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Pwyllgor Gwasanaethau Iechyd Arbenigol Cymru (PGIAC)
Welsh Health Specialised Services Committee (WHSSC)

Specialised Services
Policy Position Statement PP278

Policy Proposal

Stereotactic ablative body radiotherapy (SABR) for patients aged 18 years old and above with previously irradiated, locally recurrent primary pelvic tumours

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Policy Statement

Welsh Health Specialised Services Committee (WHSSC) propose to commission Stereotactic ablative body radiotherapy (SABR) for patients aged 18 years old and above with previously irradiated, locally recurrent primary pelvic tumours in accordance with the criteria outlined in this document.

In creating this document WHSSC has reviewed the relevant guidance issued by NHS England[1] and has concluded that SABR should be made available for this group of patients.

Welsh Language

WHSSC is committed to treating the English and Welsh languages on the basis of equality, and endeavour to ensure commissioned services meet the requirements of the legislative framework for Welsh Language, including the Welsh Language Act (1993), the Welsh Language (Wales) Measure 2011 and the Welsh Language Standards (No.7) Regulations 2018.

Where a service is provided in a private facility or in a hospital outside of Wales, the provisions of the Welsh language standards do not directly apply but in recognition of its importance to the patient experience, the referring health board should ensure that wherever possible patients have access to their preferred language.

In order to facilitate this, WHSSC is committed to working closely with providers to ensure that in the absence of a Welsh speaker, written information will be offered and people have access to either a translator or 'Language-line' if requested. Where possible, links to local teams should be maintained during the period of care.

Decarbonisation

WHSSC is committed to taking assertive action to reducing the carbon footprint through mindful commissioning activities. Where possible and taking into account each individual patient's needs, services are provided closer to home, including via digital and virtual access, with a delivery chain for service provision and associated capital that reflects the WHSSC commitment.

Disclaimer

WHSSC assumes that healthcare professionals will use their clinical judgment, knowledge and expertise when deciding whether it is appropriate to apply this policy position statement.

[1] Clinical Commissioning Policy: Stereotactic ablative radiotherapy (SABR) for patients with previously irradiated, locally recurrent primary pelvic tumours (All ages)

This policy may not be clinically appropriate for use in all situations and does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian, or Local Authority.

WHSSC disclaims any responsibility for damages arising out of the use or non-use of this policy position statement.

1. Introduction

This Policy Position Statement Proposal has been developed for the planning and delivery of Stereotactic ablative body radiotherapy (SABR) for people aged 18 years old and above with previously irradiated, locally recurrent primary pelvic tumours who are resident in Wales. This proposed service will only be commissioned by the Welsh Health Specialised Services Committee (WHSSC) and applies to residents of all seven Health Boards in Wales.

1.1 Plain language summary

The pelvis is the lower part of the torso, located between the abdomen and the legs. This area contains a number of different organs including the reproductive organs, the bladder and the large intestine (sometimes referred to as the colon or bowel).

Cancerous tumours can occur in any of these organs in the pelvis, however, they most commonly occur in the prostate, gynaecological organs and the rectum. Tumours may originate in these organs (referred to as primary cancer) or may spread to the pelvic region from other parts of the body (known as secondary cancers). Usually tumours in the pelvic region are a combination of primary and secondary cancers.

Initial treatment options for tumours in the pelvis depend on the location and size of the tumour, and a combination of different treatments is usually used including surgery, systemic anti-cancer therapy (e.g., chemotherapy) and radiotherapy.

Radiotherapy uses high energy rays, usually x-rays, to destroy cancer cells. Although radiotherapy can be a curative treatment option for many people with pelvic tumours, sometimes the cancer can come back (recur). This policy is specifically for the treatment of primary pelvic tumours which reoccur locally in the pelvis and have been previously treated with radiotherapy (i.e. previously irradiated). It does not cover either secondary tumours in the pelvis or any tumours in the abdomen or spine.

SABR is a highly targeted form of radiotherapy which uses multiple radiation beams, given from different angles around the body at the same time. The treatment is delivered in a fewer number of treatments (hypofractionation) than conventional radiotherapy. There are usually between one, three, five or eight treatments (or fractions). The aim of treatment with SABR is to ensure that the tumour receives a high dose of radiation whilst the tissues close to the tumour receive a lower dose of radiation sparing the surrounding healthy normal tissues and reducing the risk of side effects.

1.2 Aims and Objectives

This Policy Position Statement Proposal aims to define the commissioning position of WHSSC on the use of SABR patients with previously irradiated, locally recurrent primary pelvic tumours.

The objectives of this policy are to:

- ensure commissioning for the use of SABR is evidence based
- ensure equitable access to SABR
- define criteria for people with previously irradiated, locally recurrent primary pelvic tumours to access treatment
- improve outcomes for people with previously irradiated, locally recurrent primary pelvic tumours

1.3 Epidemiology

Primary tumours in the pelvis can occur in a number of different locations including the prostate, bladder, gynaecological organs and bowel. In 2019 in Wales, there were:

- 2,971 cases of newly diagnosed prostate cancer
- 535 cases of newly diagnosed bladder cancer
- 981 newly diagnosed cases of cervical, ovarian and uterine cancers
- 5,105 new cases of anal, colon, colorectal and rectal cancer[2].

Over a three-year period, 185 people with previously irradiated, locally recurrent primary pelvic tumours including the prostate, bladder, gynaecological organs and the bowel were treated through NHS England's Commissioning through Evaluation (CtE) programme[3]. In comparison, in 2017/18 319 patients were treated with exenterative surgery for either colorectal or gynaecological cancer, with approximately 20% of patients eligible for surgery, opting to have systemic treatment.

It is estimated that a maximum of 150 patients per year in England would be eligible for or could choose to have SABR pelvic re-irradiation for the treatment of locally recurrent pelvic tumours eligible for treatment with systemic therapy, positive surgical margins following surgery and lymph nodes in the pelvis. When extrapolated to the Wales population (5%) this would mean an estimated 8 people would be eligible for treatment per year.

1.4 Current Treatment

For people with previously irradiated, locally recurrent primary pelvic tumours, further treatment with more conventional forms of radiotherapy

[2] WCISU: Cancer incidence in Wales 2002-2019

[3] KiTEC. (2019). Evidence Review: Efficacy, toxicity and cost-effectiveness of stereotactic ablative radiotherapy (SABR) in patients with metachronous extracranial oligometastatic cancer. King's College Technology Evaluation Centre, London

is commonly avoided. This is because there is a risk of damage to healthy tissue with further treatment.

Some people with previously irradiated, locally recurrent primary pelvic tumours may be offered surgery with the potential for cure. However, not all people are suitable for surgery with curative intent and treatment is dependent on a number of factors including (i) patient co-morbidities; (ii) the location and size of the tumour; and (iii) the presence of scarring caused to the tissue as a result of previous treatment with radiotherapy (referred to as radiation-induced fibrosis).

Where surgery with curative intent is possible, an operation called pelvic exenteration may be performed. This is a major, complex operation which usually takes several hours to perform and involves a number of surgeons from different specialities. During the operation, multiple organs (and sometimes bones) in the pelvis are removed at the same time and this can include the bladder and/or the bowel. As a result of the surgery, most people are commonly left with a life-long stoma (a bag) to collect bowel contents and/or urine and this can have a major impact on a person's quality of life. In some cases, the tumour may be incompletely removed leaving some residual disease behind (residual margin). Furthermore, the operation is high risk with a 5% chance of surgical mortality[4], major surgical complications are reported in between 30 to 80% of cases[5] [6] [7] and only a 30% chance of success. Five-year survival after the operation is reported to be between 21 and 64%[8].

Given the possible side effects and risks associated with exenterative surgery, some people eligible for surgery decline this procedure. Where surgery with curative intent is incomplete (residual margin), not possible or is declined, systemic therapy, using drugs to treat the whole body, is the only other treatment option. Systemic therapy is offered with the purpose of keeping the disease under control (i.e. as a palliative treatment). However, this can result in significant side effects (such as fatigue, low blood count, infection risk and diarrhoea), with limited benefits. People receiving systemic therapy often require painkillers in order to support them through treatment and alleviate any pain associated with the disease.

[4] Kolomainen D.F. and Barton D. 2017. Pelvic exenteration for recurrent gynaecological cancer after radiotherapy. The Obstetrician & Gynaecologist 19: pp 109–18.
[5] Kolomainen et al 2017
[6] Platt et al 2018
[7] The PelvEx Collaborative 2018
[8] Berek and Hacker, 2010

1.5 Proposed Treatment

SABR is considered to be an alternative treatment option to systemic therapy where surgery:

- has resulted in positive surgical margins
- is not a suitable treatment option; or
- has been declined by the patient due to the associated risks and long-term side effects of surgical treatment.

Use of SABR in this indication is considered to delay the use of systemic therapies or, in a small number of cases, completely negate the need for these medicines. SABR pelvic re-irradiation can also be used to treat the site of the tumour, any positive surgical margins following surgery, and more commonly, to treat the lymph nodes in the pelvis as a palliative treatment.

1.6 What NHS Wales has decided

WHSSC has carefully reviewed the relevant guidance issued by NHS England. WHSSC have concluded that SABR should be made available within the criteria set out in section 2.1.

2. Criteria for Commissioning

The Welsh Health Specialised Services Committee propose to approve funding of SABR for previously irradiated, locally recurrent primary pelvic tumours in line with the criteria identified in the policy.

2.1 Inclusion Criteria

SABR should be considered as a treatment option for previously irradiated, locally recurrent primary pelvic tumours most commonly prostate, gynaecological and bowel cancers, eligible for treatment with systemic therapy, positive surgical margins following surgery, and the lymph nodes in the pelvis as a palliative treatment.

Treatment decisions must be made by the tumour specific (site-specific) cancer multi-disciplinary team (MDT) in conjunction with the patient and/or their parent or guardian. It is recommended that a shared decision-making tool is used to ensure patients are fully informed of their treatment decision.

The site-specific MDT is responsible for radiotherapy case selection and should take into consideration patient comorbidities, potential adverse events and likely outcomes of treatment.

For patients undergoing treatment with SABR, consideration should be given to discontinuing systemic therapy prior to SABR; concurrent hormone treatment is however permitted.

Patients meeting **all** of the following criteria will be eligible for treatment with SABR:

- ≥18 years; **and**
- initial histologically confirmed primary pelvic tumour (all types) which has recurred in the pelvis; **and**
- previous course of radiotherapy within the pelvis with no enduring significant toxicity; **and**
- ineligible for surgery with curative intent or surgery with curative intent is declined by the patient or surgery has resulted in positive surgical margins; **and**
- more than 6 months since initial radiation treatment; **and**
- World Health Organisation (WHO) performance status (PS) ≤ 2; **and**
- life expectancy of more than 6 months.

2.2 Exclusion Criteria

Treatment with SABR is not suitable in people:

- with previously irradiated pelvic bone metastases or spinal metastases;
- receiving concurrent therapies;
- in whom less than 6 months have elapsed since initial radiation treatment; or
- with a life expectancy of less than 6 months.

2.3 Dose and fractionation

It is recognised that, in the re-irradiation setting, treatment technique and dose must be individualised. The dose and fractionation are dependent on the site of the disease and clinical scenario. However, it is expected that five fractions of SABR are used for pelvic tumours.

2.4 Continuation of Treatment

Healthcare professionals are expected to review a patient's health at regular intervals to ensure they are demonstrating an improvement to their health due to the treatment being given.

If no improvement to a patient's health has been recorded then clinical judgement on the continuation of treatment must be made by the treating healthcare professional.

2.5 Acceptance Criteria

The service outlined in this specification is for patients ordinarily resident in Wales, or otherwise the commissioning responsibility of the NHS in Wales. This excludes patients who whilst resident in Wales, are registered with a GP practice in England, but includes patients resident in England who are registered with a GP Practice in Wales.

2.6 Patient Pathway (Annex i)

Radiotherapy is part of an overall cancer management and treatment pathway. Decisions on the overall treatment plan should relate back to an MDT discussion and decision to ensure appropriate patient selection. Patients requiring radiotherapy are referred to a clinical oncologist for assessment, treatment planning and delivery of radiation fractions and discussed by the SABR planning group. Each fraction of radiation is delivered on one visit, usually as an outpatient basis.

2.7 Exceptions

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If the patient wishes to be referred to a provider outside of the agreed pathway, and IPFR should be submitted.

Further information on making IPFR requests can be found at: Welsh Health Specialised Services Committee (WHSSC) | Individual Patient Funding Requests

2.8 Clinical Outcome and Quality Measures

The Provider must work to written quality standards and provide monitoring information to the lead commissioner.

The centre must enable the patient's, carer's and advocate's informed participation and to be able to demonstrate this. Provision should be made for patients with communication difficulties and for children, teenagers and young adults.

Radiotherapy providers must submit their activity to the national Radiotherapy Dataset (RTDS) on a monthly basis. Providers will collect the audit clinical outcome data through their own collection process for all SABR.

The SABR Consortium Guidelines 2019 provide detailed information on each indication contained within this policy.

The radiotherapy service should be fully compliant with the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2017.

Clinical governance systems and policies should be in place and integrated into the organisational governance with clear lines of accountability and responsibility for all clinical governance functions. Providers should produce annual clinical governance reports as part of the NHS clinical governance reporting system. Providers must have an externally accredited quality management system (e.g. BSI) in place.

All providers must be compliant with radiotherapy quality assurance for contouring and outlining. A national approach to regular peer review of patient eligibility and treatment plans will be required.

In addition, all providers of treatment with SABR must:

- ensure all patients treated are subject to an MDT approach to patient selection and treatment including discussion at the site-specific MDT and SABR planning group;
- have an adequate technical multi-professional radiotherapy SABR team present and able to deliver SABR radiotherapy; and
- have minimum of two subspecialist clinical oncologists with experience in treating SABR patients.

2.9 Responsibilities

Health Boards and WHSSC are to circulate this Policy Position Statement to all Hospitals/MDTs to inform them of the conditions under which the treatment will be commissioned.

Referrers should:

- inform the patient and/or their parent or guardian that this treatment is not routinely funded outside the criteria in this policy, and
- refer via the agreed pathway.

Clinicians considering treatment should:

- discuss all the alternative treatment with the patient and/or their parent or guardian
- advise the patient and/or their parent or guardian of any side effects and risks of the potential treatment
- inform the patient and/or their parent or guardian that treatment is not routinely funded outside of the criteria in the policy, and
- confirm that there is contractual agreement with WHSSC for the treatment.

In all other circumstances an IPFR must be submitted.

3. Documents which have informed this policy

The following documents have been used to inform this policy:

- **WHSSC policies and service specifications**
  - CP121 Stereotactic Ablative Body Radiotherapy (SABR) in the treatment of Oligometastatic Disease October 2021
  - CP219 Stereotactic Ablative Body Radiotherapy (SABR) Service Specification June 2021

- **NHS England policies**
  Clinical Commissioning Policy: Stereotactic ablative radiotherapy (SABR) for patients with previously irradiated, locally recurrent primary pelvic tumours (All ages) [201002P] (URN: 1909)

- **Other published documents**
  - Stereotactic Ablative Body Radiation Therapy (SABR): A Resource, SABR UK Consortium Version 6.1 January 2019

This document should be read in conjunction with the following documents:

- **NHS Wales**
  - All Wales Policy: Making Decisions in Individual Patient Funding requests (IPFR).

4. Date of Review

This document will be reviewed when information is received which indicates that the policy requires revision.

5. Putting Things Right

5.1 Raising a Concern

Whilst every effort has been made to ensure that decisions made under this policy are robust and appropriate for the patient group, it is acknowledged that there may be occasions when the patient or their representative are not happy with decisions made or the treatment provided.

The patient or their representative should be guided by the clinician, or the member of NHS staff with whom the concern is raised, to the appropriate arrangements for management of their concern.

If a patient or their representative is unhappy with the care provided during the treatment or the clinical decision to withdraw treatment provided under this policy, the patient and/or their representative should be guided to the LHB for NHS Putting Things Right. For services provided outside NHS Wales the patient or their representative should be guided to the NHS Trust Concerns Procedure, with a copy of the concern being sent to WHSSC.

5.2 Individual Patient Funding Request (IPFR)

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If an IPFR is declined by the Panel, a patient and/or their NHS clinician has the right to request information about how the decision was reached. If the patient and their NHS clinician feel the process has not been followed in accordance with this policy, arrangements can be made for an independent review of the process to be undertaken by the patient's Local Health Board. The ground for the review, which are detailed in the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), must be clearly stated

If the patient wishes to be referred to a provider outside of the agreed pathway, an IPFR should be submitted.

Further information on making IPFR requests can be found at: Welsh Health Specialised Services Committee (WHSSC) | Individual Patient Funding Requests

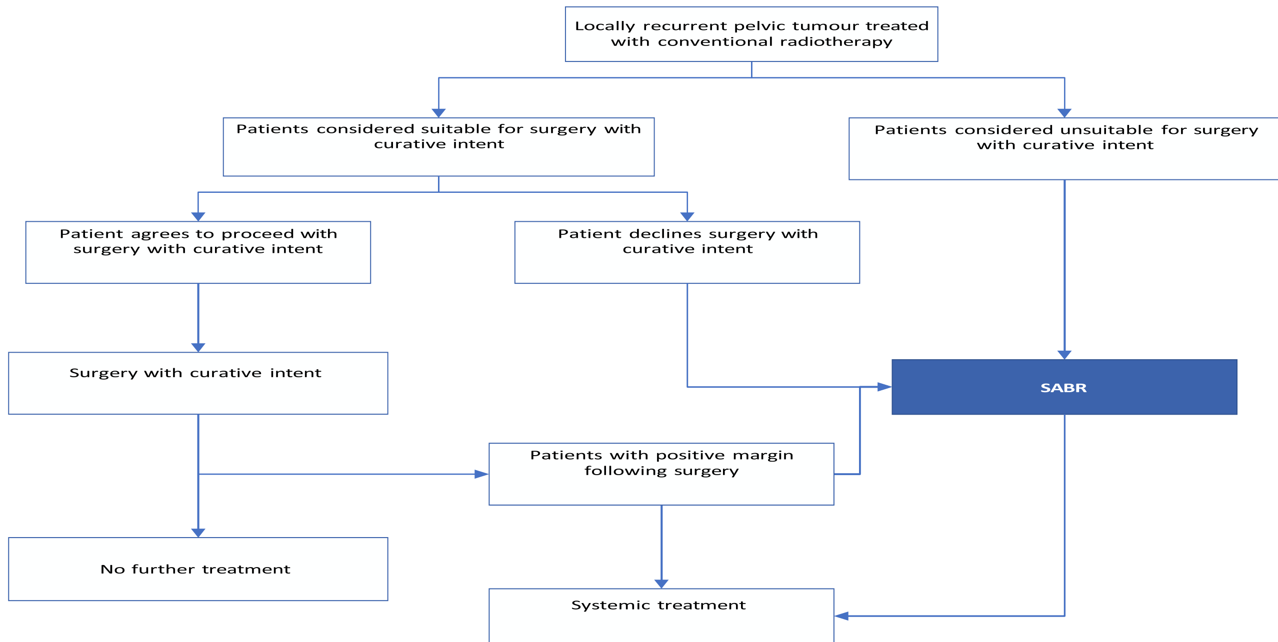
6. Equality Impact and Assessment

The Equality Impact Assessment (EQIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable Welsh Health Specialised Services Committee to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re-assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (Welsh).

This policy has been subjected to an Equality Impact Assessment.

The Assessment demonstrates the policy is robust and there is no potential for discrimination or adverse impact. All opportunities to promote equality have been taken.

Annex i Patient Pathway



Annex ii Codes

Code Category	Code	Description
OPCS	Y91.5	Megavoltage treatment for hypofractionated stereotactic radiotherapy

Annex iii Abbreviations and Glossary

Abbreviations

IPFR	Individual Patient Funding Request
MDT	Multi-disciplinary Team
PROM	Patient Recorded Outcome Measure
PS	Performance Status
SABR	Stereotactic Ablative Body Radiotherapy
WHO	World Health Organisation
WHSSC	Welsh Health Specialised Services Committee

Glossary

Bladder cancer
Cancer that starts in the lining of the bladder. The bladder is part of the urinary system, which filters waste products out of the blood and produces urine.

Bowel cancer (colorectal cancer)
The development of cancer from the colon or rectum (parts of the large intestine).

Chemotherapy
The use of a drug to kill or damage cells, most commonly used in cancer treatment.

Colostomy
An operation to divert one end of the colon (part of the bowel) through an opening in the tummy. The opening is called a stoma. A pouch can be placed over the stoma to collect stools. A colostomy can be permanent or temporary.

Exenterative surgery
A type of surgery which involves the removal of multiple organs from the pelvis. This can include the bowel or the bladder. The surgery takes approximately eight hours to complete and can involve a number of surgeons.

Fraction
The term that describes how the full dose of radiation is divided into a number of small doses (called fractions). The fractions are given as a series of treatment sessions which make up a radiotherapy course.

Gynaecological cancers
Tumours which occur in the female reproductive system. There are five gynaecological cancers: (i) womb (sometimes referred to as endometrium); (ii) ovarian; (iii) cervical; (iv) vaginal; and (v) vulva.

Hypofractionation
Describes a treatment regimen that delivers high doses of radiation using a shorter number of treatments as compared to conventional treatment regimens.

Individual Patient Funding Request (IPFR)
An IPFR is a request to Welsh Health Specialised Services Committee (WHSSC) to fund an intervention, device or treatment for patients that fall outside the range of services and treatments routinely provided across Wales.

Irradiate
Expose (someone or something) to radiation.

Local control (LC)
The proportion of patients for which the treated metastasis does not increase in size at a defined follow- up point after beginning treatment.

Lymph node
Small glands all around the body that are critical for the functioning of the body’s immune system. The lymph nodes form part of the lymphatic system, a network of organs, vessels, and nodes throughout the body, lymph nodes act like filters, trapping bacteria, viruses, and other invaders before they can cause an infection.

Metastatic cancer/metastases
Metastatic cancer is a cancer that has spread from the part of the body where it started (the primary site) to other parts of the body. Metastases is the plural form of metastasis and indicates that the cancer spread to more than one other site in the body.

Palliative treatment
Care which aims to relieve symptoms of a disease and improve and individual’s quality of life. It can also be used to reduce or control the side effects of cancer treatments. In advanced cancer, palliative treatment might help someone to live longer and to live comfortably, even if they cannot be cured. It is sometimes also called best supportive care.

Pelvic tumours
Tumours that occur in the lower part of the trunk of the body. Organs in this region include the bowel, prostate and gynaecological organs.

Performance Status (PS)
A recognised system developed by the World Health Organisation and other bodies to describe the general health and daily activity of patients.

Progression free survival (PFS)
The length of time during which the disease does not worsen, or the proportion of patients without worsening disease at a defined follow-up point after beginning treatment.

Prostate
A small gland in the pelvis which is about the size of a walnut and located between the penis and the bladder and which surrounds the urethra. The main function of the prostate is to help in the production of semen.

Radiotherapy
The safe use of ionising radiation to destroy cancer cells with the aim of cure or effective palliation.

Re-irradiation
A repeat administration of radiotherapy to a previously (metastases) exposed region of the body.

Secondary cancer
A term used to describe cancer that has spread from the primary site to another site.

Stereotactic Ablative Radiotherapy (SABR)
Refers to the irradiation of a lesion and is associated with the use of high radiation dose delivered in a small number of fractions. The technique requires specialist positioning of equipment and imaging to confirm correct targeting. It allows sparing of the healthy normal tissues.

Stoma
An opening on the abdomen that can be connected to either your digestive or urinary system to allow waste (urine or faeces) to be diverted out of your body. A bag is usually placed over this opening to collect waste products. A stoma can be a long-term consequence of exenterative surgery if the bowel or the bladder are removed as part of the procedure.

Systemic treatment/therapy
Treatment, usually involving chemotherapy or hormone treatment, which aims to treat the whole body.

Urinary diversion
A surgical procedure that reroutes urine flow from its normal pathway. The most common procedure is a urostomy which attaches the ureters to a tube

that opens out of the tummy; a bag is them placed over this opening to collect urine.

Welsh Health Specialised Services Committee (WHSSC)
WHSSC is a joint committee of the seven local health boards in Wales. The purpose of WHSSC is to ensure that the population of Wales has fair and equitable access to the full range of Specialised Services and Tertiary Services. WHSSC ensures that specialised services are commissioned from providers that have the appropriate experience and expertise. They ensure that these providers are able to provide a robust, high quality and sustainable services, which are safe for patients and are cost effective for NHS Wales.