

# Non-spine Bone Stereotactic Ablative Radiotherapy (SABR) Protocol V2.0

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# 1.0 Indications and patient population

This protocol covers treatment in the following situation: patients with metachronous oligometastatic disease meeting the NHSE criteria outlined below, and with at least one non-spine skeletal metastasis.

### 1.1 Treatment eligibility

### 1.1.a Inclusion criteria

As per NHS England commissioning document:

- Confirmed histological diagnosis of cancer (haematological malignancies excluded)
- Metachronous disease, with a disease-free interval between primary treatment and manifestation of metastases of at least 6 months
- 1-3 sites of extracranial metastatic disease only at the time of disease presentation, confined to one or two of the following organs: bone, spine, lymph nodes, liver, lungs, adrenals
- Maximum of 2 vertebral metastases
- Maximum size of 5 cm for any single metastasis
- Life expectancy of more than 6 months
- WHO Performance Status 0-2

### 1.1.b Exclusion criteria

As per NHS England commissioning document:

- Haematological malignancies
- Evidence of intracranial disease
- For spine metastases, evidence of spinal cord compression or spinal instability
- For lung metastases, evidence of severe interstitial lung disease
- For liver metastases, poor liver function/Child-Pugh score B
- More than 3 sites of metastatic disease, **or** development of new metastases post treatment of a maximum of 3 lesions
- Patients who require irradiation of a whole nodal field
- Previous SABR to the same site of metastatic disease

### 1.1.c Essential Pre-Radiotherapy investigations for patients

Patients should have whole body imaging within 6 weeks of MDT discussion, confirming eligibility for SABR.

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# 2.0 Localisation

Localisation	Notes
Position	Need for patient positioning and immobilisation methods will depend on the site being treated, and should be discussed prior to the CT localisation appointment, to ensure adequate equipment is available.
Arm/ leg/ head/ thorax position	As above
Immobilisation and	Abdominal compression can be considered for patients where breathing motion may affect the target (e.g. ribs or
supports	sternum).
	Consider patient preparation with additional analgesia as needed.
Organ pre-requisites	
Contrast	I.V. contrast will not usually be needed for non-spine bone SABR but may be helpful in selected cases to aid OAR delineation (e.g. brachial plexus).
CT acquisition	Slice thickness: 1-2 mm for bones outside the thorax; 2-3 mm for bones inside the thorax.
	Scanning limits: At least 10cm superior and inferior to expected PTV.
	If part of the liver, kidney, spleen, or lung is likely to receive a clinically significant dose then the entire organ needs to be included in the scan.
	If multiple metastases that impact on the same organ at risk are being treated, then ONE scan should be taken that covers ALL areas in order that a composite plan can be created.
	For thoracic bone metastases (e.g. ribs, sternum) an additional reduced length 4D CT planning scan may be obtained.

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Localisation	Notes
Additional imaging	A dedicated planning MRI will usually help with GTV delineation and should therefore be considered in many cases. This should then be fused with the planning CT.
	Fusion of diagnostic PET images may also help with GTV delineation, and therefore should also be considered, where available.

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# 3.0 Dose prescription & chemotherapy

Dose (Gy)/#	#/week	Chemo/ comments
30-40	3	No prior irradiation
30-40	5	For selected patients e.g. where the target is very close to critical organs at risk, or there has been prior irradiation close to target. 5-fraction regimen should also be considered when treating metastases involving the femoral head or neck

# 4.0 Target volumes

## 4.1 3D scanned GTV/CTV/ PTV

- GTV\_3D = all visible disease as defined on CT, and any additional imaging.
- CTV \_3D= GTV\_3D with a margin of 2-7mm, depending on the case, is usually recommended, and will be confirmed by the treating clinician after contouring the GTV. The CTV will then be "trimmed" back to the surface of the involved bone, unless there is clear soft tissue extension of the GTV outside the bone.
- **PTV** = CTV 3D + 0.5cm

### 4.2 4D Scanned GTV/ CTV/ PTV

- A 4D GTV is created using the 4DCT dataset (in cases of thoracic bone SABR if respiratory motion is expected)
- **GTV\_4D** = all visible disease, covered in all phases of the breathing cycle.
- CTV\_4D = GTV\_4D with a margin of 2-7mm, depending on the case, is usually recommended, and will be confirmed by the treating clinician after contouring the GTV. The CTV will then be "trimmed" back to the surface of the involved bone, unless there is clear soft tissue extension of the GTV outside the bone. This is done most accurately by applying the CTV margin to the GTV on each bin of the 4DCT, and trimming back to bone, then combining all the bins together to produce the CTV\_4D
- PTV = CTV 4D + 0.5cm

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**Note**: These are the minimum allowable PTV margins. Larger margins may be used at the clinical oncologist's/local department's discretion, where there is more uncertainty in setup, tumour motion etc.

# 5.0 Organs at risk

- Aim for the use of standard nomenclature as per Global Harmonization Group consensus guidelines (<a href="https://www.thegreenjournal.com/action/showPdf?pii=S0167-8140%2820%2930294-2">https://www.thegreenjournal.com/action/showPdf?pii=S0167-8140%2820%2930294-2</a>) and the report of the AAPM TG 263.
- All organs at risk will be contoured on the 3D planning CT. The required organs at risk will depend on the site to be treated.
- Generally, any OARs within 3cm sup-inf from the maximum extent of the PTV will need to be outlined.
- Parallel organs such as lungs, liver and kidney lying within 3cm sup-inf of the PTV need to be outlined in their entirety. Spinal canal should be outlined in all cases.
- When treating bone metastases very close to the spinal canal then spinal cord/cauda equina should also be outlined using the fused MRI images if available.

### **5.1 Constraints**

		3 Fractions		5 Fractions	
		Objective	Constraint	Objective	Constraint
	V100%	≥95%	-	≥95%	-
PTV	D95%	100%	-	100%	-
	D0.1cc	130-140%	110-140%	130-140%	110-140%
	PTV ≤ 20cc	≤ 1.25 (ideal 1.2)	≤ 1.40	≤ 1.25 (ideal 1.2)	≤ 1.40
Conformity Index (V100% / PTV V100%)	PTV 20-40cc	≤ 1.20 (ideal 1.1)	≤ 1.30	≤ 1.20 (ideal 1.1)	≤ 1.30
	PTV ≥ 40 cc	≤ 1.15 (ideal 1.1)	≤ 1.20	≤ 1.15 (ideal 1.1)	≤ 1.20
Modified Gradient Index (V50% /PTV V100%)	PTV ≤ 20cc	≤ 7.5 (ideal 5.5)	≤ 9.5	≤ 7.5 (ideal 5.5)	≤ 9.5
	PTV 20-40cc	≤ 6.0 (ideal 4.5)	≤ 7.5	≤ 6.0 (ideal 4.5)	≤ 7.5

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		3 Fractions		5 Fra	ctions
		Objective	Constraint	Objective	Constraint
	PTV ≥ 40cc	≤ 5.5 (ideal 4.5)	≤ 6.5	≤ 5.5 (ideal 4.5)	≤ 6.5
BrachialPlex_L BrachialPlex_R	D0.1cc	-	≤24Gy	≤30.5Gy	≤32Gy
Heart+A_Pulm	D0.1cc	≤26Gy	≤30Gy	≤29Gy	≤38Gy
Lungs (non-lung lesions)	V20Gy	≤10%	≤15%	≤10%	≤15%
,	Dmean	≤8Gy	-	≤8Gy	-
Chestwall_L, Chestwall_R	D0.1cc	≤36.9Gy	-	≤43Gy	-
_	D30cc	≤30Gy	-	-	-
<b>GreatVes</b> (Great Vessels)	D0.1cc	-	≤45Gy	-	≤53Gy
Trachea and Proximal bronchial tree	D0.1cc		≤30Gy	≤35Gy	≤38Gy
SpinalCanal (inc. medulla)	D0.035cc	-	≤20.3Gy	-	≤25.3Gy
CaudaEquina	D0.035cc	-	≤24Gy	-	≤32Gy
	D5cc	-	≤21.9Gy	-	≤30Gy
LumbSacPlex_L, LumbSacPlex_R	D0.1cc	≤24Gy	-	≤32Gy	-
_	D5cc	≤22.5Gy	-	≤30Gy	-
Duodenum	D0.1cc	-	≤22.2Gy	≤33Gy	≤35Gy
	D10cc	-	≤11.4Gy	≤25Gy	-
Stomach	D0.1cc	-	≤22.2Gy	≤33Gy	≤35Gy
	D10cc	-	≤16.5Gy	≤25Gy	-
	D50cc	-	-	≤12Gy	-
Bowel_Small	D0.1cc	-	≤25.2Gy	≤30Gy	≤35Gy
	D5cc	-	≤17.7Gy	-	-
	D10cc	-	-	≤25Gy	
Oesophagus	D0.1cc	-	≤25.2Gy	-	≤35Gy
Bowel_Large	D0.1cc	-	≤28.2Gy	-	≤38Gy
Rectum	D0.1cc	-	≤28.2Gy	-	≤38Gy

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		3 Fractions		5 Fractions	
		Objective	Constraint	Objective	Constraint
<b>Liver</b> (non-liver lesions)	Dmean	≤13Gy	≤15Gy	≤13Gy	≤15.2Gy
	V10Gy	-	1	≤70%	-
	D(Vтот-700cc)+	≤15Gy	≤17Gy	≤15Gy	-
Kidney_Cortex_L, Kidney_Cortex_R,	Dmean	≤8.5Gy	-	≤10Gy	-
Kidney_Cortex (Combined kidney cortices)	D(Vтот-200cc) <sup>+</sup>		≤16Gy		≤17.5Gy
If solitary  Kidney_Cortex or if one Kidney_Cortex mean dose ≥optimal constraint	V10Gy\$	1	≤33%	≤10%	≤45%
Spleen *	Dmean	10Gy	-	10Gy	-
Bladder	D0.1cc	-	≤28.2Gy	-	≤38Gy
Ureter_L Ureter_R	D0.1cc	-	≤40Gy	-	-
Urethra	D0.1cc	report			
Testes, Genitals		Avoid beam entry; dose as low as possible			ossible
<b>SkinRind</b> (the 5mm rind within	D0.1cc	≤33Gy	-	≤39.5Gy	-
Skin contour)	D10cc	≤30Gy	-	≤36.5Gy	-
Femur_HeadNeck_L, Femur_HeadNeck_R (Femoral Heads)	D10cc	≤21.9Gy	-	≤30Gy	-

OAR dose constraints as per <u>UK 2022 Consensus</u> publication.

# 6.0 Planning process/ technique

- All patients will be treated using Volumetric Modulated Arc Radiotherapy (VMAT).
- 100% of the dose will be prescribed to at least 95% of the PTV (i.e. DX%=100% where X is ≥95%). Aim to increase PTV coverage (with the prescribed dose) above 95%,

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<sup>&</sup>lt;sup>+</sup> Cold constraint (VTOT – xcc) is the total volume of organ minus a specified volume)

<sup>&</sup>lt;sup>\$</sup> Of the kidney receiving the lower dose

<sup>\*</sup>Splenic constraint is based on recent RCR recommendation



- while still achieving OAR constraints AND conformity index/modified gradient index objectives.
- For patients with two or more sites for SABR whose dosimetry impacts on the same organs, the total combined doses to these organs must be within the constraints a composite plan will be created. For retreatment or treatments near previously treated areas the dose given previously must be taken into account. For spinal cord tolerance the method described by Sahgal is recommended. This states that the maximum cumulative dose to the thecal sac should not exceed a BED of 140Gy  $(\alpha/\beta=2Gy)$ .
- All plans will be approved by the clinical oncologist.

# 7.0 Peer Review/ Contour QA

- Prospective peer review of target and OARs by a second Oncologist with SABR experience is strongly recommended.
- 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

Modality	Frequency	Match point	Additional information
CBCT Stereoscopic kV/kV FBCT	Daily*	Bone	Consider 4DCBCT for intra-thoracic bone.  Consider intra-fractional imaging to assess movement.
			**Pre and post treatment CBCTs may be taken as required

# 9.0 Side effects

Please consult side effect information available relevant to the body site being treated.

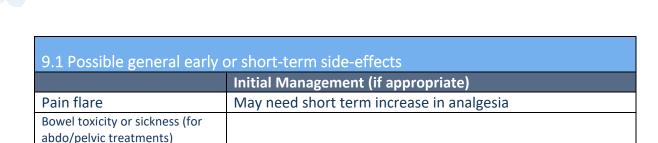
9.1 Possible general early or short-term side-effects				
Initial Management (if appropriate)				
Fatigue				
Skin reaction	Standard post-radiotherapy skincare			

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9.2 Possible late or long-term side-effects				
	Initial Management (if appropriate)			
Bowel toxicity (for abdo/pelvic				
treatments				
Increased risk of	Analgesia where needed. Referral to orthopaedic team may			
insufficiency fracture	be indicated			

# 10.0 References

Clinical Commissioning Policy Stereotactic ablative radiotherapy (SABR) for patients with metachronous extracranial oligometastatic cancer (all ages) (URN: 1908) [200205P]; March 2020. 1908-cc-policy-sbar-for-metachronous-extracranial-oligometastatic-cancer.pdf (england.nhs.uk)

Stereotactic Ablative Body Radiotherapy (SABR): A resource; UK SABR Consortium; January 2019. <u>SABRconsortium guidelines 2019 v6.1.0</u>

Standardizing nomenclatures in Radiation Oncology: The report of the AAPM Task Group; January 2018. TG-263: Standardizing Nomenclatures in Radiation Oncology (aapm.org)

Mir R et al (June 2020). Organ at risk delineation for radiation therapy clinical trials: Global Harmonization Group consensus guidelines. *Radiotherapy and Oncology* **150** (2020), 30-39. <u>Organ at risk delineation for radiation therapy clinical trials: Global Harmonization Group consensus guidelines - Radiotherapy and Oncology (thegreenjournal.com)</u>

Center for Innovation in Radiation Oncology; Contouring atlases, templates, and tools. <u>NRG > About Us > Center for Innovation in Radiation Oncology (nrgoncology.org)</u>

Diez P et al (May 2022). UK 2022 Consensus on normal tissue dose-volume constraints for oligometastatic, primary lung, and hepatocellular carcinoma Stereotactic Ablative Radiotherapy. Clinical Oncology 34 (2022), 288-300. UK 2022 Consensus on Normal Tissue Dose-Volume Constraints for Oligometastatic, Primary Lung, and Hepatocellular Carcinoma Stereotactic Ablative Radiotherapy - Clinical Oncology (clinicaloncologyonline.net)

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<u>Incidental irradiation of the spleen - RCR guidance | The Royal College of Radiologists.</u>

https://www.rcr.ac.uk/our-services/all-our-publications/clinical-oncology-publications/incidental-irradiation-of-the-spleen-rcr-guidance/

# 11.0 Members of the protocol drafting committee

Cambridge University Hospital NHS Foundation Trust: Alex Martin (Chair), Donna Routsis, Lizzie Tait, Andrew Robinson, Rosanna Stott, Hannah Chantler, Jennifer Mehrer

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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
02.10.24	V1.0			New Document
01.05.25	V2.0	V1.0	Section 11	Membership updated

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