West Midlands Radiotherapy
Operational Delivery Network

West Midlands Radiotherapy Clinical Protocol

Stereotactic Ablative Radiotherapy (SABR)
For Extracranial Oligometastatic Disease (Simple)

Revision History

Version	Date	Summary of changes
0.1	30.5.22	Initial draft Linda Farthing, based on regional protocols
0.2	13.6.22	Updated and reviewed by Dr A Chan
0.3	24.8.22	Reviewed by G Webster
0.4	21.9.22	MPE review by M Jones, UHCW
0.5	23.9.22	Reviewed and feedback from Dr J Sherriff, H Howard, Dr M Sivaramalingam, Dr S Vengalil
0.6	2.11.22	Reviewed by Dr B Kurec
0.7	3.11.22	Dr A Chan updated with final comments
0.8	29/11/22	MPE review by M Jones, UHCW.
0.9	December 2022	Updated following comments from regional review
1.0	January 2023	Sent for further regional review
1.0	February 2023	Amended following discussions at the SABR protocol meeting
1.1	February 2023	Ratified Final not approved at EAG due to more comments received
1.2	February 2023	Updated by M.Jones & Dr.A.Chan, UHCW following regional comments
1.2	14th April 2023	Submitted to EAG for ratification
1.2	14th April 2023	Ratified at the EAG
1.3	5th May 2023	Index reformat and Clinician names updated.
Review Date:	April 2025	

Approved by

This document must be approved by the following people:

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CONTENTS PAGE

Purpose

- To provide a standardised protocol for planning and delivery of external beam radiotherapy for patients undergoing Stereotactic Ablative Radiotherapy treatment for extracranial oligometastatic cancer within the West Midlands
- This document describes the procedures involved in the image acquisition, structure delineation, treatment planning, verification and treatment delivery of patients with extracranial oligometastatic cancer.
- It has been written in accordance with the UK SABR consortium guidelines v6.1
- SABR is delivered in partnership across the West Midlands, with Oncologists supported by cross regional specialist MDT's.

Information & Consent

- Each patient should be consented with individualised information of planned treatment, individualised risks-benefits and toxicities
- Patients should be consented by a clinical oncologist (or their deputy) specialising in SABR.
- Patients should be asked to give consent for the anonymised data to be collected for the purpose of audit, peer review and service development.
- Booking form and consent completed by the IR(ME)R practitioner
- Patients will receive a SABR information leaflet which details the procedure, the acute and long-term side effects, and provides the contact details for the SABR Specialist Radiographer or Radiotherapy Department.

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. See local protocols for departments with Advanced Practice Practitioners.
- Operators: Radiographers, Physicists, 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 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.

1. CLINICAL INDICATIONS FOR RADIOTHERAPY

All potential SABR patients should be reviewed at a SABR MDT meeting to ensure appropriate selection and suitability

1.1. Inclusion criteria

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

- Confirmed histological diagnosis of metastatic cancer originating from any primary cancer in the body, including carcinoma, sarcoma and melanoma.
- A disease-free interval between primary treatment and manifestation of metastases of at least six months.
- One to three sites of extracranial, metastatic disease only at the time of disease presentation, confined to one to two organs (defined after appropriate imaging) in the following: Bone; Spine; Lymph node; Liver; Adrenal gland; Lung
- Maximum size of 5 cm for any single metastasis.
- A life expectancy of at least 6 months
- World Health Organisation (WHO) performance status ≤ 2
- Primary site must be controlled

1.2 Exclusion criteria

Treatment with SABR is unsuitable in people with:

- Haematological malignancies (e.g. lymphoma, myeloma)
- Evidence of intracranial disease;
- Evidence of spinal cord compression or spinal instability;
- Evidence of severe interstitial lung disease (for lung metastases)
- More than 3 sites of metastatic disease or development of new metastases post treatment of a maximum of 3 lesions;
- A disease-free interval between primary treatment and manifestation of metastases of less than 6 months;
- Severe co-morbidities or
- WHO performance status ≥3

In addition, SABR is not suitable in people who:

- Require irradiation of whole nodal field (eg supra-clavicular recurrence for breast cancer)
- Have had previous treatment with SABR to the same site of the metastases

1.3 Lung Oligometastatic Disease and Mediastinal Lymph Nodes

- Treatment of lung oligometastatic disease and mediastinal lymph nodes should follow the WM lung SABR protocol for all aspects of patient treatment.
- Mediastinal lymph nodes to be treated as per central/ultra-central lung metastasis after careful consideration in the MDT.

2. Pre-treatment assessment

All patients will be discussed at a SABR MDT meeting (consisting of a SABR clinician, SABR physicist, SABR radiographer, and where available a dedicated radiologist) with review of the following:

- Clinical history and imaging (in particular the inclusion and exclusion criteria)
- If the patient has been reviewed in the site specific MDT with other alternative options discussed and agreed SABR is appropriate
- Any technical factors such as the presence of hip prosthesis/other implants which can hinder optimal outlining, SABR planning or treatment verification

3. Patient position / Immobilisation

- Patients should be positioned and immobilised suitable for the treatment site supine, with patient specific indexed immobilisation equipment as per local protocols.
- Ensure that the patient is comfortable in the chosen position and is able to maintain the position for at least 20 minutes.
- Centres should assess the accuracy of immobilisation device(s) used for positioning patients for SABR especially if changes are made to the equipment used

3.1. Pelvic Lymph Nodes

- Patient positioned supine with patient specific indexed combi fix for legs or similar.
- Scoop and block under head.
- Hands on chest.
- Patients scanned with an empty bladder and bowels unless the consultant specifies otherwise.
- Anterior and two lateral tattoos for alignment (can be omitted according to local protocol if utilising SGRT)

3.2. Para-aortic Lymph Nodes

- Patient positioned supine with patient specific indexed combi fix for legs or vac bag
- Scoop and block under head.
- Arms displaced out of radiotherapy field using local protocol (eg. above head using chest board or similar)
- Motion management is mandatory according to local centre where the target is affected by respiration. This can include the use of:
    - Abdominal compression devices (if tolerated) to reduce respiratory motion
    - 4DCT to enable ITV formation
    - Activated Breathing Control (ABC) / Breathold/ Gating (as per local expertise)
    - SGRT to reduce respiratory motion and/or to enable respiratory gating
- Patients to have U&E and LFTs
- Nil by mouth for 2 hours before CT planning scan
- Bladder and bowel preparation as appropriate
- IV ± oral contrast according to local protocol
- Tattoos for alignment (anterior and two lateral tattoos, tattoos at level of xiphisternum or L2) (can be omitted according to local protocol if utilising SGRT)

3.3. Bone (Non Spine)

- Immobilisation will depend on the site of bone metastases.
- Where possible, patients will be treated supine, with patient specific indexed combi fix for legs, or similar
- Scoop and block under head.
- Hands on chest (out of radiation beam).
- Respiratory motion management such as 4DCT or abdominal compression according to local centre for lesions where there is respiratory motion (e.g. rib/sternum metastases)
- Tattoos for alignment depending on site (can be omitted according to local protocol if utilising SGRT)

4. Imaging for planning

- All patients will have a planning CT scan with slice thickness ≤3mm.
- CT scanning levels will be as per local protocol, examples below

Thoracic	A 4DCT scan should be acquired sufficient to include all potential organs at risk, and account for the full range of tumour motion combine a 4DCT with a 3D scan if required Encompass all adjacent OARs to create DVHs (e.g. liver for RLL lesions) (as per local policy)	IV Contrast given at clinician's discretion and patient suitability
Lymph nodes (Pelvis) Lymph nodes (Para-aortic)	Superiorly: Top of L2 Inferiorly: Below lesser trochanter Superiorly: Top of T12 Inferiorly: 2cm below bottom of L5	IV Contrast given at clinician's discretion and patient suitability IV ± Oral Contrast given at clinician's discretion and patient suitability.
Bone (Non spine)	Scan length sufficient to include lesion and appropriate proximal joint capsule A 4DCT scan should be considered where there is respiratory motion	

5. Volume delineation

GTV	-	Gross Tumour Volume
CTV	-	Clinical Target Volume
ITV	-	Internal Target Volume
PTV	-	Planning Target Volume
PRV	-	Planning organ at risk volume
OAR	-	Organ at Risk

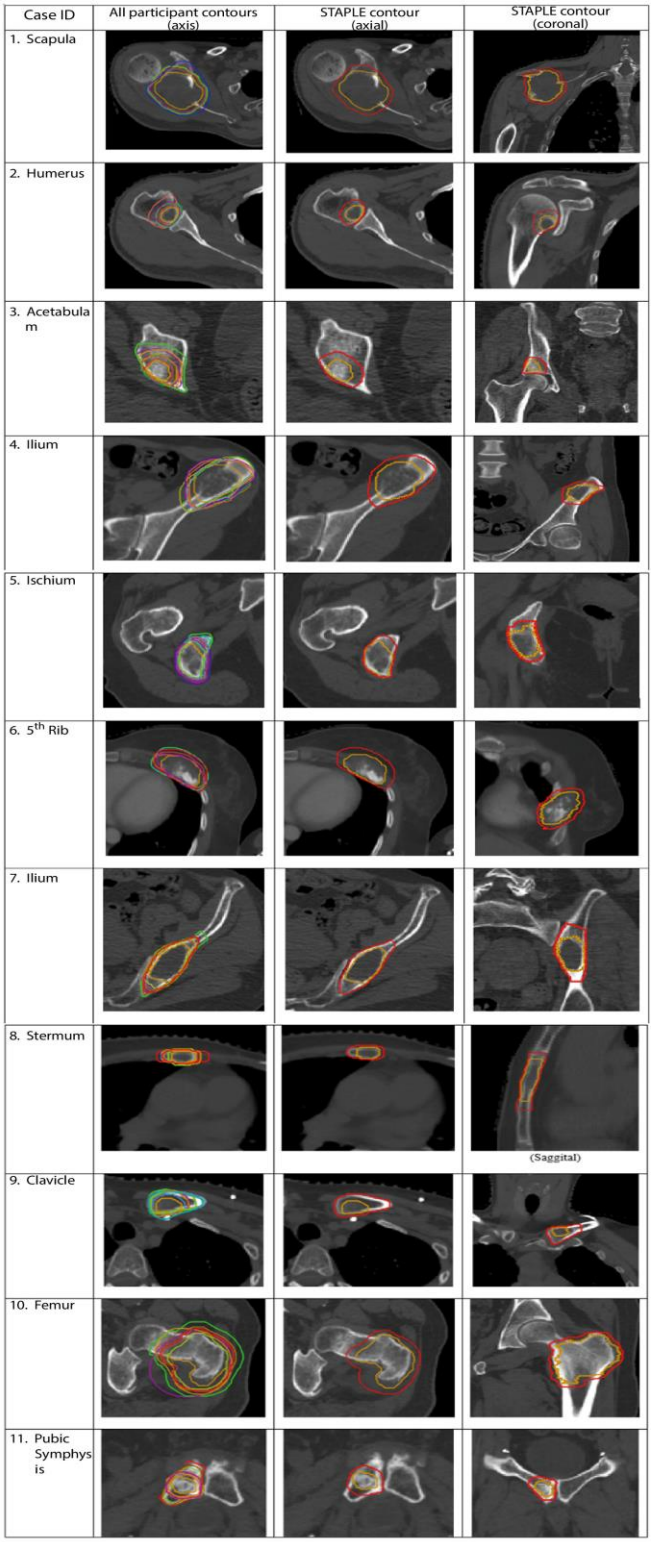
5.1. Targets

- GTV = radiologically visible tumour
  Diagnostic imaging should be used to aid target delineation and fusion with the planning CT scan is encouraged to ensure accurate localisation and delineation.
  Appropriate CT windowing should be used to aid delineation

- For Lymph Node lesions:
  CTV = GTV

- For non-spine bone lesions:
  1. an intraosseous CTV margin of 5-10mm to be considered within contiguous bone
  2. An extraosseous CTV margin of 5-10mm to be considered where there is soft tissue disease or cortical bone disruption
  3. CTVs should respect anatomic barriers to spread (e.g. peritoneal cavity, pleura, uninvolved joint space and cortical bone)

Examples of non-spine bone lesions are given below (Ref. Nguyen T et al. 2022). STAPLE (Simultaneous Truth and Performance Level Estimation) was used in this paper to produce CTV consensus contours (in red)



- Practically, the motion adapted GTV should be delineated using all phases of the respiratory cycle or considering the maximum inhalation phase (0%), maximum expiration phase (50%) and maximum intensity projection (MIP) as per locally agreed practice.

- All contours should be reviewed by another SABR oncologist and where there are any uncertainties with a radiologist.

- Peer review can be undertaken in the SABR MDT meetings or off-line outside of the meeting with recording of the outcome or any recommendations.

- PTV= CTV + 5mm isotropically (or as per local margin).
An anisotropic margin can be considered according to local policy

5.2. Organs at risk

- Any OARs which are traversed by a treatment beam should be contoured. For thoracic OARS, see the WM lung SABR protocol.
- **For coplanar planning outline OAR's within 5cm from PTV.**
- **For non-coplanar planning include all OAR's within the path of the beams.**

- Sufficient OARs should be contoured to show that the OAR constraints have been met; this may require the entire organ to be outlined.
- Consideration of a PRV should be given for serial OARs (e.g. bowel, spinal canal) to account for uncertainties in setup and interfractional anatomical changes depending on local techniques.

Large bowel	The large bowel encompasses the caecum, ascending colon, transverse colon, descending colon, and sigmoid colon in one contour. Bowel loops do not need to be joined up. Contour from the ileocaceal junction to the recto-sigmoid junction. The large bowel can be discriminated from the small bowel by the appearance of bowel contents, presence of haustra, sacculations, and appendices epiploicae. The contour adheres closely to the outer boundary of the external wall and includes large bowel contents.
Small bowel	The small bowel encompasses the duodenum, jejunum, and ileum in one contour. (Duodenum may be outlined separately for upper abdominal targets). Bowel loops do not need to be joined up. Contour from the pylorus to the ileocaecal junction. Ensure small bowel in the lower pelvis caudal to the recto-sigmoid junction is included. The small bowel can be discriminated from the large bowel by the appearance of bowel contents and the presence of valvulae conniventes. The contour adheres closely to the outer boundary of the external wall and includes small bowel contents.
Duodenum	The duodenum will be contoured to include the mucosal bowel wall and contents. The duodenal contour extends from the pylorus to the duodenojejunal junction/ligament of Treitz. The majority of the structure is fixed to the retroperitoneum and follows a C-shaped course around the head of the pancreas. The contour follows four anatomical sections: 1) 5 cm in length and anterolateral to the body of the L1 vertebra 2) 7-10 cm descending adjacent to the L1-3 vertebral bodies 3) 6-8 cm in length, turning medially and crossing the L3 vertebral body. The aorta and inferior vena cava are posterior; the superior mesenteric artery and vein lie anteriorly 4) 5 cm in length and ascending from the L3 vertebral body to the cranial border of the L2 vertebral body
Stomach	The stomach should be contoured from gastro-oesophageal junction to duodenum using mediastinal windowing.
Kidneys	The entirety of each kidney should be outlined separately to allow evaluation of individual kidney dose. A summation of the two volumes should also be created to evaluate total kidney dose. Pelvi-calyceal system and any large cysts may be excluded from the kidney parenchyma
Liver	The whole liver should be outlined, excluding the gall bladder and hepatic vessels. For liver patients, normal liver should be taken as "whole liver" minus the GTV. Care should be taken not to inadvertently include the liver vasculature and/or gall bladder
Rectum	Defined as a solid structure, including the lumen and rectal wall, extending from the anus to the rectosigmoid junction (approximately at level of S3 vertebral body). Rectosigmoid flexure best visualised on sagittal planes.

Bladder	The whole bladder should be outlined. Outer bladder wall is the external delineation limit
Ureter	The ureter will be contoured as a solid structure from the renal pelvis down to the insertion into the bladder wall. The delineation limit is the outer wall of the ureter.
Penile Bulb	The portion of the bulbous spongiosum that lies inferior to the urogenital diaphragm
Femoral Heads	Femoral heads will be contoured from their most cranial aspect to the bottom of the curvature of the femoral head (i.e. exclude the femoral neck).
Spinal canal	The spinal canal is contoured according to the inner limits of the spinal canal using bone windowing. The cranial border is at the superior level of the planning scan The caudal border is the most caudal slice where the spinal canal is visualized, usually at the level of the L5-S1 vertebral bodies. In the region of the lower abdomen and pelvis, the spinal canal is required for reporting dose constraints for both spinal cord and cauda equina. In this instance, use *SpinalCanal_SC* and *SpinalCanal_CE*, respectively, to ensure the correct constraints are applied to each region. The boundary between these two structures is at the level of L1-2 vertebral bodies.
Lumbosacral Plexus	The lumbosacral plexus should be contoured from the L4 nerve root to the superior most portion of the femoral neck. 1. At the L4 and L5 levels, the entire respective foramina should be included. 2. The L4 root should be contoured by including the space defined by the PM anterior and laterally, and the facet joint/posterior vertebral body elements posteriorly. 3. The L5 root should be contoured using the CIV and PM anteriorly, the IM laterally, and the vertebral body and sacrum posteriorly. Below the level of the L5 foramen, the SI joint should serve as the lateral border as well. 4. Beginning at the level of the S1 foramen, the LSP(L4/L5) and S1 lie in the area bounded by the IVs anteriorly, the IM/SI joint laterally, the sacral ala posteriorly, and medial margin of the S1 foramen medially. 5. Beginning at the level of origin of the Pfm, the LSP should be contoured in the space bounded by the IVs anteriorly, IM/iliac wing laterally, and Pfm posteriorly. 6. At the lower margin of the greater sciatic foramen, contour the space bounded by the OIM/ischial spine anteriorly, Pfm laterally, and GM posteriorly. The medial portion of the OIM should serve as the medial extent. 7. Below the Pfm, contour the space between the OIM anteriorly and the GM posteriorly. The medial and lateral extent should be 1 to 2 cm in length. 8. Contour to the level of the superior most portion of the femoral neck. <u>Abbreviations:</u> PM = psoas muscle CIV = common iliac vein IM = iliacus muscle LSP = lumbosacral plexus OIM = obturator internus muscle IVs = iliac vessels Pfm = piriformis muscle GM = gluteus maximus muscle SI = sacroiliac
Skin	Defined as a 3-5 mm inner rind of body contour contoured if adjacent to PTV and in regions receiving more than 10Gy.

6. Dose prescription, fractionation and technique

A clinical oncologist specialising in SABR prescribes the treatment. (Contours and plans should be reviewed by two clinicians).

- 40 Gy in 3 fractions given on alternate days.
- 30 Gy in 3 fractions given on alternate days.
- 30 - 35 Gy in 5 fractions given on alternate days for retreatment or exceptional cases in which the three fraction OAR constraints cannot be met.
- Beam energy – 6MV FFF
- Technique VMAT /RapidArc

7. Treatment Planning

- Where there is likely to be respiratory motion, the extent of that motion should be assessed prior to planning.
- The MPE should consider other methods of reducing interplay after discussion with the Clinician and Planner and depending on the complexity of the plan and the extent of tumour motion.
- If dose constraints cannot be met due to the extent of tumour motion the Clinician should be notified promptly so that alternative treatment options can be considered.

7.1. PTV Dose constraints

- The plan will be normalised such that ≥95% of the target volume receives at least 100% of the prescription dose (e.g. 30Gy/3#).
- The maximum dose within the PTV should optimally be more than 110% and below 140% of the prescription dose. A mandatory constraint is for the maximum dose to be between either 105% -145% of the prescription dose.
- Conformity of PTV coverage will be judged as given in the tables below [1]:

Vol(PTV) (cc)	Vol(100%) / PTV V100%		
	Target	Tolerance	Minor Dev
<20	1.20*	<1.25	1.25 - 1.40
20-40	1.10*	<1.20	1.20 - 1.30
>40	1.10*	<1.15	1.15 – 1.20

Vol(PTV) (cc)	Vol(50%) / PTV V100%		
	Target*	Tolerance*	Minor Dev*
<20	5.5	7.5	7.5 - 9.5
20-40	4.5	6.0	6.0 - 7.5
>40	4.5	5.5	5.5 - 6.5

Where:

Vol(100%)/PTV V100%: the ratio of prescription isodose volume to the volume of the PTV receiving at least the prescription isodose.

Vol(50%)/PTV V100%: the ratio of 50% isodose volume to volume of the PTV receiving at least the 50% isodose.

- When treating bone, the benefit of higher dose inhomogeneity should be balanced with the risk of compromising the mechanical properties of the bone, such as restricting the maximum dose (1cc volume) to 120-130% of the prescribed dose. (Clinical data shows a vertebral compression fracture rate of 23% following 20-23Gy/1#, 8.5% following 24Gy/2# treatment, but insufficient data for a 3# constraint [14], so caution is advised). The accuracy of the algorithm used for dose calculation within bone should also be considered.

7.2. OAR Dose constraints

ABDOMEN-PELVIS

Nomenclature	Metric	3 Fractions		5 Fractions	
		Optimal	Mandatory	Optimal	Mandatory
Bile Duct Common	$D_{0.1cc}$	50 Gy		50 Gy	
Bladder	$D_{0.1cc}$		28.2 Gy		38 Gy
Bowel Large	$D_{0.1cc}$		28.2 Gy		38 Gy
Bowel Small	$D_{0.1cc}$		25.2 Gy	30 Gy	35 Gy
	D_{5cc}		17.7 Gy		
	D_{10cc}			25 Gy	
Duodenum	$D_{0.1cc}$		22.2 Gy	33 Gy	35 Gy
	D_{10cc}		11.4 Gy	25 Gy	
Femur Head Neck	D_{10cc}	21.9 Gy		30 Gy	
Kidney Cortex (individual/combined)	D_{mean}	8.5 Gy		10 Gy	
	$D_{\geq 200cc}$		16 Gy		17.5 Gy
Kidney Cortex (solitary)	V_{10Gy}		33%	10%	45%
Liver (Liver minus GTV)	$D_{\geq 700cc}$	15 Gy	17 Gy	15 Gy	
	V_{10Gy}			70%	
	D_{mean}	13 Gy	15 Gy	13 Gy	15.2 Gy
Rectum	$D_{0.1cc}$		28.2 Gy		38 Gy
Stomach	$D_{0.1cc}$		22.2 Gy	33 Gy	35 Gy
	D_{10cc}		16.5 Gy	25 Gy	
	D_{50cc}			12 Gy	
Ureter	$D_{0.1cc}$		40 Gy		

THORAX

Nomenclature	Metric	3 Fractions		5 Fractions	
		Optimal	Mandatory	Optimal	Mandatory
Bronchus Prox	$D_{0.1cc}$		30 Gy	35 Gy	38 Gy
Chest wall	$D_{0.1cc}$	36.9 Gy		43 Gy	
	D_{30cc}	30 Gy			
GreatVes	$D_{0.1cc}$		45 Gy		53 Gy
Heart+A_Pulm	$D_{0.1cc}$	26 Gy	30 Gy	29 Gy	38 Gy
Lungs (non-lung lesions)	V_{20Gy}	10%	15%	10%	15%
	D_{mean}	8 Gy		8 Gy	
Oesophagus	$D_{0.1cc}$		25.2 Gy		35 Gy
Skin	$D_{0.1cc}$	33 Gy		39.5 Gy	
	D_{10cc}	30 Gy		36.5 Gy	
Trachea	$D_{0.1cc}$		30 Gy	35 Gy	38 Gy

SPINAL CORD AND NERVES

Nomenclature	Metric	3 Fractions		5 Fractions	
		Optimal	Mandatory	Optimal	Mandatory
Brachial Plex	$D_{0.1cc}$		24 Gy	30.5 Gy	32 Gy
Cauda Equina SpinalCanal (below level of cord)	$D_{0.035cc}$		24 Gy		32 Gy
	D_{5cc}		21.9 Gy		30 Gy
LumbSacPlex (no PRV)	$D_{0.1cc}$	24 Gy		32 Gy	
	D_{5cc}	22.5 Gy		30 Gy	
SpinalCanal* (non-vertebral lesions)	$D_{0.035cc}$		20.3 Gy		25.3 Gy

*Whilst the dose constraint is strictly to the Spinal Canal, the use of a locally agreed PRV margin should be considered if appropriate. An alternative suitably small volume may also be used if it is not possible to report the dose to 0.035cc within the TPS used.

A secondary analysis of the SABR-COMET trial showed that target compromise which was required in approximately 1/3 of lesions was not associated with OS, PFS or lesional control and supports the continued prioritisation of OAR constraints during planning SABR treatments for oligometastases.

- If outlined, it is recommended to report the mean dose to the spleen and $D_{0.1cc}$ to the urethra.
- Whilst no dose constraints for SABR have been currently defined for the spleen, if mean spleen dose is >10Gy (for example in cases of SABR to upper abdominal or lower lung targets) patients should be individually risk-assessed and role of appropriate vaccination/antibiotic prophylaxis should be considered where clinically appropriate

7.3. Patient specific QA

- An independent monitor unit check and patient specific quality assurance should be carried out for all plans following locally agreed protocols.

8. Treatment delivery and verification

- Treatment is delivered in fractions, one fraction per day, delivered alternate days with a maximum interval of ideally 4 days.
- Patient position as for CT planning scan.
- On-set verification frequency, process and action levels are defined within the local departmental protocols.
- If the plan is not deliverable or there are issues with patient positioning or set-up, advice should be sought from SABR clinicians, physicists and radiographers as necessary.
- 4DCBCT and intrafraction imaging should be used as per local departmental protocols.

9. On treatment support and assessments

- Patients will be reviewed by the radiographer at planning CT and prior to each treatment fraction to review any symptoms which will be recorded on the SABR Toxicity assessment form in patients notes or R&Vsystem.
- Consideration of antiemetics (such as a 5HT3 antagonist) and/or PPI for those where the stomach or duodenum are close to PTV
- The clinician will complete an initial toxicity assessment at clinic and will continue to complete these at follow-up.

10. Follow up

- All patients will have clinical follow up by the SABR clinician 6-8 weeks following SABR and appropriate follow up arranged according to local protocol. A minimum of 2 years clinical follow up of clinical outcomes and any late toxicity using CTCAE v4.0 is recommended and should be recorded.
- Any local recurrences should be documented and assessed to determine if they represent an in-field or marginal failure.
- Regular multidisciplinary review of SABR cases should be completed to include review of the plans, treatment verification/IGRT and an audit of the follow up data (clinical outcomes and toxicities) is recommended.

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