CTRad radiotherapy protocol checklist

Developing a radiotherapy protocol for a clinical trial is an important step towards delivery of high quality radiation therapy within the trial whether the key question that the trial is addressing is directly radiotherapy related or not. This document has been developed by the NCRI Clinical and Translational Radiotherapy Research Working Group (CTRad)'s workstream for phase III trials and is designed as a guide to the key components of such protocols.

It is recognised that the radiotherapy to be delivered within a clinical trial will vary in its complexity, that not all components of the checklist are important for all tumour sites, and that there are many different issues which may arise during protocol development. It is recommended that the detailed description of radiotherapy planning, treatment delivery and quality assurance is included in a stand-alone radiotherapy guidance document. This should be developed in parallel with the clinical trial protocol and in collaboration with the National Radiotherapy Trials Quality Assurance (RTTQA) group with input/review by key investigators at participating sites.

Component	**Items to consider**	**Included? (Yes / No/ N/A)**
Immobilisation, simulation and target localisation	Patient positioning and immobilisation technique (if used)	
	Use of planning CT and/or MRI scan	
	Use of oral or IV contrast	
	Scan limits and slice thickness	
	Scanning sequences (if MRI)	
	Patient preparation protocols e.g. bladder filling instructions, enema, laxatives	
	Techniques to compensate for internal organ motion e.g. '4D' CT, gating, tracking, breath-hold and/or use of abdominal compression device	
	Image registration with other modalities e.g. PET, SPECT, MRI	
Target volume delineation and treatment planning	GTV • Definition of GTV	
	• Other investigations/information needed for adequate GTV definition	
	• Use of CT windowing	
	CTV	

Component	Items to consider	Included? (Yes / No/ N/A)
	• Margins used to expand GTV to CTV	
	• CTV definition if a GTV is not defined (e.g. post surgery)	
	• Use of elective nodal irradiation or not	
	PTV • Margins used to expand CTV to PTV Note: These depend on the immobilisation/technique used and audited in house.	
	ITV • Definition of ITV	
	If ICRU GTV/CTV/PTV concept not used explain why e.g. palliative treatments, and define how field borders are placed	
Organs at risk	Organs at risk (OAR)	
	Definitions of OAR e.g. rectum from recto-sigmoid junction to anus vs defined amount above and below PTV	
	Margins and their growth for OARs particularly in reference to IGRT	
Target volume and OAR naming	Use standard naming convention for all target volumes and OARs. The RTTQA group at rttrialsqa.enh-tr@nhs.net can advise on this.	
Prescribed dose and fractionation by phase	Dose (Gy) and prescription point e.g. isocentre or prescription isodose. For IMRT the prescription should be dose to mean/median of PTV.	
	Multi-level dose prescriptions (e.g. for SIB)	
	Number of fractions, number of treatments per day, interfraction gap if >1 fraction/day, overall treatment time e.g. 50Gy in 25 x 2Gy fractions, treating once daily Monday-Friday over 5 weeks	
Dosimetry/dose specifications	Planning algorithm (use of inhomogeneity correction, superposition/convolution algorithms, Monte Carlo, algorithms taking lateral electron transport into account)	
	Imaging for dose calculation (e.g. CT or sCT from MRI, etc)	
	IMRT (forward/inverse) or 3D conformal	
	VMAT/RAPIDARC/TOMOTHERAPY (dose constraints will be different)	
	Number of beams	
	Co-planar/non co-planar	
	Beam arrangement - mandated or recommended?	
	Beam energy - mandated or recommended?	

Component	Items to consider	Included? (Yes / No/ N/A)
	Any specific consideration for density overrides (IV or oral contrast, metal implants, gas, etc)	
	Beam shaping e.g. MLC	
	Size of MLC leaf specified - e.g. 5mm/10mm etc.	
Dose/volume constraints	Max, min and median doses in target; homogeneity and conformality for multi-level plans	
	Dose constraints for PTV? (Normally would be ICRU recommendations but may need to be relaxed / specified particularly in the thorax if type B calculation algorithms used.)	
	Specific OAR DVH constraints (recommended or absolute)	
Brachytherapy	Pre-treatment requirements	
	Use of temporary or permanent implants	
	Source used and dose rate (LDR, MDR, HDR, PDR)	
	Patient preparation, anaesthesia and positioning	
	Planning imaging and use of image fusion (X-ray, CT, US, MRI)	
	Definitions of GTV/CTV/PTV/at risk volumes and planning objectives	
	Definitions of OAR and planning constraints; handling of combined EBRT and brachytherapy doses.	
	Use of pre-plan, interactive and post implant dosimetry	
On treatment verification/IGRT	• Specification, e.g. EPI, helical CT, cone beam MV or KV CT, planar kV, fiducials, MRI • Frequency of imaging, offline vs. online pre treatment, intrafraction motion monitoring • Action levels, • The justification for increased imaging dose should be considered.	
	In-vivo dosimetry (diode, TLD, EPI)	
	Action protocols to be used.	
	Adaptation strategy: • type of anatomical change (e.g. tumour shrinkage, tumour drift, weight loss, or internal motion) • Frequency of adaptation (none, intermittent or daily) • Type of adaptation (e.g. plan of the day, adapt to position or to shape; reactive or proactive).	
	Reporting of delivered dose if adaptive strategies are used	

Component	Items to consider	Included? (Yes / No/ N/A)
	Field reductions allowed or not	
Treatment delays	Compensation for delays (e.g. use of 2 fractions per day)	
Patient care during treatment	Patient preparation protocols on treatment (e.g. rectal or bladder filling)	
	Management of changes in organ filling position (e.g. altered drinking protocols	
	Any special requirements	
Systemic therapy	Scheduling of RT and chemotherapy or other drug dosing in trials of chemoradiotherapy or RT-drug combinations	
	Action to be taken if toxicity is seen	
Centre credentialing (pre-study)	Contact the RTTQA Group rttrialsqa.enh-tr@nhs.net to discuss the appropriate level of QA support, estimated costs, and participating centre credentialing process,	
	All centres in all trials coordinated by the RTTQA group must have completed the baseline questionnaire available at www.rttrialsqa.org.uk	
	Streamlining with other ongoing studies	
	On trial RT data & imaging collection	
Phantom studies, contouring and planning dry runs	These should be specified in the protocol or QA documents	

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