Engagement Report for Radiotherapy Services, Molecular Radiotherapy (all ages)

Topic details

Programme of Care	Cancer
Clinical Reference Group	Radiotherapy
Unique Reference Number (URN)	2322

1. Summary

This report summarises the feedback NHS England received from engagement during the development of the Radiotherapy Services, Molecular Radiotherapy (all ages) Service Specification, and how this feedback has been considered. 14 responses were received from a number of organisations including providers, professional bodies and individuals. Full details are in paragraph 3.2 below.

Feedback was positive overall, with stakeholders registering their broad support for the Service Specification requirements, the clinical model and the standards proposed.

2. Background

MRT is the treatment of disease with unsealed radioactive substances. It is distinct from radiotherapy that involves the use of 'solid' radiotherapy sources (such as seeds or wires) or external beam radiotherapy, which are covered in separate Service Specifications.

MRT is used to treat a variety of cancers including neuroendocrine tumours and thyroid cancers. It is also used to treat benign thyroid disease (thyrotoxicosis). Selective Internal Radiotherapy (SIRT) is used to treat cancer in the liver.

MRT uses radioactive medication which is administered orally or intravenously. The radioactive chemical (radionuclide) is linked to a cell-targeting molecule which, when put into the body, binds to a specific target found diseased cancer cells and delivers targeted radiation to those cells while limiting the harm to normal cells.

MRT is a tertiary service that is accessed only by referral from a specialist multi-disciplinary team.

The current Service Specification covers people (all ages) who are within the commissioning responsibility of NHS England and who require brachytherapy and molecular radiotherapy (MRT) services ("the Service").

The Service Specification describes a clinical model based on different levels of service:

- Level 1 – single administration MRT in pill or capsule for benign disease in an outpatient setting.
- Level 2 - intravenous administration for cancer.
- Level 3 – selective internal radiation therapy (SIRT) which is used to treat some cases of metastatic colorectal cancer and primary liver cancer.
- Paediatric – where MRT is administered to children.

The model reflects the arrangements already in place across different MRT providers, however, this is the first time that it has been documented within a Service Specification. Providers will have to meet the requirements of the service level appropriate to the treatments that they deliver – looking ahead, this will help manage any expansion of provision that may be required as new treatments are approved for use in the NHS in England.

The inclusion of SIRT within the clinical model reflects clinical advice that it better fits within MRT rather than brachytherapy because of the need for nuclear medicine and interventional radiology support.

There are currently 38 commissioned providers of MRT services in England that deliver some or all of the commissioned brachytherapy treatments.

SIRT is delivered in a specialist liver centre collocated (within the same town/city) with a radiotherapy service and it is anchored to hepato-pancreatic biliary multi-disciplinary team. SIRT is normally given in a day case setting.

The Service Specification has been developed to set out the must-do requirements for providers and:

- 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.

It is expected that the new MRT Service Specification will support Integrated Care Boards (ICBs) to take responsibility for the commissioning of MRT services when they are delegated from April 2024.

The new Service Specification is not expected to change the provider landscape or overall service delivery. As a result, the revised Service Specification is expected to be cost neutral to NHS England and other parts of the NHS.

In accordance with usual NHSE processes, this Service Specification was developed with the support and input of a Specification Working Group (SWG), comprising representation from MRT experts, referring clinical experts and patient and public voice representatives.

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).

The Service Specification was sent for stakeholder testing for two weeks from 11th July to 24th July 2023. The comments have then been shared with the Specification Working Group to enable full consideration of feedback and to support a decision on whether any changes to the specification might be recommended.

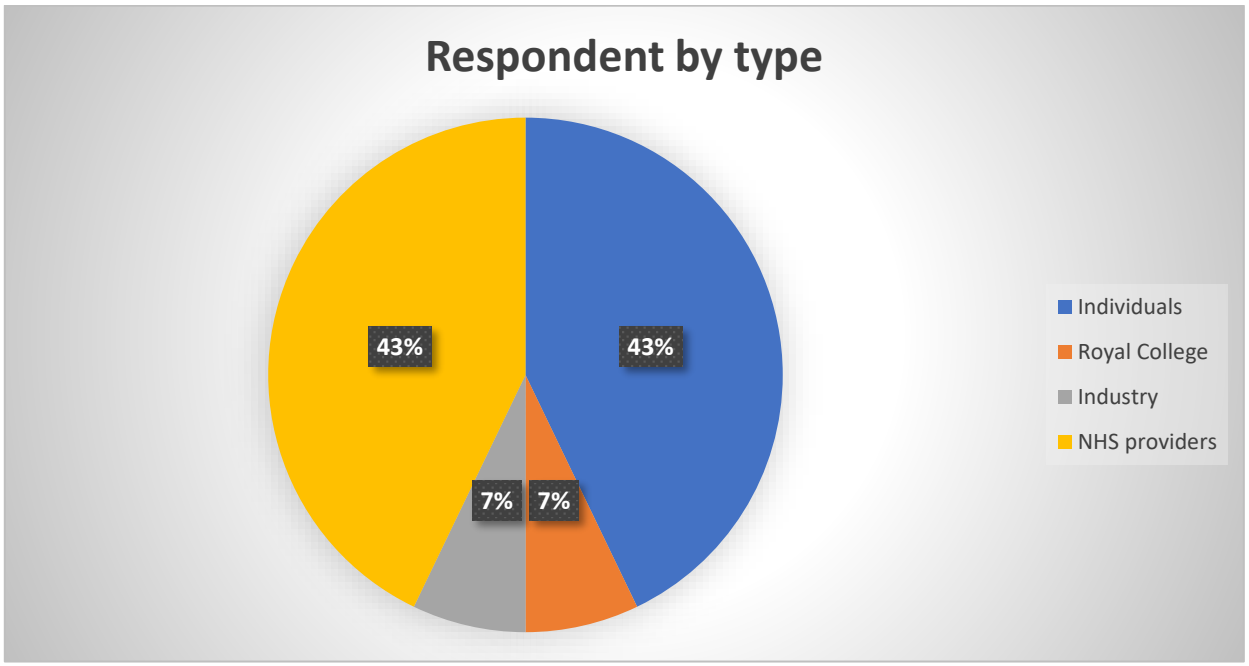
Respondents were asked the following questions:

- Do you have any comments on the proposal?
- If yes, please describe below, in no more than 500 words, any further comments on the proposal as part of this initial 'sense check'.
- What quality outcome measures could be included in the Service Specification?
- Do you support the new Clinical Model for MRT?
- If you don't support the new Clinical Model, what do you think should be changed and why?
- Do you support the Equality and Health Inequalities Impact Assessment?

3.2 Stakeholder testing results and summary of participants

14 responses were received from:

- 1 x Royal College
- 6 x Individuals
- 6 x NHS providers
- 1 x Industry



The stakeholder testing generated positive responses overall, with stakeholders registering their broad support for the Service Specification requirements and standards. There was overall support for the clinical model. Respondents were particularly supportive of the separation of the MRT specification from the brachytherapy specification.

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

Several responses suggested minor changes to the technical language in the specification, in particular in relation to job roles and naming of equipment and facilities. Suggestions were checked with the SWG and against regulatory requirements. Text was amended where necessary.

Three responses challenged the requirement for access to PET-CT imaging in the same town or city. There was concern that, based on the existing PET-CT infrastructure, this might preclude some services from continuing their operation. The SWG agreed this point and the proximity requirement was removed.

There were no responses from the charity groups that were contacted, however, as the proposal represents a minor update to an existing specification and does not change the way that services are delivered or impact on eligibility for brachytherapy, this is not considered to present an issue. In addition, 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.

Suggestions for outcome measures to be included in the specification were noted. However, following advice from the Quality and Nursing Team (QNT), it was determined that the suggested measures were quality metrics rather than outcome measures and, as such, will be considered separately as part of the quality metric development stage of the process.

A 13Q assessment has been completed following stakeholder testing. The Cancer PoC has concluded 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, 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 Specification Working Group and the Cancer PoC. The following themes were raised during engagement:

Engagement activity theme identified in e.g. stakeholder testing, public consultation	Key themes in feedback	NHS England Response
	Population and patient volumes	
Stakeholder testing	Three respondents challenged the patient volume throughput requirements detailed in the specification, some suggested higher volumes and some lower.	The figures are taken from the existing specification, which is based on clinical opinion and, for SIRT, the Commissioning through evaluation process. There was no new evidence introduced to support a change to the volumes.
	Technical Language	
Stakeholder testing	Some stakeholders commented on the language used to describe certain job roles (e.g. Nuclear Medicine Physician changed to nuclear medicine specialist Radiologist).	**Minor changes to the wording in the Service Specification where appropriate.** Suggested changes were checked against regulatory and licensing requirements and also with SWG members and, where supported by evidence, appropriate amendments were made to the specification. This did not alter the service model or delivery requirements.
	Staffing, equipment and facilities requirements	
Stakeholder testing	Two suggested that the requirement for two ARSAC practitioners for level 1 services was unnecessary.	**No change to the Service Specification** This requirement is to ensure Service resilience and is taken from ARAC Notes for guidance. All levels require two ARSAC licensed practitioners.
	Several respondents challenged the requirement for each service to have access to a radiopharmacy	**Minor change to Service Specification.**

	when many sites purchase radiopharmaceuticals from a commercial supplier and are not involved in the production of radiopharmaceuticals.	This is a valid challenge and the requirement for radiopharmacy access has been removed and replaced with “Essential equipment facilities to store, document and measure delivered doses of radiopharmaceuticals”. The amended wording reflects regulatory requirements and ensures the safe handling of radiopharmaceuticals where there is no radiopharmacy facility available.
Stakeholder testing	Three responses challenged the requirement for access to PET-CT imaging in the same town or city. There was concern that, based on the existing PET-CT infrastructure, this might preclude some services from continuing their operation.	**Minor change to Service Specification.** This point was agreed, and the proximity requirement has been removed from the Service Specification.
Stakeholder testing	Respondents noted that the term “hot toilet” is not a widely recognised term to describe toilets that designed for the disposal of radioactive waste.	**Minor change to Service Specification.** This was checked against published guidance and term “hot toilet” has been changed to shielded toilets.
	Equalities and Health Inequalities Impact Assessment	
Stakeholder testing	A number of stakeholders commented on equity of access to MRT for people living in remote or deprived areas, or a low income or citing geographical access as a problem.	**No change to the Service Specification.** These issues are not relevant to the Service Specification, the purpose of which is to set out the minimum service standards. This is a revision of an existing Service Specification and is not expected to change the provider landscape or overall service delivery so will not present any additional impact to people in the protected characteristic or vulnerable groups.
	Commissioning, and policy issues	
Stakeholder testing	Two respondents suggested the Service Specification should cover the potential commissioning of new, novel and pending molecular radiotherapies.	**No change to the Service Specification** This is a commissioning policy issue and not relevant to the specification. The specification includes a requirement for providers to implement new technologies that are

		recommended by the National Institute for Health and Care Excellence.

5 Has anything changed in the Service Specification as a result of the stakeholder testing and consultation?

The following changes based on the engagement responses have been made to the Service Specification:

- Minor changes to the language used to describe essential staff roles and some equipment.
- The requirement for PET-CT to be located in the same town or city has been removed.

6 Are there any remaining concerns outstanding following the consultation that have not been resolved in the final Service Specification?

No. 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 was reviewed at the PPVAG meeting on 17th August 2023.

Confirmation has been received that public consultation is not required.

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.