Principles for supporting radiotherapy clinical research in England

January 2016

Background

NHS England is undertaking a national review of the radiotherapy service in England. This makes radiotherapy a national priority for NHS England Specialised Commissioners. The review is looking at how the radiotherapy service should be run and the changes that need to be made to achieve the Vision for Radiotherapy\(^1\) that Cancer Research UK (CR-UK) and NHS England published in early 2014, and the cancer strategy for England\(^2\) published in July 2015. NHS England estimates that a new service specification, with a new service and clinical model will be circulated for consultation in February 2016.

Research is an integral part of the radiotherapy service, as research tests and introduces new treatments and techniques that improve patient outcomes. Clinical trials are the best way to evaluate and implement new ways to treat patients with both rare and common cancers. However, the Vision for Radiotherapy noted that there needs to be better alignment between research and the clinical service.

CR-UK is the largest funder of radiotherapy and radiobiology research in the UK, spending over £22m in this field last year. We are committed to ongoing investment in the development of radiotherapy innovations through our research strategy\(^3\). We would like the NHS England review to create a service that effectively supports research, and it’s vital that the views of the research community are taken into account. CR-UK therefore hosted a meeting in early December 2015 between NHS England and key researchers in radiotherapy (see annex A) to discuss what the review should consider.

This paper sets out CR-UK’s position on the key principles the radiotherapy service should take into account to best support research, following consultation with attendees at the meeting. While the primary audience for this paper is NHS England as they undertake the review, these principles are also relevant to other stakeholders including National Institute for Health Research (NIHR) and Public Health England (PHE).

Overarching principles to support research:

1. It is vital that NHS England and Public Health England (PHE) ensure the routine collection of outcome data from all radiotherapy treatment. High quality national outcome data would further guide decisions about configuration of services, facilitate high quality research and permit the more efficient conduct of trials. NHS England and PHE should further develop the Radiotherapy Dataset (RTDS) to ensure it collects the right data, is linked to outcomes data, and is aligned with data from the devolved nations. Appropriate resources within NHS

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\(^1\) The Vision for Radiotherapy 2014-24 sets out the key elements that radiotherapy service in England should be providing to patients over the next decade. The report was developed with input from a wide range of stakeholders in the radiotherapy community. [http://www.cancerresearchuk.org/sites/default/files/policy_feb2014_radiotherapy_vision2014-2024_final.pdf](http://www.cancerresearchuk.org/sites/default/files/policy_feb2014_radiotherapy_vision2014-2024_final.pdf)


\(^3\) [http://www.cancerresearchuk.org/funding-for-researchers/how-we-deliver-research/our-research-strategy](http://www.cancerresearchuk.org/funding-for-researchers/how-we-deliver-research/our-research-strategy)
Trusts (to provide the data) and in PHE (to collect and analyse data) will be needed to ensure this is achieved.

2. **Better patient outcomes would be supported by configuring the service so that low patient number, highly specialised treatments are concentrated in a smaller number of centres, and high volume, non-specialised treatments are provided in a larger number of centres, with centres working in partnership across a defined catchment area. This will drive up quality of care and support research by improving trial recruitment.** Centralisation of services should be guided by patient numbers and flows – more work is needed to clearly define which services will be provided in which centres. Centres where a change in treatment provision is needed must be given the necessary resource and support to put changes in place. It is vital that there is clarity on how the service is designed and the rationale for this, including which centres provide certain treatments, as this will help define where different areas of research are developed and delivered. It will also enable quicker roll out of new technologies and techniques if proved effective.

3. **NHS England must have a clearer position on its support for Excess Treatment Costs (ETCs), in which the default is that clinical trials will be supported. As recommended in the cancer strategy**, for radiotherapy trials NHS England should administer a centralised and ring-fenced fund for ETCs, with a robust mechanism of delivery that facilitates trial set up and delivery in all the suitable centres. There are valid arguments for ETCs for radiotherapy trials to be held in a central fund and administered by NHS England Specialised Commissioning. NHS England should work with funders and the radiotherapy research community to ‘horizon scan’ for upcoming trials. Research leads will need to estimate the ETCs needed for the trial, including participating centres, to aid flow of ETCs. Crucially there will need to be a certain amount of flexibility about which centres can participate to ensure trials can recruit the adequate number of patients within a reasonable timeframe.

4. **NIHR support costs for radiotherapy trials should be front loaded to allow for quicker set up of trials.** Radiotherapy trials are becoming more complex, requiring more dedicated resource to introduce innovative radiotherapy techniques and get trials up and running. For example, more medical physics time is required for complex techniques, which is currently not well resourced and leads to delays in trial set up. NIHR Local Clinical Research Networks (LCRN) should front load service support costs into centres setting up complex trials to enhance their ability to get trials open faster.

**Configuration of the radiotherapy service**

There are 50 centres providing radiotherapy in England (plus associated satellite centres). Though improvements have been made, issues with quality and equal access to modern radiotherapy, such as Intensity Modulated Radiotherapy, have persisted and must be addressed.

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The service review is likely to change the way radiotherapy is delivered to NHS patients, with a move to linked or lead provider models, where centres work together to provide the necessary treatments across a network covering 2-5 million patient populations.

Concentrating treatments for rarer cancers, including paediatric cancers, into a smaller number of centres would produce better outcomes for patients. Changes should be guided by patient numbers and flow. Centralising some services will improve quality of care, and enhance research in those services as there will be a greater concentration of expertise to set up and run trials, as well as a higher number of patients to make clinical trial recruitment more efficient. All centres should be required to provide high quality treatments for the common tumour types.

NHS England estimates that the types of treatment they provide will not change for 33 out of 50 centres. Of the 17 smaller centres remaining, around 70 per cent of their treatment activity will remain unchanged while more specialised services will be expected to transfer to larger centres. Further information and data is needed from NHS England to provide the clear rationale for any changes.

Considerations for NHS England:

- As highlighted in the cancer strategy, 126 out of 270 LINACs need to be replaced over the next three years; another 58 need to be upgraded. Up to date equipment is needed to undertake world-leading research. It is therefore vital that out of date LINACs are replaced and equipment upgraded to be able to deliver innovative treatments and clinical trials.
- More work is needed to define what the 30 per cent remaining change in activity will mean for those 17 centres – the evidence for centralisation may be clear for some disease types, but not as clear for others. Further clarity is needed on where the line should be drawn between what is centralised and what is not.
- Inconsistencies between centres that provide Stereotactic Ablative Radiotherapy (SABR) routinely and through Commissioning through Evaluation (CtE) should be addressed. This would bring the current number of centres providing SABR, and able to take part in the relevant clinical trials, to 19 at this time. In principle, clinical trials should be run wherever the facilities and expertise are in place.
- The outcomes of the NHS England review must be absolutely clear on how the service will be designed i.e. which treatments are delivered at which centres. This will provide clarity to the academic community about where appropriate research can take place – be it in all centres for a trial involving one of the more common cancers and techniques, or in a smaller number of centres treating smaller patient groups and providing more highly specialised techniques.
- More work is needed to understand whether minimum volumes of patients taking part in a trial in each participating centre would be appropriate. However, greater clarity about the service design, and therefore patient numbers being treated in centres, should enable trials to take place where eligible patients are being treated.
- Modelling, such as using the Malthus Tool, could help better define patient flows, set minimum standards by cancer types, and identify where trials could take place.

Excess treatment costs (ETCs)

NHS England is mandated to provide ETCs through the Health and Social Care Act and the NHS Mandate. However, there have been issues with provision of ETCs at a local level in recent years.
NHS England recently updated its policy on ETCs, which looks more positive. But this guidance may be more suitable for trials that are lower cost (to the NHS) and more locally delivered e.g. clinical trials of a medicine, where CCGs provide ETCs. This is different for radiotherapy where the service is centrally commissioned by NHS England, needs often expensive software and equipment, and the appropriate workforce.

NHS England has allocated £6m for ETCs to support some CR-UK funded and endorsed SABR trials. However this doesn’t cover any other types of radiotherapy trial.

**Considerations for NHS England:**

- Clinical trials are the best way to introduce and evaluate new radiotherapy technologies and techniques for both rare and common cancers. There is already a robust process of getting clinical trials peer-reviewed, approved, quality assured and set-up - obtaining ETCs should not be a barrier to trials opening. NHS England should therefore take a clearer position on its provision of ETCs, with the default being that all high quality NIHR-portfolio trials are supported.
- Complex radiotherapy trials are not usually supported by industry funding (unlike many which test medicines, for example). They can produce highly cost effective and therapeutic benefits once proven, and they are testing against well-established techniques. These are some of the arguments for treating radiotherapy clinical trials as a special case in terms of how ETCs are provided.
- The cancer strategy called for £4.3m per year to provide ETCs for upcoming trials up to 2020. NHS England should work with funders and the research community to horizon scan for upcoming trials and estimate the ETCs needed to support future trials.
- The cancer strategy recommends that ETCs for complex radiotherapy trials should be administered through a centralised and ring-fenced fund. The mechanism for allocation of ETCs must be robust and transparent, and should facilitate trial set up and delivery in all suitable centres. Provision of ETCs should not be used as a mechanism to select which centres take part in trials.
- Research leads can facilitate the process by confirming the number of participants and assessing the infrastructure needed to deliver the study in a timely manner (and therefore the centres, based on clarity of service design – see above) and feedback to NHS England an estimate of cost.
- There is also a need to address issues with the national tariff as it currently does not support participation in some trials, e.g. those addressing hypofractionation where centres lose out on income as payment is per fraction.

**Research support costs**

The NIHR provides support costs to clinical trials. These support costs – provided through Local Clinical Research Networks (LCRNs) - are the additional patient care and administration costs associated with the research, such as processing patient records to identify suitable patients for trials and obtaining consent.

Local infrastructure for cancer research used to be through NIHR Cancer Research Networks. However, these no longer exist in the same form and instead LCRNs cover all specialties, with cancer
now one of six divisions. This transition has yet to bed in but concerns have been raised about the level of resource that might be available to cancer in the new structures.

**Considerations for NIHR:**

- Radiotherapy treatment is becoming increasingly complex, and therefore so are clinical trials which are testing newer techniques and technologies.
- Set up of radiotherapy trials includes essential quality assurance. This is time consuming and requires the appropriate resource and support, particularly from medical physics professionals and radiographers, but other medical professions too. Earlier diagnosis of patients is also likely to mean more patients needing radiotherapy (as their cancer is more amenable to curative treatment when diagnosed at stage one or two), putting more strain on the ability of departments to allocate resources to trial set up.
- Lack of resource affects the speed at which trials are set up. Some trials have had to rely on the good will of departments, including absorbing costs, to facilitate trial set up. Feedback from centres is that they quality assure in their ‘extra time’ as they don’t have enough resource to support this essential activity.
- To better support the set up of complex radiotherapy trials, LCRNs should front load resource to centres setting up these trials so that the quality assurance process, and trial set up more generally, is faster.
- There is scope to streamline trial set up through better use of IT that could reduce support costs. NHS England, NIHR and the research community should explore this possibility further.
- LCRNs and local services should identify when funding gained from radiotherapy treatment is not being channelled back to the radiotherapy department and escalate to regional commissioners.

For further information please contact: Emlyn Samuel, Senior Policy Manager, Cancer Research UK (emlyn.samuel@cancer.org.uk; 020 3469 5581)
Annex A – meeting attendees

Angela Baker, Superintendent Radiographer, Mount Vernon Cancer Centre
Andrew Bates, Consultant Clinical Oncologist, University Hospital Southampton
Charlotte Coles, Consultant Clinical Oncologist, Addenbrooke’s Hospital
Anthony Chalmers, Vice-Chair of the Clinical and Translational Radiotherapy Research Working Group (CTRad), Professor of Clinical Oncology, University of Glasgow
Carolyn Chan, Radiotherapy Research Programme Manager, NCRI (CTRad)
Alison Cook, Director of Science and Policy Communications, Cancer Research UK (CR-UK)
Adrian Crellin, Chair of the Radiotherapy Clinical Reference Group and the Radiotherapy Service Review Expert Review Group
Caroline Dalton, Research Funding Manager, CR-UK
Kim Fell, Accountable Commissioner: Radiotherapy, NHS England
Emma Hall, Deputy Director Clinical Trials and Statistics Unit, Institute of Cancer Research
Maria Hawkins, Associate Professor in Clinical Oncology, University of Oxford
Tim Illidge, Professor of Targeted Therapy and Oncology, University of Manchester
Peter Johnson, Chief Clinician, CR-UK
Vincent Khoo, Consultant in Clinical Oncology, The Royal Marsden
Karen Kirkby, Professor of Proton Therapy Physics, University of Manchester
David Landau, Consultant Clinical Oncologist, Kings College Hospital
Jenni MacDougall, Head of Clinical Research Funding, CR-UK
Ranald Mackay, Director of Christie Medical Physics and Engineering
Tim Maughan, Professor of Clinical Oncology, University of Oxford
Elizabeth Miles, Coordinator NCRI Radiotherapy Trials QA (RTTQA) Group
Chris Nutting, Consultant Clinical Oncologist, The Royal Marsden
Emlyn Samuel, Senior Policy Manager, CR-UK
David Sebag-Montefiore, Professor of Clinical Oncology, University of Leeds and Leeds Cancer Centre
Matt Seymour, NIHR Clinical Research Network Theme Lead
Nick Slevin, Consultant Clinical Oncologist, the Christie Hospital, Manchester
John Staffurth, Reader in Oncology, Cardiff University School of Medicine
Nicholas Van As, Consultant Clinical Oncologist, The Royal Marsden