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# Radioligand Therapy Readiness Assessment Framework: UK

September 2021

This framework has been developed by The Health Policy Partnership as part of an ongoing project. UK materials were developed in collaboration with a UK Expert Advisory Group, who had full editorial control. The project is supported with funding from Advanced Accelerator Applications, a Novartis Company, with additional support from Nordic Nanovector.

### **About the radioligand therapy readiness assessment project**

This document has been developed by The Health Policy Partnership. It 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, developed in collaboration with a UK Expert Advisory Group. It is supported by other documents including working papers, a summary report and a policy action blueprint on health system readiness for radioligand therapy in the UK. For more information, please visit [www.radioligandtherapy.com/uk-readiness-assessment](http://www.radioligandtherapy.com/uk-readiness-assessment)

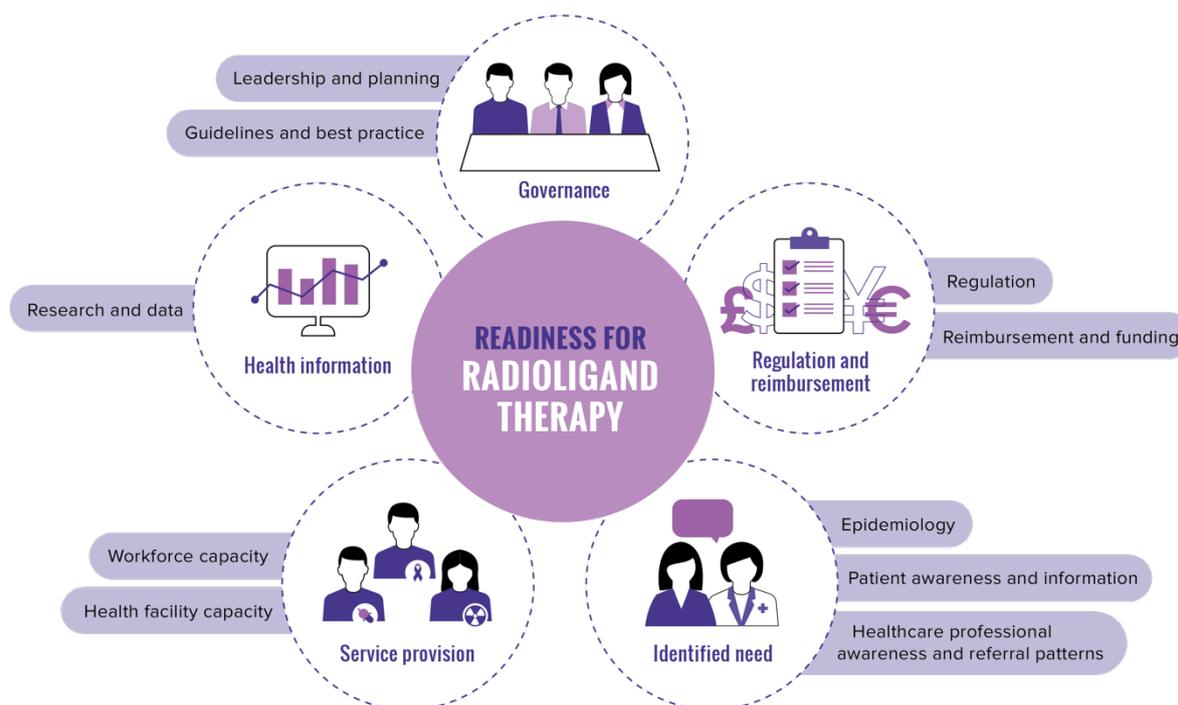
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## Introduction

The Radioligand Therapy Readiness Assessment Framework is an international tool to establish the ability of health systems to rapidly and sustainably adapt policies, infrastructure and processes to support integration of a new radioligand therapy. The intention of the framework is that it be adapted and applied to individual countries. This document is a national version of the framework following its application to the UK.

Figure 1. A systems approach to readiness for radioligand therapy



For the full framework and how it was developed, please see

[www.radioligandtherapy.com/readiness-assessment-framework/](http://www.radioligandtherapy.com/readiness-assessment-framework/)

For an overarching summary of UK findings, individual domain working papers and more

information about the project, please see [www.radioligandtherapy.com/uk-readiness-assessment](http://www.radioligandtherapy.com/uk-readiness-assessment)

# 1 Governance

## 1.1 Leadership and planning

### 1.1.1 Is there national leadership and political support for radioligand therapy?

<b>Metrics</b>	<ul style="list-style-type: none"> <li>• Are patient organisations, professional societies and political groups actively involved in raising awareness and understanding of radioligand therapy?</li> <li>• Does radioligand therapy feature in policy discussions around cancer care?</li> </ul>
<b>Contextual factors</b>	<ul style="list-style-type: none"> <li>• Which stakeholders are involved in influencing policy change?</li> <li>• Are policymakers and decision-makers aware of radioligand therapy?</li> </ul>

### 1.1.2 Are there any cancer strategies or plans in place in the UK that include, or could include, radioligand therapy?

<b>Metrics</b>	<ul style="list-style-type: none"> <li>• Which are the most relevant cancer strategies or plans and how are they organised?</li> <li>• How are therapeutic approaches considered? Is radioligand therapy included?</li> </ul>
<b>Contextual factors</b>	<ul style="list-style-type: none"> <li>• What is the reach and perceived influence of these strategies or plans?</li> <li>• Are there mechanisms in place to ensure these strategies or plans are implemented?</li> </ul>

### 1.1.3 Are there any disease-specific strategies or plans in place in the UK that include, or could include, radioligand therapy?

<b>Metrics</b>	<p><i>Assess separately for each indication where radioligand therapy has been authorised for use by the Medicines and Healthcare products Regulatory Agency (MHRA) or is in late-stage clinical trials.</i></p> <ul style="list-style-type: none"> <li>• Is there a national disease management strategy or plan?</li> <li>• How are therapeutic approaches considered? Is radioligand therapy included?</li> </ul>
<b>Contextual factors</b>	<ul style="list-style-type: none"> <li>• How important are these strategies or plans in clinical practice?</li> <li>• Are there mechanisms in place, at a local NHS trust level, to ensure the strategy or plan is implemented?</li> </ul>

## 1.2 Guidelines and best practice

### 1.2.1 Do national disease-specific guidelines, published by any UK professional society or health body, include radioligand therapy?

<b>Metrics</b>	<p><i>Assess separately for each indication where radioligand therapy has been authorised for use by the MHRA or is in late-stage clinical trials.</i></p> <ul style="list-style-type: none"> <li>Do any disease-specific guidelines include radioligand therapy? In what circumstances is it recommended?</li> </ul>
<b>Contextual factors</b>	<ul style="list-style-type: none"> <li>If more than one guideline exists for a specific disease, how do they differ? Who uses which guideline and under what circumstances?</li> </ul>

### 1.2.2 Is there guidance for the delivery of radioligand therapy across clinical indications published centrally by any UK professional societies or other health bodies?

<b>Metrics</b>	<ul style="list-style-type: none"> <li>Does guidance exist in the UK for the delivery of radioligand therapy in general?</li> <li>Does it provide guidance on:             <ul style="list-style-type: none"> <li>the roles and responsibilities of members involved in delivery?</li> <li>the built environment and equipment for delivery?</li> <li>preparation and administration of treatment?</li> <li>radiation protection and disposal of radioactive waste?</li> </ul> </li> <li>Are there local frameworks and/or protocols, published at hospital, trust/board or clinical commissioning group (CCG) level, to support the implementation of national guidance for radioligand therapy in the local context?</li> </ul>
<b>Contextual factors</b>	<ul style="list-style-type: none"> <li>If more than one piece of guidance exists, how do they differ?</li> <li>Are these pieces of guidance actively used in the UK health system? By which clinicians?</li> </ul>

## 2 Regulation and reimbursement

### 2.1 Regulation

#### 2.1.1 Are regulatory approval processes in the UK suitable for radioligand therapy?

<b>Metrics</b>	<ul style="list-style-type: none"> <li>• How is radioligand therapy classified by the MHRA?</li> <li>• Has radioligand therapy been approved for use in the UK? For which indications?</li> <li>• How does the MHRA regulatory approval process work for diagnostics and associated radioligand therapies?</li> </ul>
<b>Contextual factors</b>	<ul style="list-style-type: none"> <li>• Is the MHRA the only body responsible for providing regulatory approval for radioligand therapy? Do devolved nations provide their own regulatory decisions?</li> </ul>

#### 2.1.2 Are regulations for the production and supply of radioisotopes in the UK appropriate for radioligand therapy?

<b>Metrics</b>	<ul style="list-style-type: none"> <li>• How does the UK obtain imaging and therapeutic radioisotopes for radioligand therapy?</li> <li>• Are there mechanisms to ensure consistent supply of radioisotopes into the UK?</li> </ul>
<b>Contextual factors</b>	<ul style="list-style-type: none"> <li>• Are there any current or foreseen capacity issues in the supply of radioisotopes for radioligand therapy?</li> <li>• Would the production, procurement or regulation of radioisotopes need adaptation if use of radioligand therapies increased in the UK?</li> </ul>

#### 2.1.3 Are regulations for the administration of radioisotopes in the UK appropriate for radioligand therapy?

<b>Metrics</b>	<ul style="list-style-type: none"> <li>• What are the regulations for individuals working with medical radioisotopes in the UK?</li> <li>• What are the regulations for institutions providing radioligand therapy in the UK?</li> </ul>
<b>Contextual factors</b>	<ul style="list-style-type: none"> <li>• How do regulatory issues in the licensing of medical professionals and employers/institutions impact access to radioligand therapies?</li> <li>• Is the current number of UK healthcare professionals licensed to deliver radioligand therapy sufficient to meet potential increased demand?</li> </ul>

### 2.1.4 Are regulations for the management of medical radioactive waste in the UK applicable to radioligand therapy?

<b>Metrics</b>	<ul style="list-style-type: none"> <li>• What are the regulations specific to the UK for the management of radioactive waste?</li> <li>• Are differences in radioisotopes considered, such as half-lives, purity and radiation quality?</li> </ul>
<b>Contextual factors</b>	<ul style="list-style-type: none"> <li>• Are UK healthcare facilities able to manage current and future radioactive waste resulting from radioligand therapy?</li> </ul>

## 2.2 Reimbursement and funding

### 2.2.1 How are existing UK reimbursement and funding mechanisms applied to radioligand therapy?

<b>Metrics</b>	<p><i>Assess separately for each indication where radioligand therapy has been authorised for use by the MHRA.</i></p> <ul style="list-style-type: none"> <li>• Has radioligand therapy been granted reimbursement or undergone a health technology assessment that has led to it being funded by the NHS?             <ul style="list-style-type: none"> <li>◦ If yes, by which body?</li> <li>◦ If yes, what are the conditions for reimbursement/funding?</li> </ul> </li> <li>• How is radioligand therapy funded (e.g. NHS England, CCGs, special drugs funds)?</li> </ul>
<b>Contextual factors</b>	<ul style="list-style-type: none"> <li>• Are existing National Institute for Health and Care Excellence (NICE) evaluation evidence requirements considered applicable to, or appropriate for, radioligand therapy?</li> <li>• Would the level of reimbursement change if radioligand therapy were used in new and larger patient populations?</li> <li>• Is funding provided for imaging agents used to assess a person's eligibility for radioligand therapy?</li> </ul>

### 3 Identified need

#### 3.1 Epidemiology

##### 3.1.1 What is the current burden of disease in the UK?

<b>Metrics</b>	<p><i>Assess separately for each indication where radioligand therapy has been authorised for use by the MHRA or is in late-stage clinical trials.</i></p> <ul style="list-style-type: none"> <li>• What is the prevalence and incidence for the UK?</li> </ul>
<b>Contextual factors</b>	<ul style="list-style-type: none"> <li>• How many people may be eligible for radioligand therapy in the UK?</li> <li>• How are incidence and prevalence in the UK expected to change in the next 5–10 years?</li> </ul>

#### 3.2 Patient awareness and information

##### 3.2.1 Is there information for patients on radioligand therapy as a treatment option?

<b>Metrics</b>	<p><i>Assess separately for each indication where radioligand therapy has been authorised for use by the MHRA or is in late-stage clinical trials.</i></p> <ul style="list-style-type: none"> <li>• Is information available to UK patients on radioligand therapy as a treatment option?</li> <li>• Does information on radioligand therapy clearly address eligibility criteria, delivery procedure, and potential benefits and side effects?</li> </ul>
<b>Contextual factors</b>	<ul style="list-style-type: none"> <li>• How and by whom is information disseminated?</li> </ul>

### 3.3 Healthcare professional awareness and referral patterns

#### 3.3.1 Are relevant healthcare professionals aware of radioligand therapy as a treatment option?

Please consider *Table A1* in the [Appendix](#) while answering the metric in this section.

<b>Metrics</b>	<p><i>Assess separately for each indication where radioligand therapy has been authorised for use by the MHRA or is in late-stage clinical trials.</i></p> <ul style="list-style-type: none"> <li>• Do relevant healthcare professionals consider radioligand therapy when making treatment decisions?</li> </ul>
<b>Contextual factors</b>	<ul style="list-style-type: none"> <li>• How do previously available radioligand therapies impact healthcare professionals' perceptions of the approach?</li> <li>• Is radioligand therapy covered as part of the training for the role? If so, how?</li> </ul>

## 4 Service provision

### 4.1 Workforce capacity

Please consider *Table A2* in the [Appendix](#) while answering the metrics in this section.

#### 4.1.1 How are nuclear medicine specialists involved in multidisciplinary decision-making around treatment in the UK?

<b>Metrics</b>	<p><i>Assess separately for each indication where radioligand therapy has been authorised for use by the MHRA or is in late-stage clinical trials.</i></p> <ul style="list-style-type: none"> <li>• What are the role and responsibilities of nuclear medicine professionals in the cancer multidisciplinary team (MDT)?</li> </ul>
<b>Contextual factors</b>	<ul style="list-style-type: none"> <li>• How will involvement of the nuclear medicine professional in the MDT change if the use of radioligand therapy increases?</li> <li>• What are the key barriers and facilitators for collaboration between nuclear medicine and the MDT in the UK?</li> </ul>

#### 4.1.2 Which healthcare professionals are involved in managing and delivering radioligand therapy in the UK?

<b>Metrics</b>	<p><i>Assess separately for each indication where radioligand therapy has been authorised for use by the MHRA or is in late-stage clinical trials.</i></p> <ul style="list-style-type: none"> <li>• Which professionals are included in the delivery team and what are their roles and responsibilities in the radioligand therapy pathway?</li> <li>• At what point(s) in the pathway are they involved?</li> </ul>
<b>Contextual factors</b>	<ul style="list-style-type: none"> <li>• Who can prescribe radioligand therapy?</li> <li>• What barriers and facilitators exist in terms of ensuring optimal referral and delivery of radioligand therapy?</li> <li>• Do referring healthcare professionals and the delivery team generally reside at the same institution e.g. same hospital? How does this impact the provision of radioligand therapy?</li> </ul>

### 4.1.3 Is there sufficient capacity in the UK to meet the current demand for radioligand therapy?

<b>Metrics</b>	<p><i>Assess separately for each healthcare professional included in the delivery team.</i></p> <ul style="list-style-type: none"> <li>• How many healthcare professionals of each role are there in the UK?</li> <li>• Is radioligand therapy included in the training curriculum for the role?             <ul style="list-style-type: none"> <li>◦ If yes, how is the approach addressed?</li> </ul> </li> </ul>
<b>Contextual factors</b>	<ul style="list-style-type: none"> <li>• Are there perceived gaps in training for radioligand therapy in the UK?</li> <li>• Will the delivery team be able to keep pace with the potential increased demand for radioligand therapy in the UK?</li> </ul>

## 4.2 Health facility capacity

### 4.2.1 Are diagnosis and eligibility assessments for radioligand therapy appropriate to meet current and future demand in the UK?

<b>Metrics</b>	<p><i>Assess separately for each indication where radioligand therapy has been authorised for use by the MHRA or is in late-stage clinical trials.</i></p> <ul style="list-style-type: none"> <li>• What are the criteria for establishing eligibility for radioligand therapy and how are they established?</li> <li>• How many sites have imaging capacity for radioligand therapy across the UK?</li> <li>• Is there an adequate number of trained professionals to perform imaging and interpret scans for radioligand therapy?</li> </ul>
<b>Contextual factors</b>	<ul style="list-style-type: none"> <li>• What barriers and facilitators exist to achieving optimal imaging capacity for radioligand therapy?</li> <li>• How will imaging capacity need to change if use of radioligand therapy increases?</li> </ul>

#### 4.2.2 Is the built environment in the UK appropriate to the delivery model of radioligand therapy?

<b>Metrics</b>	<ul style="list-style-type: none"> <li>• Is radioligand therapy generally delivered as an inpatient or outpatient procedure?</li> <li>• Do sites delivering radioligand therapy have:             <ul style="list-style-type: none"> <li>◦ a dedicated lead-lined room and bathroom for patients?</li> <li>◦ appropriate storage space for radioactive waste?</li> </ul> </li> </ul>
<b>Contextual factors</b>	<ul style="list-style-type: none"> <li>• Are there differences in the infrastructure for the delivery of radioligand therapy depending on the radioisotope that is used?</li> <li>• How will the built environment in the UK need to be adapted if use of radioligand therapy increases?</li> </ul>

#### 4.2.3 How are radioligand therapy services organised in the UK health system?

<b>Metrics</b>	<p><i>Assess separately for each indication where radioligand therapy has been authorised for use by the MHRA or is in late-stage clinical trials.</i></p> <ul style="list-style-type: none"> <li>• How many sites provide radioligand therapy in the UK?</li> <li>• Are there criteria for becoming a site that delivers radioligand therapy?</li> <li>• Where does (or could) radioligand therapy sit in the indication's treatment pathway?</li> </ul>
<b>Contextual factors</b>	<ul style="list-style-type: none"> <li>• In which hospital department is radioligand therapy typically delivered?</li> <li>• How are radioligand therapy services distributed across the UK?</li> <li>• What are the barriers and facilitators to the delivery of radioligand therapy at the hospital level?</li> </ul>

## 5 Health information

### 5.1 Research and data

#### 5.1.1 Is there sufficient data collection on radioligand therapy in the UK to guide future planning and practice?

<b>Metrics</b>	<ul style="list-style-type: none"> <li>• Are the following data collected in relation to radioligand therapy?             <ul style="list-style-type: none"> <li>◦ Registry and audit data</li> <li>◦ Real-world data on effectiveness in clinical practice</li> <li>◦ Patient-reported outcomes data</li> <li>◦ Economic data</li> </ul> </li> </ul>
<b>Contextual factors</b>	<ul style="list-style-type: none"> <li>• To what extent are data used to support UK healthcare workforce and system-level planning?</li> <li>• To what extent is it feasible to integrate data collection on the use of new treatments into existing disease-specific data collection mechanisms such as the National Prostate Cancer Audit (NPCA)?</li> <li>• What data are needed to support informed decision-making on radioligand therapy in the future?</li> </ul>

## Appendix

Table A1. Healthcare professionals involved in referrals for radioligand therapy in the UK

Clinical indication	Relevant referring healthcare professionals
Neuroendocrine neoplasms	Endocrinologists, gastroenterologists, clinical/medical oncologists
Lymphoma	Haematologists, haemato-oncologists
Prostate cancer	Urologists, uro-oncologists, clinical/medical oncologists

Table A2. Care delivery teams in the UK

Team	Healthcare professionals involved in each team
Radioligand therapy team	Nuclear medicine specialists, clinical/medical oncologists, clinical nurse specialists, radiopharmacists, medical physicists, patient coordinator
Multidisciplinary team	Clinical/medical oncologists, clinical nurse specialists, nuclear medicine specialists, radiologists, pathologists, surgeons, multidisciplinary team coordinator

## About The Health Policy Partnership

[The Health Policy Partnership](#) (HPP) is an independent research organisation, working with partners across the health spectrum to drive the policy and system changes that will improve people's health.

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## Contact information

The Health Policy Partnership Ltd  
68–69 St Martin's Lane, London WC2N 4JS, United Kingdom

For more information, please see [www.radioligandtherapy.com](http://www.radioligandtherapy.com) or contact Christine Merkel, Programme Lead for health system readiness at The Health Policy Partnership: [christine.merkel@hpolicy.com](mailto:christine.merkel@hpolicy.com)

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