• Foot drop (need for permanent ankle support)</li> <li>• Dependence on walking aid (frame/crutch/stick)</li> <li>• Short distance mobility only</li> <li>• Unable to walk more than a short distance</li> <li>• Modified car to drive</li> </ul> |

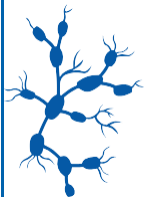
## What will I have removed & what does that POTENTIALLY mean for me?

(It doesn't necessarily mean it will happen to you)

| TICK IF APPLICABLE TO ME | ORGAN                                                                                           | IMPLICATION                                                                                                                                                                                                                                                                                                                                                                                                                      | POTENTIAL SHORT TERM CONSEQUENCES (0-3 MONTHS)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | POTENTIAL LONG TERM CONSEQUENCES (3 MONTHS + LONGER)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|--------------------------|-------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          | <b>Nerves</b>  | <b>Depending on what nerves are cut:</b> <ul style="list-style-type: none"> <li>• It can affect your bladder control (if it is not removed)</li> <li>• It can affect your bowel control (if you have been joined up)</li> <li>• It can affect your legs – mobility, weakness, numbness, pins and needles.</li> <li>• Long term pain can be an issue.</li> <li>• You may not be able to have an erection or ejaculate.</li> </ul> | <ul style="list-style-type: none"> <li>• Need to catheterise to pass water (urine) if no urostomy</li> <li>• Altered leg control</li> <li>• Leg weakness</li> <li>• Leg numbness</li> <li>• Leg pain</li> <li>• Difficulty walking</li> <li>• Foot drop (at rest foot remains pointing to floor and you are unable to lift it to a normal position)</li> <li>• Reduced mobility</li> <li>• Inability to walk without frame/ crutch/stick</li> <li>• Able to walk short distance only</li> <li>• Inability to control bowel (incontinence)</li> <li>• Sexual dysfunction</li> <li>• Infertility</li> <li>• Buttock, leg or foot numbness</li> <li>• Nerve pain - Shooting pain, pins and needles.</li> <li>• Episodes of wetting yourself, if you have a bladder.</li> </ul> | <ul style="list-style-type: none"> <li>• Need to catheterise to pass water (urine) if no urostomy</li> <li>• Altered leg control</li> <li>• Leg weakness</li> <li>• Leg numbness</li> <li>• Leg pain</li> <li>• Difficulty walking</li> <li>• Foot drop (need for long term ankle support)</li> <li>• Reduced mobility</li> <li>• Inability to walk without stick</li> <li>• Able to walk short distance only</li> <li>• Inability to run</li> <li>• Modified car to drive</li> <li>• Inability to control bowel (incontinence)</li> <li>• Sexual dysfunction</li> <li>• Infertility</li> <li>• Long term pain</li> <li>• Episodes of wetting yourself (if you have a bladder)</li> </ul> |

## What will I have removed & what does that POTENTIALLY mean for me?

(It doesn't necessarily mean it will happen to you)

| TICK IF APPLICABLE TO ME | ORGAN                                                                                                               | IMPLICATION                                                                    | POTENTIAL SHORT TERM CONSEQUENCES (0-3 MONTHS)                                                                                                                                                                                        | POTENTIAL LONG TERM CONSEQUENCES (3 MONTHS + LONGER)                                                                                                                                                                                                                                         |
|--------------------------|---------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          | <b>Vessels</b><br>                 | It can affect the blood supply to the affected leg                             | <ul style="list-style-type: none"> <li>Swelling of the leg</li> <li>Loss of blood supply to the leg</li> </ul>                                                                                                                        | <ul style="list-style-type: none"> <li>Leg pain</li> <li>Leg swelling</li> </ul>                                                                                                                                                                                                             |
|                          | <b>Reconstructive Surgery</b><br>  | New area of skin will look and feel different.                                 | <ul style="list-style-type: none"> <li>Inability to sit for more than short periods</li> <li>Numbness</li> <li>Flap may lose blood supply leading to issues with wound breakdown and prolonged wound healing (see page 26)</li> </ul> | <ul style="list-style-type: none"> <li>Altered sensation and appearance</li> </ul> <p>Potentially you may experience a hernia* (*The new area may bulge down further than surrounding tissue)</p>                                                                                            |
|                          | <b>Lymph nodes in pelvis</b><br> | It can affect the drainage of lymphatic fluid from your leg back to your body. | <ul style="list-style-type: none"> <li>Build up of lymph fluid in your legs (lymphoedema)</li> </ul>                                                                                                                                  | <p>Build up of lymph fluid in your legs (lymphoedema) leading to:</p> <ul style="list-style-type: none"> <li>Aching, heavy feeling</li> <li>Difficulty with movement</li> <li>Skin infections</li> <li>Hard, tight skin</li> <li>Fluid leaking through skin</li> <li>Skin growths</li> </ul> |

## What are the other POTENTIAL things to expect after surgery?

| Impact                  | Short Term                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Long Term                                                                                                                                                      |
|-------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Pain</b>             | <p>Pain is normal after major surgery. We will use different ways to control your pain. These include:</p> <ul style="list-style-type: none"> <li>• Epidural (fine tube inserted into your back giving you painkiller)</li> <li>• Patient controlled analgesia (PCA) (painkiller via a drip into your vein on demand with a button)</li> <li>• Spinal (injection into your back before the operation)</li> <li>• Rectus sheath catheters (local anaesthetic being dripped into your six-pack muscles)</li> <li>• Tablets/liquids/patches</li> </ul> <p>The pain relief appropriate for you will be discussed with the anaesthetist.</p> | <p>Long term painkilling medication may be necessary. Doses and types will change over time as your body starts to heal.</p>                                   |
| <b>Physical changes</b> | <p><b>Functional:</b></p> <ul style="list-style-type: none"> <li>• Weakness</li> <li>• Tiredness</li> <li>• Inability to do normal tasks – for example washing, dressing</li> <li>• Poor sleep</li> <li>• Bad dreams and night terrors</li> <li>• Weight loss (and need for nutrition)</li> <li>• Nausea and vomiting</li> </ul>                                                                                                                                                                                                                                                                                                        | <p><b>Functional:</b></p> <ul style="list-style-type: none"> <li>• Fatigue (tiredness that doesn't go away with rest) lasting longer than 12 months</li> </ul> |
|                         | <p><b>Body changes:</b></p> <ul style="list-style-type: none"> <li>• Your body will be very different following the surgery</li> <li>• You may have one or two stomas</li> <li>• You will have scars</li> <li>• You may no longer have a back passage (anus)</li> <li>• You may have a skin flap which has altered or no sensation and you may have another area where the flap was taken from which may look different.</li> <li>• Your body will feel different</li> <li>• Your penis may get smaller and shorter with time</li> </ul>                                                                                                |                                                                                                                                                                |

| Impact                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Emotional changes</b> | <p><b>Emotions:</b><br/>Some people describe feelings of Anxiety, Anger, Regret, Fear, Depression, Sadness. Some Men report feeling less of a man and describe an element of loss or bereavement for their former body.</p> <p>These emotions will change with time. You will get good days as well as bad days. These emotions may or may not disappear with time. Experience of other patients suggests you will adapt. There are support mechanisms to help you through it.</p> <p><b>Infertility:</b><br/>If cancer treatment results in the inability to get your partner pregnant this can affect you psychologically. There is the option of sperm collection and freezing prior to treatment and subsequent IVF.</p> <p><b>Body image:</b><br/>Body changes can affect the way you think and feel about your body which can affect your self-confidence. You might also worry that people will treat you differently because of the change to your body.</p> <p><b>Low self-esteem or lack of confidence:</b></p> <p>It is normal to find these changes difficult to adapt to physically and mentally. Different patients adapt in different ways. Some patients have reported:</p> <ul style="list-style-type: none"> <li>• Being too embarrassed to leave home</li> <li>• Withdrawing from social activities</li> <li>• Avoiding intimacy with a partner</li> <li>• Low mood</li> <li>• Changing the way they dress</li> </ul> |

| Impact                | Short Term                                                                                                                                                                     | Long Term                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Sexual changes</b> |                                                                                                                                                                                | <p>Pre-existing sexual status will determine recovery of your sex life. The tumor, previous radiotherapy and surgery will affect your ability and desire to have sex. If you do not have sexual intercourse now (before surgery) then this may not be relevant to you. If you do engage in sexual relations then sex is unlikely to be the same following this surgery.</p> <p>You should discuss with your partner the changes that will happen to your body and that sexual relations may resume in the long term however it may be very different to its current state.</p> <p>Following surgery you may not be able to get an erection naturally (you will be impotent). There are ways using both tablets and physical aids to assist getting an erection. There are different mechanical aids in the form of pumps and injections or implants. Your team can discuss this further with you. This may or may not be successful for you. If you are able to have an erection with aids, it may feel different to before. It may not be as pleasant as before the surgery. You may not be able to ejaculate.</p> <p>Your penis may change in appearance over time. It may get smaller and shorter. There is a choice to try to pursue penetrative sex - some may accept not to.</p> <p>It is normal to feel nervous if you decide to have sex again - Discuss this with your team.</p> |
| <b>Relationships</b>  | <p>Altered relationships with partner</p> <p>Altered relationships with family and friends</p> <p>Dependence on others for normal activities – washing, dressing, cleaning</p> | <p><b>Altered relationship with partner</b><br/>Although physically sexual intercourse will change, you will find other ways of being intimate. There is more to sex than the physical part. There is an interrelationship between psychological and sexual aspects so how you feel sexually is not just how you feel physically but it's how you feel psychologically too. You can still express desire and arousal but this will be shown differently.</p> <p><b>Altered relationships with family and friends</b><br/>You may feel differently after this surgery and that may or may not impact your relationships with others.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

| Impact          | Short Term                                                                                                                                                                                                    | Long Term                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Work</b>     | You are unlikely to work short term unless you can work from home and this doesn't require you to sit for long periods. Your employer should understand that you would need some flexibility within your day. | <p>Your employer should understand the extent of surgery you are undertaking and be prepared for a sickness of up to a year.</p> <p>You may not be able to return to the same job you performed before.</p>                                                                                                                                                                                                                                                |
| <b>Finance</b>  | Potential loss of income.                                                                                                                                                                                     | <p>Financial difficulty can be addressed by support charities who can direct you to places for help with money problems. Benefits can help you through financial difficulties. These are means tested but can help you with loss of income as well as directing you towards extra entitlements during your period of recovery and adjustment.</p> <p>Your nurse specialist can identify sources of financial support and help you through the process.</p> |
| <b>Exercise</b> | <p>Short term pain. Lack of energy.</p> <p>Change in routine that effect exercise.</p>                                                                                                                        | You may or may not be able to do the same exercises as you did pre-operatively. Your team may advise you not to do excessive exercise or prolonged amounts of sitting. Swimming and cycling may not be possible until the wound has completely healed. Returning to 'normal' activity is the goal and this is expected in most patients.                                                                                                                   |



## Will I have reconstructive surgery?

After organs affected by the cancer have been removed, some patients may benefit from reconstructive surgery. This is usually done at the same operation as the pelvic exenteration, by a Plastic Surgeon working with the surgical team. It involves moving tissue from elsewhere in the body into the pelvis and bottom end. **Your surgeon will decide if this is appropriate for you.**

The tissue that is moved is known as a flap. It usually consists of skin, fat and muscle. Flaps can be moved from several places, including the tummy (abdomen), buttocks or thighs. For a flap to work well it must have a good blood supply. This is usually not a problem but if it is, part or all of the flap may lose its blood supply and need to be removed.

The benefits of reconstructive surgery are:

- To fill up the space left when organs in the pelvis are removed
- To prevent long term problems, such as a pelvic hernia or chronic infection
- To help wounds to heal quickly

The risks of reconstructive surgery are:

- Adding time on to a long operation
- It may fail resulting in prolonged wound problems, hernia, occasionally need for re-operation
- It may leave a deformity in the area the flap is taken from

Reconstructive surgery **cannot make things totally normal again**. For instance, it cannot recreate a back passage (anus) that works.

**There are different types of flaps (see page 27) but your surgeon will decide which type they will offer you.**

## Do I have to have reconstructive surgery if it's offered to me?

If a 'flap' has been discussed with you it is usually necessary in order to fill the space following the removal of the cancer. It is

important that you speak to your Surgeon.

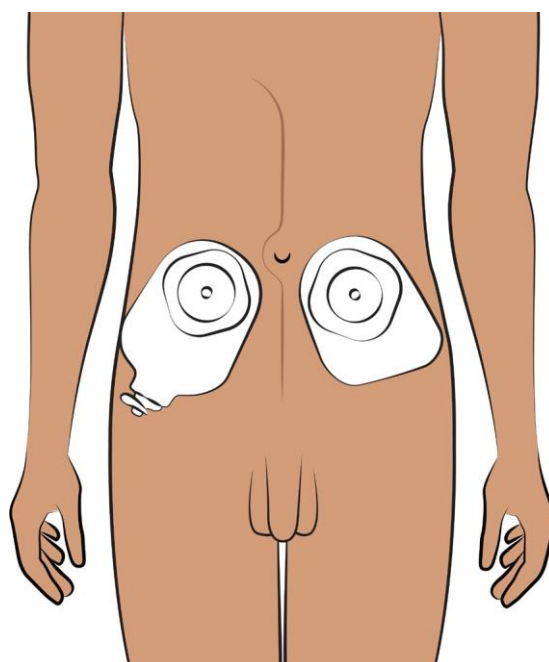
## Will I be able to sit after the surgery?

Patients who have had reconstructive surgery will be nursed from side to side in the bed for several days after surgery. This is to stop any pressure on the flap tissue. It is then sometimes best not to sit for 1 to 2 weeks. Once sitting is allowed, a pressure-relieving air cushion is recommended, this is for 10 minutes at a time. A graduated sitting programme is started to help you adjust to sitting, which will be directed by your team.

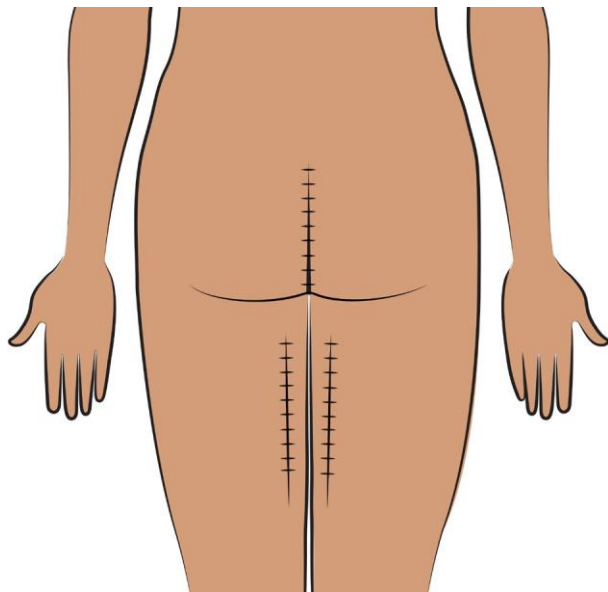
## What will things look like after my surgery?

Surgery always leaves scars. In normal clothes these will not be visible, but without clothes on you will be able to see scars on your tummy (abdomen) and elsewhere. Your stoma (or stomas) will also be visible and the shape of your abdomen, buttocks or thighs may also have changed if a flap from these areas has been used. Following surgery, your bottom end (perineum) may also feel numb and can also feel a bit swollen which can change the way you sit or balance sitting.

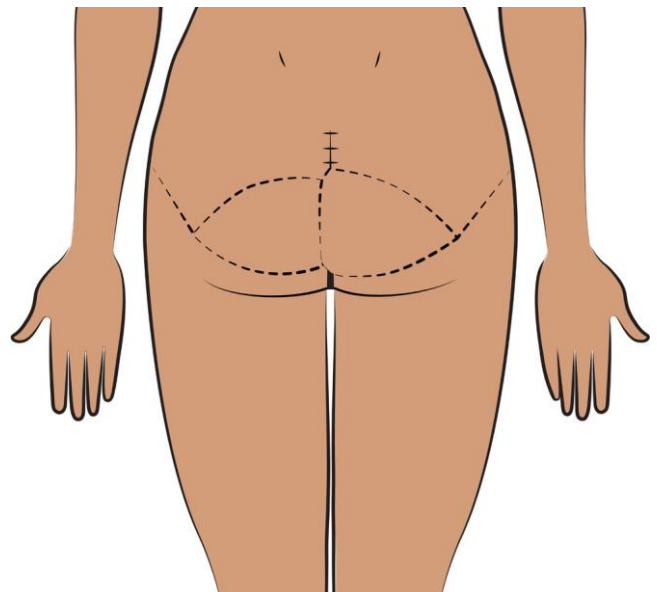
When a flap from the abdomen is used, the scars are as shown in diagram A. Scars from thigh and buttock flaps are shown in diagrams B & C.



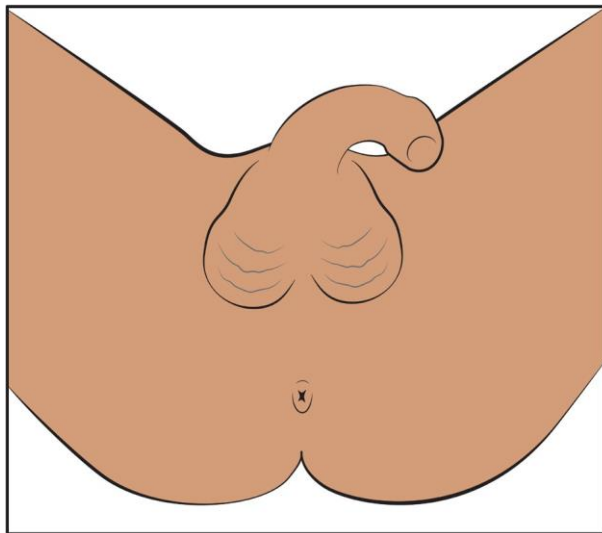
**A Abdomen scar**



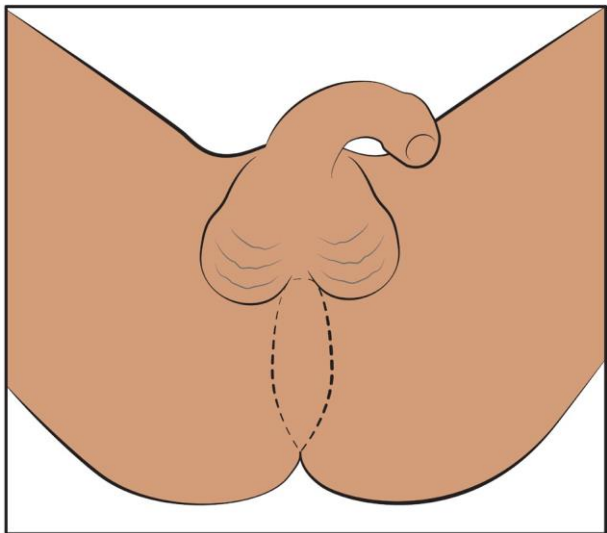
**B Thigh scar**



**C Buttock flaps**



**Normal penis & anus**



**Flap in position**

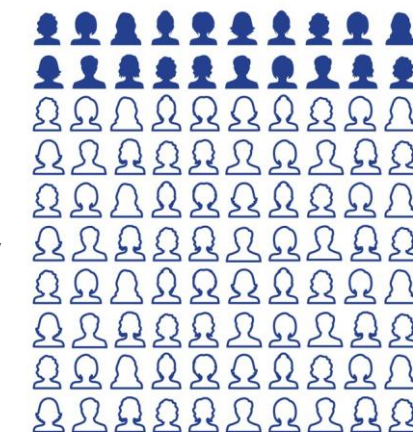
## What are the potential complications?

The risks depend on the complexity of the operation you need.

Around 1 in 5 patients (20%) will experience a major complication from the surgery.

### Major risks of surgery include:

- Excessive bleeding (return to theatre, major blood transfusion)
- Heart attack (myocardial infarction)
- Blood clot in the chest (pulmonary embolism)
- Risk of the wound including muscle fully opening up
- Risk of the plastic surgical flap dying
- Collection in the pelvis
- Injury to the bowel & bowel join leaking
- Injury to the urinary tract
- Kidney failure
- Bowel obstruction
- Formation of an abnormal passage between two places (fistula)
- Incomplete removal of the cancer or it not being possible to proceed with cancer removal during the operation
- Need for re-operation in around 1 in 10 patients (10%)

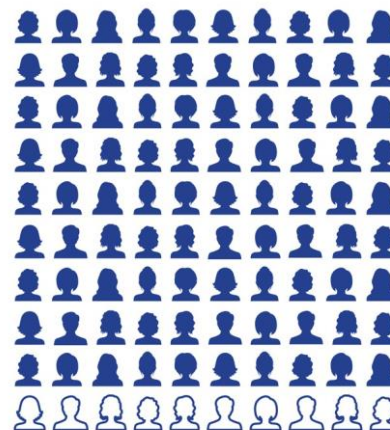


*20 out of 100 experience major complications*

Most patients experience some minor complications after surgery. This happens in 9 out of 10 patients (90%).

### Minor risks of surgery include:

- Infection (chest/wound/urine)
- Risk of skin wound opening up
- Blood clot in the legs (Deep Vein Thrombosis or DVT)
- Bowels slow to start working again but usually resolves in time (ileus)



*90 out of 100 experience minor complications*

To minimise the risks of clots we give you elastic stockings to wear and give you blood-thinning injections to prevent clots. These injections are usually continued for 28 days after your operation.

## Can I die as a result of surgery?

The risk of dying within 30 days of the surgery is low. 98 out of 100 patients (98%) will be alive 30 days after surgery.



***2 out of 100 die after the operation***

95 out of 100 patients (95%) will be alive after 90 days of surgery.

There are things you can do to get you through the recovery easier. The more you do before with regard to exercise, then the easier the recovery. Important things to maximise your recovery are;

- Exercise (getting fit)
- Healthy diet
- Get the right support
- Bring key people to your clinic appointments
- Have a positive state of mind

## Aftercare

You will need nursing care after going home. They will help you look after your wounds and stoma(s). District nurses will be arranged (sometimes they will need to visit daily). Stoma nurses will be available if required to support you.



If you decide to have the surgery you will be followed- up for five years afterwards. Two to three weeks after your operation the results of what your tumour looked like under the microscope will be available. The team looking after you will talk through the results to you. They may suggest that you consider chemotherapy treatment.

## **Do I have to have chemotherapy if it's offered?**

You will have a discussion with your oncologists regarding the risk and benefit for you as an individual. If it is offered as an option, it is usually only beneficial within 8 - 12 weeks after surgery.

You may have lots of questions regarding more chemotherapy. These can be discussed with your oncologist. If you decide to have chemotherapy and cannot tolerate it, then you can stop treatment.

## **What is my follow-up?**

Your follow-up will consist of clinic visits, surveillance CT scans and blood tests at different intervals for the 5 year period. If you have any questions at any time, please ask any member of your team. They will be pleased to explain anything that concerns you or your family. Another good tip is to write your thoughts and questions down so that you do not forget when you meet your team.

## Support - Who are we?

We are a specialist team dealing with pelvic cancers. The team includes surgeons, doctors, surgical nurse practitioners and other specialist nurses including stoma care nurse specialists.

**Your Consultant is** .....

**Contact number (Secretary)** .....

**Your specialist nurse is** .....

**Contact number** .....

**Your stoma care nurse is** .....

**Contact number** .....

**Ward contact number 24/7** .....

## Who do I contact with concerns after my operation?

If you have concerns after you have gone home then you can contact your specialist nurse or stoma care nurse or consultant via the secretary on the numbers above. you can also contact the ward.

If you experience any of the following:

- Persistent nausea (feeling sick) or vomiting (being sick)
- Fever or a high temperature (37.5°C/101.5°F or above)
- Oozing or increasing redness around either of the wound sites
- New pain
- Change in stoma activity (new loose stool/diarrhea via stoma)

Please get in contact with any of the team above or your GP. If you are unable to access these contacts out of hours then please contact the ward or the GP out of hours service or attend the A&E department of your nearest hospital.



## Support

**Your team will support you. They will do everything possible to support you and give you the best possible care. Do not be afraid to ask questions.**

You may want to discuss your options further. Your specialist nurse will always be available to discuss things and can help you direct you to charities and support groups that can sometimes help. There are also online communities and support groups that you can talk to. You will need to discuss things with your family and/or friends which may mean some difficult conversations.

It is important that you get the right support for you as you come to terms with the decision you face. It is important that you understand the implications of what life may look like by surviving the disease. Families and friends may need support with the idea of adapting in a new role as a carer or emotional support in coming to terms with what their relative is going through. You can be put in touch with a support group where you can meet people in a similar situation and get information first-hand about your type of cancer. You are not alone and we can signpost you to various additional support you require. You may also want to re-discuss things with your team and it is important that you get in touch if you feel this is something you need to do.

### **For additional support services or further discussions (outside your medical team), we recommend:**

Macmillan Cancer Support: [www.macmillan.org.uk](http://www.macmillan.org.uk) Tel: 0808 808 0000

Maggie's: [www.maggies.org](http://www.maggies.org) Tel: 0300 123 1801

Bowel Cancer UK: [www.bowelcanceruk.org.uk](http://www.bowelcanceruk.org.uk) Tel: 020 7940 1760

Beating Bowel Cancer: [www.beatingbowelcancer.org](http://www.beatingbowelcancer.org) Tel: 020 8973 0011

Bladder and Bowel Foundation: [www.bladderandbowelfoundation.org](http://www.bladderandbowelfoundation.org) Tel: 0845 345 0165





Urostomy Association: [www.urostomyassociation.org.uk](http://www.urostomyassociation.org.uk) Tel:  
01889 563191

Colostomy Association: [www.colostomyassociation.org.uk](http://www.colostomyassociation.org.uk) Tel:  
0800 328 4257

It is important to get as emotionally prepared as possible before you decide to have this operation. There are NHS psychological support services available to help you adjust to the losses in your body as well as the permanent changes of how your body will function. You may feel you are getting enough support from your family, GP and hospital team including your CNS, however, sometimes more specialist input is needed.

## **Psychosexual issues**

College of Sexual Relationship Therapists: [www.cosrt.org.uk](http://www.cosrt.org.uk) Tel:  
020 8543 2707

RELATE. Low cost relationship & sexual therapy services across the UK.  
[www.relate.org.uk](http://www.relate.org.uk)

## **Psychological issues**

NHS psycho-oncology services and psychological support services are available in specialist centres. However, additional psychological counselling can be found:

British Psychological Society  
<https://www.bps.org.uk/public/find-psychologist>

British Association for Counselling & Psychotherapy  
<https://www.bacp.co.uk/search/Therapists>

UK Council for Psychotherapy <https://www.psychotherapy.org.uk/>

## **Sexual issues**

Your CNS or Urologist will provide specialist practical support.

## Clothing Support

Vanilla Blush [www.vblush.com](http://www.vblush.com)

## Maximising Recovery

Book by Sarah Russell, The Bowel Cancer Recovery Toolkit

## Do not identify as heterosexual / cisgender?

LGBTQI Cancer Charity for those individuals who do not identify as heterosexual / cisgender: [www.livethroughthis.co.uk](http://www.livethroughthis.co.uk)

**If you decide to have surgery you may want to revisit this document after surgery to remind you of the adjustments you may face.**

## Sources

Patient Decision Aid for Men.

Produced as part of study IRAS 257890.

First published: May 2021. Review date: May 2023.

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Quyn AJ, Austin KK, Young JM, Badgery-Parker T, Masya LM, Roberts R, Solomon MJ. Outcomes of pelvic exenteration for locally advanced primary rectal cancer: Overall survival and quality of life. Eur J Surg Oncol. 2016 Jun;42(6):823-8.

Solum AM, Riffenburgh RH, Johnstone PA. Survival of patients with untreated rectal cancer. J Surg Oncol. 2004; 87:157–161

## Questions

Many people will forget what they want to say or ask at the time of their consultation. You may find it helpful to write things down here and bring it to your appointments.

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## Questions

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## Questions

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