

Clinical Commissioning Policy: Hypofractionated external beam radiotherapy in the treatment of localised prostate cancer (adults)

Reference: NHS England: 170021/P



NHS England INFORMATION READER BOX

Directorate		
Medical	Operations and Information	Specialised Commissioning
Nursing	Trans. & Corp. Ops.	Commissioning Strategy
Finance		

Publications Gateway Re	ference: '06331	
Document Purpose	Policy	
Document Name	Clinical Commissioning Policy: Hypofractionated external beam radiotherapy in the treatment of localised prostate cancer (adults)	
Author	Specialised Commissioning Team	
Publication Date	20 October 2017	
Target Audience	CCG Clinical Leaders, Care Trust CEs, Foundation Trust CEs, Medical Directors, Directors of PH, Directors of Nursing, NHS England Regional Directors, NHS England Directors of Commissioning Operations, Directors of Finance, NHS Trust CEs	
Additional Circulation List		
Description	Routinely Commissioned - NHS England will routinely commission this specialised treatment in accordance with the criteria described in this policy.	
Cross Reference		
Superseded Docs (if applicable)		
Action Required		
Timing / Deadlines (if applicable)		
Contact Details for further information	england.specialisedcommissioning@nhs.net	

Document Status

This is a controlled document. Whilst this document may be printed, the electronic version posted on the intranet is the controlled copy. Any printed copies of this document are not controlled. As a controlled document, this document should not be saved onto local or network drives but should always be accessed from the intranet.

Clinical Commissioning Policy: Hypofractionated external beam radiotherapy in the treatment of localised prostate cancer (adults)

First published: October 2017

Prepared by NHS England Specialised Services Clinical Reference Group for Radiotherapy

Published by NHS England, in electronic format only.

1	Introduction	9
2	Definitions	10
3	Aims and Objectives	12
4	Epidemiology and Needs Assessment	12
5	Evidence Base	13
6	Criteria for Commissioning	19
7	Patient Pathway	20
8	Governance Arrangements	21
9	Mechanism for Funding	21
10	Audit Requirements	21
11	Documents which have informed this Policy	22
12	Date of Review	22
Ref	erences	23

Policy Statement

NHS England will commission hypofractionated external beam radiotherapy in the treatment of localised prostate cancer in accordance with the criteria outlined in this document.

In creating this policy NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population in England.

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 prostate cancer

The prostate is a small gland located at the base of the bladder. Prostate cancer only affects people with a prostate, this means that this policy applies to males that have a prostate, transgender women and intersex individuals. The condition usually develops very slowly meaning that there may be no signs of the cancer for many years. It is the most common cancer affecting men in the UK, with 41,736 new cases in 2011 (Cancer Research UK, 2017).

When prostate cancer is diagnosed it is 'staged', this provides an indication of how large the cancer is and how far it has spread and helps to identify the best treatment for patients. Where prostate cancer is diagnosed at an early stage, which means that it is completely contained (or 'localised') within the prostate and has not spread anywhere else in the body, the chances of survival are generally good, with almost all people surviving 5 years or more after diagnosis. Since the introduction of prostate-specific antigen (PSA) testing, most prostate cancer cases are now diagnosed at an early stage (Cancer Research UK, 2017).

About current treatments

Management options for prostate cancer include different types of radiotherapy (external-beam radiotherapy and brachytherapy), surgery (called 'radical prostatectomy') or active surveillance. Treatment choice is determined by individual patient preference, stage of cancer and overall health status. As well as being staged, localised prostate cancer is also risk assessed into three groups, high, intermediate and low. These risk categories also play a role in determining the best treatments and overall management plan for patients.

All prostate cancer treatments are associated with side-effects. Prostate cancer, and its treatment, are the leading cause of cancer years lived with disability. This is because prostate cancer is a common cancer and because men with localised disease usually have a long life expectancy. Management plans and treatment

choices are often influenced by the potential treatment-related toxicities and sideeffects.

About the new treatment

Radiotherapy is the safe use of ionising radiation to kill cancer cells with the aim of cure or effective symptom relief (called 'palliation'). It is not a new treatment for prostate cancer. Hypofractionated radiotherapy is a new way of delivering external beam radiotherapy treatments that involves the safe delivery of the overall dose of radiation in fewer daily treatments. This means that each daily fraction of treatment requires the delivery of a larger dose of radiation as compared to usual (or 'conventional') external beam radiotherapy treatment.

What we have decided

NHS England has carefully reviewed the evidence to treat localised prostate cancer with hypofractionated external beam radiotherapy and have concluded that there is sufficient evidence to make the treatment available, alongside other nonradiotherapy treatment options for localised prostate cancer.

1 Introduction

Radiotherapy is the safe use of ionising radiation to kill cancer cells with the aim of cure or effective palliation. The aim of radiotherapy is to deliver as high a dose of radiation as possible to the cancerous tumour/s, whilst sparing the surrounding normal tissues. Radiotherapy is often used on its own or as part of a treatment plan which may also include surgery, hormonal treatment or chemotherapy

External beam radiotherapy is generally delivered by a megavoltage machine, usually a Linear Accelerator, which is a generic term for all megavoltage radiotherapy equipment. Hypofractionation describes a treatment regimen that delivers high doses of radiation using fewer treatments as compared to conventional treatment regimens.

Hypofractionated external beam radiotherapy for the treatment of localised prostate cancer uses larger than conventional fraction sizes (more than 2Gy) usually delivered over a shorter overall treatment time, for example, 60Gy in 20 daily fractions of 3Gy over 4 weeks. Conventionally fractionated radiotherapy is defined as 2Gy per day up to a usual dose of at least 74Gy in 37 daily fractions over 7 $\frac{1}{2}$ weeks.

Prostate cancer is the most common cancer in men in the UK, with 41,736 new cases in 2011 (Cancer Research UK, 2017). Since the introduction of prostate-specific antigen (PSA) testing, most cases are diagnosed with localised disease.

Management options include external beam radiotherapy, brachytherapy, radical prostatectomy, active surveillance (for low-risk disease) and watchful waiting (for those unsuitable for radical curative treatment). External-beam radiotherapy is most appropriate for cases of intermediate or high risk disease (National Comprehensive Cancer Network, 2011).

All prostate cancer treatments are associated with side-effects. Prostate cancer and its treatment are the leading cause of cancer years lived with disability (Soerjomataram et al., 2012) because prostate cancer is both common and has

good prospects of long-term survival post diagnosis and treatment. Management plans and treatment choices are often influenced by potential treatment-related toxicities.

2 **Definitions**

The prostate - is 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. Prostate cancer can only develop in people that have a prostate. This means that this policy applies to males that have a prostate, transgender women and intersex individuals.

The main function of the prostate is to help in the production of semen. It produces a thick white fluid that is mixed with the sperm produced by the testicles, to create semen.

Localised Prostate Cancer - is defined as disease which is confined to the prostate gland and immediate surrounding area including the seminal vesicles.

Risk – localised prostate cancer is grouped into low, intermediate and high risk categories. The risk category influences how the prostate cancer is managed. This assessment is based on tumour extent ("T" stage), histological architecture (Gleason score) and Prostate Specific Antigen level.

Low risk localised prostate cancer – is unlikely to grow or spread for many years and generally is diagnosed where all of the following factors are present:

- PSA level less than 10 ng per ml;
- Gleason score no higher than 6;
- T stage of between T1 and T2a (National Comprehensive Cancer Network 2016)

Intermediate risk localised prostate cancer – is unlikely to grow or spread for a few years and generally is diagnosed where one or more of the following factors is present:

- PSA level between 10 and 20 ng/ml
- Gleason score of 7;
- T stage of T2b and T2c (National Comprehensive Cancer Network 2016)

High risk localised prostate cancer – may grow or spread within a few years and generally is diagnosed where any one of the following factors is present:

- PSA level higher than 20 ng/ml;
- Gleason score between 8 and 10; and
- T stage of equal to or greater than T3 (National Comprehensive Cancer Network 2016)

Radiotherapy - is the safe use of ionising radiation to kill cancer cells with the aim of cure or effective palliation.

External beam radiotherapy - is delivered by a linear accelerator, which focuses high-energy radiation beams onto the area requiring treatment.

Fractionation – is the 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.

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

Alpha/Beta (a/b) Ratio – describes the curvature for a cell survival curve for a particular tissue type which usefully predicts which pattern of radiotherapy fractionation should be used to maximise tumour sensitivity whilst sparing normal tissue.

Image Guided Radiotherapy (IGRT) - Imaging at pre-treatment and delivery, the result of which is acted upon, that improves or verifies the accuracy of radiotherapy.

IGRT encompasses the whole range of imaging, from simple to more complex imaging, that allows direct visualisation of the tumour and surrounding tissue.

Gray (Gy) is the international system (SI) unit of radiation dose. One gray is the absorption of one joule of energy, in the form of ionizing radiation, per kilogram of matter

Conventionally fractionated radiotherapy - is defined as 2Gy per day up to a usual dose of at least 74Gy in 37 daily fractions over 7 ½ weeks.

Hypofractionated external beam radiotherapy – describes a treatment regimen that uses larger than conventional fraction sizes (more than 2Gy) usually delivered over a shorter overall treatment time e.g. 60Gy in 20 daily fractions of 3Gy over 4 weeks.

Intensity modulated radiotherapy (IMRT) - is a type of conformal radiotherapy (a type of external beam radiotherapy). Conformal radiotherapy shapes the radiation beams to fit the area of the cancer; IMRT sculpts this shape even more precisely. Volumetric modulated arc therapy (VMAT) – is a form of IMRT.

3 Aims and Objectives

This policy considered: Hypofractionated external beam radiotherapy, as part of the treatment pathway for adult patients with localised prostate cancer.

The objectives were to establish via an evidence review the following: Efficacy, safety and toxicity profile of hypofractionated radiotherapy compared with conventional radiotherapy in the treatment of localised prostate cancer.

4 Epidemiology and Needs Assessment

Epidemiology

Prostate cancer is the most common cancer in men in the UK, with 41,736 newly diagnosed cases in 2011(Cancer Research UK, 2017). Prostate cancer can only

develop in people that have a prostate, this means that it can affect males that have a prostate, transgender women and intersex individuals.

Needs Assessment

The national Radiotherapy Dataset (RTDS) records radiotherapy activity; data contained within RTDS identifies that approximately 13,000 patients receive radical prostate external beam radiotherapy every year in England (RTDS, 2015). Of those patients currently receiving radical prostate external beam radiotherapy, at least 70% are suitable for hypofractionated external beam radiotherapy, in accordance with the clinical eligibility criteria.

The needs assessment is based on expert clinical consensus because not all patients receiving radical prostate external beam radiotherapy, as reported within RTDS, would be eligible for hypofractionated radiotherapy. The ineligible groups are: (i) patients requiring treatment to the prostate and pelvic nodes (i.e., not localised); and (ii) patients that require both brachytherapy and external beam radiotherapy. RTDS does not currently routinely report this level of clinical detail.

5 Evidence Base

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

An evidence review was undertaken to assess the evidence for the use of hypofractionated external beam radiotherapy in the treatment of prostate cancer. Four large randomised trials have been reported in the last 12 months. All reported efficacy outcomes as well as toxicity profiles:

The CHHiP trial (Dearnaley et al., 2016; Wilkins et al., 2015; Dearnaley et al., 2012) randomised 3,216 men, with low, intermediate and high risk disease, to receive either conventional fractionated radiotherapy (CFRT) delivering 74Gy in 37 fractions over 7.4 weeks compared with hypofractionated radiotherapy (HFRT) 60Gy/20 fractions over 4 weeks or 57Gy/19 fractions over 3.8 weeks. It tested the hypothesis that HFRT is non-inferior for efficacy compared with CFRT.

- The PROFIT trial (Catton et al., 2017) randomised 1206 men with intermediate risk disease. They received CFRT of 78Gy delivered in 39 fractions over 8 weeks or HFRT 60Gy delivered in 20 fractions over 4 weeks. This tested the hypothesis that HFRT is non-inferior for efficacy compared with CFRT.
- The RTOG 0415 trial (Lee et al., 2016) randomised 1092 men with low risk disease comparing daily schedules of 73.8Gy delivered in 41 fractions with 70Gy delivered in 28 fractions. This tested the hypothesis that HFRT is noninferior for efficacy compared with CFRT in men.
- The HYPRO trial (Inrocci et al., 2016; Aluwini et al., 2016; Aluwini et al., 2015) randomised 804 men with intermediate and high risk prostate cancer to receive either CFRT of 78Gy delivered over 39 fractions in 8 weeks or HFRT with 64Gy delivered over 19 fractions in 6.5 weeks. This tested the hypotheses that dose-escalated HFRT was superior to CFRT but without increasing side-effects.

Survival outcomes

The CHHiP trial (Dearnaley et al., 2016) reported that after a median follow-up of 62 months the proportion of patients who were biochemical/clinical failure free at 5 years was:

- 74 Gy 88.3% (95% confidence interval 86.0-90.2);
- 60 Gy 90.6% (88.5-92.3);
- 57 Gy 85.9% (83.4-88.0).

60Gy was shown to be non-inferior to 74Gy (hazard ratio 0.84) but non-inferiority could not be claimed for 57Gy (hazard ratio 1.20). There was no heterogeneity of effect for different risk groups. Overall survival was similar between CFRT and HFRT groups; of 252 deaths reported, only 16% were prostate cancer related.

The improvement in 5-year disease control for a 3 Gy dose difference between the 57 Gy and 60 Gy groups is in keeping with a review of the six randomised controlled dose-escalation trials previously reported- and a recent meta-analysis of biologically equivalent dose escalation. However patients aged over 75yrs were shown to have a

very good efficacy (PSA control) outcome with both 60 and 57Gy in comparison with 74Gy.

The PROFIT (Catton et al., 2017) trial primary end point was biochemical-clinical failure: the critical hazard ratio for non-inferiority was 1.32. The median follow-up was 6.0 years. The 5 year biochemical-clinical failure event rate was 21% in both groups (hazard ratio 0.96).

The estimated 5 year disease-free survival in RTOG 0415 (Lee et al., 2016) was 85% for CFRT and 86% for HFRT (hazard ratio 0.85). The cumulative incidence of biochemical recurrence at 5 years was 8% and 6% in the CFRT and HFRT groups, respectively (hazard ratio 0.77). Both end points met the protocol-specified non-inferiority criterion (hazard ratio<1.52, P< 0.001). Overall 5 year estimated survival was similar at 93%. Deaths were most commonly due to cardiovascular disease and second cancers. The HFRT schedule was non-inferior to CFRT.

In the HYPRO trial the proportion of patients free of biochemical/clinical failure at 5 years was 81%/ 77% (hazard ratio 0.86; P=0.36) for HFRT/CFRT groups, respectively (Inrocci et al, 2016).

Genitourinary and Gastrointestinal toxicity outcomes

In the CHHiP study (Dearnaley et al., 2016; Dearnaley et al., 2012), acute Radiation Therapy Oncology Group bowel and bladder symptoms peaked sooner with HFRT schedules (4 - 5 weeks) than CFRT (7 - 8 weeks). There was a higher proportion of grade 2 peak gastrointestinal toxicity in both HFRT groups (CFRT 25%: HFRT 38%; P < 0.0001). By 18 weeks both bowel and bladder toxicity was similar for CFRT/HFRT. There were no differences in long-term side-effects between CFRT and HFRT groups in either the proportion or cumulative incidence of patients reporting grade 2 gastrointestinal/genitourinary toxicity at 5 years (cumulative incidence: 74Gy: 13.7%/9.1%; 60Gy: 11.9%/11.7%; 57Gy: 11.3%/6.6%). There was a slightly higher rate of grade 2 gastrointestinal/genitourinary side-effects in the 60Gy group compared with 57Gy at 2 and 5 years. Patient reported outcomes suggest an overall low incidence of gastrointestinal and genitourinary symptoms in all treatment groups (Wilkins et al., 2015). The PROFIT trial (Catton et al., 2017) reported acute genitourinary/gastrointestinal toxicity as similar in both arms of trial, based on the abstract review. However, late gastrointestinal toxicity favoured the 60Gy arm (grade 2 CFRT 14%: HFRT 9%; P=0.006).

In the RTOG 0415 trial (Lee et al., 2016) the reported results for toxicity show acute gastrointestinal/genitourinary side-effects were similar in the randomised groups. Late grade 2 gastrointestinal/ genitourinary adverse events were increased with hypofractionation (HFRT 22%/30%: CFRT 14%/23%).

In the HYPRO trial (Aluwini et al., 2015) grade 2 acute bowel toxicity was higher with hypofractionation (CFRT 31%; HFRT 42%; P=0.0015) although the difference disappeared three months after radiotherapy and there was no difference in bladder toxicity. The cumulative grade 3 late genitourinary toxicity (Aluwini et al., 2016) was higher with hypofractionation (HFRT 19%, CFRT 13%; P=0.02) but the incidence of grade 2 bowel toxicity at 3 years was similar (CFRT 18%, HFRT 22%). The study did not demonstrate that HFRT was non-inferior for either acute or late genitourinary/gastrointestinal toxicity compared with CFRT.

Radiobiological interpretation

The CHHiP trial suggests that 60Gy in 20 fractions is equivalent to about 76Gy/38 fractions - very like the 78Gy/39 fractions in PROFIT. The identical outcomes in the two arms of the PROFIT study are ideal for calculating the a / b ratio for prostate cancer. Using the outcomes at 5 years the a/b ratio is estimated as 1.3Gy, which is slightly lower than the estimate from the CHHiP trial of 1.8Gy which used ADT in most patients (Dearnaley et al., 2017).

The HYPRO study had a hypofractionated schedule designed to be equivalent to 90.4Gy in 2Gy/fraction (assuming a/b of 1.5Gy) compared with 78Gy/39 fractions for CFRT, yet the increase in outcome at 5 years was only 3.4%. The schedule was protracted by delivering three fractions per week and it may be that the effect of overall treatment time contributed, with the course taking 6.5 weeks as shown in table 1. Similarly the hypofractionated arm of the RTOG 0415 trial might also have

been expected to result in less biochemical failures than the standard arm (assuming a low a/b ratio), yet there is only a 2% increase in prostate-specific antigen control at 5 years (Dearnaley et al., 2016b).

Clinical predictors for adverse events and/or relapse

The HYPRO trial results show that a strong independent predictor of relapse was high risk (>25%) of seminal vesicle involvement. Conversely the authors also report lower failure rates for the HFRT group in patients with a Gleason score <6. The authors have also published a single abstract (Wortel et al., 2016) noting that sexual function outcomes, including erectile deterioration and orgasmic function, were similar between both arms of the study and that no statistically significant differences between the HFRT and CFRT groups were observed.

For genitourinary and gastrointestinal toxicity a number of the studies reported statistically significant results following treatment for those patients reporting toxicity at baseline. In particular, the study by (Pollack et al., 2013) concluded that the hypofractionation regimen used is most appropriate for men without "substantial baseline urinary dysfunction". The RTOG 0415 trial also noted that patients with large prostates may be at higher risk of adverse events (Lee et al., 2016). A major caveat is that none of the studies was specifically designed to address some of these specific clinical sub-grouping questions. Further refinement of study designs and sub-group analyses are needed to address these questions more robustly.

Summary

- The largest and most generalizable study to NHS practice is the CHHiP trial which randomised 3,216 patients to receive either conventional fractionated radiotherapy (CFRT) at 74Gy delivered in 37 fractions over 7.4 weeks, hypofractionated radiotherapy (HFRT) 60Gy/20 fractions over 4 weeks or 57Gy/19 fractions over 3.8 weeks.
- The CHHiP study confirms that the 60Gy/20 fractions schedule is safe and effective when compared to the CFRT with 90.6% of patients biochemical/clinical failure free at 5 years compared to 88.3% in the CFRT

group. 60Gy was shown to be non-inferior, hazard radio 0.84 compared to the CFRT group at 5 years.

- There was no difference in long term genitourinary and gastrointestinal side effects at 5-years, although data showed acute, short-lasting side effects peaked sooner in the HFRT group at 4-5 weeks.
- Evidence from the CHHiP trial shows that treatment of the prostate with seminal vesicles is safe and effective at 60Gy/20. The PROFIT trial has used the same HFRT schedule as CHHiP and results further demonstrate noninferiority compared to CFRT.
- All patient subgroups (NCCN low, intermediate and high risk) can be considered for HFRT. The evidence is most robust for the intermediate risk group, but no heterogeneity of effect has been shown between risk groups.
- Presently the safety data related to high dose HFRT for the treatment of pelvic lymph nodes is limited and the recommendation for hypofractionation relates to radiotherapy for prostate +/- seminal vesicles alone (the most usual indication). It is presently uncertain whether it is possible to identify some patients with troublesome urinary/bowel symptoms pre-radiotherapy who may be unsuited to HFRT.

Conclusion

Hypofractionated radiotherapy has been shown to be both safe and effective when delivered at 60Gy / 20 fraction schedule over a four week period when compared to conventional radiotherapy.

Intensity modulated radiotherapy techniques with strict normal tissue dose constraints should be used and image guidance techniques recommended to reduce side effects.

Long term follow-up of phase 3 studies is recommended to determine if differences between radiotherapy schedules become apparent after 10 years or more. Evaluation of clinical and biological parameters to predict outcome (efficacy and side effects) on an individual patient basis is encouraged.

6 Criteria for Commissioning

All patients with prostate cancer should have their care managed by a variety of different specialists working together as part of a tumour specific cancer Multi-Disciplinary Team (MDT). This includes Urologists, Clinical and Medical Oncologists, specialist nurses, Therapeutic Radiographers, Radiologists and Pathologists.

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

Eligibility Criteria

Patients meeting the following criteria should be considered for hypofractionated radiotherapy:

1. Low risk localised prostate cancer which is suitable for treatment with external beam radiotherapy rather than active surveillance, brachytherapy or radical prostatectomy.

 Intermediate risk localised prostate cancer which is suitable for treatment with external beam radiotherapy rather than radical prostatectomy or brachytherapy.
High risk localised prostate cancer where the target volume is limited to the prostate and seminal vesicles.

Exclusion criteria

Where the target volume also includes the pelvic lymph nodes, involved seminal vesicles (T3b) or in post-prostatectomy patients, conventional external beam radiotherapy using 1.8Gy–2.0Gy daily fractions may be used to a total dose appropriate for the patients' condition e.g. 64Gy-70 Gy post-prostatectomy or 74Gy-78 Gy for locally advanced disease involving seminal vesicles. Combined external beam and brachytherapy techniques may be used where clinically appropriate. Further well designed studies of hypofractionation in these patient groups are encouraged.

Dose and fractionation

The recommended dose and fractionation schedule for the majority of patients will be 60Gy in 20 fractions. In accordance with the CHHiP trial protocol, it is expected that patients will receive 20 fractions of radiotherapy over 27 days.

As with all treatments, there is a balance to be struck between efficacy and toxicity. Some frail patients with a relatively poor life-expectancy may tolerate side effects less well. For such patients the lower dose schedule of 57Gy in 19 fractions with an overall treatment time of \geq 26 days, which is associated with a slightly lower incidence of both bowel and bladder side effects, may be considered.

Additional scientific inquiry is needed to determine if the presence of troublesome pre-radiotherapy bladder or bowel symptoms should be used to modify fractionation recommendations for particular patient groups.

Treatment techniques

Intensity modulated radiotherapy techniques (including VMAT) should be used (forward or inverse planned). In addition, a high level of treatment accuracy using image guidance (IGRT) at appropriate points during the course of treatment is required and dose constraints must be rigorously applied.

7 Patient Pathway

The service specification for radiotherapy (B01/S/a) describes the detail of the care pathways for this service.

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. Patients requiring radiotherapy are referred to a clinical oncologist for assessment, treatment planning and delivery of radiation fractions. Each fraction of radiation is delivered on one visit, usually on an outpatient basis.

8 Governance Arrangements

The service specification for radiotherapy (B01/S/a) describes the governance arrangements for this service. In particular, it is imperative that the radiotherapy service is compliant with the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000.

Clinical Governance systems and policies should be in place and integrated into organisational governance with clear lines of accountability and responsibility for all clinical governance functions and Providers should produce annual Clinical Governance reports as part of NHS Clinical Governance reporting system.

9 Mechanism for Funding

Radiotherapy planning and delivery is reimbursed though national prices included within the National Tariff Payment System.

10 Audit Requirements

Radiotherapy providers must submit their activity to the national Radiotherapy Dataset (RTDS) on a monthly basis. For reporting purposes, it is expected that 70% of prostate cancer patients requiring radical external beam radiotherapy should receive hypofractionated radiotherapy (i.e., ≤20 fractions of treatment).

Where the reporting benchmark is not met (i.e., 70%), reasons must be recorded by the Trust and be shown to be appropriate for the treated case-mix. Providers should be aware that NHS England will audit variation in the rates of treatment courses exceeding 20 fractions using RTDS data.

Radiotherapy services are subject to regular self-assessment by the national Specialised Commissioning Quality Surveillance Team. The Quality System and its treatment protocols will be subject to regular clinical and management audit.

11 Documents which have informed this Policy

- Radiotherapy service specification for radiotherapy (B01/S/a).
- NICE Urology Improving Outcomes Guidance.

12 Date of Review

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

References

Aluwini S, Pos F, Schimmel E, et al. Hypofractionated versus conventionally fractionated radiotherapy for patients with prostate cancer (HYPRO): acute toxicity results from a randomised non-inferiority phase 3 trial. Lancet Oncol 2015; 16: 274–83.

Aluwini S, Pos F, Schimmel E, Krol S, van der Toorn PP, de Jager H, Alemayehu WG, Heemsbergen W, Heijmen B, Incrocci L. Hypofractionated versus conventionally fractionated radiotherapy for patients with prostate cancer (HYPRO): late toxicity results from a randomised, non-inferiority, phase 3 trial. Lancet Oncol. 2016; 17: 464-74.

Cancer Research UK. (2017). Prostate cancer statistics. [online] Available at: http://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/prostate-cancer [Accessed 11 Jan. 2017].

Catton CN, Lukka H, Gu CS, et al Randomized Trial of a Hypofractionated Radiation Regimen for the Treatment of Localized Prostate Cancer.J Clin Oncol. 2017 Mar 15: [Epub ahead of print]

Dearnaley D, Syndikus I, Sumo G, et al. Conventional versus hypofractionated highdose intensity-modulated radiotherapy for prostate cancer: preliminary safety results from the CHHiP randomised controlled trial. Lancet Oncol 2012; 13: 43–54.

Dearnaley D, Syndikus I, Mossop H, et al. Conventional versus hypofractionated high-dose intensity-modulated radiotherapy for prostate cancer: 5-year outcomes of the randomised, non-inferiority, phase 3 CHHiP trial. Lancet Oncol 2016; 17: 1047-1060.

Dearnaley D, Syndikus I, Guilford S, Hall E. Hypofractionation for Prostate Cancer: Time to Change, Clin Oncol (R Coll Radiol). 2017 Jan;29(1):3-5.

Incrocci L, Wortel RC, Alemayehu WG, et al. Hypofractionated versus conventionally fractionated radiotherapy for patients with localised prostate cancer (HYPRO): final

efficacy results from a randomised, multicentre, open-label, phase 3 trial. Lancet Oncol 2016; 17: 1061-1069.

Lee WR, Dignam JJ, Amin MB, Bruner DW, Low D, Swanson GP, Shah AB, D'Souza DP, Michalski JM, Dayes IS, Seaward SA, Hall WA, Nguyen PL, Pisansky TM, Faria SL, Chen Y, Koontz BF, Paulus R, Sandler HM. Randomized Phase III Noninferiority Study Comparing Two Radiotherapy Fractionation Schedules in Patients With Low-Risk Prostate Cancer. J Clin Oncol. 2016; 34:20: 2325-2332.

National Radiotherapy Data Set (NRDS). Personal communication September 2015

National Comprehensive Cancer Network (NCCN), Clinical Practice Guidelines in Oncology for Prostate Cancer. 2011.

National Institute for Health and Care Excellence. Prostate cancer: diagnosis and management Clinical Guideline 175. 2008.

Pollack A, Walker G, Horwitz EM, et al. Randomized trial of hypofractionated external-beam radiotherapy for prostate cancer. J Clin Oncol 2013; 31: 3860–8.

Soerjomataram I, Lortet-Tieulent J, Parkin DM, et al. Global burden of cancer in 2008: a systematic analysis of disability-adjusted life-years in 12 world regions. Lancet 2012; 380: 1840–50.

Wilkins A, Mossop H, Syndikus I, et al. Hypofractionated radiotherapy versus conventionally fractionated radiotherapy for patients with intermediate-risk localised prostate cancer: 2-year patient-reported outcomes of the randomised, noninferiority, phase 3 CHHiP trial. Lancet Oncol 2015; 16: 1605e1616.

Wortel R, Inrocci L. Sexual function after hypofractionated verses conventionally fractionated radiotherapy for prostate cancer: Results of the prospective, randomised phase 3 trial. Journal of Urology 2016. Vol 195. No 4S Supplement.

Zumsteg ZS, Spratt DE, Pei I, Zhang Z, Yamada Y, Kollmeier M, Zelefsky MJ. A new risk classification system for therapeutic decision making with intermediate-risk prostate cancer patients undergoing dose-escalated external-beam radiation therapy. Eur Urol 2013 Dec; 64(6): 895-902.