Engagement Report for Stereotactic Radiosurgery and Stereotactic Radiotherapy (SRT) (Intracranial) (All Ages)

1 November 2023, Version 1

Topic details

Programme of Care	Cancer Programme of Care
Clinical Reference Group	Radiotherapy CRG
Unique Reference Number (URN)	2323 Tier 1&2 Indications and 2324 All Indications

1. Summary

This report summarises the feedback NHS England received from stakeholder engagement following revision to the current Stereotactic Radiosurgery (SRS) and Stereotactic Radiotherapy (SRT) Service Specifications (i)Tier 1 & 2 indications for adults and Teenagers and Young Adults (TYA) URN 2323; and (ii) SRS/SRT All indications (all ages) URN 2324.

(All ages) (and how this feedback has been considered.

The current published Service Specification was developed over seven years ago following stakeholder engagement and public consultation and linked to a national service review programme. That specification has now been amended, based on the advice of the Specification Working Group (SWG), (Appendix A) and linked to a new service review programme, to better reflect current clinical practice. In revising the published specification, it has been agreed to retain the current tiered model but to separate the current specification into two, to better reflect service provision and pathways. This means that there are now two service specifications, covering: (i) Tier

1&2 provision (URN 2323); and (ii) All Tiers (1-4) including paediatric provision (URN 2324).

For ease, this engagement report summarises the feedback received in relation to both areas.

2. Background

SRS/SRT are methods of delivering doses of precisely targeted radiotherapy treatment to a wide range of malignant and benign brain conditions affecting a heterogenous patient cohorts. This includes arteriovenous malformations, vestibular schwannoma, meningioma, pituitary adenoma, ocular melanoma, trigeminal neuralgia and selected sub-groups of patients with cerebral metastases.

The current published Service Specification describes a tiered service model and groups together more common, less complex conditions, referred to as Tier 1&2 (adults and TYA), and less common, more complex conditions, referred to as Tier 3&4 (adults and children). Under that service model, every neurosurgical network (or groups of networks with an aggregate population of at least 2 million) has a Tier 1&2 service within its geography. Because of the lower volume and increased complexity for both Tier 3&4 and paediatrics, provision is concentrated into three centres, two offering Tier 3&4 indications and two offering paediatric indications.

As part of the normal arrangements for revising service specifications, as standard, the revisions focus on setting the must-do requirements for providers, specifically ensuring that they:

- Reflect current care pathways;
- Reference up to date national guidance and guidelines, as well as appropriate national policy, for example Faster Diagnosis and elective recovery;
- Incorporate meaningful quality outcome measures which will support improved outcomes and experiences of care; and
- Avoid duplication with other schedules within the NHS Standard Contract.

In relation to SRS/SRT, the revisions also included clarifications to:

(i) Population requirements

In separating the current published specification into two, the SWG have considered how best to reflect the existing requirements and provision arrangements within the population section of the specification template. For Tier 1&2 this was straightforward, and the specification reflects the 2 million population and 100 cases of Tier 1&2 activity per year. However, for All Tiers (including paediatric) provision, the position was more complicated because:

- Though the existing published service specification describes Tier 3&4 and paediatric services as supra-network and NHS England approved a service review recommendation to establish only two Tier 3&4 and two paediatric services, the specification did not include any calculation of population volumes or any annual caseload volumes, beyond those stated for Tier 1&2.

- A review of expected demand compared to actual activity indicated that there was unmet need, particularly for trigeminal neuralgia cases in the South West of England. The SWG considered that this was likely related to the travel burden for that patient population to access the Tier 3&4 service in London. There were also lower than expected numbers of paediatric activity. For this reason, the SWG recommended a slight increase to the number of providers delivering Tier 3&4 and paediatric activity, from two to four.

Taking all these factors into consideration, the SWG advised that the minimum population size sufficient to support four providers would need to be sufficient to generate circa 200 Tier 3&4 (combined) cases per year, flowing from the demand modelling completed as part of the service review and linked to the epidemiology of the different clinical indications covered by clinical commissioning policy. The SWG advice is that this reflects the requirements that are implicit within the current published specification and explicit in the current provider landscape, which were designed and consulted on to provide balance between case volume, quality and access.

The advice of the SWG was included within the linked 2023 service review, the aim of which is to recommission services which were established as part of a national procurement undertaken 7 years ago. The service review recommends that up to four All Tiers (including paediatric) services are commissioned – this has been agreed by the Delegated Commissioning Group, following an assessment of activity and expected demand and clinical advice. This change will result in improved access for trigeminal neuralgia, vascular conditions and paediatric brain cancer cases by increasing existing Tier 3&4 and paediatric brain cancer provision from two centres to four centres.

(ii) Whole body dose

The current published specification includes a requirement for providers to ensure that the consequent “whole body dose” is kept to a minimum appropriate to the condition and patient group being treated and the application of this requirement was tested with bidders as part of the procurement process in 2015/16. In separating the current published specification into two, the SWG have considered how best to reflect these existing requirements within the service model section of the revised specifications. Following consideration of more recently published literature, the SWG recommended that whole-body dose standards should be more clearly defined when treating children, teenagers, young adults (TYA) and adults under the age of 40 years with benign disease, to manage the consequences of being treated with radiation and has been clarified as:

a) All Tiers Service Specification

- For children (0-16th birthday) regardless of clinical indication the point dose measurement must be kept below 6mGy at a representative reference distance of 30cm inferior to the target.
- For TYA regardless of clinical indication and adults up to age 40 with benign disease the point dose measurement must be no greater than 20mGy at a presentative reference distance of 30cm inferior to the target.

b) Tiers 1&2 Service Specification

- For TYA treatments, the point dose measurement must be no greater than 20mGy at a representative reference distance of 30cm inferior to the target and must be referred to a Tier 3 &Tier 4 SRS Centre where this cannot be achieved.

- For adults up to age 40 with benign disease, the point dose measurement must be no greater than 20mGy at a representative reference distance of 30cm inferior to the target. Where this cannot be achieved locally, the risks should be fully discussed and referral to a Tier 3 &Tier 4 SRS Centre be offered.

This is because published data confirms that children, TYAs and adults under the age of 40 have the greatest lifetime risk from radiation induced cancers.

3. Engagement Results

3.1 Stakeholder Testing

NHS England has a duty under Section 13Q of the NHS Act 2006 (as amended) to 'make arrangements' to involve the public in commissioning. Full guidance is available in the Statement of Arrangements and Guidance on Patient and Public Participation in Commissioning. In addition, NHS England has a legal duty to promote equality under the Equality Act (2010) and reduce health inequalities under the Health and Social Care Act (2012).

Both service specifications were sent for stakeholder testing for two weeks from 27th September 2023 to 11th October 2023. The comments have then been shared with the SWG to enable full consideration of feedback and to support a decision on whether any changes to the specification might be recommended.

Respondents were asked the following questions:

- To what extent they support the minimum population size needs to be sufficient to generate circa 200 Tier 3 and Tier 4 (combined) cases per year.
- What impact the amendments to "whole body dose" standards and updating the technical treatment planning requirements to reflect advances in the capability of treatment and planning technology is likely to have.
- Are the service quality outcomes appropriate to the service?
- What quality outcome measures would you want to see included in the service specification?
- Do you support the Equality and Health Inequalities Impact Assessment?

3.2 Stakeholder testing results and summary of participants

29 responses were received from:

16 x Providers

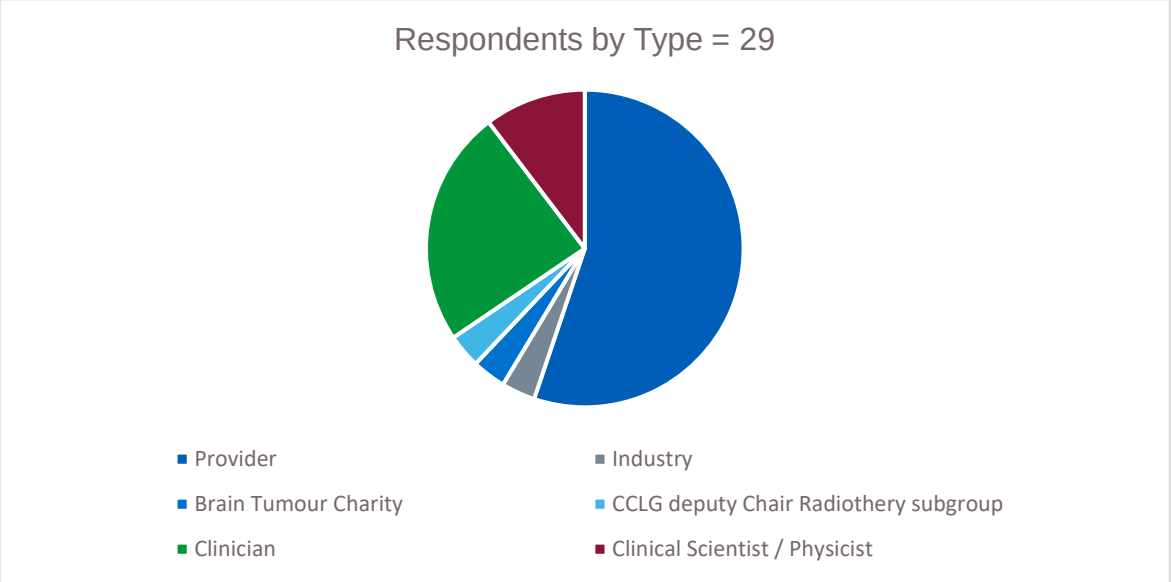
7 x Clinicians

3 x Clinical Scientists / Physicists

Brain Tumour Charity

Deputy Chair of the Radiotherapy subgroup of the Children's Cancer and Leukaemia Group

1 x Industry organisation



The stakeholder engagement generated positive responses overall, with stakeholders registering their broad support for the requirements and standards set out within the new specifications.

The findings from the stakeholder engagement process were considered by the SWG Chair and Cancer Programme of Care (PoC) and changes made as required.

Whilst only one response was received from a patient association, the Brain Tumour Charity was fully supportive of the proposed changes. In addition, there was Patient and Public Voice (PPV) representation on the SWG. Finally, as part of internal NHS England engagement, feedback was received on the proposal and the EHIA from the PPV representative within the Cancer PoC Assurance Group, noting their full support for the proposal and confirmed at PoC Assurance.

A 13Q assessment has been completed following stakeholder testing.

The Programme of Care has decided that the service specification and proposed amendments does not constitute material changes to the way in which services are delivered or the range of services available and therefore further public consultation was not required. This decision has been assured by the Patient Public Voice Advisory Group.

4. How has feedback been considered

Responses to engagement have been reviewed by the SWG and the Cancer PoC. The following themes were raised during engagement:

Engagement activity theme identified in e.g stakeholder testing, public consultation	Keys themes in feedback	NHS England Response
	Relevant Evidence	
Stakeholder Engagement	**Volume.** • Paediatric Brain Tumour SRS cases should be incorporated into those centres that are both Tier 1&2 and a paediatric RT centre. • Palliative paediatric SRS/SRT should be incorporated into those centres that are both Tier 1&2 and a paediatric RT centre. • Trigeminal Neuralgia to be considered a Tier 1 &2 indication. • Arteriovenous malformations (AVMs) should be considered a Tier 1&2 indication. • Dilution of the current throughput of AVM patients, and the implications for maintaining a robust service and achieving the best possible outcomes for patients Split Tier 3&4 where a centre has expertise in trigeminal neuralgia but not in managing vascular indications. • Diluting Tier 3 patient volume across additional centres potentially raises concerns around service viability, patient safety, and treatment outcomes. Tier 4 case volume is even lower and could compromise optimal treatment outcomes and patient safety	Following review of the points raised, SWG agreed that whilst geographical access is an important consideration, the number of children with brain cancer receiving SRS/SRT is less than 15 cases per year and extremely complex and rare such that maintaining a sufficient volume of cases to ensure clinical competency and service sustainability is considered critical. Following further review, the SWG considered that no further action was needed as generating sufficient volume to ensure service and workforce sustainability and maintaining professional expertise was essential to balancing an increase in access. SWG considered that no further action was needed as the majority of respondents supported the inclusion of explicit case volumes for Tier 3&4.

Stakeholder Engagement	One stakeholder from an NHS Trust raised concerns relating to the requirement for integration between neurosurgeons and neuro-oncologists noting this service should be oncology led.	The points have been considered by the SWG confirming that no further action is needed. The requirements in the current service specification, approved in 2016, are still appropriate because close working arrangements between subspecialists including neuro-radiologists as part of the MDT (neuro-oncology and SRS) are essential to good quality clinical care and SRS/SRT treatment planning.
Stakeholder Engagement	**Impact of including whole body dose standards.** • Some respondents noted that there would be relatively little impact on providers because the number of patients impacted by this clarification per year is so few. (<10%) • It was suggested that potentially this clarification could limit the number of sites available to TYA and adults < 40 and lengthen pathways. • Some contradictory comments were received concerning the inclusion of all TYA cases and the adult age limit.	The current published specification includes a requirement for providers to ensure that the consequent “whole body dose” is kept to a minimum appropriate to the condition and patient group being treated with specific reference to TYA. The clarification within the Service Specifications to define point dose measurements has been made to ensure that the long-term consequences of radiation treatment are considered for children, TYA and adults up to age 40 with benign disease. Following review, SWG considered that no further action was needed as the majority of respondents supported the inclusion of whole-body dose standards, and where the point dose measurement of no greater than 20mGy at a representative reference distance of 30cm inferior to the target cannot be achieved locally, the risks should be fully discussed and referral to a Tier 3 &Tier 4 SRS Centre be offered.
Stakeholder Engagement	The requirement to measure whole body dose for each individual patient.	The SWG has reviewed the responses and the two specifications have been slightly amended to clarify the requirement for a baseline measurement for each **machine,** not each patient.

Stakeholder Engagement	There needs to be clarification provided around the clinical justification for the treatment of <0.01cc sized metastases.	SWG noted the feedback and considered that no change was needed as this requirement was assessed as part of the last procurement.
	Sieverts and mSv refer to an equivalent dose to either an organ, or through a weighted sum of relative tissue sensitivities the equivalent whole-body dose) a better metric would be something akin to the Therapeutic Reference Level (TRL) proposed by Paddick et al (Acta Neurochirurgica, 2021, 163 : 971-979)	SWG considered the evidence and noted that the cited publication suggests measurement at 60cm inferior to the target. SWG did not support this change as dose is difficult to measure (tiny doses) at this distance and could inadvertently restrict the use of some treatment platforms.
	We support the minimum volume size as above, but this should be re-classified as 'PTV volume' as opposed to 'lesion'. This is in order to ensure a total accuracy of the system should be <1mm.	SWG considered that the approach suggested was not an accurate reflection of clinical practice and agreed that this question better sits within the external quality assurance (RTTQA) programme.
	The risk of over specifying services (e.g. treating < 0.01 cc targets, without any evidence for benefit) risks reducing availability of services by restricting to specific technology. The requirement for treatment "to 5mm width or less with treatment planning modulation capable to conformally treat small volume lesions of <0.01cc." is inappropriate and potentially dangerous.	SWG considered that no change was needed following consideration of the evidence which demonstrates that centres can achieve an acceptable dosimetrical accuracy and that all platforms have been able to achieve this as demonstrated by Paddick et al. It was agreed that this will be assessed as part of the RTTQA programme
	Potential impact on equality and health inequalities	
Stakeholder Engagement	The EHIA should reflect that patients may be adversely impacted by defining minimum volumes for Tier 3&4 indications to increase access to up to four centres.	Most respondents supported the EHIA. Following review, SWG considered that no further action The activity and demand assessment demonstrated a significant shortfall in expected demand for trigeminal neuralgia and, furthermore, that there was a geographical pattern to this. To address this, the aim is to increase access from the current two centres to four.

	Changes/addition to specification	
Stakeholder Engagement	**Therapeutic radiographer role** in pathway co-ordination omitted.	Following review, SWG agreed amendments to include subspecialist therapeutic radiographer role.
Stakeholder Engagement	**Essential Staffing** The staff involved are appropriately trained, competent and have the experience required to meet the requirements of IRMER.	Following review, SWG agreed amendments to the specifications.
Stakeholder Engagement	**Essential Equipment and facilities** Requirements in relation interventional radiology not required for Tier 1&2 services.	Following review, SWG agreed amendments to the Tier 1&2 specification.
Stakeholder Engagement	**Pathways** The pathway diagram should be amended to remove the reference to QA and OP attendance for consent	SWG agreed changes to the pathway diagram.
Stakeholder Engagement	**Outcome measures** Suggestions were submitted but considered to be quality metrics rather than outcome metrics by SWG.	Most stakeholders agreed that the outcome metrics were appropriate However, the Quality and Nursing Team (QNT) have determined that the suggested measures were 'quality metrics' rather than outcome measures and, as such, were considered separately as part of the quality metric development stage of the process. As the metrics submitted were measures of quality the SWG has considered these as part of the quality dashboard review.
Stakeholder Engagement	Technical points raised: • Needs to be better formulation for the whole-body dose standards. • Paediatric patients are likely to have already received substantial radiotherapy doses. Applying a dose constraint of 4mSv 30cm inferior to the target would not be appropriate	SWG a that the measurement at 30 cm from the target should be retained but to change mSv to mGy in the Specifications. SWG agreed to slightly amend the requirement to 6mGy based on clinical advice.

	to limit access of care for these life-limited patients. • 30cm directly inferior from the brain target would usually be somewhere inside the person's thorax, where you could measure inside a phantom, but we wouldn't insert a TLD at depth into the patient. • to deliver accurate treatment that is compliant with conformity and gradient indices'. No metrics are given, and without such this these are open to interpretation and need standardisation. A maximum GI of 4.0, and a maximum CI of 1.5 should be achievable for all plans. • The field size and treated volume requirements are the same for both service specifications (both the Tier 1 & 2 and the all-tier specifications), a greater requirement for smaller treatment volumes in highly specialised functional applications? • The risk of over specifying services (e.g. treating < 0.01 cc targets, without any evidence for benefit) risks reducing availability of services by restricting to specific technology. • The requirement for treatment "to 5mm width or less with treatment planning modulation capable to conformally treat small volume lesions of <0.01cc." is inappropriate and potentially dangerous.	SWG agreed to slightly amend the requirement to clarify this is a baseline measurement for each **machine** and not each patient using either an anthropomorphic phantom or in vivo dosimetry. SWG agreed to include a reference to provide advice on conformity and gradient indices.ISRS_certification_standards_New_Logo.pdf (isrsy.org) SWG agreed an amendment to the All tiers specification to less than or equal to 4mm width with treatment planning modulation capable to conformally treat small volume lesions equal to 0.02cc as demonstrated by Paddick et al. SWG agreed no change following consideration of the evidence which demonstrates that centres can achieve an acceptable dosimetrical accuracy and that all platforms have been able to achieve this as demonstrated by Paddick et al.

5. Has anything changed in the service specification as a result of the stakeholder testing and consultation?

The following change(s) based on the engagement responses has (have) been made to the service specifications:

- Minor changes have been made to both specifications to better define the measurement of the whole-body dose. This has been amended to better reflect the requirement for the service to undertake a baseline measurement at a representative reference distance of 30cm inferior to the target for each **machine** rather than each individual patient.
- The rationale for the volume of cases was omitted from the revised All Tiers service specification and this has now been amended.
- The pathway role of Therapeutic radiographer has now been included in the specifications.
- A revision to the point dose measurement for children has been made in the All-Tiers specification to below 6mGy rather than 4mSv.
- A reference to provide advice on conformity and gradient indices has been included. ISRS_certification_standards_New_Logo.pdf (isrsy.org)
- The requirement relating to the clinically commissioned beam size has been amended from 5mm to less than or equal to 4mm width in the All-Tiers specification. Paddick et al.
- The pathway diagrams for paediatric brain tumours and the generic pathway have been updated with minor changes to reflect current practice.
- The requirement that the staff involved are appropriately trained, competent and have the experience required to meet the requirements of IRMER has been included.
- The Essential Equipment and facilities section in the Tier 1&2 specification has been removed and access to General Anaesthesia and interventional radiology moved to the essential staffing section.

6. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final service specification?

None. No material changes were required to the service specification as a result of the stakeholder engagement feedback received. There are no remaining concerns outstanding following the consultation that have not been resolved in the final service specification.

The 13Q assessment has been completed following stakeholder testing. The proposal and the 13Q will be reviewed at the PPVAG meeting on Thursday 16th November 2023.

7. What are the next steps including how interested stakeholders will be kept informed of progress?

A summary of the feedback from stakeholder engagement will be made available to the registered and relevant stakeholders.

Appendix A - Membership of the Specification Working Group

- National Clinical Lead: Brain and CNS Tumours and Consultant Clinical Oncologist, subspecialist SRS
- Consultant Neurosurgeon
- Radiotherapy CRG PPV Representative
- Consultant Neurosurgeon, subspecialist SRS (GammaKnife)
- Consultant Neurosurgeon, subspecialist SRS (GammaKnife)
- Clinical Oncologist, Subspecialist SRS (Cyberknife)
- Consultant Paediatric Clinical Oncologist subspecialist SRS paediatric brain tumours (GammaKnife)
- Head of Radiotherapy Physics (Linear Accelerators)
- Consultant Physicist (GammaKnife)
- Consultant in Public Health
- Senior Commissioning Manager