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

Commissioning position

Summary

SABR is recommended to be available as a treatment option through routine commissioning for the treatment of previously irradiated, locally recurrent primary pelvic tumours within the criteria set out in this document.

Executive summary

Equality statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

Plain language summary

About previously irradiated, locally recurrent primary pelvic tumours

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. These 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 (i.e. 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.

About current treatments

For people with previously irradiated, locally recurrent primary pelvic tumours, further treatment with more conventional forms of radiotherapy 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 and/or urine contents 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 (Kolomainen and Barton, 2016), major surgical complications are reported in between 30 to 80% of cases (Kolomainen et al 2017, Platt et al 2018, The PelvEx Collaborative 2018) and only a 30% chance of success. Five-year survival after the operation is reported to be between 21 and 64% (Berek and Hacker, 2010).

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.

About stereotactic ablative radiotherapy (SABR)

SABR is a highly targeted radiation therapy which targets a tumour with radiation beams from different angles and is delivered in fewer numbers of treatments (hypofractionation) than conventional radiotherapy typically, using three, five or eight fractions. The aim of the new treatment is to ensure that the tumour receives a high dose of radiation whilst the tissues close to the tumour receives a lower dose of radiation, sparing the surrounding healthy normal tissues reducing toxicity and damage.

The use of SABR in the treatment of locally recurrent, previously irradiated primary pelvic tumours is believed to stop further growth of the tumour and relieve any symptoms associated with the disease.

SABR is considered to be an alternative treatment option to systemic therapy where surgery: (i) has resulted in positive surgical margins; (ii) is not a suitable treatment option; or (iii) 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.

What we have decided

NHS England has carefully reviewed the evidence to treat previously irradiated, locally recurrent primary pelvic tumours with SABR. We have concluded that there is enough evidence to make the treatment available at this time.

Links and updates to other policies

This document updates the section relating to the treatment of previously irradiated tumours of the pelvis:

- Clinical Commissioning Policy: Stereotactic ablative radiotherapy in the treatment of previously irradiated tumours of the pelvis, spine and nasopharynx (NHS England Reference: 16021/P). (NHS England, 2016)

This document also links to:

- Clinical Commissioning Policy Statement: Stereotactic ablative radiotherapy (SABR) for patients with previously irradiated, locally recurrent para-aortic tumours [URN: 1918] [201001P]. (NHS England 2020)
- Clinical Commissioning Policy: Stereotactic ablative radiotherapy (SABR) for patients with metachronous extracranial oligometastatic cancer (All ages) (URN:1908) [200205P]

Committee discussion

The Clinical Panel considered the evidence presented for SABR for patients with previously irradiated, locally recurrent primary pelvic tumours and considered it was sufficient enough to support routine commissioning of SABR in this indication.

See the committee papers considered by CPAG (link) for full details of the evidence.

The condition

A variety of primary tumours may arise in the pelvic region, most common are colorectal, prostatic, bladder and gynaecological cancer. At initial presentation, these tumours will be treated according to tumour specific protocols that may include a combination of different treatments including radiotherapy. Most people with tumours in the pelvis will receive external beam radiotherapy whereby radiotherapy is given by a machine outside of the body, however, some people may have pieces of radioactive material placed inside the body near the cancer (known as brachytherapy). After initial treatment with radiotherapy, primary tumours in the pelvis can recur in the pelvic region (locally recurrent), requiring further treatment.

Current treatments

There are two main treatment options for people with previously irradiated, locally recurrent primary pelvic tumours – systemic therapy and/or surgery. Systemic therapy is usually adopted with palliative intent, however, in the absence of widespread disease, this can lead to increased toxicity with low potential for keeping the disease under control.

Surgery offers a curative treatment option for some people with gynaecological, colorectal and urological cancers, however, it may be impossible given the proximity of the recurrence to neuro-vascular structures, concerns regarding the chances of complete resection, or because of concerns over the extent of radiation-induced fibrosis in the treated area (Schmidt et al. 2012, Murray et al. 2017).

Where surgery with curative intent is possible, exenterative surgery, removing multiple organs and sometimes bones from the pelvis, can be performed. However, extensive surgery of this nature can result in hospital stay of several weeks and almost half of patients being re-admitted

post discharge with complications such as infection or bleeding (Katory et al. 2017). In the long-term patients may be left with permanent urinary diversion or colostomy, which has been shown to have a detrimental effect on quality of life and psychological outcomes (Dessole et al 2018, Harji et al 2016).

Exenterative surgery is not an option for all patients and success rates of treatment are very much related to multi-disciplinary team discussion and case selection. It is estimated that approximately 80% of people suitable for exenteration proceed with surgery (Young et al, 2014). Five-year survival after the operation is reported to be between 21 and 64% (Berek and Hacker, 2010). In addition, some patients will suffer a recurrence after surgery meaning systemic therapy in a palliative setting is then often required.

Proposed treatments

SABR is a form of hypofractionated external beam radiotherapy. The treatment limits the volume of normal tissue exposed to radiation (in comparison to conventional radiotherapy), potentially minimising toxicity and increasing local control. In addition, it is thought that SABR may prolong survival and improve symptom control.

SABR would offer an alternative treatment option for people with previously irradiated, locally recurrent primary pelvic tumours eligible for treatment with systemic therapy, delaying or in some cases avoiding completely the use of these medicines in this indication. 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. See Figure 1 which describes the proposed patient pathway.

Epidemiology and needs assessment

Primary tumours in the pelvis can occur in a number of different locations including the prostate, bladder, gynaecological organs and the bowel. In 2016 in England, there were: (i) 40,489 cases of newly diagnosed prostate cancer; (ii) 8,437 cases of newly diagnosed bladder cancer; (iii) just over 18,100 cases of gynaecological cancers; and (iv) approximately 40,000 cases of bowel cancer (Cancer Research UK, 2019).

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 (KiTEC, 2019). 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 (80 patients).

It is therefore 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.

Evidence summary

NHS England has concluded that there is sufficient evidence to support a policy for the routine commissioning of this treatment for the indication.

Evidence Review

Following a systematic search of medical databases, 3 studies were identified which met the inclusion criteria for this review. These included:

- 1 systematic review reporting on pelvic tumours (Murray et al, 2017); and
- 2 non-comparative cohort studies on prostate cancer (Loi et al, 2018; Miszczyk et al, 2018).

The strongest evidence came from the systematic review, although study did not report pooled analyses or patient level data. Murray et al (2017), reporting on 205 patients with pelvic tumours, found that SABR delivered local control rates at 1-year ranging from 51-100%. Overall survival ranged from 11.5-14 months (1-year survival was 46-52%). SABR was generally well tolerated with grade 3-4 toxicities occurring in 13 patients (6.3%). The systematic review included small retrospective case series of between 3 and 31 patients.

For the studies focusing on prostate cancer, local control ranged from 82-86%, while grade 3-4 genitourinary and gastrointestinal toxicities were seen in 3.7% and 2% of patients, respectively. Loi et al (2018) reported biochemical relapse free survival at 1-year of 80%.

There are severe limitations to the evidence for SABR re-irradiation with no published comparative studies and very high levels of heterogeneity in patient population and intervention among the studies. Furthermore, outcomes such as local control, progression free survival, and pain response are reported in different ways.

Commissioning through Evaluation (CtE) Report

Between 2015 and 2018, the CtE scheme collected outcomes from 203 (185 undergoing pelvic and 18 spinal re-irradiation) patients recruited from 8 centres nationally. From these 149 patients had their data also linked to the Hospital Episode Statistics (HES) and Office for National Statistics (ONS) registries. The median age of patients was 68 and 60 years, respectively, and most (61.1%) were men. The cohort undergoing pelvic re-irradiation was mainly comprised of patients with prostate (39.5%) and colorectal cancer (28.6%). Approximately half of the patients (49.19%) undergoing pelvic re-irradiation were treated with Cyberknife. Cone beam CT (CBCT) image guidance was the most commonly used technique to assist treatment delivery in this patient cohort.

The analysis of people treated under the CtE scheme reported median overall survival (OS) >24 months for both cohorts. The 1-year actuarial OS was 92.0% (95%CI 86.0-95.5%) for people undergoing pelvic re-irradiation. Results were higher than the OS targets proposed at the beginning of the CtE scheme (1-year target = 60% for both cohorts). In addition, the CtE analysis reported a 2-year OS estimate for people undergoing pelvic re-irradiation at 71.9% (95%CI 60.5-80.5%). The literature does not provide an estimate of 2-year OS for pelvic re-irradiation, therefore, the CtE data is the only evidence available.

The findings of the CtE scheme on the effect of SABR in OS of patients undergoing pelvic re-irradiation, is partially supported by low quality evidence, mainly from retrospective single centre case series. This study reported median OS between 11.5-40 months for people undergoing pelvis re-irradiation respectively.

The CtE data analysis also reported local control (LC) rates at 1-year of 75.8% (95%CI 66.7-82.7%) for people undergoing pelvic re-irradiation. Results were higher than the local control targets proposed at the beginning of the CtE scheme (1-year target = 50%). The results are in accordance with the range of LC outcomes reported in the literature. These studies reported a 1-year local control between 51.4-100% for pelvis re-irradiation.

The CtE data analysis reported grade 3 toxicity of 3.8% (95%CI: 1.5 to 7.6%) for people undergoing pelvic re-irradiation which is within than the proposed target of 20%. No grade 4 or 5 toxicity was reported which is lower than the target set of 5%. The CtE findings are supported from low quality evidence from the literature that reports low rates of grade 3 toxicity and absence of grade 5 events. The combined findings from the CtE and the published literature, provide low quality evidence that SABR can achieve LC and can be delivered without severe toxicity.

Data on quality of life (QoL) were available for 169 (83%) patients at baseline. Due to the low number of people undergoing spinal re-irradiation, both CtE cohorts were analysed together. According to the summary analysis, the majority of patients did not report issues at baseline and

during follow-up. Data completeness decreased over time with approximately 50% and 20% of the patients returning their questionnaires at 12 and 24 months, respectively.

Data on pain scores were available for 185 (91%) patients at baseline. According to the summary analysis, the majority of patients (70%) of patients did not report any pain at baseline. This proportion remained stable until 18 months of follow-up and decreased in the final follow-up time point (24 months) by approximately 15 points. This finding is in agreement with the analysis of the QoL pain/discomfort dimension that reported a small increase of people reporting worsening symptoms between baseline and last follow-up (9%). Data completeness decreased over time with approximately 50% and 20% of the patients returning their questionnaires at 12 and 24 months, respectively. For both QoL and pain scores, the analysis assumed that missing data have a random distribution and do not introduce bias. Based on the providers' feedback, however, often missing data are associated with a decline in the patient's performance status and clinical condition. There is, therefore, a lot of uncertainty about the QoL and pain conclusions and the results should be interpreted with caution.

In the published evidence, pain control rates are reported between 50-100% for pelvis. The included studies report good safety outcomes with SABR, with crude rates of vertebral body fracture ranging from 4.5%-22% and a symptomatic radiation induced myelopathy rate of 1.2%. These results provide low quality evidence that SABR re-irradiation does not lead to severe toxicity. The results reported have a high degree of variability and there is an absence of comparative data and thorough long-term follow-up. There is absence of quality of life outcomes, and of outcomes in children.

According to the patient experience questionnaire, 93% of CtE people undergoing pelvic reirradiation were extremely likely or likely to recommend the SABR service to their friends and family.

The cost-effectiveness analysis found that for adult patients undergoing pelvic re-irradiation following recurrence of cervical or colorectal cancer, SABR results in more QALY gains and lower cost compared to pelvic exenteration, indicating SABR is the more cost-effective intervention. The finding needs to be interpreted carefully in the light of limitations in the available data on exenteration and the comparability of the cohort undergoing SABR with patients undergoing exenteration in the literature. If, as seems likely, it is reasonable to assume that outcomes in patients amenable to surgical exenteration would be improved, the analysis is likely to be conservative with respect to SABR and would support a role for SABR instead of exenteration for patients in which surgery is feasible.

The main limitation of the current evidence (including the analysis of the CtE data) is that no comparative data exists, therefore, the clinical efficacy and safety of SABR versus standard care is unknown. The main implication from the available evidence is that the use of SABR in people undergoing pelvic re-irradiation can lead to increased local control without an increase in severe toxicity.

Implementation

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. 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, any targeted therapies or systemic treatment consideration should be given to discontinuing targeted systemic chemotherapy and individualised for each patient's specific situation prior to SABR; concurrent hormone treatment is however permitted.

Inclusion Criteria

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

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

Exclusion criteria

Treatment with SABR is not suitable in people:

- With previously irradiated pelvic bone metastases or spinal metastases;
- Receiving concurrent targeted therapies or systemic therapies;
- In whom less than 6 months have elapsed since initial radiation treatment; or
- With a life expectancy of less than 6 months.

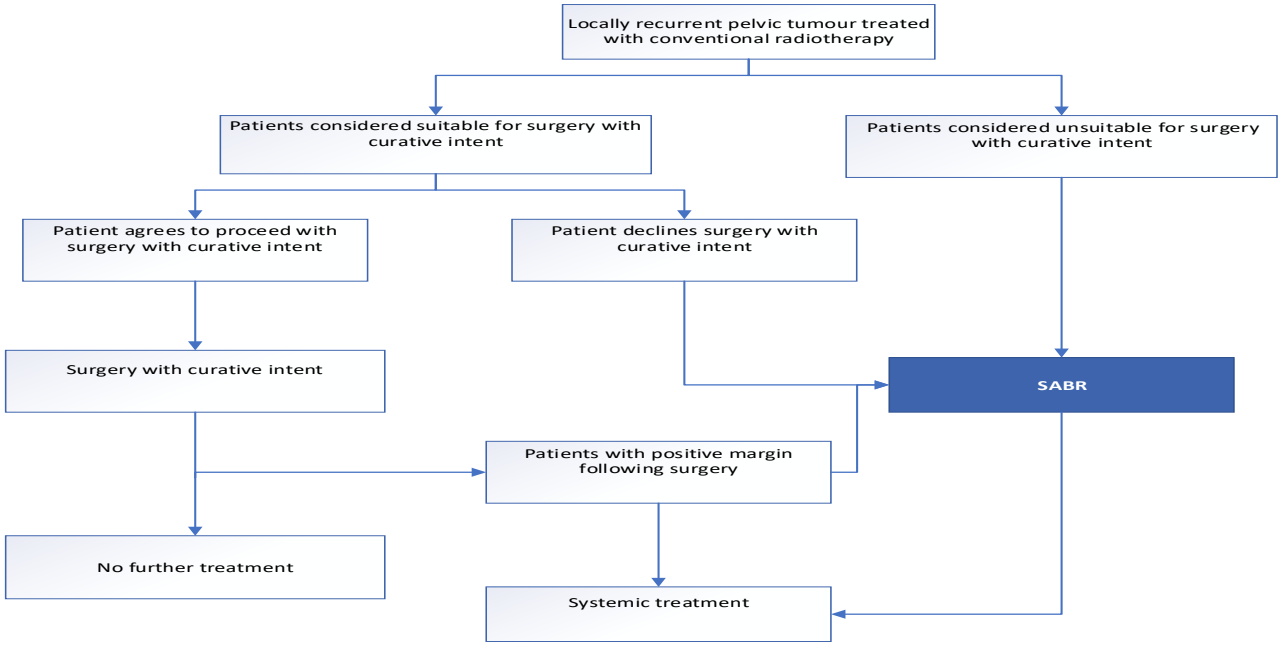
Dose and fractionation

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.

Patient pathway

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.

Figure 1: Proposed Patient Pathway



Governance arrangements

The Service Specification for External Beam Radiotherapy (NHS England Reference: 170091S) describes the governance arrangements for this service. It is imperative that the radiotherapy service is fully compliant with this Service Specification and in particular, 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. British Standards Institution) in place.

All providers must satisfy national quality assurance requirements for contouring and outlining.

Mechanism for funding

Radiotherapy planning and delivery is reimbursed through both national prices and nationally consistent local prices as part of the National Tariff Payment System.

Audit requirements

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.

Radiotherapy services are subject to regular self-assessment by the national Specialised Commissioning Quality Surveillance. The quality system and its treatment protocols will be subject to regular clinical management and audit as part of the development of radiotherapy networks in England.

Policy review date

This document will be reviewed when information is received which indicates that the policy requires revision. If a review is needed due to a new evidence base then a new Preliminary Policy Proposal needs to be submitted by contacting england.CET@nhs.net.

Our policies provide access on the basis that the prices of therapies will be at or below the prices and commercial terms submitted for consideration at the time evaluated. NHS England reserves the right to review policies where the supplier of an intervention is no longer willing to supply the treatment to the NHS at or below this price and to review policies where the supplier is unable or unwilling to match price reductions in alternative therapies.

Definitions

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).
Cancer	A disease in which cells, almost anywhere in the body, begin to divide uncontrollably.
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.
Fractionation/Fractions	A term describing how the full dose of radiation is divided into a number of smaller 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.
Hypofractionated/hypofractionation	Describes a treatment regimen that delivers high doses of radiation using a shorter number of treatments as compared to conventional treatment regimens.
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.
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.
Primary cancer	Defined as the original site at which the cancer began.
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	A cancer treatment that uses high dose radiation to kill cancer cells.
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.
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.
Stereotactic Ablative Radiotherapy (SABR)	Refers to the irradiation of an image defined extra cranial lesion and is associated with the use of high radiation dose delivered in a small number of fractions. The technique requires specialist positioning equipment and imaging to confirm correct targeting. It allows sparing of the healthy normal tissues.
Systemic therapy/chemotherapy	Treatment, usually involving chemotherapy or hormone treatment, which aims to treat the whole body.
Tumour	Abnormal cells that form lumps or growths usually in organs, muscle or bone. Tumours can grow and behave differently depending on whether they are cancerous (malignant) or non-cancerous (benign). Tumours may spread to surrounding tissues through the blood and lymph systems.
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.

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