West Midlands Radiotherapy Clinical Protocol

Radiotherapy Prostate Protocol

Revision history

Version	Date	Summary of changes
1.0	2.07.21	Ratified EAG
2.0	14.2.25	Ratified by EAG
3.0	11.9.26	Bladder constraints corrected (March 2025); peer review section amended (July 2026); Pre-treatment section amended (Sept 2026)
Review Date:	September 2028	

Ratification

This document was ratified by the Radiotherapy Expert Advisory Group (EAG) at its September 2026 meeting.

Contents

1. INTRODUCTION 3
2. PURPOSE 3
3. RESPONSIBILITY 3
4. DIAGNOSIS AND STAGING 4
5. RISK STRATIFICATION GROUPS 6
6. PRE-TREATMENT 6
   6.1. Information and Consent 6
   6.2. Clinical Trials 6
   6.3. Patient preparation 7
   6.4. Planning technique 7
   6.5. Target Volume Delineation 7
7. TREATMENT TECHNIQUE AND DOSE PRESCRIPTION 7
8. PROSTATE AND SEMINAL VESICLES RADIOTHERAPY 8
   8.1. Target Volume Delineation 8
   8.2. Dose and Fractionation 10
   8.3. Definitions of PTVs for Dose Reporting Planning Approach 1 10
   8.4. Planning Approach 2 12
9. PROSTATE, SEMINAL VESICLES AND PELVIC NODES 13
   9.1. Target Volume Delineation 13
   9.2. Margins 13
   9.3. Dose and Fractionation[7] 14
10. ANDROGEN DEPRIVATION THERAPY (ADT) AND RADIOTHERAPY (RT)[7] 14
11. PROSTATE BED RADIOTHERAPY WITH OR WITHOUT PELVIC NODAL COVERAGE 15
12. BRACHYTHERAPY BOOST 16
13. HORMONAL SENSITIVE LOW VOLUME METASTATIC PROSTATE CANCER 16
14. PALLIATIVE RADIOTHERAPY 17
15. OTHER CLINICAL SCENARIOS 17
16. DEFINITION OF ORGANS AT RISK 18
17. DOSE VOLUME CONSTRAINTS[11,12] 18
   17.1. Organs at risk 18
   17.2. Organs at risk 19
18. RECTAL SPACERS 20
19. PEER REVIEW 20
20. TREATMENT VERIFICATION 20
21. ON TREATMENT REVIEW 20
22. FOLLOW UP AND TREATMENT LETTER 20
23. LATE EFFECTS 21

24. REFERENCES 21

1. INTRODUCTION

- The role of radiotherapy has been well established as a curative treatment option for localised prostate cancer alongside other management options which include surgery and active surveillance in selected patients.
- Early clinical trials investigated developments in the precision of radiotherapy delivery allowing for dose escalation which showed a benefit in biochemical progression free survival (bFPS).[1,2] These trials led to further advancements in radiotherapy techniques with the development of modern image-guided intensity-modulated radiotherapy with many centres utilising arc therapy to improve the efficacy, safety and efficiency of radiotherapy.
- Hypo-fractionated radiotherapy schedules have been explored in view of the accumulating evidence that the alpha-beta ratio of prostate cancer is low and therefore are more sensitive to higher dose per fraction (> 2Gy per day conventional fractionation).[3,4]
- Moderate hypofractionation trials such as the CHHiP trial have shown a non-inferior bPFS and similar toxicity to conventional fractionation with the additional benefit of cost and convenience.
  Therefore, the CHHiP regime has been recommended as the current standard of care for external beam radiotherapy for localised prostate cancer.[5]
- Ultra hypofractionation (SBRT style) has been shown to be feasible and safe in cohort studies, with high levels of disease control [23]. HYPO-RT-PC trial has shown that ultra hypofractionation is non inferior regarding biochemical control compared to conventionally fractionated radiotherapy [24]. Recently the published PACE B trial has also demonstrated non-inferiority for five-fraction SBRT compared with conventional radiotherapy for low to intermediate risk prostate cancer in terms of biochemical and clinical failure[25].
- Radiotherapy in advanced prostate cancer has in the past been reserved for symptomatic metastases with palliative doses of radiotherapy. The STAMPEDE trial has shown a survival advantage when prostate radiotherapy is given in addition to androgen deprivation therapy in men with low- volume metastatic disease.[6]

2. PURPOSE

- To provide a standardised departmental protocol for the planning and delivery of external beam radiotherapy (RT) for prostate cancers within the West Midlands.
- This protocol is based on the Royal College of Radiologists (RCR) Radiotherapy dose fractionation (Fourth Edition, 2024)[7], NICE guideline for Prostate cancer (2021)[8] and current prostate cancer clinical trials.

The interpretation and local implementation of this document is dependent on the centre's local resources, equipment and internal audit data, and therefore remains the responsibility of the treating centre.

3. RESPONSIBILITY

- To comply with the Ionising Radiation (Medical Exposure) Regulations 2017 the following roles are defined:
  - Referrer & Practitioner: The consultant clinical oncologist is responsible for the care of the patient including correct referral for treatment consent, justification prescription and treatment authorization as defined in

departmental protocol but in accordance with this regional protocol.
    - Operators: Radiographers, physicists and technologists Consultant clinical Oncologists and other medical staff are responsible for individual tasks associated with the plan production, verification and treatment delivery as per departmental protocols but in accordance with this regional protocol and are undertaken on the auspices of the practitioner.

- It is the responsibility of department management teams to ensure departmental protocols are consistent with this regional protocol and that any disagreement with the content of this protocol is raised through the West Midlands EAG.

4. DIAGNOSIS AND STAGING

- Clinical history and examination as appropriate
- WHO Performance status and index PSA should be recorded
- Symptoms – urinary symptoms (using IPSS – International Prostate Symptom Score), bowel symptoms and potency should be recorded at baseline
- All patients should have histological confirmation of prostate carcinoma with grading according to the Gleason scoring system in those undergoing curative intent radiotherapy
- Primary staging
    - Multiparametric MRI (mpMRI) scan is the standard for local staging unless there is a clinical contraindication and this should ideally be completed before prostate biopsies.
    - Staging for metastases can include a bone scan, SPECT-CT or CT thorax to pelvis scan according to local policy and as clinically indicated such as to investigate bone pain. It is not necessary to routinely offer a bone scan in low-risk localised prostate cancer (for definitions see Risk Stratification Groups below)[27].
    - Other imaging modalities such as whole body MRI, or PSMA PETCT[26] can be utilised, where available, for equivocal findings if clinically appropriate, and on review in the Urology MDT, if this would significantly alter treatment. The use of novel imaging modalities is an emerging area which for the purposes of this protocol will not be covered here.
- Staging for biochemical recurrence following radical treatment
    - Offer PET in patients with biochemical recurrence, where there is intent for further salvage therapy (e.g. SABR)[26].
- PET scans utilising variety of tracers may also be used as part of clinical trials in all clinical settings (radical, recurrent, metastatic)[26]
- Document TNM staging based on imaging and clinical examination findings using TNM version 8.
- Patients with localised disease on routine imaging should not be denied radical local treatment solely because metastatic lesions are identified on the novel imaging techniques.[9]

TNM classification of prostatic carcinomas (UICC TNM 8)[10]

Primary tumour (T)

Tx Primary tumour cannot be assessed

T0 No evidence of primary tumour

T1* Clinically inapparent tumour not palpable or visible by imaging
- T1a* Tumour incidental histological finding in 5% or less of tissue resected
- T1b* Tumour incidental histological finding in more than 5% of tissue resected
- T1c* Tumour identified by needle biopsy (e.g. because of elevated PSA)**

T2 Tumour confined within prostate
- T2a Tumour involves one half of one lobe or less
- T2b Tumour involves more than half of one lobe, but not both lobes
- T2c Tumour involves both lobes

T3 Tumour extends through the prostate capsule***
- T3a Extra-prostatic extension (unilateral or bilateral) including microscopic bladder neck involvement
- T3b Tumour invades seminal vesicle(s)
- T4 Tumour is fixed or invades adjacent structures other than seminal vesicles external sphincter, rectum, levator muscles or pelvic wall

*The pT and pN categories correspond to the T and N categories. However, there is no pT1 category because there is insufficient tissue to assess the highest pT category.

**Tumour found in one or both lobes by needle biopsy, but not palpable or visible by imaging, is classified as T1c.

***Invasion into the prostatic apex or into (but not beyond) the prostatic capsule is not classified as T3, but as T2.

Regional lymph nodes (N)

NX Regional lymph nodes cannot be assessed

N0 No regional lymph node metastasis

N1 Regional lymph node metastasis

Distant metastasis (M)

M0 No distant metastasis

M1 Distant metastasis
- M1a Non-regional lymph node(s)
- M1b Bone(s)
- M1c Other site(s)

5. RISK STRATIFICATION GROUPS

Localised prostate carcinoma can be stratified to the following risk groups (www.nccn.org)[27] for the purposes of treatment, target volume delineation and guiding prognosis.

NCCN Risk group[27]	Clinical/Pathologic Features		
Low	Has all of the following but does not qualify for very low risk: • cT1–cT2a • Gleason ≤ 6 • PSA <10 ng/mL		
Intermediate	Has one or more intermediate risk factors (IRFs), but no high risk features: • cT2b-cT2c • Gleason 7 • PSA 10-20 ng/mL	Favourable Intermediate	Has **all** of the following: • 1 IRF • Gleason 6 or 3+4=7 • <50% biopsy cores positive (eg, <6 of 12 cores)
		Unfavourable Intermediate	Has one or more of the following: • 2 or 3 IRFs • Gleason 4+3=7 • ≥ 50% biopsy cores positive (eg, ≥ 6 of 12 cores)
High	Has at least one of the following: • ≥ T3a • Gleason 8-10 • >20 ng/ml		

6. PRE-TREATMENT

6.1. Information and Consent

- Each patient should be consented with individualised information of the planned treatment, individualised risk-benefits and side effects.
- Patients should also receive a local patient information sheet which includes the department contact details/numbers or a Macmillan information booklet.
- The booking form and consent are completed by the IR(ME)R practitioner.

6.2. Clinical Trials

- Patients are encouraged to participate in clinical trials where possible and available.
- Details of clinical trials are included in the West Midlands radiotherapy network website. See: Clinical trials - West Midlands Radiotherapy Network.

6.3. Patient preparation

Patient Preparation

- A local protocol should be in place whereby the radiographer team will contact the patient prior to the planning CT scan, approximately 1 -2 weeks if possible, to provide appropriate support and counselling relating to the planning and treatment pathway.
- Appropriate advice regarding dietary adjustments with an information leaflet, a good oral fluid intake and other measures to avoid constipation should be provided in preparation for the planning CT scan.
- The use of micro enemas/laxatives before the planning scan and each treatment will be according to a local protocol in order to achieve an optimally empty rectum.

6.4. Planning technique

Planning Technique

Local CT scanning protocols to include scanning levels and patient immobilisation (***for example*** *CT scans to be taken at ≤ 3mm from the top of L4 vertebra/L2 when treating pelvic nodes to 1cm below the ischial tuberosities with block and scoop under head, Combi-fix*).

- Patients should be supine with a comfortably full bladder and have an empty rectum.
- An AP rectal diameter of >4cm at the mid-point of the prostate should be considered to be rescanned with appropriate advice and medical management given to the patient (a local policy such as the use of Movicol or phosphate enemas can be used).
- A comfortably full bladder is recommended for the planning CT scan and treatment. *For example, patients will be asked to empty the bladder 1 hour before the appointment and then to drink 325ml of water over 10 minutes* (or in accordance with local protocol).
- A bladder volume of < 200ml should be considered to be rescanned with the patient asked to drink further water to improve this where possible. The above measures may need to be adjusted depending on the hydration status of the patient and the use of a bladder US can be helpful.
- If a patient is not able to sufficiently fill the bladder due to clinical reasons, planning may still proceed at the guidance of the treating clinician.
- The use of IV contrast is recommended for cases involving pelvic nodal irradiation providing there are no contraindications and renal function is satisfactory.
- Consider following local protocol/PGD for administration of oral contrast. Oral contrast can be used at the discretion of the CCO to assess bowel positioning e.g. when the patient has bowel related co-morbidities.

6.5. Target Volume Delineation

Target Volume Delineation

- All diagnostic imaging, clinical history and histology will be reviewed by the clinician to aid target volume delineation.
- MR-CT fusion is encouraged where possible in cases with metal hip prostheses or other scenarios in which there may be challenges or uncertainties with target delineation.
- Refer to individual sections for target delineation.

7. TREATMENT TECHNIQUE AND DOSE PRESCRIPTION

- Radical radiotherapy should be delivered using inverse planned IMRT with online image-

guided radiotherapy. Various IMRT techniques include static field, VMAT, helical Tomotherapy or robotic gantry.

- Volumes will be defined according to ICRU Report 50 and 62. Dose prescription and recording for IMRT will conform to the Principles of ICRU 83.
- IMRT will be prescribed to the median dose point on the dose volume histogram (DVH) such that the prescription dose is received by 50% of the PTV (D50%).
- Maximum dose is defined as D2%.
- Minimum dose is defined as D98%.

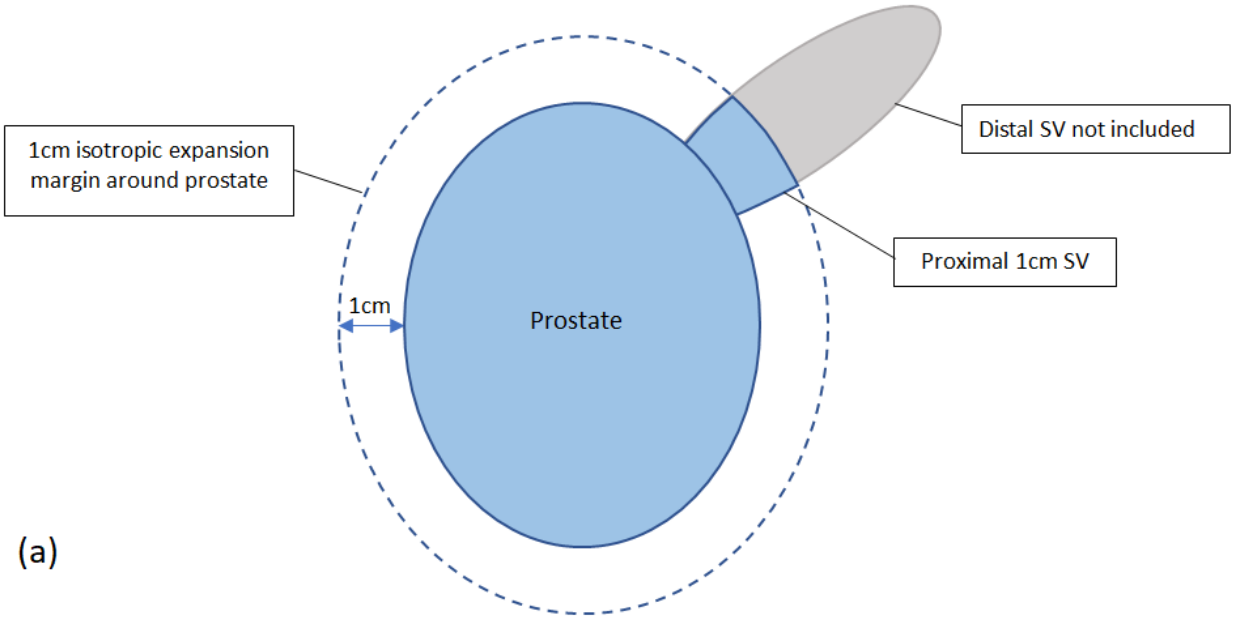
Refer to individual sections for dose prescription, target objectives and OAR dose constraints.

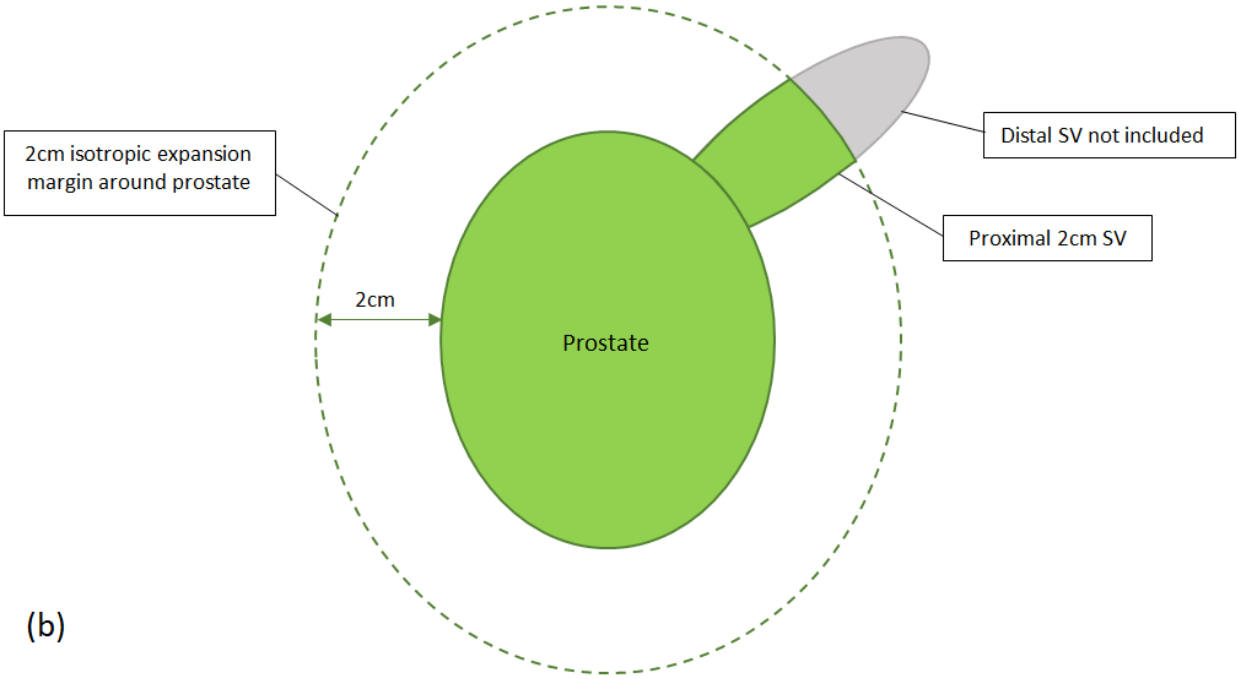
8. PROSTATE AND SEMINAL VESICLES RADIOTHERAPY

8.1. Target Volume Delineation

For centres following Planning Approach 1 (as detailed later), nomenclature for target volume delineation is from the Pivotal boost trial[11]:

CTVp (image a below)	=	Prostate, plus proximal centre of seminal vesicles (SV), 1 cm above the origin and any extraprostatic extension (periprostatic fat, seminal vesicle or base of bladder). If the seminal vesicles are short, include the appropriate length. For extensive tumours (T3b, T4, Grade group 4 or 5, or extensive tumour in the base), increase the volume of SV included in CTVp appropriately
CTVpsv (image b below)	=	CTVp and up to 2 cm of the remaining SV (central and peripheral) above base of prostate; if the SV are shorter then this needs to be shortened. For extensive tumours (T3b, T4, Grade group 4 or 5, or extensive tumour in the base), include the whole SV


1cm isotropic expansion margin around prostate
Distal SV not included
Proximal 1cm SV
1cm
Prostate
(a)



For centres following Planning Approach 2 (as detailed later), nomenclature for target volume delineation is from the CHHiP trial

Prostate = Prostate

SV = Seminal vesicles

8.2. Dose and Fractionation

Radiotherapy regimes:

- 60Gy in 20 fractions over 4 weeks – recommended standard for prostate-only radiotherapy
- 74Gy in 37 fractions over 7.5 weeks can be used for those patients with a clinical indication to keep to 2Gy fractions such as previous pelvic surgery or significant urinary symptoms/bowel conditions

8.3. Definitions of PTVs for Dose Reporting Planning Approach 1

- The following describes simultaneously treating multiple dose-level PTV structures in a single phase in line with contemporary prostate radiotherapy trials (PIVOTALboost and PACE trials).[11,12] Therefore, an IMRT planning technique must be used to obtain the prescription doses for adjacent PTVs.
- PTV margins will be determined according to local practices relating to IGRT data and whether fiducials are utilised. The following table are suggested PTV margins according to the PIVOTALboost trial. 11

Planning target volume		Dose to PTV (60Gy/20)
PTVp_6000	CTVp + 3mm (with fiducials) OR + 4mm (no fiducials)	Report dose to PTVp_6000 D50% = 60Gy (median**) *D*98% ≥ 57.0 Gy (95%)

		*D*2% ≤ 64.2 Gy (107%)
PTVpsv_4700	CTVpsv + 6mm (with fiducials) OR + 8mm (no fiducials)	Report dose to PTVpsv_4700–PTVp_6000 *D*50% ≥ 47.0 Gy (median**) *D*98% ≥ 44.65 Gy (95%)

*** For median doses, values within 1% of the stated figure are acceptable*

CTV definition for specific risk categories[11, 12, 25]

NCCN Risk group[27]	CTV definition	
Low	CTVp = prostate only	
Intermediate	Favourable Intermediate	CTVpsv = prostate plus proximal 1 cm of seminal vesicles CTVsv = identical to CTVpsv
	Unfavourable Intermediate	CTVpsv = prostate plus proximal 1 cm of seminal vesicles (from insertion point in the sagittal plane, see diagram above) CTVsv = prostate plus proximal 2 cm of seminal vesicles (from insertion point in the sagittal plane, see diagram above)
High	CTVpsv = prostate (+ volume of the involved seminal vesicle) plus proximal 1 cm of remaining seminal vesicles (from insertion point in the sagittal plane, see diagram above). When in doubt, consider including the whole length of the seminal vesicle, weighing up doses delivered to OARs and the risks of late toxicity. CTVsv = prostate (+ volume of the involved seminal vesicle) plus proximal 2 cm of remaining seminal vesicles (from insertion point in the sagittal plane, see diagram above). When in doubt consider including the whole length of the seminal vesicle. When in doubt, consider including the whole length of the seminal vesicle, weighing up doses delivered to OARs and the risks of late toxicity.	

8.4. Planning Approach 2

- Some centres may aim to continue using planning according to the CHHiP protocol which uses forward- planned IMRT.[5] Inverse planned IMRT is now the recommended standard.

	Low risk of SV involvement	Intermediate risk of SV involvement	High Risk of SV involvement	Target isodose
PTV1	Outline: Prostate + base (proximal 2cm) of SV Add: 10mm margin all directions	Outline: Prostate + SV Add: 10mm margin all directions	Outline: Prostate + SV Add: 10mm margin all directions	76% minimum ≥ 80% median to PTV1 - PTV2
PTV2	Outline: Prostate only Add:* 10mm margin except 5mm towards rectum unless moderate/large degree of rectal distension when 10mm towards rectum (only use 10mm on individual CT slices showing moderate/large rectal distension)		Outline: Prostate and SV Add:* 10mm margin except 5mm towards rectum	91% minimum > 96% median to PV2 - PTV3
PTV3	Outline: Prostate only Add: 5mm margin except 0mm towards rectum (all cases)		Outline: Prostate and SV Add: 5mm margin except 0mm towards rectum (all cases)	100% (±1%) median 95% minimum

Low risk of seminal vesicle involvement

a) Clinical stages T1b/c or T2a/b and with PSA + ((Gleason score -6) x10) <15

Moderate or high risk of seminal vesicle involvement

a) Clinical stages T1b/c or T2a/b, and with PSA + ((Gleason score -6) x10) >15

b) T2c or T3a

9. PROSTATE, SEMINAL VESICLES AND PELVIC NODES

- Suitable patients for prostate, seminal vesicle and pelvic nodal irradiation should have completed appropriate staging investigations ensuring there is no extra-pelvic disease.
- Patients should not have any contraindications to large volume pelvic irradiation such as any significant pre-existing bowel conditions which would pose difficulties in meeting bowel dose constraints or be foreseen to risk excessive bowel toxicity.

9.1. Target Volume Delineation

CTVp	=	Prostate, plus proximal centre of seminal vesicles (SV), 1 cm above the origin and any extraprostatic extension (periprostatic fat, seminal vesicle or base of bladder). If the seminal vesicles are short, include the appropriate length. For extensive tumours (T3b, T4, Grade group 4 or 5, or extensive tumour in the base), increase the volume of SV included in CTVp appropriately
CTVpsv	=	CTVp and up to 2 cm of the remaining SV (central and peripheral) above base of prostate; if the SV are shorter then this needs to be shortened. For extensive tumours (T3b, T4, Grade group 4 or 5, or extensive tumour in the base), include the whole SV
CTVn	=	Pelvic nodes (as per the PIVOTAL trial pelvic atlas to include internal and external iliacs, obturator and prescacral nodes)[13,14]

https://cdn.mednet.co.il/2019/06/Consensus-Guidelines-and-Contouring-Atlas-for-Pelvic-Node-Delineation- in-Prostate-and-Pelvic-Node.pdf

CTVnbst	=	Involved node(s) (GTV of the involved LN + 0-5mm expansion and edit off muscle, bone, rectum, bladder or bowel. Expansion margin should be adjusted accordingly to respect OAR dose constraints

To allow boost to individual involved nodes depending on surrounding OAR dose constraints, label individual involved nodes, eg: CTVnbstRtiliac, CTVnbstLtobt

Local adoption of the NRG Oncology Updated International Consensus Atlas on Pelvic Lymph Node Volumes for Intact and Postoperative Prostate Cancer[15] is optional providing local measures are in place for peer review.

9.2. Margins

PTVp_7400	=	CTVp + 5mm except 0mm posteriorly
PTVp_7100	=	CTVp + 10mm except 5mm posteriorly
PTVpsv_6000	=	CTVpsv + 10mm
PTVn_6000	=	CTVn + 5mm (and exclude PTVpsv60)
PTVnbst_6500	=	CTVnbst +5mm[PTVnbst_6500 should be within PTVn_6000)

The above PTV margins are suggested margins and should be determined according to local

practices relating to IGRT data.

9.3. Dose and Fractionation[7]

- Primary - 74Gy in 37 fractions over 7.5 weeks or 60Gy in 20 fractions over 4 weeks
- Nodal irradiation - 55-60Gy in 37 fractions over 7.5 weeks or 44-47Gy in 20 fractions over 4 weeks
- Nodal boost - 60-65Gy in 37 fractions over 7.5 weeks (providing dose constraints met) or up to 51Gy in 20 fractions over 4 weeks

						Comment
PTVp_7400	=	74 Gy/37	PTVp_6000	=	60 Gy/20	
PTVp_7100	=	71 Gy/37	PTVp_57600	=	57.6 Gy/20	When using 3 dose levels (optional)
PTVpsv_6000	=	60 Gy/37	PTVpsv_4700	=	47 Gy/20	
PTVn_6000	=	60 Gy/37	PTVn_4400 (4700)	=	44 (up to 47) Gy/20	
PTVnbst_6500	=	65 Gy/37	PTVnboost_5100	=	51 Gy/20	

If it is not possible to achieve PTVn_6000 or PTVnbst_6500 with 60 Gy or 65 Gy in 37 fractions respectively or corresponding PTVn_4700/PTVnboost_5100 in 20 fractions, without exceeding bowel tolerance, the doses prescribed to these volumes can be reduced to achieve 55Gy and 60Gy in 37 fractions or 44Gy and 47Gy in 20 fractions respectively.

10. ANDROGEN DEPRIVATION THERAPY (ADT) AND RADIOTHERAPY (RT)[7]

For low and intermediate risk with favourable features, the addition of short-duration ADT (6 months) to radiotherapy (RT) significantly improves metastasis-free survival (MFS).

For patients with intermediate risk with unfavourable features or high-risk patients treated with radical RT, ADT prolongation from 6 to 18–36 months improves disease-related endpoints including MFS.

Neoadjuvant and concurrent ADT have been found to have a more favourable 10-year progression-free survival (PFS) with prostate and pelvic nodal RT and adjuvant ADT; the reverse was found when prostate-only RT had been delivered[28].

Local dose escalation does not negate the benefits of ADT.

➢ In summary:

- Patients treated with prostate-only RT and 6 months of ADT, radiotherapy should commence shortly after starting ADT;
- For extended-course ADT (>12 months) and prostate and pelvic nodal RT (PNRT), any neoadjuvant, concurrent and adjuvant sequencing can be used.

11. PROSTATE BED RADIOTHERAPY WITH OR WITHOUT PELVIC NODAL COVERAGE

• Three randomized controlled trials (RADICALS-RT, GETUG-AFU17, RAVES) have shown that early salvage radiotherapy has comparable efficacy (event-free survival) to adjuvant radiotherapy with decreased toxicity.16

- RADICALS criteria for salvage radiotherapy:
    - 2 consecutive rises and PSA >0.1
    - Or 3 consecutive rises

Target Volume Delineation

- All preoperative imaging and histopathology findings will be reviewed by the clinician to aid outlining.

Guidance from RADICALS[17]

• The prostate bed CTV is based on the estimated location of the preoperative prostate volume plus sites of possible microscopic tumour extension, plus the extent of the surgical bed and should normally include any surgical clips provided that normal tissue dose constraints are satisfied.

• The original volume of seminal vesicles (including any residual seminal vesicles postop) will not be considered target if they were not pathologically involved with tumour and if the preoperative risk of seminal vesicle involvement was <15% using the Roach formula:

(% SV involvement risk = PSA +10 x (Gleason score -6)

• If there was pathological seminal vesicle involvement or if the predicted involvement was ≥ 15%, then the seminal vesicles can be considered target.

Anterior border:

i. Caudal (less than 2cm above anastamosis) – posterior aspect of symphysis pubis
ii. Cranial (more than 2cm above anastamosis) – posterior 1/3 of bladder wall

Posterior border: Anterior rectal wall

Lateral border: Medial border of obturator internus and levator ani muscles

Superior border:

i. If SV low-risk and pathologically uninvolved: base of SV
ii. If SV high risk or pathologically involved: tips of SV
iii. If SV absent, the superior border should be determined with reference to the estimated position of the pre-operative SV using the longitudinal dimension superiorly from urogenital diaphragm to reflect preoperative size of prostate, together with the position of any surgical clips

Inferior border: 5mm cranial to the superior border of the penile bulb

• Pelvic nodal coverage is determined by the treating clinician and for target volume delineation refer to Section 7.

Dose and Fractionation [7]

- 66Gy in 33 fractions over 6.5 weeks (+/- 52-55Gy to pelvic nodes)
- 52.5-55Gy in 20 fractions over 4 weeks (+/- 44-47Gy to pelvic nodes)
- For gross/PET avid recurrence in the prostate bed 74Gy/37# or 60Gy/20# may be considered at the discretion of treating consultant, respecting OARs dose constraints, and with appropriate peer review.
- For gross/PET avid recurrence in the pelvic nodes (PTV_nbst) dose may be considered for further escalation at the discretion of treating consultant, respecting OARs dose constraints, and with appropriate peer review. Due to limited data, dose per fraction should not exceed 2 Gy[29].

Margins

PTV_6600 in 33# (or PTV_5250 - 5500 in 20#)	= CTVprostatebed + 5-10mm
PTV_5200 - 5500 in 33# (or PTV_4400 - 47000 in 20#)	= CTVn + 5mm
PTV_7400 in 37# (or PTV_6000 in 20#) for gross recurrence	= GTV + 3-5 mm
PTV_nbst_xxxx in 33-37# only (i.e. ≤ 2Gy/#)	= GTV + 3-5mm

The above PTV margins are suggested margins and should be determined according to local practices relating to IGRT data.

12. BRACHYTHERAPY BOOST

The following schedules are from RCR Radiotherapy Dose Fractionation (4th Edition) which can be utilised where available:

• 37.5Gy in 15 fractions over 3 weeks followed by 15Gy HDR brachytherapy boost

13. HORMONAL SENSITIVE LOW VOLUME METASTATIC PROSTATE CANCER

Inclusion criteria for radiotherapy to the prostate

- New diagnosed hormonal-sensitive prostate carcinoma with low burden metastatic disease (4 or fewer bone metastases and no visceral metastases)
- No previous radical treatment and within 3 months of starting hormonal therapy or within 6-12 weeks after completing Docetaxel if given
- Patient convenience is a key consideration and particularly important for patients with metastatic disease. A schedule of six weekly fractions of radiotherapy is recommended by NHS England.[18]

Dose fractions schedules and target volumes:

- 2 radiotherapy dose-fractionation schedules were used in the STAMPEDE trial (36Gy/6 once

weekly over 6 consecutive weeks or 55Gy/20 daily for five days per week over 4 consecutive weeks).[6] The consensus view of the WM group is that 60Gy/20 would be an acceptable regime to consider based on tolerability, no additional hospital visits when compared to 55Gy/20 and providing OAR dose constraints are acceptable by the treating clinician.

- Inclusion of the involved seminal vesicle to encompass macroscopic disease within prescription dose is at the discretion of the treating clinician, respecting OARs dose constraints.
- IMRT/VMAT planned, image guidance protocol according to local practice
- PTV to receive at least 95% of the prescribed dose

Rectal dose volume constraints[19]

36Gy/6	55 Gy/20	60Gy/20	Max Volume
33.3Gy	52.5Gy	48.6Gy	50%
27.8Gy	43.5Gy	40.8Gy	60%
16.7Gy	26.1Gy	24.6Gy	80%

Bladder dose volume constraints[19]

36Gy/6	55Gy/20	60Gy/20	Max Volume
33.3Gy	52.5Gy	48.6Gy	25%
27.8Gy	43.5Gy	40.8Gy	50%

14. PALLIATIVE RADIOTHERAPY

- Clinical indications include pain, bleeding or troublesome outflow symptoms
    - Prostate radiotherapy regimes:
        - 8-10Gy single dose
        - 21Gy in 3 fraction alternate days over 1 week
        - 20Gy in 5 fractions over 1 week
        - 30Gy in 10 fractions over 2 weeks
    - Planning technique:
    - Single or parallel pair/conformal/VMAT

- Clinical indications include bone pain, spinal cord compression
    - Radiotherapy regimes:
        - 8Gy single dose
        - 20Gy in 5 fractions over 1 week
        - 30Gy in 10 fractions over 2 weeks
        - Planning technique:
        - Single or parallel pair/conformal/VMAT

- For Oligometastatic disease
  Refer to SABR consortium guidance - SABR consortium guidelines 2019 v6.1.0

15. OTHER CLINICAL SCENARIOS

- Small cell carcinoma of the prostate to be treated with chemotherapy for SCLC +/- radiotherapy
- Transitional cell carcinoma of prostate to be treated as for urothelial carcinoma

16. DEFINITION OF ORGANS AT RISK

Rectum
• The outer circumference of the rectum is delineated to include rectal contents extending from the rectosigmoid junction to the anus
• Superior extent - rectosigmoid junction (defined as the level at which bowel reflects anteriorly which is best seen on the sagittal views of the planning scan)
• Inferior extent - bottom of the ischial tuberosities or the anal margin (whichever is inferior)
• This will approximate to 10-12cm in length in most cases

Bladder
• The outer circumference of the entire bladder is delineated

Bowel
• Individual small, large bowel and the sigmoid colon down to the level of the recto-sigmoid junction are delineated as a combined volume of 'Bowel' for the purposes of dose-volume constraints.
• Bowel may be outlined as a 'Bowel Bag'
• Superior extent - 2cm beyond the superior extent of CTVs
• During outlining of CTVn, 'Bowel' is expanded by an isotropic 3mm margin to create an outlining assistance volume 'Bowel3mm' which is used as an avoidance structure and is excluded from CTVn

Penile bulb
• The portion of the bulbous spongiosum that lies inferior to the urogenital diaphragm best seen on MRI scan. Use MRI scan as guidance and then adapt to location on CT scan.

Femoral heads
• Right and left femoral heads are to be delineated from their most cranial aspect to the bottom of the curvature of the femoral head (ie. exclude femoral neck)

17. DOSE VOLUME CONSTRAINTS[11,12]

- Following dosimetric analyses using CHHiP trial data, revised optimal rectal dose constraints have been derived. However, these are constraints to aim for plan optimisation (ie. optimal constraints should not be achieved at the expense of PTV coverage).[12]
- Standardised nomenclature of structures will facilitate automated treatment plan quality control, peer review and analysis of radiotherapy plan data. [20]
- The below tables are adapted from the PACE and PIVOTALboost trials

17.1. Organs at risk

Dose-volume constraints (max volume) Prostate +- LNs

	Naming convention	Dose for 60Gy/20 (Gy)	Dose for 74Gy/37 (Gy)	Optimal	Mandatory
Rectum	**Rectum**	24	30	70%	80%
		32	40	51%	65%

		40	50	38%	50%
		48	60	27%	35%
		52	65	-	30%
		56	70	-	15%
		60	74	1%	3%
Bladder	**Bladder**	40	50	50%	
		48	60	25%	50%
		60	74	5%	35%
Sigmoid, Small & Large Bowel	**Bowel**	36	45	78cc	158cc
		40	50	17cc	70cc
		44	55	14cc	28cc
		48	60	0.5cc	6cc
		52	65	0cc	0cc
Femoral heads	**FemoralHead_L FemoralHead_R**	40	50	5%	50%
Penile bulb	**PenileBulb**	22	50	50%	
		48	60	10%	

17.2. Organs at risk

Dose-volume constraints (max volume) Prostate bed +- LNs

	Naming convention	Dose for 52.5Gy/20 (Gy)	Dose for 66Gy/33 (Gy)	Optimal	Mandatory
Rectum	**Rectum**	24	30	70%	80%
		32	40	51%	65%
		40	50	38%	50%
		48	60	27%	35%
		52	65	-	30%
		56	70	-	15%
		60	74	1%	3%
Bladder	**Bladder**	40	50	50%	
		48	60	25%	50%
		60	74	5%	35%
Sigmoid, Small & Large Bowel	**Bowel**	36	45	78cc	158cc
		40	50	17cc	70cc

		44	55	14cc	28cc
		48	60	0.5cc	6cc
		52	65	0cc	0cc
Femoral heads	**FemoralHead_L** **FemoralHead_R**	40	50	5%	50%
Penile bulb	**PenileBulb**	22	50	50%	
		48	60	10%	

18. RECTAL SPACERS

- The consensus view of the WM group is that whilst selected cases, such as those with pre-existing clinically significant bowel conditions and in those where a radiotherapy plan has demonstrated an unacceptable rectal dose to the treating clinician, could benefit with a rectal spacer, this at the time of writing this protocol is not considered routinely available given the current resource provision in the WM, local commissioning and additional visits which are required.
- Recent results from the PACE arm B trial have shown very low rates of rectal toxicity without the use of rectal spacer[21] and the net benefit of a rectal spacer may be justified in selected cases as described above or where fiducial makers are being inserted and thereby additional visits and procedure room/theatre space are not required.
- The pathway for rectal spacers would require sufficient quality assurance measures to be in place such as an appropriately trained health care professional, a streamlined protocol for the timing of insertion, accurate delineation of the rectal spacer with utilisation of an MRI in those with non-contrast rectal spacers with appropriate peer review support and quality assurance protocols for daily image verification.

19. PEER REVIEW

- Peer review should be undertaken in line with the West Midlands regional guidance agreed in December 2025 which identifies which cases should be subject (as a minimum) to peer review.

20. TREATMENT VERIFICATION

- Daily imaging using cone beam CT, fiducial markers or MV CT with online correction
- Local protocols must be available describing action levels and concomitant imaging doses.
- Palliative / Vsim cases to be imaged as per local policy.

21. ON TREATMENT REVIEW

- Patients reviewed as per local policy.
- This may be a Review Radiographer during treatment and Clinician review at the end of treatment or earlier as clinically indicated.

22. FOLLOW UP AND TREATMENT LETTER

- On completion of treatment a summary of the radiotherapy dose and side effects are documented. Potential future acute and late side effects are detailed.

- Patients should be provided with the contact details of the department if there are any queries relating to the treatment and can also be provided with the contact of the Acute Oncology Service outside of hours where available.
- Patients suggested routine follow up appointment at 8-12 weeks after completion of treatment unless otherwise indicated in a clinical trial protocol.

23. LATE EFFECTS

Late effects will have been discussed as part of the initial discussions and counselling by the treating clinician and is dependent on the radiotherapy target volumes.

• Erectile dysfunction - can be supported by referral to Erectile Dysfunction Clinic
• Infertility
• Leg or groin lymphoedema - depending on whether pelvic nodes are covered and if a pelvic nodal dissection has been completed
• Change in bladder or bowel habit/capacity
• Rectal bleeding requiring surgical investigation/intervention (in region of <5%)
• Pelvic bone thinning, insufficiency fractures or avascular necrosis is rare
• Bladder or bowel incontinence is rare
• Possible small long-term increase in risk of rectal cancer is rare (<1%)

24. REFERENCES

1. Dearnaley DP, Jovic G, Syndikus I et al. Escalated-dose versus control-dose conformal radiotherapy for prostate cancer: Long term results from the MRC RT01 randomised controlled trial. Lancet Oncol 2014; 15:464-473.
2. Michalski JM, Moughan J, Purdy J et al. Effect of standard vs dose-escalated radiation therapy for patients with intermediate-risk prostate cancer: The NRG Oncology RTOG 0126 randomized clinical trial. JAMA Oncol 2018: 4(6) e180039.
3. Dasu A, Toma-Dasu I. Prostate alpha/beta revisted – an analysis of clinical results from 14 168 patients. Acta Oncol 2012; 51: 963-974.
4. Proust-Lima C, Taylor JM, Secher et al. Confirmation of a low alpha/beta ratio for prostate cancer treated by external beam radiation therapy alone using a post-treatment repeated-measures model for PSA dynamics. Int J Radiat Oncol Biol Phys 20111; 79: 195-201.
5. 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.
6. Parker CC, James ND, Brawley CD et al. Radiotherapy to the primary tumour for newly diagnosed, metastatic prostate cancer (STAMPEDE): a randomised controlled phase 3 trial. Lancet 2018; 392: 2253-2366.
7. Royal College of Radiologists Radiotherapy dose fractionation (Fourth Edition, 2024).
8. NICE guideline (NG131). Prostate cancer: diagnosis and management (last update Dec 2021).
9. Parker C, Castro K, Fizazi K et al. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow up. Ann Oncol 2020; 31(9): 1119-1134.
10. Prostate. *In*: Brierley JD, Gospodarowicz MK, Wittekind C (eds). *TNM Classification of Malignant Tumours (8th edition).* Oxford, UK: Wiley-Blackwell, 2017.
11. PIVOTALboost. A phase III randomised controlled trial of prostate and pelvis versus prostate alone radiotherapy with or without prostate boost (v6, July 2020).
12. The PACE Trial (Prostate Advances in Comparative Evidence). International randomised study of prostatectomy vs stereotactic body radiotherapy (SBRT) and conventional radiotherapy vs SBRT for organ-confined prostate cancer (v11, April 2020).

13. Dearnaley D, Griffin C, Lewis R et al. Toxicity and Patient-Reported Outcomes of a Phase 2 Randomized Trial of Prostate and Pelvic Lymph Node Versus Prostate only Radiotherapy in Advanced Localised Prostate Cancer (PIVOTAL) Int J Radiat Oncol Biol Phys 2019; 103: 605-617.
14. https://cdn.mednet.co.il/2019/06/Consensus-Guidelines-and-Contouring-Atlas-for-Pelvic-Node-Delineation-in- Prostate-and-Pelvic-Node.pdf
15. Hall WA, Paulson E, Davis BJ et al. NRG Oncology Updated International Consensus Atlas on Pelvic Lymph Node Volumes for Intact and Postoperative Prostate Cancer. Int J Radiat Oncol Biol Phys 2021; 109(2): 413-424.
16. Vale CL, Fisher D, Kneebone A et al. Adjuvant or early salvage radiotherapy for the treatment of localised and locally advanced prostate cancer: a prospectively planned systematic review and meta-analysis of aggregate date. Lancet 2020; 396: 1422-1431.
17. RADICALS. Radiotherapy and androgen deprivation in combination after local surgery. A randomised controlled trial in prostate cancer (v5, March 2014).
18. Clinical Commissioning Policy: External beam radiotherapy for patients presenting with hormone sensitive, low volume metastatic prostate cancer at the time of diagnosis. NHS England November 2020.
19. STAMPEDE. Systemic therapy in advancing or metastatic prostate cancer: evaluation of drug efficacy. A multi-arm multi-stage randomised controlled trial (v15, March 2016).
20. Santanam L, Hurkmans C, Mutic S et al. Standardizing naming conventions in radiation oncology. IJROBP 2012; 83(4): 1344-9.
21. Brand DH, Tree A, Ostler P et al. Intensity-modulated fractionated radiotherapy versus stereotactic body radiotherapy for prostate cancer (PACE-B): acute toxicity findings from an international, randomised, open-label, phase 3 non-inferiority trial. Lancet Oncol 2019: 20(11): 1531-1543.
22. Andruska N, Fischer-Valuck BW, Agabalogun T. Propensity-weighted survival analysis of SBRT vs. conventional radiotherapy in unfavourable intermediate-risk prostate cancer. Clin Genitourin Cancer 2022 Apr; 20(2): 123–131.
23. Widmark A, Gunnlaugsson A, Beckman L et al. Ultra-hypofractionated versus conventionally fractionated radiotherapy for prostate cancer: 5-year outcomes of the HYPO-RT-PC randomised, non-inferiority, phase 3 trial. Lancet 2019 Aug 3; 394(10196): 385–395.
24. N. van As, C. Griffin, A. Tree, J. Patel, P. Ostler, H. van der Voet, A. Loblaw, W. Chu, D. Ford, S. Tolan, S. Jain, P. Camilleri, K. Kancherla, J. Frew, A. Chan, O. Naismith, J. Armstrong, J. Staffurth, A. Martin, I. Dayes, P. Wells, D. Price, E. Williamson, J. Pugh, G. Manning, S. Brown, S. Burnett, and E. Hall. Phase 3 Trial of Stereotactic Body Radiotherapy in Localized Prostate Cancer. N Engl J Med 2024;391:1413-25. DOI: 10.1056/NEJMoa2403365.
25. Royal College of Radiologists. Evidence-based indications for the use of PET-CT in the United Kingdom 2022
26. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Prostate Cancer Version 4.2024 — May 17, 2024
27. Roach M, Moughan J, Lawton CAF et al. Sequence of hormonal therapy and radiotherapy field size in unfavourable, localised prostate cancer (NRG/RTOG 9413): long-term results of a randomised, phase 3 trial. Lancet Oncol 2018; 19: 1504–1515.
28. Alan Pollack, Theodore G Karrison, Alexander G Balogh, Leonard G Gomella, Daniel A Low, Deborah W Bruner, et al. The addition of androgen deprivation therapy and pelvic lymph node treatment to prostate bed salvage radiotherapy (NRG Oncology/RTOG 0534 SPPORT): an international, multicentre, randomised phase 3 trial. Lancet 2022 May 14; 399(10338):1886-1901.