NHS England

Modernising Radiotherapy Services in England

Supporting Information

1 Introduction

1. This document has been produced to describe the literature used by Expert Advisory Group (EAG) members in designing the radiotherapy Clinical Model which is an important element of the proposed Radiotherapy Service Specification. The document also provides examples of how the proposed clinical and service model for radiotherapy could work in practice.

2. It should be noted that this document was first published as part of the stakeholder engagement on the proposed Clinical Model, which took place during October-December 2016. This document now includes the methods and results of a literature search undertaken to support the EAG.

2 Literature Search – Methods and Results

3. A literature search was undertaken by Public Health England on behalf of the EAG to establish what, if any, published literature was available to support the development of new models of working in radiotherapy.

4. The literature search was supported by a PICO (Appendix 1) and focussed on addressing three specific questions:

    - What is the volume outcome relationship for radical or curative radiotherapy or brachytherapy (intracavity) for curable cancer?
    - What is the population base for radiotherapy access?
    - What organisational structures or configurations might impact on access to radiotherapy and radiotherapy outcomes?

5. In total, the search identified 155 separate papers of which 11 were considered to be relevant to the search questions and PICO criteria. These are shown in Appendix 2.

6. The literature search highlighted a lack of high quality evidence relating to the terms set out in the PICO. Specifically, the search returned a high number of papers related to the ‘dose volume’ relating to radiotherapy practice, as opposed to ‘volume-outcome’ which was subject of one of the search questions and parameters.

7. No systematic reviews, randomised controlled trials, or meta analyses were identified in relation to the search terms set out, with the majority of evidence being case series based.

8. However, some relevant evidence for specific tumour sites and the method of delivery was identified:

    - prostate cancer (Chen et al, 2016; Bockholt et al, 2013);
    - oesophageal cancer (Tsukada et al, 2015);
    - cervical cancer (Wright et al, 2015; Lee et al, 2014)
    - head and neck cancer (Lee et al, 2011)

- Models of care (Teshima et al, 2010)
- IMRT (Shumway et al, 2015)
- Brachytherapy (Symonds et al, 2013)
- A number of these papers focussed on the learning curve impact and training (Shumway et al, 2015; Bockholt et al, 2013)

9. The search also returned ten Clinical Guideline documents published by the National Institute of Health and Care Excellence (NICE) and two Royal College of Radiologist (RCR) guidelines:

    a. The role and development of afterloading brachytherapy services in the United Kingdom (2012)
    b. Quality assurance practice guidelines for transperineal LDR permanent seed brachytherapy of prostate cancer (2012).

10. The EAG also identified a further six papers that had not been identified within the literature search.

11. All of the available material has been taken into account by the EAG in the development of the new Clinical Model and Service Specification. However, because there is an absence of compelling evidence relating to service structure and organisation, population catchment and sup-specialisation volumes, the EAG has also used clinical expertise.

3 Discussion of the evidence

12. This section sets out the recommendations of the EAG together with the available evidence.

3.1 Radiotherapy and Volumes

15. 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.

16. 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, for example:

    - 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.

- 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'.

- 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.

- 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.

17. These studies provide support that more complex radiotherapy and outlining quality can impact directly on outcomes and are analogous to surgical competencies and experience.

18. In addition, 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 set against a background of decreasing incidence of cervical carcinoma. The evidence is as follows:

    - 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.

    - 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.

3.2 Standards

19. Existing standards or specifications already exist with minimum case numbers in radiotherapy for England.

20. The RCR published guidelines on the use of Brachytherapy which include 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.

21. The NHS England Radiotherapy Service Specification uses a figure of a minimum of 25 cases per annum for a centre to treat Lung SABR. This is based on a consensus recommendation of the National Radiotherapy Implementation Group Expert Working Group.

22. The NHS England SRS/SRT service specification has a centre volume minimum threshold of 100 cases per annum.

23. The RCR has also published a recommendation for clinicians to have a maximum of 2 areas of major site specialisation in order to maintain competency, site specialist knowledge and participate in appropriate continuing professional development (CPD).

4 Exemplars of partnership working

24. Each Network will be supported by the creation of a single integrated governance framework. This describes how the network partnership will operate to safeguard and improve quality and will include agreements about the range of conditions to be treated by each provider within the Network.

25. Network Boards will be responsible for implementing the Model of Care across the Network. This will take account of tumour site-specific activity levels in order to ensure a critical mass of patients and staff expertise and the options available for partnership working arrangements to support delivery of care as close to home as possible.

26. This section sets out the thinking of the EAG in relation to partnership working arrangements using gynaecology and head and neck cancer as exemplars, referencing published evidence where it exists.

4.1 Gynae-oncology radiotherapy

27. Gynaecological radiotherapy is relatively uncommon comprising less than 5% of radiotherapy episodes. Data from the National Radiotherapy Dataset (RTDS) shows that some centres are treating very small numbers (less than 25 in total per year).

28. Of the four 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.

29. 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 are likely to be less detrimental.

30. There is therefore a strong argument for centralising the brachytherapy component (intracavity, interstitial and vault) for cervix cancer to promote practical expertise and minimise delays to care. Any patient having combined modality treatment should have both components planned centrally with the prospect of the external beam element being delivered at a centre locally if designated by the Network Board as part of the network Gynae-oncology radiotherapy team.

31. The expectation is that at least two 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.

32. 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.

33. This would point to at least two clinical oncologists per treating centre with a ‘buddy system’ within that centre to ensure that there is cover for absence.

34. Management would involve at least weekly review of patients on treatment and a full multidisciplinary array of support staff available.

35. 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.

36. 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.

37. For some potential networks there would be a limited number of radiotherapy patients in total, split between several providers. The Network 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.

38. The vault (uterine body) treatment (library plan) could be done locally, subject to any investment in the necessary equipment being made.

39. 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 does it warrant full infrastructure support.

4.2 Head and neck cancer radiotherapy

40. 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.

41. However, some radiotherapy centres are currently treating very small numbers of radical head and neck cancer patients. The majority of head and neck cancers (squamous) are category 1 patients, therefore, delays and uncompensated gaps in their treatment should be avoided (RCR, 2005).

42. The EAG did consider whether a networked team for head and neck radiotherapy could potentially provide cover for an existing single-handed practitioner in smaller centres, however, this is regarded as suboptimal. Whilst this may look attractive in terms of patient access the cover arrangements and comprehensive infrastructure support required at a local level would point to this being a less resilient and cost effective solution.

43. There is general consensus amongst the EAG 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.

44. 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 (Buero et al, 2016; Wuthrick et al, 2015; Peters et al, 2010).

45. 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.

46. 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.

47. Therefore, there must be a minimum of two clinical oncologists who are members of the Head and Neck cancer multidisciplinary team (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 must 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.

48. 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 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.

49. The treating centre should also have in place; dedicated dietetic, gastrostomy, speech and language therapists, clinical nurse specialists, dental and health promotion support.

50. 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.

51. 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 and reliable way to secure improved outcomes for patients.

52. 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 two subspecialist clinical oncologists, each planning a minimum of 2-4 cases case per month;
    - a process of weekly contouring Quality Assurance;
    - a prospective data collection mechanism (database) to generate outcomes; and
    - a full array of specialist staff to support these patients through their treatment.

53. 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 throughput, infrastructure, tumour stage/subsite and whether radiotherapy was used without chemotherapy.

54. 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 even fewer radiotherapy services. Even large centres see small numbers of nasopharynx or ethmoid cancer.

55. 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.

56. 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.

5 Appendices

Appendix 1: PICO

PICOS and Research Question Template
Radiotherapy Review

1. Search strategy

Question(s)	
Identify all aspects of the topic that need to be explored in order to develop a policy • Is it a specialised service? • Is it in tariff? • Is it, or can it be, adequately covered by the appropriate detail in the service specification? • Is it very low volume or does it have a low number of requests, such as less than 10 per year? If it is low volume then it may not merit a clinical commissioning policy or may be deferred to the next round of policy reviews. • Does it appear too difficult to establish an evidence base or find suitable evidence to support a new clinical commissioning policy? If there is such limited evidence that it will not be possible to answer the review question then it will not be possible to generate a clinical commissioning policy. • Is it a clinical area included within the scope? If not, then a clinical commissioning policy may not be suitable for this	
Search strategy *Indicate all terms used in the search*	
P – Patients / Population Which patients or populations of patients are we interested in? How can they be best described? Are there subgroups that need to be considered?	- *Radical / curative radiotherapy (external beam) OR brachytherapy (intracavity) for curable cancer*
I – Intervention Which intervention, treatment or approach should be used?	- Radiotherapy - Brachytherapy
C – Comparison What is/are the main alternative/s to compare with the intervention being considered?	- Invasive / surgical - PBT - SRS – Stereotactic radiotherapy? SABR - Conservative management - Chemotherapy?
O – Outcomes What is really important for the patient? Which outcomes should be considered? Examples include intermediate or short-term outcomes; mortality; morbidity and quality of life; treatment complications; adverse effects; rates of relapse; late morbidity and re-admission; return to work, physical and social functioning, resource use.	**Service** - Volume outcome relationship **Clinical measures** - Survival - Tumour control rates - Morbidity 30 day and longer term post 90d - Complications - Non-tumour: vascular re-bleed rate - Pain control rates - Quality of life outcomes - Safety
Assumptions / limits applied to search *As above. Possibly consider 'tumour' and 'non-tumour' related split in search groups.*	

2. Research Questions

1. Is there a volume / outcome relationship?
2. Is there enough evidence to suggest an appropriate population base for Radiotherapy access?
3. What organisational configurations /structures might impact on access to RT and RT outcomes

Appendix 2: Search results and relevant papers

Study Type	Number	Clinically relevant following screening
Guidelines	12	2
Cochrane library - systematic reviews	44	0
Evidence summaries	1	0
Literature reviews	1	0
Cochrane library - other reviews with critically appraised abstracts from the Centre for Reviews and Dissemination	18	0
Cochrane library – Health Technology Assessments	12	0
Randomised controlled trials / meta analysis	1	0
Cost effectiveness	19	0
Cohort	8	0
Case studies	29	8
Study type not clear	10	1
Total	**155**	**11**

6 References

Bockholt, N. A., DeRoo, E. M., Nepple, K. G., et al. 2013. First 100 cases at a low volume prostate brachytherapy institution: learning curve and the importance of continuous quality improvement. The Canadian journal of urology 20(5) 6907-12.

Boero IJ, Paravani AJ et al. 2016. Importance of Radiation Oncologist Experience Among patients with head and neck cancer treated with Intensity Modulated Radiation Therapy. Journal of Clinical Oncology published online on January 4, 2016; DOI:10.1200/JCO.2015.63.9898.

Chen, Y. W., Mahal, B. A., Muralidhar, V., et al. 2016. Association between treatment at a high-volume facility and improved survival for radiation-treated men with high-risk prostate cancer. International Journal of Radiation Oncology Biology Physics 94(4) 683-690.

Corry J, Peters LJ, Rishon D. 2015. Impact of Center Size and Experience on Outcomes in Head and Neck Cancer. Journal of Clinical Oncology 33:138-140.

Lee, C.-C., Huang, T.-T., Lee, M.-S., et al. 2011. Survival rate in nasopharyngeal carcinoma improved by high caseload volume: a nationwide population-based study in Taiwan. Radiation oncology (London, England) 6:92.

Lee, M.-S., Tsai, S.-J., Lee, C.-C., et al. 2014. Higher caseload improves cervical cancer survival in patients treated with brachytherapy. Radiation oncology (London, England) 9 234.

Peters L J, O'Sullivan B et al. 2010. Critical Impact of Radiotherapy Protocol Compliance and Quality in the Treatment of Advanced Head and Neck Cancer: Results from TROG 02.02. Journal of Clinical Oncology 28:2996-3001.

Royal College of Radiologists. 2012. The role and development of afterloading brachytherapy services in the United Kingdom. The Royal College of Radiologists.

Royal College of Radiologists. 2012. Quality assurance practice guidelines for transperineal LDR permanent seed brachytherapy of prostate cancer. The Royal College of Radiologists.

Shumway, D. A., Griffith, K. A., Pierce, L. J., et al. 2015. Wide variation in the diffusion of a new technology: Practice-based trends in intensity-modulated radiation therapy (IMRT) use in the state of Michigan, with implications for IMRT use nationally. Journal of Oncology Practice 11(3) e373-e379.

Symonds, P., Davidson, S., Vale, C., et al. 2013. Caseload and Outcome after Brachytherapy. Clinical Oncology 25(9) 519-521.

Teshima, T., Numasaki, H., Shibuya, H., et al. 2010. Japanese structure survey of radiation oncology in 2007 based on institutional stratification of patterns of care study. International journal of radiation oncology, biology, physics 78(5) 1483-93.

Thompson SR, Delaney GP et al. 2014. Patterns of care study of brachytherapy in New South Wales; cervical cancer treatment quality depends on caseload. Journal of Contemp Brachytherapy 6:28-32.

Tsukada, Y., Nakamura, F., Iwamoto, M., et al. 2015. Treatment patterns for T4 stage III esophageal cancer in Japan: Analysis from 233 designated cancer care hospitals. International Journal of Radiation Oncology Biology Physics 93(3 SUPPL. 1) E142.

Wright, J. D., Huang, Y., Ananth, C. V., et al. 2015. Influence of treatment center and hospital volume on survival for locally advanced cervical cancer. Gynecologic oncology 139(3) 506-12.

Wuthrick EJ, Zhang Q et al. 2015. Institutional Clinical Trial Accrual Volume and Survival of Patients with Head and Neck Cancer. Journal of Clinical Oncology 33:156-164.