



**Modernising Radiotherapy
Services in England –
Developing Proposals for
Future Service Models
Supporting Information**

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1. Introduction

This document has been produced to provide examples of how the proposed clinical and service model for radiotherapy could translate into clinical practice. This document also includes the supporting evidence used by Expert Advisory Group (EAG) members in designing the model.

2. Exemplars for partnership working in a “networked” service

The network will be supported by the creation of a single integrated governance framework. This will describe how the networked partnership will operate to safeguard and improve quality and will include:

- Agreement about the range of conditions to be treated by each provider within the networked service. This will be determined by the number of cases of each tumour site treated by each service to ensure a critical mass of patients and staff expertise; this needs regular review of projected versus actual patients treated. Examples using the treatment of gynaecological cancer and head and neck cancer are provided as a separate document.

Gynae-oncology radiotherapy

1. Gynaecological radiotherapy is relatively uncommon comprising less than 5% of radiotherapy episodes. Data from the radiotherapy dataset (RTDS) shows that some centres are treating very small numbers (less than 25 in total per year).
2. Of the 4 subsites (cervix, vagina, vulva and uterine body), uterus and cervix usually constitute 90% or more of the total radiotherapy cases. Both cervix and uterine body cases can be treated with brachytherapy, external beam RT or both.
3. Radiotherapy for cervix and uterine cancer is quite different. Cervix patients often have their primary tumour intact (squamous cancer / category 1) such that delays should be minimised; Uterine body cancer patients are post-operative, category 2 (adenocarcinoma) and delays / gaps likely to be less detrimental.
4. There is a strong argument for centralising the brachytherapy component (intracavity, interstitial and vault) for cervix cancer to promote practical expertise. Any patient having combined modality treatment should have BOTH components planned centrally with the prospect of the external beam element being delivered locally as part of the networked Gynae-oncology radiotherapy team.
5. The expectation would be to have at least 2 Clinical Oncologists in the treating centres, each treating a minimum of 25-50 radical gynae-radiotherapy cases a year i.e. a minimum total of 50-100 cases per year for the treating centre.

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6. Cervix, vagina and vulval cancer are all category 1 patients (delays and gaps in treatment are potentially detrimental to tumour control) emphasising the importance of a networked team system of care to avoid planning delays and ensure continuity of care including management of acute toxicities.
7. This would point to at least 2 clinical oncologists per treating centre with a 'buddy system' within that centre to ensure that there is cover for absence.
8. Management would involve at least weekly review of patients on treatment and a full multidisciplinary array of support staff available.
9. A single-handed practice using a buddy system with a nearby neighbouring provider would not be considered optimal even if it were arranged as part of the networked gynae-oncology radiotherapy team structure; moreover this may well not be cost effective as a model of service.
10. For some providers, a pooling of patients between neighbouring centres with a functional team in fewer treating centres should create a more resilient service in terms of critical mass of staffing and increased patient throughput.
11. For some potential networks there would be a limited number of radiotherapy patients in total, split between several providers; the networked provider board will need to examine activity levels, and capability in the provider units in order to decide on where brachytherapy should be delivered and whether a central plan / local delivery model is appropriate for the pelvic radiotherapy component of treatment.
12. The vault (uterine body) treatment (library plan) could be done locally if the investment for equipment is deemed justified.
13. Some centres treat a total of less than 25 radical cases of gynaecological cancer with radiotherapy a year; this lack of patient throughput does not justify a local dedicated Clinical Oncology team nor full infrastructure support.
14. Whilst accepting that patients may prefer local access and treatment compliance could be affected, a pooling of patients between neighbouring centres or centralisation of care is warranted.
15. For any reconfiguration of service there would be a discussion /decision at the Networked provider Board (the 'who does what where and how' board).

Head and neck cancer radiotherapy

16. Less common cancers such as head and neck are more difficult to place into this tiered model of provision, particularly as treatment planning is complex, treatment duration is generally 6-7 weeks of daily fractions and the patient may require access to the broader supportive care a multidisciplinary team.
17. However, some radiotherapy centres are currently treating very small numbers of radical head and neck cancer patients. The majority of head and neck cancers

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(squamous) are category 1 patients, i.e. delays and uncompensated gaps in their treatment should be avoided (RCR 2005).

18. The Expert Advisory Group did consider whether a networked team for head and neck radiotherapy could potentially provide cover for an existing single-handed practitioner in smaller centres but this is regarded as suboptimal. Whilst this may look attractive in terms of patient access (which is important for disinclined patients) the cover arrangements and comprehensive infrastructure support required at a local level would point to this being a less resilient and cost effective solution
19. There is general consensus amongst the Expert Advisory Group therefore that common cancers should be treated locally to facilitate access for patients whilst the treatment of uncommon cancers should be concentrated to a smaller number of centres to engender staff expertise and promote best practice and achieve better outcomes for patients.
20. The head and neck Clinical Reference Group has discussed whether surgical management should be concentrated to fewer centres in England. Should any surgical reconfiguration occur a review of the radiotherapy provision within the networked geography will need to be undertaken to ensure realignment.
21. There is evidence from the trial literature that correlates the rate of inverse planned intensity modulated radiotherapy (IMRT) delivered for this cohort of patients, patient numbers treated at any given centre, the number of patients recruited into trials and adherence to quality assurance processes, with an improvement in patient outcomes (Bueno I et al J Clin Oncol 2016 Wuthrick E et al J Clin Oncol 2015; Peters L et al J Clin Oncol 2010);
22. This would suggest that there should be a minimum number of patients that each clinical team should treat per year in order to maintain contouring, planning and treatment expertise in order to ensure robust quality assurance mechanisms are met.
23. A single "networked" clinical oncology team providing non-surgical head and neck oncology treatment for the whole networked population in a limited number of treatment centres is considered to be the most likely way to secure improved outcomes for patients.
24. Therefore, there must be a minimum of 2 clinical oncologists who are members of the Head and Neck cancer MDT who plan and supervise these treatments at each service. Each clinician must be responsible for a minimum of 25-50 radically treated head and neck cancer patients each year and each to provide cross-cover at times of holiday or unforeseen circumstances. Therefore any radiotherapy service treating head and neck cancer patients should be undertaking a minimum of 50-100 of these cases a year.
25. Higher patient and planning throughput is likely to engender expertise; moreover, it is not cost effective to have two clinical oncologists managing small numbers of

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patients at every radiotherapy service within a networked solution nor is it considered acceptable for each to treat below the recommended number of patients per year.

26. The treating centre should have in place; dedicated dietetic, gastrostomy, speech and language therapists, clinical nurse specialists, dental and health promotion support.
27. Many patients receive synchronous chemo-radiotherapy which is associated with mortality (up to 3%) and possible serious enduring toxicity effects, such that judicious selection and expert supervision of patients for this intense treatment is warranted.
28. A single “networked” team, working as part of the head and neck cancer MDTs across the geography, and providing non-surgical head and neck oncology treatment for the whole networked population in a limited number of treatment centres is considered to be the most likely way to secure improved outcomes for patients.
29. A networked radiotherapy service will need to identify sufficient centres across the geography to treat the number of patients currently receiving radical radiotherapy. These services will need to demonstrate a sufficient head and neck radiotherapy workload to justify at least 2 subspecialist clinical oncologists, each planning a minimum of 2-4 cases case per month, a process of weekly contouring QA, a prospective data collection mechanism (database) to generate outcomes and the full array of specialist staff to support these patients through their treatment.
30. There are less complex cases (e.g. larynx cancer) which could be treated locally as part of a “networked” provider solution as long as the above criteria are met, including adequate consultant supervision during treatment, infrastructure support and use of consistent adaptive protocols. This would very much depend on patient characteristics, throughput, infrastructure, tumour stage/subsite and whether radiotherapy was used without chemotherapy.
31. Within head and neck, there are very uncommon (approximately 5% of head and neck tumours) and particularly complex cases, especially in the nasal passages including cancer of nasopharynx and paranasal sinuses. These cases should be concentrated to fewer radiotherapy services. Even large centres see small numbers of nasopharynx or ethmoid cancer.
32. These changes in service configuration will help to improve the outcomes for these patients. When determining the number of services required in any networked service all head and neck (excluding those above) should be taken as a whole; there would be little merit of subdivision by subsite to attribute complexity or gauge activity.
33. Partnerships across the networked geography will be essential in providing the

support to patients in terms of supervising recovery from treatment and addressing other important associated survivorship issues and much of this should be done as locally as possible. If patients do have to travel considerable distances for treatment, then provision should be made to accommodate (e.g. hostel) these patients at the treatment centre.

34. A decision needs to be made by the single overarching networked head and neck team, as part of the “networked” provider board arrangements as to which constituent parts of head and neck radiotherapy should be treated by which component services. This decision should be based on a review of activity and expertise as well as infrastructure to decide where head and neck planning and delivery should be undertaken.

3. Radiotherapy Centre / Clinician Volume and Improved Outcomes

Background Evidence

35. The association between higher volume clinicians or centres and improved outcomes is generally now accepted. It is the basis for varying degrees of centralisation in many healthcare systems, including the UK. The relationship between individual clinician volume and hospital volume is complex. For some complex procedures there is a clear clinician volume effect related to technical competency but in others the impact of highly specialised teams such as anaesthesia and post-operative, supportive care, pathology and imaging can make centre volume important. There is good evidence of a volume effect in many surgical areas such as aortic valve, oesophageal resection, pancreatic resection, coronary by-pass grafting, lung resection, prostatectomy, knee replacement and hip replacement. There is clear evidence for a volume effect interventional coronary vascular and neurovascular procedures.
36. For some complex specialised services there is a mix of volumes associated with a critical mass of team expertise, resource and individual competencies, which will include both surgery and radiotherapy. The UK has already reconfigured some specialist cancer surgical services and associated supportive services and MDTs to concentrate care in higher activity centres and clinicians (Paediatric / Gynaecological / Lung / Pancreatic / Hepatic / Oesophageal / Sarcoma / Brain / Bone tumours) through the Implementing Outcomes Guidance series and NICE. The London Cancer Specialist Services reconfiguration Report 2013 also details the evidence base for higher volume expert centres which is particularly strong in Head and Neck and Urological Cancers. The NICE IOG for Head and Neck Cancer stipulates a specialist MDT managing a minimum of 100 cases per annum in a designated centre. This direction is reinforced by the Independent Cancer Taskforce in 2015 that recommends further evaluation of the benefits to be gained by greater degrees of centralisation and aligned commissioning for larger populations of 4-5 million where national procedure volumes are less than 2500 per annum.
37. The exact numbers and threshold required for a service or individual clinician to

maintain skills or minimise morbidity is variable. For some such as Interventional cardiac procedures numbers such as 75 per annum can be defined. In others such as those recommended by professional standards organisations such as The Association of Upper GI Surgeons gives the minimum number of procedures for oesophago-gastric, pancreatic and liver resections ranging from 15-25 and minimum numbers of surgeons in teams ranging from 4-6. This has been transferred into the NHS England Service Specification. For commoner cancers and procedures it is clearly preferential to maintain locally delivered care wherever possible, as incidence and volumes will be high enough, backed by minimum quality standards, training and audited outcomes.

38. Clearly volume alone is not a guarantee of good outcomes and there must be quality standards and quality assurance backed by the measurement of clinical outcomes. The impact of wider links between improved survival and expert care which includes assessment, imaging, pathology and decision making as well as clinical trial activity in expert academic centres has been demonstrated in ovarian and colorectal cancer studies in the UK.
39. For some wider cancer groups such as Head and Neck, Upper GI/HPB, Urological and CNS cancers there is in reality a heterogeneous group of differing tumours in incidence and treatment requirements. In all the above, guidance suggests greater degrees of sub-specialisation or concentration of treatment numbers or critical co-locations for certain less common tumours.

Radiotherapy and Volumes

40. There is good evidence of surrogate quality markers linking clearly to surgical outcomes with excellent validated early markers such as post-operative mortality, infection rates, anastomotic leak rates /reoperation rates/ nodal yield resection margin rates or even local recurrence rates. Radiotherapy however has few if any such early surrogate markers of quality. It would be hard to argue that radiotherapy, as an increasingly complex local therapy would be exceptional in there being no clinician expertise or volume impact.
41. There have been some important recent publications in Head and Neck Cancer (HNC) that strongly suggest that there a similar effect as seen in surgery.
42. Peters et al in 2010 looked at outcomes in a major 687 patient TROG trial of radiotherapy in advanced head and neck cancer and demonstrated that radiotherapy protocol compliance and centre volume was linked to local control and overall survival. Firstly it underlines the importance of quality assurance procedures but secondly it demonstrated a clear relationship between outcomes with the probability of a patient receiving poor quality radiotherapy in those centres submitting >20 cases a year was 5.4% and 29.8% for centres submitting < 5 cases.
43. Wuthrick et al in 2015 reported a major impact on overall survival in RTOG trials of advanced head and neck cancer, between high volume (>41 patients per centre and low volume centres (69.1% and 51.0% respectively at 5 years) and

again protocol deviation rates differing with volume 6% vs 18%). The accompanying editorial in the JCO3 is clear in stating that ‘the evidence is now compelling to recommend that curative treatment of patients with complex HNC be consolidated at high-volume centers to achieve optimal Outcomes’

44. Boero et al in 2016 report a study of 6,212 patients in advanced head and neck cancer with improved outcomes for patients treated at high volume centres with the risk of mortality decreasing by 21% with every additional 5 patients treated per provider per year. This was specifically seen in patients treated with IMRT as opposed to conventional 3D conformal radiotherapy.
45. Lee et al report in 2011 a study in nasopharyngeal carcinoma also supporting a volume effect linking directly to survival in significant numbers of patients.
46. These studies provide support that more complex radiotherapy and outlining quality can impact directly on outcomes and are analogous to surgical competencies and experience.
47. There is now some evidence of a clinician volume effect in gynaecological brachytherapy lending support to the RCR guidance. The variation in access to MRI guided brachytherapy linked to integrated planning would also suggest a need to concentrate clinicians and resource able to deliver high technical quality and volume services. This is on a background of decreasing incidence of cervical carcinoma.
48. Lee et al in 2014 demonstrate a significant impact of treating cervical carcinoma with brachytherapy and 5 year survival differences of 60% vs 54% in low and high volume clinicians respectively.
49. Thompson in 2014 report higher compliance with technical delivery of point A dose and treatment times for higher volume centres treating at least 10 patients per annum

Standards

50. Existing standards or specifications already exist with minimum case numbers in radiotherapy for England.
51. The RCR brachytherapy guidelines use a threshold of a minimum overall brachytherapy activity of 50 cases per year with minimum of 10 intra-uterine insertions per annum and an individual clinician minimum of 5 insertions per annum.
52. The NHS England Radiotherapy Service Specification uses a figure of a minimum of 25 cases per annum for a centre to treat Lung SABR, based on a consensus recommendation of an NRIG expert working group.
53. The NHS England SRS/SRT service specification has a centre volume minimum threshold of 100 cases per annum.

54. The RCR already has a recommendation for clinicians to have of a maximum of 2 areas of major site specialisation on the basis of maintaining competency and site specialist knowledge and CPD.

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Conclusion

62. There is now convincing evidence for a need to configure cancer services so that expert clinical, technical and supportive care can be delivered to patients and achieve optimal clinical outcomes.
63. Where it is possible to achieve this by local clinical services in radiotherapy delivering adequate higher volumes with sustainable teams and expertise, particularly for commoner cancers and treatment indications this is desirable.
64. However for less common cancers or treatment indications or where critical co-dependencies, or complex or expensive equipment requirements exist, there is a case for ensuring appropriate patients receive treatment in higher volume specialist centres.