East of England Radiotherapy Network:

Prostate Protocol V3.0

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1.0 Indications and patient population

This protocol covers external beam radiotherapy treatment in the following situations:

- a. Treatment of localised prostate cancer with curative intent
- i. Prostate +/- SV radiotherapy
- ii. Prostate +/- SV radiotherapy and pelvic lymph node radiotherapy

EBRT should be considered in combination with brachytherapy dose escalation (LDR or HDR)¹ for intermediate and high risk localised prostate cancer following MDT discussion. Where necessary patients may be referred for the brachytherapy boost component with the EBRT delivered locally.

For brachytherapy treatment refer to EOE RT HDR Prostate Network Protocol²

- b. Post operative radiotherapy (PORT)
- i. Following publication of the RADICALS trial and ARTISTIC meta- analysis^{3,4} early salvage prostate bed radiotherapy rather than adjuvant PORT is recommended. Planned adjuvant PORT may be indicated in individual cases following MDT discussion. The use of additional pelvic lymph node radiotherapy is at clinician discretion.
- c. Palliative radiotherapy
- i. In low volume (as per CHAARTED and STAMPEDE⁵) de-novo hormone sensitive metastatic prostate cancer⁶
- ii. For local control/palliation in other groups of patients

1.1 Curative treatment eligibility

1.1.1 Inclusion criteria

- a. T1-T4N0-1M0 adenocarcinoma of the prostate.
 - For information on the management of other histological subtypes, e.g. small cell carcinoma, refer to the EOE Cancer Alliance Guidelines for the Management of Prostate Cancer (14-1C-113g)
- b. Life expectancy >10 years in low/intermediate risk disease
- c. Life expectancy >5 years in high-risk disease

1.1.2 Exclusion criteria

a. Absolute:

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- a. Previous pelvic radiotherapy
- b. Active inflammatory bowel disease

b. Relative:

- a. History of inflammatory bowel disease
- b. Previous major pelvic surgery
- c. Significant bowel dysfunction from other causes
- d. Significant LUTS that cannot be optimised
- e. Large gland volume

If gland volume >100cc +/- significant LUTS (IPSS>10 , Q max <10ml/sec) consider TURP/HoLEP prior to RT or a longer course of neoadjuvant ADT

1.1.3 Essential Pre-Radiotherapy investigations

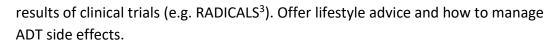
- a. Histological confirmation of prostate adenocarcinoma
- b. PSA
- c. Pelvic MRI (CT if MRI incompatible pacemaker or unable to tolerate MRI)
- d. Bone scan in all high-risk patients i.e. one or more of G4+4; PSA>20 or T3 or higher and in any patient symptomatic with bone pain or raised ALP
- e. Consider additional cross-sectional imaging if high risk disease to exclude distant metastatic disease

1.1.4 Preparation for localised prostate radiotherapy treated with curative intent

- Signed, written informed consent. Use of standard RCR consent form recommended
 National radiotherapy consent forms | The Royal College of Radiologists (rcr.ac.uk)
- Consider entry into clinical trials (EofE RTN Clinical Trials database)
- Bowel and bladder preparation as per departmental guidelines
- If patient has one or two THRs, request either metal artefact reduction reconstruction on CT planning scan or an MRI planning scan.
- Where possible obtain a radiotherapy planning MR and fuse to the planning CT to facilitate dominant lesion delineation and rationalise target volume definition⁷
- Consider use of hydrogel rectal spacer e.g. in patients planned for HDR brachytherapy (<u>www.nice.org.uk/guidance/ipg752</u>)
- Consider method of IGRT to be used (CBCT; gold seed fiducials if suitable and where available)⁷
- ADT may be given for 3-6 months prior to EBRT (may be omitted in patients with Gleason grade group 1; T1/2N0M0 disease).
 - Patients with high-risk disease should be offered extended androgen deprivation following completion of RT. Consider ADT in the post-operative setting pending

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• Patient should be given written patient information sheet detailing treatment and should be offered a copy of their consent form.

2.0 Localisation

Localisation	Notes	
Position	Supine	Refer to local policies ⁷
Immobilisation and supports	Prostate board with knees	
	adequately supported	
	Feet in foot stocks	
Organ pre-requisites	Empty rectum, typically <4cm A-P	
	Bladder comfortably full	
Contrast	For all patients receiving pelvic node	
	RT	
CT acquisition	Slice thickness: 2.0-2.5mm slices	
	Scanning limits P +/- SV	
	Superior = Top of L5, Inferior = 4cm	
	below ischium	
	Scanning limits P + N	
	Superior scan limit = Top of L3,	
	Inferior – 4cm below ischium	

3.0 Dose prescription⁸

Intent	Dose (Gy)/#	#/week	Comments
a. Localised prostate cancer with curative intent	60Gy/47-48Gy/20# P/SV 44-47Gy/20# pelvic nodes	5	Overall treatment time >=27 days ⁹ . Departments may wish to adopt CHHiP 3 dose level or PIVOTAL Boost/PACE C 2 dose level approach for P and SV
	55Gy/20# P/SV	5	If required for OAR sparing or co-morbidities
	74Gy/59.2-60Gy/37# P/SV 55/37# to pelvic nodes	5	If unsuitable for hypofractionation
	37.5Gy/15# P/SV with HDR boost 46Gy/23# P/SV +/- pelvic nodes with HDR boost	5	15Gy HDR boost approx. 2 weeks prior to or after EBRT
	46Gy/23# P/SV +/- pelvic nodes with LDR boost	5	110Gy LDR boost ¹¹
	Stereotactic radiotherapy (SBRT) 36.25Gy in 5#	Max 3	For patients meeting PACE-B trial criteria ¹²
b. Post- operative	66Gy/33# 52-54Gy/33# to pelvic nodes	5	Pelvic nodal radiotherapy at clinician discretion
prostate bed radiotherapy	52.5-55Gy/20# 44/20# to pelvic nodes	5	
c. Palliative radiotherapy	36Gy/6#	1	Recommended dose fractionation for low volume hormone sensitive metastatic prostate cancer
	55Gy/20#	5	Alternative for low volume hormone sensitive metastatic prostate cancer
	36Gy/6#	1	Varying dose/fractionation
	30Gy/10#	5	schedules at clinician discretion
	20Gy/5#	5	for local control/palliation of
	21Gy/3#	3	symptoms.
	8Gy/1#	1	

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4.0 Target volumes

- Outlining is performed with reference to the diagnostic MRI scan and in line with ESTRO-ACROP consensus guidelines 2018¹³ or according to trial protocol if applicable.
- Standard target volume nomenclature should be used: https://www.aapm.org/pubs/reports/RPT_263.pdf
- Target volumes should match agreed naming conventions unless there are operational reasons for use of other naming. PTV ProKnow nomenclature should be used for NHSE ProKnow Collections and Scorecard Templates for upload.

4.1 Curative radiotherapy GTV/CTV

GTV

• It is helpful to outline the dominant intraprostatic lesion (DIL) as the GTV, but the entire prostate gland will be included in the CTV_Prostate

CTV

- CTV_Prostate (CTVp) is defined according to consensus guidelines¹⁴ and
 encompasses the entire prostate gland and any microscopic extraglandular
 extension and/ or extension of GTV into SVs. Care should be taken to exclude the
 base of the bladder (unless involved) and the urogenital diaphragm (unless apex
 affected).
- CTV_Seminal vesicles (CTVsv)will vary and is dependent on trial protocol if applicable or individual risk¹⁴
 - For low-risk cases no inclusion or inclusion of proximal 1.4cm of the SV (in the axial plane) according to institutional policy
 - For intermediate-risk cases inclusion of at least proximal 1.4cm of the SV (in the axial plane)
 - o For high-risk cases inclusion of at least 2.2cm of the SV (in the axial plane)
 - Where the SVs extend significantly posteriorly around the rectum, the posterior tips of the SVs may be excluded at the clinician's discretion to improve the dose distribution to the rectum
- CTV_nodes (CTVe) is best created by a multi-step process such as that described in the PIVOTAL-Boost Trial Atlas, initially outlining pelvic vessels, and using a bowel expansion technique. 2021 amendments to the RTOG/NRG atlas guidelines¹⁴ indicate that the nodes to be included extend superiorly to the bifurcation of the aorta though this has not yet been adopted in UK trial guidelines.

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4.2 Post-operative radiotherapy CTV

• CTV_Prostate Bed (CTVpb)

- Several guidelines exist for contouring the postoperative prostate bed CTV.¹⁵⁻¹⁹
 Additional information is available in the POPS trial protocol. The CTV will vary depending on operative histological findings (SV involvement, positive apical margin etc)
- The addition of pelvic lymph node radiotherapy (CTV as for primary curative radiotherapy above) is at clinician discretion

4.3 Curative / adjuvant radiotherapy PTV

- PTV margins from CTV for primary curative radiotherapy are as defined for each department with reference to departmental verification methods and audit.
- PTVpb = CTVpb +7-10mm

4.4 Palliative radiotherapy

- Low volume de novo metastatic prostate cancer
 - CTV includes prostate gland and base of seminal vesicles if involved macroscopically⁵
- Palliative radiotherapy for local control/symptoms
 - o CTV includes all symptomatic macroscopic disease

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5.0 Organs at risk

 Aim for the use of standard nomenclature as per Global Harmonization Group consensus guidelines: https://www.thegreenjournal.com/action/showPdf?pii=S0167-8140%2820%2930294-2

Structure name	Description
Rectum	Superiorly rectosigmoid junction (anterior reflection at ~S3), minimum 2cm above CTV_SV; inferiorly c.2cm below lowest prostatic apex contour/inferior border of ischial tuberosities
Bladder	Whole bladder excluding CTV_P
Bowel	All bowel loops up to min of 2cm above sup most PTV
PenileBulb	Best visualised on MRI T2 sequences
Femur_Head_L or _R	Optional. If femoral head not contoured, then clinician accepts optimal constraints may not be met.
Urethra	Prostatic urethra - the lumen-mucosal interface, extending from bladder neck to the membranous urethra.

5.1 Constraints

- OAR dose constraints for Radical and Palliative dose schedules are shown below.
- If any dose constraints fail, the planner will discuss with a consultant prostate oncologist whether the plan is acceptable or whether alterations to CTV, dose/fractionation, or compromise on PTV coverage should be made on an individual patient basis.

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Radical dose schedules - Localised prostate cancer

- 20 fraction treatments 60Gy/20#/daily
 - Radical Prostate/SV Only
 - PTVp 6000 = 60Gy
 - PTVpsv 4700-4800 = 47-48Gy
 - Radical Prostate/SV and pelvic lymph nodes
 - PTVp 6000 = 60Gy
 - PTVpsv_4700= 47Gy
 - PTVe_4400-4700 = 44-47Gy
 - These constraints also to be used when Radical patients are treated with 55Gy/20#

Structure name	Constraint	Optimal	Mandatory
	(Gy)		
Rectum	V20	85% ²⁰	-
	V24	70%	80%
	V30	57% ²⁰	-
	V32	51%	65%
	V40	38% ²⁰	50%
	V48	27%	35%
	V50	22% ²⁰	-
	V52	-	30%
	V56	-	15%
	V60	0.01% ²⁰	3%
	V64	0%	1%
	V67	-	0%
	D mean	<= 35Gy	-
Bladder	V40	50%	-
	V48	25%	50%
	V60	5%	35%
Bowel	V36	78cc	158cc
	V40	17cc	70cc
	V44	14cc	28cc
	V48	0.5cc	6сс
	V52	-	Осс
PenileBulb	V22	50%	-
	V48	10%	-
Femur_ Head_ L or _R	V40	5%	50%

 OAR constraints from PIVOTAL BOOST protocol v2.3 May 2020 (without HDR) and updated CHHiP anorectal constraints 2020²⁰.

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• 37 fraction treatments – 74Gy/37#/daily

- Radical Prostate/SV Only
- Radical Prostate/SV and pelvic lymph nodes
 - o PTVp_7400= 74Gy
 - o PTVpsv_5920-6000 = 59.2-60Gy
 - PTVe_5500= 55Gy

Structure name	Constraint (Gy)	Optimal	Mandatory
Rectum	V30	80%	-
	V40	65%	-
	V50	50%	60%
	V60	35%	50%
	V65	-	30%
	V70	-	15%
	V74	-	3%
Bladder	V50	50%	-
	V60	25%	-
	V65	-	50%
	V70	5%	35%
	V74	-	5%
Bowel	V45	78cc	158cc
	V50	17cc	110cc
	V55	14cc	28cc
	V60	0.5cc	6cc
	V65	-	Осс
PenileBulb	V27	50%	-
	V60	10%	-
Femur_Head_L or _R	V50	5%	50%

 OAR constraints from PIVOTAL trial protocol. Penile bulb and femoral head constraints from Atlanta V2.0 December 2021²¹

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• SBRT - 36.25Gy/5#

o Radical Prostate/SV Only

Structure name	Constraint (Gy)	Optimal	Mandatory
Rectum	18.1	-	50%
	29	-	20%
	36	1cc	2cc
Bladder	18.1	-	40%
	37	5cc	10cc
Bowel	18.1	-	5cc
	30	-	1cc
PenileBulb	29.5	50%	-
Femur_Head_L or _R	14.5	5%	-
Urethra (if visualised)	42	50%	-
	45	<0.001cc*	-

• OAR constraints from PACE trials; *PACE-NODES

Palliative dose schedules

- Prostate and SV +/- nodes
 - o 55Gy/20#/4 weeks
 - o PTVpsv_5500 = 55Gy
 - o PTVe_4400 = 44Gy (clinician discretion)

Structure name	Constraint (Gy)	Optimal	Mandatory
Rectum	V22.6	70%	80%
	V29.7	51%	65%
	V37.4	38%	50%
	V44.6	27%	35%
	V48.4	1	30%
	V52.3	-	15%
	V55	3%	5%
Bladder	V37.4	50%	1
	V44.6	25%	50%
	V55	5%	35%
Bowel	V37.4	1	17cc
PenileBulb	V20.2	50%	-
	V44.6	10%	-
Femur_Head_L or_R	V37.4	5%	50%

• OAR constraints from ATLANTA protocol V2.0

Prostate and SV ONLY

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o 36Gy/6#/6 weeks

o PTVpsv_3600 = 36Gy

Structure name	Constraint (Gy)	Optimal	Mandatory
Rectum	V14.8	70%	80%
	V19.4	51%	65%
	V24.5	38%	50%
	V29.2	27%	35%
	V31.7	1	30%
	V34.2	-	15%
	V36	3%	5%
Bladder	V24.5	50%	ı
	V29.2	25%	50%
	V36	5%	35%
Bowel	V24.5	-	17cc
PenileBulb	V24.5	50%	1
	V29.2	10%	-
Femur_Head_L or _R	V24.5	5%	50%

OAR constraints from ATLANTA protocol V2.0 December 2021

Structure name	Constraint (Gy)	Optimal	Mandatory
Rectum	V33.3	-	50%
	V27.8	-	60%
	V16.7	-	80%
Bladder	V33.3	-	25%
	V27.8	-	50%

Alternative OAR constraints from STAMPEDE⁵ trial



Constraints are for the EBRT plans only, separate constraints for brachytherapy are included in the EofE ODN protocol for HDR Prostate².

Prostate and SV 37.5Gy/15# +15Gy HDR

Structure name	Constraint (Gy)	Optimal	Mandatory
Rectum	V25	38%	50%
	V30	27%	35%
	V33	-	30%
	V36	-	15%
	V37.5	3%	5%
Bladder	V25	50%	-
Bowel	V36	78cc	158cc

OAR constraints from PIVOTAL BOOST trial protocol v2.3 May 2020 (with HDR) for 37.5 Gy/15 #

Prostate and SV +/- nodes 46#/23# +15Gy HDR or 110Gy LDR

Structure name	Constraint (Gy)	Optimal	Mandatory
Rectum	V18.6	80%	•
	V24.9	65%	1
	V31.1	50%	60%
	V37.3	35%	50%
	V40.4		30%
	V43.5	-	15%
Bladder	V31.1	50%	ı
	V37.3	25%	1
	V40.4	-	50%
	V43.5	5%	35%
Bowel	V37.6	78cc	158cc
	V41.8	17cc	110cc
	V46	14cc	28cc
	V50.2	0.5cc	6сс
	V54.4	-	Осс

OAR constraints scaled from Pivotal trial protocol 74Gy/37# to 46Gy/23# assuming Rectum/Bladder receive 74Gy and Bowel receives nodal dose of 55Gy

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6.0 Planning process/ technique

- VMAT/RapidArc or IMRT for radical RT
- VMAT/IMRT or Simple field arrangements for palliative RT

7.0 Peer Review/ Contour QA

- Prospective peer review should occur for cases where considerable individual judgement is required²². This may include
 - o Radical prostate and pelvic nodal volumes
 - Post-operative prostate bed +/ nodes
 - o Patients receiving an HDR or LDR boost
 - Difficult volumes at consultant request
- A proportion of standard radical prostate volumes should be reviewed retrospectively.
 If a patient develops significant acute or late toxicity retrospective peer review should occur.
- A description of the contouring (planning note) and of the peer review process including changes made should be saved in the patient record.
- The peer review process and outcomes should be audited.

8.0 Target verification

Daily online IGRT with soft tissue matching or fiducials⁷

Modality	Frequency		Additional information
СВСТ	Daily	Prostate	Kv planar if gold fiducials in place +/- CBCT

9.0 Side effects

Acute and late side effects are detailed in the RCR National Consent Form for prostate
 RT National radiotherapy consent forms | The Royal College of Radiologists (rcr.ac.uk)

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12.0 Amendment History

A record of changes in this document

Date	Updated version number	Previous version number	Page Number/ Section (updated version)	Details
06/03/23	V1.0			New Document
19/03/24	V2.0	V1.0	1.2.4 3.0 5.1 p14	Added abbreviated names for Targets e.g. CTVe. Updated elective nodal nomenclature from n to e in line with Proknow reporting. Reference to NICE guidelines added for rectal spacers 46Gy/23# +/- pelvic nodes (instead of just + nodes) with HDR boost added, as option to give 46Gy/23# for localised disease when not treating nodes. Updated formatting for all constraints table OAR constraints for EBRT with HDR boost added as not covered by ODN HDR Prostate protocol. Updated reference to ODN HDR Prostate protocol V2.0 as now issued.
23/05/24	V2.1	V2.0	15	Mandatory constraint for rectum V40.4 corrected to 30% and optimal constraint removed
09.12.25	V3	V2	Section 11	Membership updated
			Section 4	Target volume information updated
			Section 3	Dose prescription table updated
			Section 5	OAR structures updated
			Section 5	OAR constraints tables added for px updates
			Throughout	60Gy for elective nodes removed from px and OARs etc.

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