

The
Health Policy
Partnership
[research, people, action]

Health system readiness for radioligand therapy in the UK

Identified need

Working paper

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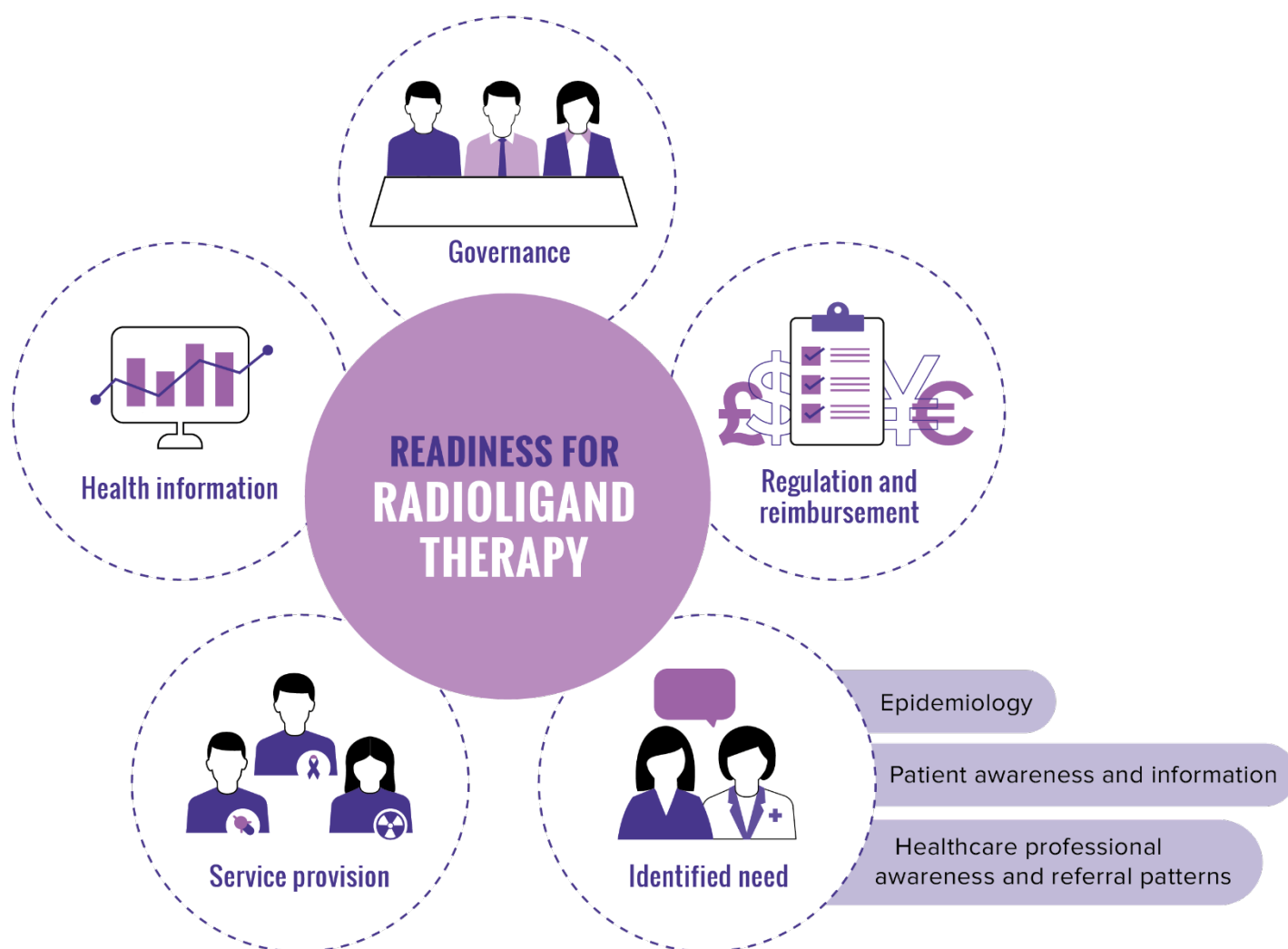
About this working paper

This working paper 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 explores current integration and future readiness for the approach as it relates to identified need, one of the five domains of the Radioligand Therapy Readiness Assessment Framework (*Figure 1*). The working paper provides answers to questions from the framework, with key findings from relevant subdomains outlined in a summary assessment at the start of each section. We focus on the situation in neuroendocrine neoplasms, lymphoma and prostate cancer in England, though we also include examples from across the devolved nations. Many of the findings in this paper may be applicable across the UK and in other areas of cancer care.

- This working paper is supported by other documents on health system readiness for radioligand therapy in the UK. For more details, please visit:
www.radioligandtherapy.com/framework/UK

This working paper uses the term radioligand therapy, but there are various terms used for the approach, including: peptide-receptor radionuclide therapy (PRRT), systemic radiation therapy, targeted radionuclide therapy, targeted radiotherapy and molecular radiotherapy. When the ligand used is an antibody, the approach is known as radioimmunotherapy.

Figure 1. Domains of the Radioligand Therapy Readiness Assessment Framework



What is identified need?

Identifying the need for health services is the first step to effectively plan for care and ultimately have the ability to deliver therapies to the people who would benefit from them. In the context of radioligand therapy, identifying need is the process of understanding what proportion of the population could benefit from the approach. This relies on rigorous epidemiological data collection. It also depends on good awareness of radioligand therapy among patients and healthcare professionals, so that the people who would benefit from the approach are informed about it and can be promptly identified.

How is the need for radioligand therapy effectively identified?

Up-to-date epidemiological data, as well as patient and clinician awareness, are needed to ensure health systems can plan for and deliver radioligand therapy. Reliable epidemiological data are needed to quantify the number of people with cancer who may be eligible for radioligand therapy, and plan and supply the service accordingly. Healthcare professionals' awareness of the approach is crucial to ensure that people who would benefit from radioligand therapy are accurately identified and referred, and that the epidemiological data reflect actual use of the approach. Patient awareness is also key. The availability of clear, accurate, consistent and timely patient information on radioligand therapy can help ensure people fully understand the approach, its potential benefits and risks. This will help them be involved in treatment decision-making, ensuring that they can make informed decisions about their care and that treatment meets with their personal goals and priorities.

1 Epidemiology

Summary assessment

Indicator	Assessment
What is the current burden of disease in the UK?	<p>Neuroendocrine neoplasms: Over 5,000 people are diagnosed with NENs each year, and the incidence is increasing.</p> <p>Lymphoma: In 2016, more than 16,000 people were diagnosed with a type of lymphoma in the UK. This is an increase of over 36% since the early 1990s, and the number is likely to grow in future.</p> <p>Prostate cancer: In 2017, approximately 48,600 people were diagnosed with prostate cancer. It is predicted that incidence will rise by 12% between 2014 and 2035.</p>

1.1 Neuroendocrine neoplasms

Epidemiological data demonstrate that the incidence of neuroendocrine neoplasms (NENs) in the UK has increased in recent years. In 2015, over 5,000 people were diagnosed with at least one type of NENs in the UK, compared with under 2,000 in 2001.¹ NENs is a collective group of cancers with heterogeneous symptoms, poor awareness of which among healthcare professionals challenges accurate and timely diagnosis,^{2,3} potentially leading to an underestimation of incidence and prevalence figures. As the number of people with NENs increases, existing service capacity for NENs, including provision of radioligand therapy, may become overstretched without further investment.²

Due to increasing incidence, NENs may in time be reclassified from a rare to a ‘less common’ cancer. This reclassification could have major implications for access to therapies and healthcare services. A number of initiatives have been established to ensure that research and treatments for rare cancers receive adequate funding.⁴⁻⁶ For example, the International Rare Cancers Initiative helps fund research and clinical trials in rare cancers.⁶ Treatments for rare cancers are also eligible for orphan designation,⁷ which is meant to encourage pharmaceutical companies to conduct research in designated conditions. Less common cancers do not benefit from these initiatives, but also do not receive as much funding as more common cancers. Therefore, reclassification of NENs as a less common cancer could actually reduce the attention this indication receives.

Data on specific types of NENs should be consistently collected to ensure an accurate understanding of how many people would benefit from radioligand therapy.

The National Institute for Health and Care Excellence (NICE) has estimated that 430 people with unresectable or metastatic, progressive, well-differentiated NENs may be eligible for radioligand therapy each year in England.⁸ However, this estimate is largely based on clinical expert opinion rather than epidemiological data, and should be viewed with this caveat in mind. Similar estimates are not currently available across the devolved nations. New data from clinical trials in NENs and ongoing epidemiological data analysis supported by Neuroendocrine Cancer UK may improve the accuracy of estimates in the future.⁹ These initiatives, alongside formalised UK-wide systematic collection of data in this area, would help to assess the need for radioligand therapy and assist with capacity planning for delivery of the approach.

1.2 Lymphoma

The incidence and prevalence of lymphoma are increasing. In 2016, more than 16,000 people were diagnosed with a type of lymphoma in the UK – an increase of over 36% since the early 1990s.¹⁰⁻¹² As incidence of lymphoma increases and overall survival improves,^{13 14} the prevalence of the condition is likely to grow. It is important that haematology services have sufficient capacity to respond to this growing demand for care.¹⁵

While data are typically available for specific lymphoma subtypes, information by different lines of treatment is not routinely available. Radioligand therapy is under investigation and licensed for use in people with specific lymphoma subtypes and treatment history, e.g. in CD20 positive relapsed or refractory follicular lymphoma. While information about the number of people with follicular lymphoma is available,^{16 17} information about the number of people in whom lymphoma has relapsed or is refractory is not. This type of information is essential to properly plan healthcare resources.

1.3 Prostate cancer

Prostate cancer is the most commonly diagnosed cancer among men in the UK and its incidence and prevalence figures are predicted to rise further. In 2017, approximately 48,600 new cases of prostate cancer were diagnosed in the UK.¹⁸ More men in the UK are diagnosed with prostate cancer than any other cancer.¹⁹ It is predicted that

incidence rates will rise by 12% between 2014 and 2035, to an estimated 233 people per 100,000 across the devolved nations.²⁰

Although nationally collected data on prostate cancer are available, data collected specifically on advanced prostate cancer are difficult to find. As is the case for many other cancers, accurate incidence and prevalence data on prostate cancer by clinical stage are not available. Although one study estimates such data for metastatic castration-resistant prostate cancer (mCRPC),²¹ these data cannot be extrapolated to the population level as the study sample is small. As a result, it is unclear how many people with prostate cancer may be eligible for radioligand therapy. It is estimated that expanding the use of radioligand therapy to prostate cancer could increase the number of eligible people at least tenfold.²² Data on prostate cancer should also be collected by treatment stage, so that we have a better understanding of how many people are receiving first-, second- and third-line treatments.

- For more information on data and research related to radioligand therapy, read the working paper on [health information](#).

2 Patient awareness and information

Summary assessment

Indicator	Assessment
Is there information for patients on radioligand therapy as a treatment option?	<p>Neuroendocrine neoplasms: Information on radioligand therapy as a therapeutic option for NENs is typically provided by charities and healthcare providers. Its type and content vary between sources.</p> <p>Lymphoma: Lymphoma Action provides some of the only patient information about licensed radioligand therapy and clinical trials using this approach. This is not surprising, as use of radioligand therapy for lymphoma is restricted in the UK.</p> <p>Prostate cancer: Information on radioligand therapy as a potential investigational therapeutic option for prostate cancer focuses on signposting people to participation in clinical trials.</p>

2.1 The value of patient awareness and information

People with cancer must be well informed about different treatment options so that they can be involved in making decisions about their care. Across indications, there is evidence that shared decision-making can improve patient adherence and treatment experience, and may contribute to more positive treatment outcomes.²³⁻²⁵ To increase understanding of a therapy among people with cancer, organisations must develop clear, accurate and consistent information materials that meet the needs of patients. This type of information is especially important in the context of radioligand therapy, where negative beliefs or perceptions about radiation may make people less likely to consider the approach.²⁶

2.1.1 Neuroendocrine neoplasms

Information on radioligand therapy for people with NENs is provided by a range of different organisations and healthcare providers. Charities such as Cancer Research UK and Neuroendocrine Cancer UK have been particularly active in this area.^{27 28} Patient information has also been produced at the NHS trust and hospital level, for example by Guy's and St Thomas' NHS Foundation Trust²⁹ and The Christie Hospital.³⁰

Overall, information available to people with NENs could benefit from alignment in several areas. Information on radioligand therapy for NENs includes some detail on the therapy's administration and potential side effects, but tends to be variable in the following areas:

- **Different sources do not always specify at what stage of the patient pathway radioligand therapy is provided.** For example, information produced by Cancer Research UK²⁷ and Guy's and St Thomas' Hospital²⁹ clearly outlines that radioligand therapy is a second- or third-line therapy used when the cancer may be progressing and when patients are not responding to other therapies. However, this is not explained by other information sources, such as those from The Christie Hospital³⁰ or Neuroendocrine Cancer UK.²⁸
- **There are inconsistencies in terminology used to refer to radioligand therapy.** Terms used include lutetium therapy, peptide-receptor radionuclide therapy and internal radiotherapy.²⁸⁻³⁰ The variety of terminology may be confusing to patients and healthcare professionals alike.
- **Information for patients is not tailored by age group.** This is particularly important for children and adolescents, who benefit from age-appropriate resources.³¹ Although extremely rare in children, NENs can be diagnosed at a young age,³² so tailored resources are important.

To begin to tackle some of these inconsistencies and increase the availability of high-quality information for people with NENs, the British Nuclear Medicine Society and UK and Ireland Neuroendocrine Tumour Society (UKINETS) are currently working to develop a comprehensive patient information sheet.³³

2.1.2 Lymphoma

- **Patient information about radioligand therapy is not widely available, as access to the approach is very limited.** Lymphoma Action's website provides some of the only patient information about radioligand therapy for the treatment of lymphoma.³⁴ It acknowledges that only one form of radioligand therapy is currently licensed for use in the UK and that it is not routinely reimbursed on the NHS. Lymphoma Action also summarises how radioligand therapy is administered, who

is eligible for the approach and what clinical trials are ongoing.^{35 36} Information about clinical trials is not provided by other organisations.³⁷

- For more information about the availability of radioligand therapy in lymphoma, read the working paper on [regulation and reimbursement](#).

2.1.3 Prostate cancer

Patient information on treatment for prostate cancer is widely available, but does not currently include radioligand therapy. The NHS and leading patient organisations (such as Prostate Cancer UK) provide in-depth patient information on treatment options for prostate cancer.^{38 39} However, as radioligand therapy is currently used only in an investigational capacity, its inclusion in patient resources would be premature. Prostate Cancer UK and Cancer Research UK signpost people with prostate cancer to clinical trials, and Cancer Research UK has a list of ongoing and recently closed trials on its website,^{40 41} though this does not include trials of radioligand therapy.

3 Healthcare professional awareness and referral patterns

Summary assessment

Indicator	Assessment
Are relevant healthcare professionals aware of radioligand therapy as a treatment option?	<p>Nuclear medicine: The nuclear medicine community has good awareness of radioligand therapy and imaging.</p> <p>Oncology: Radioligand therapy is not explicitly included in training for medical or clinical oncologists, and awareness is based on individuals' involvement with centres of excellence and larger hospitals where radioligand therapy is provided.</p> <p>Neuroendocrine neoplasms: Endocrinologists, gastroenterologists, clinical nurse specialists and other members of the team delivering care to people with neuroendocrine neoplasms have a good awareness of radioligand therapy, but the approach is not yet formally addressed in their training.</p> <p>Lymphoma: Experienced haematologists and clinical nurse specialists are often aware of radioligand therapy, but limited access to the approach for over a decade means that it is not regularly considered for patients. Radioligand therapy is not formally included in training, so recently trained haematologists and nurse specialists will likely not be aware of it.</p> <p>Prostate cancer: As radioligand therapy is currently used only in an investigational capacity for prostate cancer, relevant training for urologists and uro-oncologists is limited and awareness of the approach is centred in larger hospitals with a research focus.</p>

Radioligand therapy and imaging are well integrated into training programmes for nuclear medicine physicians, clinical radiologists and radiotherapists. The nuclear medicine community plays a key role in providing radioligand therapy and associated imaging techniques, and the approach is well embedded in training for nuclear medicine physicians.⁴² Other specialists involved include clinical radiologists and radiotherapists, as imaging is crucial to the use of radioligand therapy. The training curriculum for these specialties covers imaging that is used in radioligand therapy, such as positron emission tomography-computed tomography (PET-CT) imaging, but does not specifically address the use of therapeutic radioisotopes.^{43 44}

Some referring clinicians are aware of radioligand therapy through individual experience, ad hoc events and training. Outside of nuclear medicine, clinicians may gain an understanding of the approach through their involvement in clinical trials, or by working in hospitals or centres of excellence where the approach is used.⁴⁵ Relevant professional societies and patient organisations can play a role in helping raise awareness of radioligand therapy. For example, UKINETS and Neuroendocrine Cancer UK have a range of training resources and guidance for healthcare professionals that reference radioligand therapy.⁴⁶⁻⁴⁸ Thanks to these sources and high levels of multidisciplinary collaboration, many gastroenterologists, endocrinologists and clinical nurse specialists involved in NENs care have good awareness and understanding of radioligand therapy. In lymphoma, for reasons outlined in the summary of this section, the approach is mainly known among individuals who have been involved in lymphoma management for ten years or more.^{45 49} Radioligand therapy is rarely considered for treatment of lymphoma,⁵⁰ and newly trained healthcare professionals may not be aware of it.⁴⁵

The absence of radioligand therapy from training curricula may negatively impact healthcare professionals' understanding of the approach if they do not work in a centre that delivers this care. Training curricula for specialties that typically refer people with cancer for treatment – such as medical oncology,⁵¹ clinical oncology,⁵² gastroenterology,⁵³ endocrinology⁵⁴ and haematology^{55 56} – do not reference radioligand therapy, limiting clinicians' knowledge of the approach. Many of these curricula are also not updated regularly, which limits their use regarding novel therapies in line with new evidence becoming available.

It is important that radioligand therapy be efficiently incorporated into formal and informal training for all relevant specialists upon approval of a new therapy. This will ensure that newly trained healthcare professionals (including referring clinicians and clinical nurse specialists) understand when the approach could be beneficial. Additionally, it is also important to ensure that experienced healthcare professionals are kept up to date with new therapies. Continuing professional development may come in the form of informal learning opportunities as part of multidisciplinary working, as has been seen in NENs, but it may also consist of more formal knowledge-sharing between institutions and healthcare professionals.⁴⁵ An example of this is The Christie NHS Foundation Trust's training courses for proton beam therapy (*Real-world example 1*). A similar approach could

be used to increase awareness and understanding of radioligand therapy among trained healthcare professionals.

- For more information on referral patterns and healthcare professional roles related to radioligand therapy, read the working paper on [service provision](#).

Real-world example 1. Proton beam therapy training in the UK

Managed by The Christie NHS Foundation Trust, The Christie Proton School provides a range of teaching and training opportunities for healthcare professionals, with a focus on service development and delivery.⁵⁷ This includes specialist courses, study days, two-week observational opportunities and year-long fellowships. Training is grounded in lessons learnt from The Christie's experiences in developing the UK's first high-energy NHS proton beam therapy centre in the UK.

Conclusion

Appropriate information about radioligand therapy must be made available to patients and healthcare professionals to ensure equitable and appropriate use of the approach. A more rigorous approach to estimating the number of people eligible for radioligand therapy is essential to support appropriate planning and service delivery within each patient population. Demand for novel therapies is driven by patients who are aware of them and by knowledgeable healthcare professionals who can refer eligible patients. Information for people with cancer needs to be standardised across available sources to better explain the complexities around eligibility and administration of radioligand therapy. Healthcare professional training bodies and professional societies should also update training curricula regularly in line with national recommendations on the use of radioligand therapy. But it is also important that individual healthcare professionals continue to use multidisciplinary working as an opportunity to informally raise awareness and understanding of the approach, as has been seen in NENs. Up-to-date and aligned training programmes will likely facilitate a common understanding and awareness of the approach and streamline multidisciplinary working to better integrate it into cancer care.

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