PROTOCOL DEVELOPMENT, REVIEW AND IMPLEMENTATION STANDARD OPERATING PROCEDURE

Name of SOP	Radiotherapy Protocol Development, Review and Implementation
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Background

One of the key functions of the Operational Delivery Network (ODN) is to reduce variation in quality by adopting standardised best practice protocols. In doing so, there will be improvement to Service User outcomes including reducing mortality and morbidity from adverse side effects.

Protocols are an agreed framework outlining the care that will be provided to patients in designated areas of practice. The ODN role is to "*develop, agree and implement network-wide standardised tumour-specific treatment protocols to eradicate unwarranted clinical variation and improve clinical care and user experience*."

NOTE: Regional Protocols will be superseded by national protocols.

Purpose

The purpose of this SOP is to outline the processes, timelines, roles and responsibilities for the development, review and implementation of network-wide protocols.

Scope

This SOP applies to protocols relating to:

Anal
Bladder
Breast
Cervix
Emergency On Call Provision
Haematological
Head & Neck
Lung NSCLC
Lung SABR NSCLC
Lung SCLC
Oligomets SABR
Primary CNS
Prostate
RARE Paediatric CNS Protocol
RARE Paediatric Protocol
RARE Penile Protocol
Rectal / Colorectal
Upper GI

Uterine Endometrial
Vagina & Vulva

The advantages/disadvantages of using protocols are set out below:

ADVANTAGES OF USING PROTOCOLS	DISADVANTAGES OF USING PROTOCOLS
✓ Framework for a complex ✓ Specialised sequence of activities. ✓ Provides increased autonomy with a focus to shape future work. ✓ Ensures consensus within the team. ✓ Legal protection. ✓ Identifies training needs. ✓ May facilitate change.	○ Stifles individual care management. ○ May reduce need for qualified staff. ○ Require regular review. ○ Compliance may be problematic. ○ Restricts clinical discretion.

Protocol development

Should the need for a brand new protocol be agreed, the ODN will seek volunteers to be involved in developing the protocol, involving as a minimum a lead clinician, physics and radiographer rep (i.e. 3 people in total). Other volunteers are welcome to be involved and support the process.

A protocol template will be used as a framework for the protocol to be drafted. Protocol development will be carried out virtually where this is appropriate, but relevant stakeholders will be convened to discuss, debate and agree revisions where differences of opinion arise that need resolution, and/or where this is warranted.

Once a draft has been developed, this will be circulated widely to relevant stakeholders for their comment and a virtual Teams meeting will be organised for wider discussion/involvement of all trusts. Those unable to attend the meeting will be able to feed in remotely.

The ODN team will liaise with the volunteers and support the timely progression of the review process. Volunteers will escalate any emerging issues to the ODN office for action.

A ‘track changes’ document and any accompanying commentary/discussion will be kept as a record of any changes made, whilst a final (clean) copy will be presented to the EAG for ratification.

The aim will be to complete the protocol development, ready for EAG ratification within 3-4 months.

The Network Oversight Group (NOG) will be notified of all ratified protocols, but this is for information purposes and does not need to delay the dissemination of the ratified protocol.

Protocol review

The ODN will maintain a planned schedule for the review of protocols, where protocols are reviewed no later than 2-3 years after the previous ratification.

Progress against this schedule will be monitored as appropriate by the Expert Advisory Group (EAG) and Network Oversight Group (NOG) – and the workload involved in scheduling the review will be factored into the annual ODN workplan.

Protocol review will be carried out virtually where this is appropriate, but relevant stakeholders will be convened to discuss, debate and agree revisions where differences of opinion arise that need resolution, and/or where this is warranted.

Like protocol development, protocol review is undertaken by volunteers from across the 6 trusts in the West Midlands, involving as a minimum a lead clinician, physics and radiographer rep (i.e. 3 people in total). Other volunteers are welcome to be involved and support the process.

4 months prior to the protocol being due for review, the ODN office will seek volunteers for the review process, which then allows circa 3 months for the review process to take place. Timing will be informed by the dates of the EAG meetings which is where reviewed protocols are ratified. The ODN will ensure the process is commenced in a timely manner, by using protocol review trackers and ensuring reviews are timetabled into calendars and the ODN workplan.

The ODN will liaise with the volunteers and support the timely progression of the review process. Volunteers will escalate any emerging issues to the ODN office for action.

A ‘track changes’ document and any accompanying commentary/discussion will be kept as a record of any changes made, whilst a final (clean) copy will be presented to the EAG for ratification.

The Network Oversight Group (NOG) will be notified of all ratified protocols, but this is for information purposes and does not need to delay the dissemination of the ratified protocol.

Change requests

In addition, to the above scheduled review of documents, it is possible for any radiotherapy stakeholder in the West Midlands to request a review at any time prior to the planned review, by completing a change request proforma (see appendix) where they believe this is warranted e.g. change in national commissioning policy or the outcomes of clinical trials.

However, a change request should follow also on from where clinicians have used three or more concessions.

Protocol implementation

Once ratified, the reviewed protocol will have its front cover updated and the date of review/next review confirmed.

Dissemination and awareness raising will be via three routes:

- Direct email to named RT manager, clinical lead, head of physics and QA for each trust
- Added to the radiotherapy protocol page hosted on the WMCA website
- Included in the next quarterly ODN newsletter

Alongside the finalised protocol, a copy showing the main changes from any previous version will be shared, so QA teams can easily identify the differences. It is the responsibility of the speciality /department leads to ensure the new protocol is checked and audited against previous to establish the change requirement.

Each trust (via their QA lead and/or RT manager) will be asked to confirm at a 3-month interval that the trust has raised awareness of the updated protocols with all relevant staff members and embedded the WM regional protocol into their clinical practice, by adding to Q-Pulse (or equivalent).

This confirmation is to be sent back to the ODN, so that it an fulfil is assurance role in this respect. Trusts are also asked to send back any appendices or local documents that are also used in clinical practice. All returns and documents will be saved onto the ODN folders in case of future need.

Protocol review and implementation: timelines

	-4 months	-3 months	-2 months	-1 month	0	+1 month	+2 months	+ 3 months	+4 months
Review due									
Review volunteers sought									
Review underway									
EAG meeting and ratification									
Protocol documentation updated									
Dissemination									
Notification to NOG									
Awareness raising at trust level									
Confirmation of implementation/local adoption due									
Exercise completed									

Roles and responsibilities

ODN Office	• Maintain schedule for protocol review and provide updates on progress to EAG and NOG • Factor in protocol review into annual workplan • Recruit volunteers and support the protocol review process, ensuring timely completion • Ensure protocol review documentation is properly records and maintain version control for final ratified copies • Ensure timely dissemination of ratified protocols • Ensure website is kept up to date • Liaise with trusts to secure implementation responses
Protocol review/ development volunteers	• Ensure full participation on the review/development process • Supporting the revisions, providing justification for any proposed changes and seeking to discuss/agree with others

	• Maintain up-to-date knowledge of latest evidence based and relevant guidance
EAG Members	• Review and ratify protocols • Check with internal colleagues to get assurance that they have had the opportunity to feed in/review • Monitor progress of planned reviews
NOG	• Acknowledge ratification from EAG • Monitor progress of planner reviews
Quality Assurance	• Ensure Local system update and document record are adhered to • Email ODN Office confirmation of full implementation and execution of Protocol in the relevant department(s) • Understanding the changes made and implications for local practice • Remove and archive the obsolete document
Clinical Speciality Leads	• Communicate any changes to current protocols with relevant departments • Review, revise, approve and issue in accordance with National, ODN and Local procedures. • Encourage implementation at the earliest possible time.
All clinical practitioners, therapeutic radiographer, medical physicist, dosimetrist and clinical oncologists	• Ensure they are following the most up to date and coherent protocol and they meet the minimum standard of being clearly documented lines of accountability, specific referral criteria, clear and concise. • Clearly document any deviation from these protocols ensure concessions are regularly reviewed • Submit change request forms if required

West Midlands Radiotherapy Network

Protocols Change Request

This form is to request an amendment to an approved West Midlands Radiotherapy ODN Regional Protocol.
Please email your completed forms to WestMidlandsRadiotherapyNetwork@uhcw.nhs.uk

Name of Requester	
Trust	
Date	
Document name / version number	
Details of Requests Amendment /Change	
Justification	
FOR OFFICE USE	
Status	New / Accepted / Rejected (with reasons)
Request agreed / rejected by (Name)	
Date	
Updated Document name / version number	
Ratified by EAG (date)	
Notified to NOG (date)	
Revised copies disseminated (date)	

Off Protocol
When an off protocol prescription is requested
Change in dose fractionation: authorisation is required from a same site CCO
Change of delineation CTV-PTV margins: authorisation is required from a same site CCO and a Medical Physics Expert

In both cases Peer Review of the treatment plan is recommended