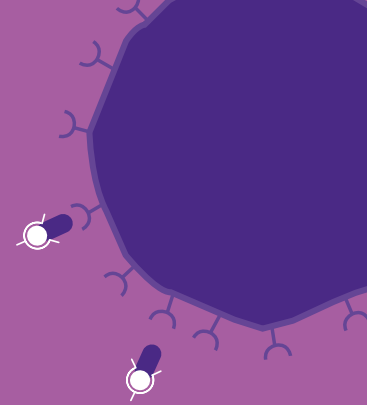




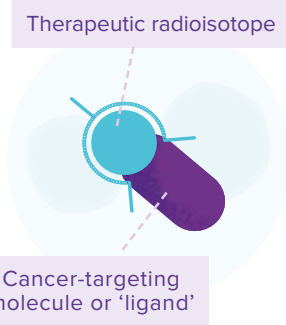
Creating a ready health system for radioligand therapy in the UK

POLICY ACTION BLUEPRINT



What is radioligand therapy?

Radioligand therapy is a highly targeted cancer therapy. A radioligand is made of two parts: a ligand, which is able to find cancer cells that present a particular receptor, and a radioisotope, which is able to treat the cancer.^{1,2} Radioligands find and deliver radiation directly to cancer cells, regardless of where these cells are located in the body. There are many terms for radioligand therapy, including molecular radiotherapy, peptide-receptor radionuclide therapy and, when the ligand used is an antibody, radioimmunotherapy.



Radioligand therapy has been shown to significantly improve survival and quality of life for people with certain types of neuroendocrine neoplasms (NENs), lymphoma and prostate cancer.³⁻⁸ Unlike conventional cancer therapies, radioligand therapy's targeted interaction with cancer cells leaves healthy cells largely unaffected.^{1,9,10}

Readiness for radioligand therapy

Planning for radioligand therapy requires a multidisciplinary and multi-sectoral approach. Furthermore, as the therapy evolves and new applications emerge, the health system must be ready to accommodate this innovation quickly and sustainably. Therefore, we need to proactively plan for its integration into the UK health system both now and in the future, to ensure it is available to all who may benefit from it.

→ **INTEGRATION** is the adoption and assimilation of radioligand therapy into every aspect of a health system to ensure its availability to all people who may benefit from it.

→ **READINESS** is the ability of the health system to rapidly and sustainably adapt policies, infrastructure and processes to support integration of a new radioligand therapy.

6 KEY STRATEGIC CHALLENGES must be addressed to improve the current integration and future readiness for radioligand therapy in the UK:



Recognition and leadership



Data collection and analysis



Professional training and licensing



Clinical guidelines and care pathways



Logistics and infrastructure



Equitable access

6 KEY STRATEGIC CHALLENGES



Recognition and leadership

Radioligand therapy is poorly integrated into cancer planning and there is limited political recognition and leadership

WE NEED:

- > **Relevant professional societies, patient organisations, NHS England and the devolved nations' health authorities** to co-develop a national strategic vision on radioligand therapy, which outlines investment and resources required to ensure its wider availability in the future
- > **All relevant professional societies and patient organisations** to develop evidence-based patient materials on radioligand therapy, tailored to each condition in which it is indicated and suitable for people with different levels of health literacy



Data collection and analysis

Current data collection systems for radioligand therapy do not collect adequate data to inform evidence-based decision-making

WE NEED:

- > **NHS Digital and all healthcare professionals and centres delivering radioligand therapy** to collect standardised data on radioligand therapy use in clinical practice, including:
 - training and licensing of all professionals involved in the delivery of radioligand therapy
 - the locations and facilities of centres delivering radioligand therapy
 - the number of people treated for each indication
 - clinical and patient-reported outcomes
- > **NHS England, NHS Digital and equivalent agencies in devolved nations** to ensure appropriate funding, workforce and infrastructure to implement comprehensive data collection and analysis to inform care planning and resource allocation



Professional training and licensing

Professional training and licensing requirements for radioligand therapy do not adequately reflect current practice or working patterns

WE NEED:

- > **Health Education England, Joint Royal Colleges of Physicians Training Board and relevant professional societies** to update training curricula in line with radioligand therapy approvals and recommendations from Medicines and Healthcare products Regulatory Agency (MHRA), National Institute for Health and Care Excellence (NICE) and equivalent bodies in the devolved nations
- > **Administration of Radioactive Substances Advisory Committee (ARSAC) and training bodies** to adapt training and licensing procedures to ensure the process is feasible and accessible in light of changing work patterns, and create a larger and sustainable workforce for the delivery of radioligand therapy
- > **Health Education England, NHS England and equivalent agencies in devolved nations** to develop formalised training programmes for radioligand therapy clinical nurse specialists and patient coordinators and ensure there is appropriate funding for these roles



Clinical guidelines and care pathways
Clinical guidelines and care pathways for radioligand therapy are not always up to date with scientific advances or regulatory approvals

WE NEED:

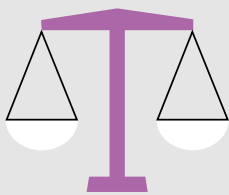
- > **All relevant professional societies and colleges** to support multidisciplinary collaboration to develop or ensure availability of appropriate guidelines for the optimal use of radioligand therapy in all indications upon approval by NICE
- > **NHS England, Strategic Clinical Networks and equivalent agencies in the devolved nations** to formalise a clear national pathway and standards for referrals and delivery of radioligand therapy for NENs, where radioligand therapy is already available, and ensure a timely expansion of pathways as new therapies become available



Logistics and infrastructure
Logistics and infrastructure for radioligand therapy are not always seamless or secure

WE NEED:

- > **NHS England and equivalent organisations in the devolved nations** to ensure appropriate funding for the infrastructure and resources needed to safely and effectively provide radioligand therapy and comply with existing regulations
- > **The UK government** to ensure a secure supply of imaging and therapeutic radioisotopes from national and international sources, and establish mutual recognition agreements on manufacturing certifications for internationally sourced radioisotopes



Equitable access
Existing delivery models are unlikely to scale appropriately, threatening equitable access to radioligand therapy should demand grow

WE NEED:

- > **NHS England and equivalent organisations in the devolved nations** to evaluate gaps in current services and drive investments in underserved areas to address geographical inequalities in access to treatment centres
- > **All relevant professional societies, patient organisations, Cancer Alliances, Cancer Vanguard and radiotherapy delivery networks** to develop a set of radioligand therapy delivery models appropriate to different settings, sizes of centres and patient populations, which encourage robust multidisciplinary collaboration and take advantage of technology and new ways of working resulting from the COVID-19 pandemic to help seamlessly scale up use of the approach



Why does the NHS need to be ready for the wider use of radioligand therapy?

In the UK, radioligand therapy is currently licensed for use by the MHRA in NENs and lymphoma. While the approach is widely used for people with NENs, official integration of radioligand therapy within cancer pathways is limited and there remains a 'postcode lottery' in terms of access.^{9 11 12} Radioligand therapy is rarely used for people with lymphoma.¹³

With many new therapies on the horizon, the UK must improve existing care and prepare for the future. Advances in genomics and increasing identification of specific cancer receptors mean that radioligand therapy could theoretically be applied to any cancer where a suitable receptor is identified. It is currently under investigation for prostate, breast and other types of cancer.¹³⁻¹⁷ This could mean a significant increase in patient numbers – for example, should radioligand therapy be approved for use in advanced prostate cancer, the number of people eligible for the approach may increase at least tenfold.¹² Therefore, an expansion into new types of cancer will require a reevaluation of our infrastructure, workforce and models of care to ensure equitable access to the approach.

Establishing readiness for radioligand therapy has benefits for the whole health system. Preparing the NHS for radioligand therapy sets an important precedent for integrating new, innovative cancer therapies into clinical practice and ensuring that people with cancer receive the best possible care. However, it is important that innovation does not occur at the expense of sustainability. Careful planning and preparation will ensure that innovation is integrated in a viable manner. Wider use of radioligand therapy can also support national ambitions to increase access to personalised care,¹⁸ and will ultimately help to reinforce the UK's position at the forefront of healthcare innovation.

REFERENCES

1. Jadvar H. 2017. *AJR Am J Roentgenol* 209(2): 277-88
2. Fahey F, Zukotynski K, Capala J, et al. 2014. *J Nucl Med* 55(2): 337-48
3. Strosberg J, El-Haddad G, Wolin E, et al. 2017. *N Engl J Med* 376(2): 125-35
4. Marinova M, Mücke M, Mahlberg L, et al. 2018. *Eur J Nucl Med Mol Imaging* 45(1): 38-46
5. Sartor AO, Morris MJ, Messman R, et al. 2020. *J Clin Oncol*: 10.1200/JCO.2020.38.6_suppl.TPS259
6. Cheson BD. 2003. *Blood* 101(2): 391-98
7. Kolstad A, Madsbu U, Beasley M, et al. 2018. *Blood* 132: 2879
8. Witzig TE, Gordon LI, Cabanillas F, et al. 2002. *J Clin Oncol* 20(10): 2453-63
9. National Cancer Research Institute. 2016. *CTRad: identifying opportunities to promote progress in molecular radiotherapy research in the UK*. NCRI
10. Herrmann K, Schwaiger M, Lewis JS, et al. 2020. *Lancet Oncol* 21(3): e146-e56
11. Davis L, Smith A-L, Aldridge MD, et al. 2020. *J Pers Med* 10(4): 174
12. Buscombe J. 2021. *Clin Oncol*: 10.1016/j.clon.2020.11.012
13. Rojas B, McGowan DR, Guy MJ, et al. 2019. *Nucl Med Commun* 40(7): 657-61
14. Clinicaltrials.gov. <https://www.clinicaltrials.gov/ct2/show/NCT03511664>
15. Clinicaltrials.gov. <https://clinicaltrials.gov/ct2/show/NCT04529044?term=177Lu&cond=Metastatic+Breast+Cancer&draw=2&rank=1>
16. Clinicaltrials.gov. <https://clinicaltrials.gov/ct2/show/NCT00445965?term=131I-3F8&cond=leptomeningeal+cancer&draw=2&rank=1>
17. Clinicaltrials.gov. <https://clinicaltrials.gov/ct2/show/NCT03971461?term=177Lu&cond=meningioma&draw=2&rank=1>
18. Clinicaltrials.gov. <https://clinicaltrials.gov/ct2/show/NCT04022213?term=131I-Omburtamab&draw=2&rank=3>
19. NHS England. 2019. *The NHS Long Term Plan*. NHS

ABOUT THE RADIOLIGAND THERAPY READINESS ASSESSMENT PROJECT

This policy action blueprint is part of a broader piece of work aiming to define what is needed to establish system-level readiness for radioligand therapy in the UK. It is supported by other documents including a UK summary report, working papers on health system readiness for radioligand therapy in the UK and an associated national framework.

All documents have been developed by The Health Policy Partnership in collaboration with the UK Expert Advisory Group. The project was supported with funding from Advanced Accelerator Applications, a Novartis company, with additional support from Nordic Nanovector. For more details, please visit www.radioligandtherapy.com/framework/UK