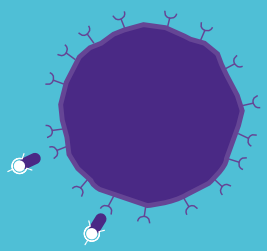
How to measure health system readiness for radioligand therapy



KEY PERFORMANCE INDICATORS

The Health Policy Partnership
[research, people, action]

DECEMBER 2024

These key performance indicators were developed by The Health Policy Partnership (HPP) with guidance from a group of international experts. HPP had full editorial control over the output. The project is supported with funding by Advanced Accelerator Applications, a Novartis Company.

ACKNOWLEDGEMENTS

The Health Policy Partnership is grateful to the experts involved in this project, who volunteered their time to guide the development of the document.

Dr Ronald Ennis, American Society for Therapeutic Radiology and Oncology, US

Professor Stefano Fanti, University of Bologna, Italy

Dr Nicola Fazio, European Institute of Oncology, Italy

Professor Ken Herrmann, Essen University Hospital, Germany

Dr Jolanta Kunikowska, Medical University of Warsaw, Poland

Josh Mailman, Northern California CarciNET Community, US

Professor Wim Oyen, Professor of Nuclear Medicine, Humanitas University, Milan, Italy

Professor Vineet Prakash, Royal Surrey NHS Foundation Trust, UK

Professor Hein van Poppel, European Association of Urology, Belgium

For more information, please see www.healthsystemreadiness.com or contact Lucy Morgan, Programme Lead for health system readiness at The Health Policy Partnership: lucy.morgan@hpolicy.com.

Contents

Health system readiness for radioligand therapy: why key performance indicators are necessary

Radioligand therapy: a growing component of cancer care

Demand for radioligand therapy may continue to increase as it is approved for different types of cancer. Radioligand therapy is a precision cancer therapy that uses molecular targets to help radiation reach tumour cells.[1,2] It is currently licensed for use in certain types of neuroendocrine neoplasms and advanced prostate cancer in the UK, US and Europe.[3-11] There are also clinical trials underway for the application of radioligand therapy in breast cancer, skin cancer and a range of brain cancers, among others.[12]

There is evidence that many health systems have not fully integrated radioligand therapy into care, resulting in inequities in availability and access both between and within countries. These gaps are often due to system-level barriers, including lack of infrastructure or workforce capacity.[13-15] With the growing prevalence of cancer, health systems are under pressure to deliver innovative treatments – including radioligand therapy[16,17] – to meet patient needs.

Ensuring health system readiness for radioligand therapy

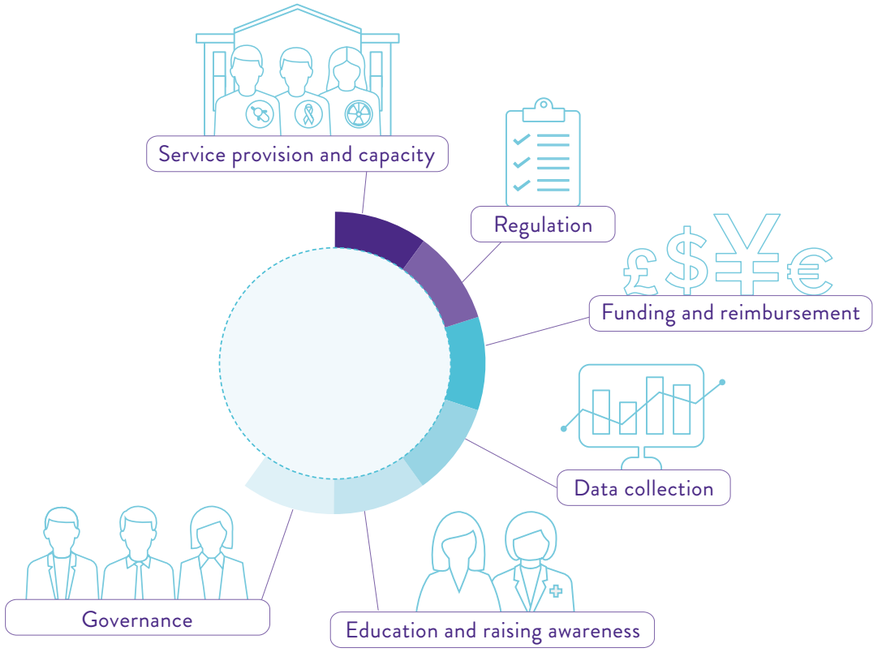
Health systems need advanced, evidence-based preparation for innovative precision medicines such as radioligand therapy; otherwise, existing gaps and inequities in access to care may worsen. The effective delivery of radioligand therapy requires collaboration and coordination across multiple sectors and medical disciplines. This necessitates new regulations, logistics and ways of working – all of which must be carefully and collaboratively planned.[13-15]

To guide countries that are trying to prepare their health systems for radioligand therapy, we developed a readiness assessment framework (*Figure 1*). It takes a systems-based approach to readiness, building on the World Health Organization's Health System Building Blocks,[18] by looking at five domains of the health system: governance, regulation and reimbursement, identified need, service provision and health information.

Measuring system readiness and monitoring progress

Building on the framework, this document presents a series of key performance indicators that can serve as targets for countries looking to improve readiness for the integration of radioligand therapy. These indicators provide policymakers with the targets and data needed to drive evidence-based decision-making. They can help countries identify where further action is needed, and can facilitate cross-stakeholder collaboration to bring about policy change to address identified gaps. Ultimately, the indicators support working towards full integration of radioligand therapy across all pillars of a health system.

Figure 1. Domains of health system readiness for radioligand therapy



How the key performance indicators were developed

The topics covered in the indicators are evidence-based and consensus driven. The questions were based on a literature review and input from a group of multidisciplinary, international experts during development of the Radioligand Therapy Readiness Assessment Framework (*Figure 2*).[19] The additional context, global ambitions and targets for the indicators were developed with expert input and based on a review of relevant literature published prior to April 2024.

Figure 2. Background to developing the key performance indicators

Radioligand therapy: realising the potential of targeted cancer care

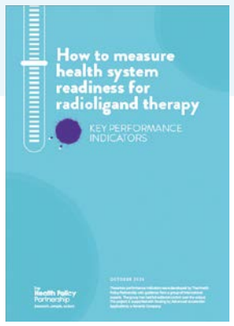
This policy report (January 2020) highlighted barriers to the integration of radioligand therapy into cancer care in Europe

Radioligand Therapy Readiness Assessment Framework

This framework (June 2021) was developed to help countries evaluate which actions are needed to integrate radioligand therapy into care

How to measure readiness for radioligand therapy: key performance indicators

The key performance indicators (November 2024) build on the framework by providing targets that can be met by countries looking to improve readiness for the integration of radioligand therapy



How can readiness for radioligand therapy be measured?

Service provision and capacity

What does optimal provision of radioligand therapy look like?

Optimising the way radioligand therapy is delivered in health systems is key, and it requires looking at all facets of service provision. This includes all care provided (diagnostic, therapeutic and follow-up services) as well as the inputs required to deliver them (including the healthcare workforce, infrastructure and equipment).[20]

The delivery of radioligand therapy ideally requires a network of healthcare facilities to deliver quality diagnostic and therapeutic care in a safe and effective manner. One way of ensuring equitable access to radioligand therapy is through a hub-and-spoke model of service provision.[21] This involves a central 'hub' equipped to deliver radioligand therapy working in conjunction with 'spoke' centres, which have fewer specialist staff but can rely on sharing capacity and expertise from the central hub to deliver high-quality services.[22] Because radioligand therapy uses radioactive material, centres that deliver the therapy must follow the specific regulations that govern the production, delivery and disposal of radiopharmaceuticals.[23]

Providing radioligand therapy also requires a well-coordinated multidisciplinary workforce. Many different processes, healthcare professionals and services are involved in the delivery of radioligand therapy, so clear referral pathways are crucial.[23] Multidisciplinary care is essential, but the make-up of a multidisciplinary team for radioligand therapy may vary depending on the health system. Regardless, it is crucial to involve experts in nuclear medicine, and radiation delivery and safety, as well as disease specialists, to ensure that appropriate administration and safety procedures are adhered to.[23]

Why is good service provision important?

Safe, streamlined and effective cancer care services are fundamental to ensuring positive outcomes for people with cancer. The United Nations calls for countries to continue to strengthen their healthcare and research workforce while developing infrastructure to support equitable access to services. The United Nations' Sustainable Development Goals urge countries to develop 'reliable, sustainable and resilient infrastructure' to support human wellbeing and 'upgrade technological capabilities of industrial sectors'.[24] This is particularly relevant for radioligand therapy, as it requires complex technology. In addition,

the Sustainable Development Goals call for a substantial increase in financing to bolster the healthcare workforce, as well as boosting the number of people working in medical research and development.[24 25]

Which key performance indicators measure service provision and capacity for radioligand therapy?

Key question	Key performance indicator
Workforce capacity	
Is there sufficient workforce capacity to meet the demand for radioligand therapy?	Number of professionals licensed to deliver radioligand therapy per 100,000 population
	Number of medical physicists per 100,000 population
	Number of nurses working in cancer care per 100,000 population
	Number of radiation therapy technicians per 100,000 population
	Number of patient coordinators/treatment managers per 100,000 population
	Number of healthcare administrative staff per 100,000 population
Pathways and care structure	
Which healthcare professionals are involved in providing radioligand therapy?	Percentage of patients receiving radioligand therapy whose care is guided by a multidisciplinary team
Are patients able to access treatment in a timely manner?	Time from diagnosis to beginning of radioligand therapy treatment
Infrastructure	
Is imaging capacity sufficient to meet current and future demand?	Number of positron emission tomography (PET) and single-photon emission computed tomography (SPECT) scanners per 100,000 population
Does the system ensure that patients are diagnosed in a timely manner?	Percentage of patients receiving PET/SPECT scan within national target waiting time
How are radioligand therapy services organised?	Number of radioligand therapy delivery sites (beds, treatment bays etc.) per 100,000 population
	Percentage of people who are eligible for radioligand therapy who state that travel is a barrier to access for this therapy, but that it would not be a barrier for other therapies
Is the built environment appropriate for the delivery of radioligand therapy?	Percentage of facilities that provide radioligand therapy and are equipped with the necessary radiation safety infrastructure (including lead-lined rooms, dedicated bathrooms, appropriate storage space for radioactive waste and pre-administered radioisotopes)

Regulation

What does good regulation of radioligand therapy look like?

Regulation should ensure safe delivery of care, with additional consideration given to workforce licensing and careful waste management for therapies which use radioactive material. In cancer care, the goal of regulation is to define why, when and how an intervention should be provided and delivered safely.[26-28] It is crucial that regulation ensures safety but is not so onerous as to disincentivise innovation or inhibit access to effective treatments. The International Atomic Energy Agency, which promotes nuclear safety, 'encourages Member States to plan, develop and implement national long-term programmes or approaches for the safe management of radioactive waste and put mechanisms in place to ensure adequate resources are available, and to share experience and lessons learned in this regard'.[29]

The effective regulation of radioligand therapy requires input from a range of disciplines. Radiation safety regulations protecting patients, healthcare professionals and the environment must be carefully considered by centres administering radioligand therapy to allow for the appropriate management and disposal of radioactive materials.[19] The International Atomic Energy Agency encourages nations to develop clear and strong regulations for nuclear medicine,[29] including radioligand therapy.

Why is appropriate regulation important?

Appropriate regulation for radioligand therapy is recognised as an important component of Europe's mission to reduce cancer mortality. The Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA) Action Plan is the energy sector's contribution to Europe's Beating Cancer Plan. SAMIRA highlights the importance of improving the quality, safety and security of radiation used in medicine.[30]

Which key performance indicators measure regulation for radioligand therapy?

Key question	Key performance indicator
Are regulations for the production and supply of radioisotopes appropriate for radioligand therapy?	Percentage of current developers of cyclotrons for medical radioisotope production who state that the guidelines for the development of these facilities are clear
	Percentage of current developers of nuclear reactors for medical radioisotope production who state that the guidelines for the development of these facilities are clear
	Total medical radioisotope supply (nationally produced and/or imported) as a percentage of anticipated radioisotopes required for radioligand therapy
Are regulations for the administration of radioisotopes appropriate for radioligand therapy?	Percentage of licensing applications submitted by facilities for radioisotope administration that are processed within the national target time frame
	Percentage of licensing applications submitted by healthcare professionals for radioisotope administration that are processed within the national target time frame
	Percentage of patients meeting international or national regulatory criteria for safe discharge following radioligand therapy
Are regulations for the management of medical radioactive materials and waste applicable to radioligand therapy?	Guidance is in place for the appropriate management of radioactive materials and waste from nuclear medicine procedures
	Percentage of radioactive waste from radioligand therapy that is managed at its recommended risk level

Funding and reimbursement

What do good funding and reimbursement of radioligand therapy look like?

Optimal reimbursement processes for radioligand therapy should consider the costs of delivering the therapy, inclusive of all system needs.

Reimbursement is the process by which institutions (such as hospitals) and healthcare professionals are paid for the services they provide to patients. Depending on the health system, reimbursement may be provided by governments, sickness funds and insurance companies – and, if a given intervention is not reimbursed, people must pay for it out of pocket. Costs associated with radioligand therapy include investment in specialist equipment and infrastructure, workforce expansion and training, and adherence to safety regulations.[31]

Reimbursement should account for both diagnostic and therapeutic radioligands; the value of one is dependent on the availability of the other. If reimbursement for an appropriate diagnostic is not available, it may not be possible for patients to access the therapy. One option would be to use bundled payment approaches to reimbursement that combine diagnostic and therapeutic services, potentially offering greater value to health systems.[32]

Why is appropriate funding and reimbursement important?

Ensuring that people have access to affordable health services and medicines is a tenet of good reimbursement policies. The United Nations' Sustainable Development Goals call for countries to 'achieve universal health coverage, including financial risk protection, access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines and vaccines for all'.[25] While this goal is built around the list of essential medicines, which does not include radioligand therapy, the premise of good reimbursement is still supported.

Inadequate or inappropriate funding and reimbursement can contribute to inequities in access to radioligand therapy. For example, experts have highlighted that geographical inequities in access to radioligand therapy in the UK may be due to insufficient funding being available for workforce training and staff.[22] Furthermore, some reimbursement models in the US can disincentivise referrals to hospitals that offer radioligand therapy.[33 34] Without adequate reimbursement systems in place, facilities may be unable or unwilling to provide radioligand therapy, limiting people's access to it.[33 35]

Which key performance indicators measure funding and reimbursement for radioligand therapy?

Key question	Key performance indicator
How are existing reimbursement and funding mechanisms applied to radioligand therapy?	Calculations for the reimbursement of care providers account for investment costs related to radioligand therapy implementation, such as specialist equipment, staffing, workforce training and infrastructure
	The health technology assessment process is value-based and adequately reflects potential improvements to quality of life after radioligand therapy
	Percentage of radioligand therapy costs that are covered by insurance (national or commercial) or a public health system
	Percentage of reimbursement policies for radioligand therapy or relevant imaging that do not involve 'lifetime limitations' (US only)

Data collection

What does good data collection for radioligand therapy look like?

We need to collect, analyse and report data on the use of radioligand therapy in a comprehensive and consistent way:[19]

- Relevant clinical data should be collected in trials and real-world settings to learn more about the impact of radioligand therapy on patient outcomes.
- Information from registries that collect data on radioligand therapy should be published regularly to allow for the comparison of trends over time.
- Patient-reported experience and outcomes data should also be collected and used to inform clinical decision-making and guide service improvements.
- Economic data should be collected to understand the cost-effectiveness and impact of the approach, providing a foundation for improved mechanisms for funding and reimbursement.

All data must be collected responsibly and stored appropriately, in line with national standards and regulations. As with all health data, data collected in relation to radioligand therapy can be personal and sensitive in nature. Depending on national legislation, this may mean that certain criteria must be met to justify data collection, and careful measures may need to be taken to ensure that data collection and storage are legal and ethical.

Data analysis and reporting should be disaggregated, efficient, transparent and validated. To ensure that healthcare professionals, regulators and people receiving care can make decisions based on the most up-to-date and accurate data, research that is meant to be publicly available should be shared soon after it is collected. It should be disaggregated to ensure that the most appropriate data can be used in decision-making. When data are shared, funding sources and conflicts of interest should be declared. To ensure data are of good quality, they should be validated through a national or regional registry.

Why is appropriate data collection important?

High-quality data collection is essential to better understand when radioligand therapy could be most beneficial, and to support planning for its use. Regional initiatives are supporting increased collaboration and coordination on high-quality data collection. The European Commission's European Cancer Imaging Initiative, launched in September 2023, seeks to pull together scattered cancer imaging data sets to provide a central data hub. This hub could support greater precision and speed of both diagnostics and treatments for people with cancer.[36]

Which key performance indicators measure data collection for radioligand therapy?

Key question	Key performance indicator
When were the last data published looking at the number of people living with a cancer for which radioligand therapy has been approved?	Time since publication of latest prevalence data
	Time since publication of latest incidence data
Is there sufficient data collection on radioligand therapy to guide future planning and practice?	Average frequency with which centres delivering radioligand therapy publish or share data about how the therapy is being used
	Percentage of cancer registries (national and/or regional) that collect real-world data on effectiveness and toxicity in clinical practice in relation to radioligand therapy
	Percentage of centres delivering radioligand therapy that collect patient-reported outcomes data related to this therapy
	Percentage of centres delivering radioligand therapy that collect economic data related to this therapy
	Percentage of centres that appropriately categorise radioligand therapy in data-collection practices

Education and raising awareness

What do good education about, and awareness of, radioligand therapy look like?

Medical education and training for relevant disciplines should include radioligand therapy. Awareness of this type of care among healthcare professionals ensures that people who would benefit from radioligand therapy are accurately identified and referred. The appropriate healthcare professionals could receive training in radioligand therapy through medical curricula or as part of continuing professional development programmes. The 2023 Global Curriculum in Medical Oncology advocates for continuing medical education, such as courses, symposia or self-learning processes.[37]

People living with cancer should be provided with accessible information about radioligand therapy when this type of care is a viable option for them. The European Cancer Organisation states that people with cancer have a right to information about their condition, its treatment and the consequences of that treatment. This could be provided by healthcare professionals, patient organisations or professional societies.[38] The information should be provided at an appropriate time, when the individual with cancer is making treatment decisions or thinking about next steps.

Why are education about, and awareness of, radioligand therapy important?

The World Health Organization has called for health systems to increase workforce capacity and education. In 2021, the World Health Assembly advocated for 'multisectoral and interprofessional competency-based education and training, based on the [World Health Organization] patient safety curricula and continuous professional development'.

The Council of Europe has advocated for improved patient knowledge and risk perception. Appropriate information enables people receiving care to be more involved in their care planning, make informed decisions about their care, and ensure that treatment aligns with their goals and priorities. The Council of Europe emphasises that shared decision-making, facilitated by informed and empowered patients, can help improve health outcomes and ensure safer, cost-effective and efficient care delivery.[39] The council also stated that this can help reduce disparities in outcomes.

Which key performance indicators measure education and awareness for radioligand therapy?

Key question	Key performance indicator
Is there information for patients on radioligand therapy as a treatment option?	Percentage of patient organisations (for types of cancer for which radioligand therapy is approved) that have publicly available, accurate, accessible and evidence-based information on radioligand therapy
	Percentage of relevant professional societies that have publicly available, accurate, accessible and evidence-based information on radioligand therapy
	Percentage of relevant government bodies and regulators that have publicly available, accurate, accessible and evidence-based information on radioligand therapy
	Percentage of radioligand therapy manufacturers that provide publicly available, accurate, evidence-based and non-promotional information on radioligand therapy
	Percentage of eligible patients who receive information about radioligand therapy from their healthcare professional at the appropriate time
	Percentage of cancer patients who receive information via reliable and appropriate sources about opportunities to participate in relevant clinical trials using radioligand therapy
Are relevant healthcare professionals aware of radioligand therapy as a treatment option?	For healthcare professionals who can be licensed to deliver radioligand therapy, training curricula include comprehensive information about the therapy
	Training curricula for medical physicists include information about safety requirements and calculations to support safe delivery of radioligand therapy
	Percentage of physicians (treating patients with types of cancer for which radioligand therapy has been approved) who state that they have some knowledge of radioligand therapy
	Percentage of cancer nurse specialists (for types of cancer for which radioligand therapy has been approved) who state that they have some knowledge of radioligand therapy
	Continuing professional development on radioligand therapy is available for healthcare professionals licensed to deliver it
	Continuing professional development on radioligand therapy is available for medical physicists

Governance

What does good governance for radioligand therapy look like?

The governance of a health system has direct impact on the availability, accessibility and standards of delivery for any diagnostic or therapy – ultimately influencing health outcomes. Governance provides a framework within which to act; it is the means by which services are organised and managed at the macro level,[40] and so is shaped by a country's context and history. In cancer care, governance includes national health strategies and plans that set targets and a clear direction for cancer care, as well as guidelines and protocols informing best practice.

Effective governance for radioligand therapy requires planning and recognition of this type of care in relevant strategies. The World Health Organization's Health System Performance Assessment states that governments should have a strategic vision in written and traceable form (through documents, directives, regulations, guidelines etc.).[41] Preparation for radioligand therapy involves establishing national health plans and strategies that consider the therapy as a component of cancer care, and committing to its integration and funding.

Governance should outline clear accountability and encompass well-defined guidance with a forward-looking perspective. Plans and strategies should lay out short-, medium- and long-term priorities for the use of the therapy, and should describe how greater integration is to be achieved through implementation and monitoring measures. Progress should be regularly assessed, audited and reported in the public domain to ensure accountability. Planning for the effective integration of radioligand therapy also involves including it in clinical guidance, which should be actively used in practice.

Why is governance that includes radioligand therapy important?

Development of appropriate governance for radioligand therapy will help achieve aims set out by the International Atomic Energy Agency. The agency's 2023 nuclear and radiation safety resolution encourages its Member States to develop, maintain and improve their nuclear and radiation safety infrastructure and related scientific and technical capabilities, including through international nuclear cooperation.[29]

Which key performance indicators measure the governance of radioligand therapy?

Key question	Key performance indicator
Is there a national/regional cancer strategy or plan that includes, or could include, radioligand therapy?	There is a national cancer plan, or a plan for non-communicable diseases, that includes radioligand therapy
	Percentage of senior staff (ministers and secretaries, or national equivalent) working in health and energy government departments who are aware of radioligand therapy
Is there national guidance for the delivery of radioligand therapy?	There is national guidance for standardised delivery of radioligand therapy
	Time from a favourable health technology assessment and approval for reimbursement of new radioligand therapy to updates of relevant guidelines
Do disease-specific guidelines include radioligand therapy?	There are relevant disease-specific guidelines that include radioligand therapy

Key performance indicators

Key performance indicators in full

How can key performance indicators be used?

The indicators presented in *Tables 1–6* can be used to understand a country's current level of readiness and plan to appropriately integrate radioligand therapy into care. Researchers, healthcare officials, hospital workers or clinicians can collect data to calculate their country's performance for each indicator. Additional information provides context on the importance of each indicator and examples of progress in other countries. Users can address every indicator in this document, or may focus on specific sections.

Comparison between a country's existing capacity and the target can inform national planning and investment strategies. Three types of targets have been developed:

1) A logical formula that allows the assessor to develop the most appropriate target for that setting. This accounts for every country having unique structures, including ways of working, processes, governance, regulation and reimbursement. This formula can support the development of national targets that are feasible and relevant based on the local context.
2) Proportions, which are percentage-based and require simple calculations based on available data. These are aspirational targets; aiming for a less-than-optimal outcome could do a disservice to some patients.
3) Yes/no targets give a clear aim with no further calculation needed.

The following tables of key performance indicators are associated with each of the parts of the health system described in the previous chapter of this report.

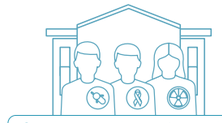


Table 1. Key performance indicators for service provision and capacity

Question	Key performance indicator	Context	Target
Workforce capacity			**(Expected demand ÷ Capacity) ÷ Population = Target**
Is there sufficient workforce capacity to meet current demand for radioligand therapy?	Number of professionals licensed to deliver radioligand therapy per 100,000 population	Nuclear medicine physicians often hold these licences, but other healthcare professionals, including certain radiologists and clinical or radiation oncologists, may also be licensed to administer the therapy. In some countries, different types of radioligand therapy require different licences. *In Germany and Australia, there are 2 and 1.9 nuclear medicine specialists per 100,000 population, respectively.*[42 43]	**Target number of full-time nuclear medicine specialists per 100,000 population** = *(Expected demand:* Anticipated number of doses of radioligand therapy delivered in 2030 ÷ *Capacity:* Working hours available for radioligand therapy in a day ÷ hours spent by a nuclear medicine specialist to deliver one dose of radioligand therapy × working days in a year) ÷ *Population:* (National population in millions × 0.001)
	Number of medical physicists per 100,000 population	This expertise is needed to ensure the appropriate dosing and safe delivery of radioligand therapy. Experts should be familiar with national and international standards. *In the US and Australia, there are 1.9 and 3.1 medical physicists per 100,000 population, respectively.*[44]	**Target number of medical physicists per 100,000 population** = *(Expected demand:* Anticipated number of doses of radioligand therapy delivered in 2030 ÷ *Capacity:* Working hours available for radioligand therapy in a day ÷ hours spent by a medical physicist on one dose of radioligand therapy × working days in a year) ÷ *Population:* (National population in millions × 0.001)

Question	Key performance indicator	Context	Target
Workforce capacity			(Expected demand ÷ Capacity) ÷ Population = Target
Is there sufficient workforce capacity to meet current demand for radioligand therapy? (continued)	Number of nurses working in cancer care per 100,000 population	Nurses are crucial for patient education, pre- and post-treatment support, monitoring during therapy and other auxiliary functions. The role of nurses differs between institutions. Nurses should receive training on handling radioactive material and managing people who have received radioactive therapies or diagnostics. Cancer nurses' responsibilities extend beyond treatment, affecting the whole patient pathway. For this reason, the methodology for developing a target for the number of cancer nurses is centred around patient numbers rather than doses. *In Germany and Australia, there are 75 and 27 nurses working in cancer care per 100,000 population, respectively.*[45 46]	**Target number of nurses working in cancer care per 100,000 population** = (*Expected demand:* Anticipated number of people who are eligible to receive radioligand therapy in 2030 ÷ *Capacity:* Hours spent by a cancer nurse on each radioligand therapy patient ÷ (working hours in a day available for radioligand therapy × working days in a year)) ÷ *Population:* (National population in millions × 0.001)
	Number of radiation therapy technicians per 100,000 population	Technologists support the administration of radioligand therapy. The role of technologists differs between institutions; the number required will depend on the structure of the institution. *The median number of radiation therapy technicians in high-income countries is 0.4 per 100,000 population.*[47]	**Target number of radiation therapy technicians per 100,000 population** = (*Expected demand:* Anticipated number of doses of radioligand therapy delivered in 2030 ÷ *Capacity:* Working hours available for radioligand therapy in a day ÷ (hours spent by a radiation therapy technician on one dose of radioligand therapy) × working days in a year) ÷ *Population:* (National population in millions × 0.001)
	Number of patient coordinators/ treatment managers per 100,000 population	Patient coordinators and treatment managers schedule appointments and support logistics around radioligand therapy along the treatment pathway. For this reason, the methodology for developing a target for the number of patient coordinators and/ or treatment managers is centred around patient numbers rather than doses.	**Target number of patient coordinators and/or treatment managers per 100,000 population** = (*Expected demand:* Anticipated eligible population that can receive radioligand therapy in 2030 ÷ *Capacity:* Hours spent by a patient coordinator on each radioligand therapy patient ÷ (working hours in a day available for radioligand therapy × working days in a year)) ÷ *Population:* (National population in millions × 0.001)

Question	Key performance indicator	Context	Target
Workforce capacity			(Expected demand ÷ Capacity) ÷ Population = Target
Which healthcare professionals are involved in providing radioligand therapy?	Number of healthcare administrative staff per 100,000 population	Administrative staff are an essential part of the organisation of a hospital and may be responsible for budgets, medical records and communications. *In Denmark and Australia, there are 420 and 470 non-medical hospital staff (including administrative staff) per 100,000 people, respectively.*[48 49]	**Target number of healthcare administrative staff per 100,000 population** = (*Expected demand:* Anticipated number of people eligible for radioligand therapy in 2030 ÷ *Capacity:* Hours spent by healthcare administrative staff member on each radioligand therapy patient ÷ (working hours in a day available for radioligand therapy × working days in a year)) ÷ *Population:* (National population in millions × 0.001)
Pathways and care structure			
	Percentage of patients receiving radioligand therapy whose care is guided by a multidisciplinary team	A multidisciplinary approach to care contributes to the effective management of people undergoing radioligand therapy. Multidisciplinary teams (MDTs) can be tumour- or disease-specific e.g. a prostate cancer MDT. Ideally, all patients receiving radioligand therapy should be guided by a multidisciplinary team.[23]	**100%**
	Time from diagnosis to beginning of radioligand therapy treatment	Measuring the time from diagnosis to initiating treatment can be a way of establishing the effectiveness of the radioligand therapy referral pathway. A referral pathway should clearly outline who is responsible for a patient's care while they are undergoing radioligand therapy. *Data from Germany and Spain suggest that the time from diagnosis to receiving radioligand therapy is 7–8 weeks.*[50]	**No longer than 8 weeks**[50]

Question	Key performance indicator	Context	Target
Infrastructure			
Is imaging capacity sufficient to meet current and future demand?	Number of PET and SPECT scanners per 100,000 population	PET/SPECT scans can be used to determine a person's eligibility for radioligand therapy, which allows healthcare professionals to offer the approach only to people who might benefit from it. *The highest number of PET and SPECT scanners per 100,000 people in the Organisation for Economic Co-operation and Development (OECD) are in Denmark and the US, respectively (0.9 PET scanners per 100,000 in Denmark and 4.9 SPECT scanners per 100,000 in the US).*[48 51]	**Target number of PET and SPECT scanners per 100,000 population** = (*Expected demand:* Anticipated number of doses of radioligand therapy delivered in 2030 × mean number of scans per radioligand dose per year ÷ *Capacity:* Optimal number of scans performed by PET or SPECT scanner per year) = *Population:* (National population in millions × 0.001)
	Percentage of patients receiving PET/SPECT scan within national target waiting time	Delays in PET/SPECT scans can be caused by issues around workforce capacity and radioisotope tracer supply. Having sufficient access to all radioisotope tracers will require a secure supply chain, through either homegrown production or import agreements. Common tracers include Gallium-68 (which is used for neuroendocrine tumour imaging) and Fluorine-18 (used for prostate cancer imaging). Insufficient access to these can limit imaging capacity, regardless of how many machines a health system may have. There are many emerging radioisotope tracers in addition to the examples mentioned above. *The global median waiting time for a PET scan for prostate cancer is 10 days.*[52]	**100%**
How are radioligand therapy services organised?	Number of radioligand therapy delivery sites (beds, treatment bays etc.) per 100,000 population	Radioligand therapy can be delivered as an inpatient or outpatient procedure, depending on the therapy, the condition and the person receiving care, as well as the health system and regulatory structure. Each of these factors will influence the number of beds or treatment bays required. Ideally, the complete administration of lutetium (177Lu) oxodotreotide for neuroendocrine neoplasms should take 5 hours,[53] while delivery of lutetium Lu-177 vipivotide tetraxetan for prostate cancer should take up to 1 hour.[54] In some cases, patients may stay overnight after therapy (e.g. if they have travelled a long distance to the centre, or need to be monitored for adverse effects). This can increase overall duration of care and hospital costs. *Spain and Germany have 75–80 and 55–60 identified treatment slots per 100,000 people, respectively.*[50]	**Target number of radioligand therapy delivery sites per 100,000 population** = (*Expected demand*: Anticipated number of doses of radioligand therapy delivered in 2030 ÷ *Capacity:* Average number of hours a delivery site is used per dose ÷ number of operational hours per year) ÷ *Population:* National population in millions × 0.001
	Percentage of people who are eligible for radioligand therapy who state that travel is a barrier to access for this therapy, but that it would not be a barrier for other therapies	Geographical location should not be a barrier to care. If travelling for cancer services is a burden, this can impact the stage at diagnosis, treatment received, prognosis and quality of life.[55] Ensuring that people do not need to travel long distances to access radioligand therapy is crucial. This may be achieved through a hub-and-spoke model of service provision.	**0%**
Is the built environment appropriate for the delivery of radioligand therapy?	Percentage of facilities providing radioligand therapy that are equipped with necessary radiation safety infrastructure (including lead-lined rooms, dedicated bathrooms, appropriate storage space for radioactive waste and pre-administered radioisotopes)	Pre-treatment: Secure and safe storage is needed for radioactive materials, including pre-administered radioisotopes for therapeutic or imaging purposes. During/post-treatment: Lead-lined treatment rooms shield others from radiation emitted by radioactive materials. Dedicated bathrooms for people who have received radioligand therapy protect others from radiation emitted by the person after treatment. Radioactive waste associated with radioligand therapy must be safely managed. The level of radioactive waste that may be stored varies by country.	**100%**

Table 2. Key performance indicators for regulation

Question	Key performance indicator	Context	Target
Are regulations for the production and supply of radioisotopes appropriate for radioligand therapy?	Percentage of current developers of cyclotrons for medical radioisotope production who state that the guidelines for the development of these facilities are clear	Overly cumbersome set-up processes may discourage the building of production facilities. Regulations for setting up a facility should be readily available on request, and regulators should engage with people developing a radioisotope production facility to support streamlined and appropriate processes. The US Nuclear Regulatory Commission (NRC) provides clear guidelines for cyclotron facilities involved in medical isotope production. The guidelines cover such aspects as licensing, safety protocols, radiation protection and waste management.[56]	**100%**
	Percentage of current developers of nuclear reactors for medical radioisotope production who state that the guidelines for the development of these facilities are clear	The regulatory environment can affect the speed of set-up processes, and may discourage the building ofproduction facilities. Regulators, governments and private organisations should work together to support streamlined and appropriate processes. The need for medical radioisotopes should be taken into account when developing the nuclear reactor.	**100%**
	Total medical radioisotope supply (nationally produced and/or imported) as a percentage of anticipated radioisotopes required for radioligand therapy	Medical radioisotopes can be produced nationally or imported. Clear agreements for the long-term import of radioisotopes can contribute to greater levels of certainty on the supply of radioisotopes, particularly in countries with limited or no national production facilities.	**100% or greater** It may be useful to use the following methodology to calculate this figure: **Total medical radioisotope supply (nationally produced and/ or imported) as a percentage of anticipated radioisotopes required for radioligand therapy** = *Total medical radioisotope supply:* (Number of medical radioisotopes produced nationally that are available for radioligand therapy + number of imported medical radioisotopes that are used for radioligand therapy) ÷ *Expected demand:* (Number of medical radioisotopes needed to administer the anticipated number of doses of radioligand therapy delivered in 2030 + number of medical radioisotopes needed for anticipated demand for diagnostic scans delivered in 2030) × 100
Are regulations for the administration of radioisotopes appropriate for radioligand therapy?	Percentage of licensing applications submitted by facilities for radioisotope administration that are processed within the national target time frame	Comprehensive licensing requirements support the safe and effective delivery of radioligand therapy. Regulators should ensure that licensing requirements are transparently available and efficiently managed. Regulators should engage with applicants before, during and after the application to facilitate learning and streamline the process. Licensing approval processes should be clear and appropriate to the context. They should avoid being so cumbersome that institutions are discouraged from applying, or that approval causes substantial delays to care delivery. National targets for processing times can hold regulators accountable for efficient review. *In Australia, applications for complex facilities can take 60–90 days.*[57]	**100%**
	Percentage of licensing applications submitted by healthcare professionals for radioisotope administration that are processed within the national target time frame	Countries have different licensing requirements; some may require a license for each radioisotope, while in others a general licence may be sufficient to administer all radioisotopes. Regardless, comprehensive licensing requirements support the safe and effective delivery of radioligand therapy. Regulators should ensure that licensing requirements are transparently available and efficiently managed. Regulators should engage with applicants before, during and after the application to facilitate learning and streamline the process. National targets for processing times can hold regulators accountable for efficient review.	**100%**
	Percentage of patients who meet international or national regulatory criteria for safe discharge following radioligand therapy	Radiation safety measures are required after a person has received radioligand therapy. These should be appropriate to the level of radiation risk, and information about discharge should also be provided to patients. Where no national criteria are in place, International Atomic Energy Agency criteria should be met.[58]	**100%**

Question	Key performance indicator	Context	Target
Are regulations for the management of medical radioactive materials and waste applicable to radioligand therapy?	Guidance is in place for the appropriate management of radioactive materials and waste from nuclear medicine procedures (YES / NO / SOMEWHAT)	Guidance should clearly outline requirements for the safe disposal of radioactive waste. It should also stipulate the amount of radioactive material a medical institution may hold.	YES
	Percentage of radioactive waste from radioligand therapy that is managed at its recommended risk level	Most radioactive waste from nuclear medicine procedures, such as radioligand therapy, is classified as low-level, which means it can be stored and allowed to decay in medical facilities before being transferred. Overly cautious management of waste may add complexities to, or increase the cost of, administering radioligand therapy. A lack of distinction between levels of radiation may cause medical facilities to face burdensome processes for managing waste from radioligand therapy.	100%

Table 3. Key performance indicators for reimbursement

Question	Key performance indicator	Context	Target
How are existing reimbursement and funding mechanisms applied to radioligand therapy?	Calculations for the reimbursement of care providers take into account investment costs related to radioligand therapy implementation, such as specialist equipment, staffing, workforce training and infrastructure (YES / NO / SOMEWHAT)	Implementing radioligand therapy can require high upfront costs to ensure adherence to clinical guidance and safety standards. The costs of different radioligand therapies vary, e.g. to account for those that require more time from healthcare professionals. For example, the UK's National Institute for Health and Care Excellence stipulates that changes in infrastructure, ongoing fees for use and maintenance, and staff training costs should be included in the economic evaluation of health technology assessments.[59] Reimbursement that does not help to cover these costs may discourage health systems from implementing radioligand therapy.	YES
	The health technology assessment process is value-based and adequately reflects potential improvements to quality of life after radioligand therapy (YES / NO / SOMEWHAT)	Value-based healthcare encompasses the use of innovative payment systems that monitor and adapt reimbursement based on the value of a service provided. This can be particularly applicable for personalised medicine, such as radioligand therapy.	YES
	Percentage of radioligand therapy costs that are covered by insurance (national or commercial) or a public health system	If radioligand therapy is not adequately reimbursed by insurance providers or paid for by a public health system, hospitals or people receiving care may not be able to afford the treatment, and access to care may be inequitable.	100%
	Percentage of reimbursement policies for radioligand therapy or relevant imaging that do not involve 'lifetime limitations' (US only)	In the US, the reimbursement of certain procedures, such as PET scans, may be limited to a certain number per person in their lifetime. This may be a barrier to appropriate and sustained access to radioligand therapy, particularly for those who live with cancer for a long time. These types of policies do not exist in most other countries.	100%

Table 4. Key performance indicators for data collection

Question	Key performance indicator	Context	Target
When were the last data published looking at the number of people living with a cancer for which radioligand therapy has been approved?	Time since publication of latest prevalence data	Where radioligand therapy is approved or in clinical trials for certain indications, accurate data on the prevalence of these indications can provide a more detailed picture of the current and future eligible population. Prevalence data should be disaggregated by cancer type and stage.	**Under five years**
	Time since publication of latest incidence data	Accurate data on incidence provides insight into the expected future demand for radioligand therapy. Incidence data should be disaggregated by cancer type and stage.	**Under five years**
Is there sufficient data collection on radioligand therapy to guide future planning and practice?	Average frequency with which centres delivering radioligand therapy publish or share data about how the therapy is being used	Data on radioligand therapy – for example, on waiting times or frequency of use – must be regularly collected, analysed and transparently reported so healthcare professionals, regulators and legislators can make informed decisions.	**6 months or under**
	Percentage of cancer registries (national and/or regional) that collect real-world data on effectiveness and toxicity in clinical practice in relation to radioligand therapy	Cancer registries should collect comprehensive data on radioligand therapy (e.g. patient demographics, number of doses delivered per person)	**100%**
	Percentage of centres delivering radioligand therapy that collect patient-reported outcomes data related to this therapy	Patient-reported outcomes are key to understanding the benefits of radioligand therapy and its potential impact on a person's quality of life. These data can be collected by different people e.g. healthcare providers or researchers. A consistent methodology should be applied to all disease areas to enable effective analysis and comparison.	**100%**
	Percentage of centres delivering radioligand therapy that collect economic data related to this therapy	Comprehensive data on cost-effectiveness and budget impact can ensure that the potential value of radioligand therapy is accurately assessed. The costs of radioligand therapy may be collected at the national, regional or local level by healthcare providers. Additional assessments of cost-effectiveness may involve public and/or private actors. All economic data should be collected in line with a country's data standards.	**100%**
	Percentage of centres that appropriately categorise radioligand therapy in data-collection practices	If radioligand therapy is not categorised correctly, it may be inappropriately grouped with other treatment types (e.g. with all radiation treatments).	**100%**

Table 5. Key performance indicators for education and raising awareness

Question	Key performance indicator	Context	Target
Is there information for patients on radioligand therapy as a treatment option?	Percentage of patient organisations (for types of cancer for which radioligand therapy is approved) that have publicly available, accurate, accessible and evidence-based information on radioligand therapy	Patient organisations are often the first place people with cancer turn to for support; as such, these organisations should provide evidence-based, accessible and accurate information about the risks and benefits of radioligand therapy to allow patients to make an informed decision about their treatment.	**100%**
	Percentage of relevant professional societies that have publicly available, accurate, accessible and evidence-based information on radioligand therapy	Relevant professional societies include cancer, nuclear medicine and radiology societies. These organisations should be a source of reliable information for people with cancer and healthcare professionals, to support informed decision-making.	**100%**
	Percentage of relevant government bodies and regulators that have publicly available, accurate, accessible and evidence-based information on radioligand therapy	Relevant government bodies include environmental and health regulators, as well as ministries or departments of health. These agencies should be a source of reliable information for people with cancer, to support informed decision-making on their care.	**100%**
	Percentage of radioligand therapy manufacturers that provide publicly available, accurate, evidence-based and non-promotional information on radioligand therapy	Adequate regulation can ensure that manufacturers of radioligand therapies are a trusted source of information.	**100%**
	Percentage of eligible patients who receive information about radioligand therapy from their healthcare professional at the appropriate time	Healthcare professionals should ensure that people with cancer are informed about the risks associated with radioligand therapy. Patients should have the opportunity to ask questions about all treatment options.	**100%**
	Percentage of cancer patients who receive information via reliable and appropriate sources about opportunities to participate in relevant clinical trials using radioligand therapy	Clinical trials can provide people with cancer early access to innovative treatments; they should be aware of this option.	**100%**

Question	Key performance indicator	Context	Target
Are relevant healthcare professionals aware of radioligand therapy as a treatment option?	For healthcare professionals who can be licensed to deliver radioligand therapy, training curricula include comprehensive information about the therapy (YES / NO / SOMEWHAT)	Healthcare professionals licensed to deliver radioligand therapy should be trained to provide it safely and comprehensively. They should also understand radioisotopes, patient selection, radiation protection and the risks and benefits of the therapy.	YES
	Training curricula for medical physicists include the appropriate level of information to support their role in radioligand therapy delivery	Medical physicists should have a comprehensive understanding of radioligand therapy to ensure its safe delivery.	YES
	Percentage of physicians (treating patients with types of cancer for which radioligand therapy has been approved) who state that they have some knowledge of radioligand therapy	Referring physicians may be oncologists or disease specialists who are not licensed to deliver radioligand therapy, but treat people who would benefit from the therapy. They should have a good understanding of who may benefit from the approach to support improved access. They should also have clear guidance on where to direct people with cancer for more detailed information.	100%
	Percentage of cancer nurse specialists (for types of cancer for which radioligand therapy has been approved) who state that they have some knowledge of radioligand therapy	Nurses are crucial for patient education, pre- and post-treatment support, monitoring during therapy and other auxiliary functions. As such, they should have knowledge of the approach, as well as its risks and benefits.	100%
	Continuing professional development on radioligand therapy is available for healthcare professionals licensed to deliver it (YES / NO / SOMEWHAT)	Continuing professional development is an opportunity to further educate healthcare professionals delivering radioligand therapy on new therapies and changes to guidelines or safety standards.	YES
	Continuing professional development on radioligand therapy is available for medical physicists (YES / NO / SOMEWHAT)	Continuing professional development is an opportunity to further educate medical physicists on new radioligand therapies and changes to guidelines or safety standards.	YES

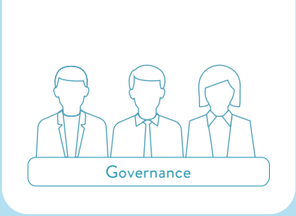


Table 6. Key performance indicators for governance

Question	Key performance indicator	Context	Target
Is there a national/regional cancer strategy or plan that includes, or could include, radioligand therapy?	There is a national cancer plan, or a plan for non-communicable diseases, that includes radioligand therapy (YES / NO / SOMEWHAT)	The inclusion of radioligand therapy in cancer plans shows that politicians and healthcare decision-makers are aware of the therapy, which may improve appropriate availability of this type of care.	YES
	Percentage of senior staff (ministers and secretaries, or national equivalent) working in health and energy government departments who are aware of radioligand therapy	Awareness of radioligand therapy in government is crucial to ensure that policy and guidance accurately reflect the latest innovations.	Greater than 50%
Is there national guidance for the delivery of radioligand therapy across clinical indications?	There is national guidance for the delivery of radioligand therapy for relevant indications (YES / NO / SOMEWHAT)	Guidance on the delivery of radioligand therapy can include referral pathways, patient selection, radiation safety, waste management and the roles/ responsibilities of the healthcare professionals involved. National guidance helps facilities and healthcare professionals deliver the therapy in a consistent manner.	YES
	Time from a favourable health technology assessment and approval for reimbursement of new radioligand therapy to updates of relevant guidelines	Ensuring that guidelines include the latest radioligand therapies is crucial to allowing equitable access to the approach. *For example, the UK's National Institute for Health and Care Excellence aims to update recommendations on key topics within 3–6 months of new evidence emerging.*[60]	6 months
Do disease-specific guidelines include radioligand therapy?	There are relevant disease-specific guidelines that include radioligand therapy (YES / NO / SOMEWHAT)	Radioligand therapy is approved for use in some cancers. For example, in the US and Europe, it is approved for use in neuroendocrine neoplasms[39] and prostate cancer.[45] The inclusion of radioligand therapies in current and future guidelines for these diseases would improve access. *European guidelines for neuroendocrine neoplasms are an example of disease-specific recommendations for the use of radioligand therapy.*[61]	YES

References

1. Jadvar H. 2017. Targeted Radionuclide Therapy: An Evolution Toward Precision Cancer Treatment. *AJR Am J Roentgenol* 209(2): 277-88
2. Fahey F, Zukotynski K, Capala J, *et al.* 2014. Targeted radionuclide therapy: proceedings of a joint workshop hosted by the National Cancer Institute and the Society of Nuclear Medicine and Molecular Imaging. *J Nucl Med* 55(2): 337-48
3. European Medicines Agency. 2017. Lutathera EPAR Product Information. Available from: https://www.ema.europa.eu/en/documents/product-information/lutathera-epar-product-information_en.pdf [Accessed 04/10/24]
4. European Medicines Agency. 2022. Pluvicto. Available from: https://www.ema.europa.eu/en/medicines/human/EPAR/pluvicto [Accessed 10/10/24]
5. U. S. Food and Drug Administration. 2022. FDA approves Pluvicto for metastatic castration-resistant prostate cancer. Available from: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-pluvicto-metastatic-castration-resistant-prostate-cancer [Accessed 04/10/24]
6. European Medicines Agency. 2018. Xofigo: EPAR - medicine overview. Available from: https://www.ema.europa.eu/en/documents/overview/xofigo-epar-medicine-overview_en.pdf [Accessed 04/10/24]
7. National Institute for Health and Care Excellence. 2018. Lutetium (177Lu) oxodotreotide for treating unresectable or metastatic neuroendocrine tumours. Available from: https://www.nice.org.uk/guidance/ta539 [Accessed 04/10/24]
8. European Medicines Agency. Lutathera: EPAR - Summary for the public. Available from: https://www.ema.europa.eu/en/documents/overview/lutathera-epar-summary-public_en.pdf [Accessed 24/10/24]
9. National Cancer Institute. FDA Approves New Treatment for Certain Neuroendocrine Tumors. Available from: https://www.cancer.gov/news-events/cancer-currents-blog/2018/lutathera-fda-gastrointestinal-nets [Accessed 04/10/24]
10. Bayer HealthCare Pharmaceuticals. 2013. Full prescribing information: Xofigo. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/203971lbl.pdf [Accessed 24/10/24]
11. European Medicines Agency. Xofigo. [Updated 01/08/24]. Available from: https://www.ema.europa.eu/en/medicines/human/EPAR/xofigo [Accessed 24/10/24]
12. Mittra E, Bodei L. 2021. Landscape Analysis of Phase 2 and 3 Clinical Trials for Targeted Radionuclide Therapy. *J Nucl Med* 62(8): 1031-32
13. The Health Policy Partnership. 2021. *Health system readiness for radioligand therapy in the US: Situation analysis report.* London: HPP
14. The Health Policy Partnership. 2021. *Health system readiness for radioligand therapy in the UK: Situation analysis report.* London: HPP
15. The Health Policy Partnership. 2020. *Radioligand therapy: realising the potential of targeted cancer care.* London: The Health Policy Partnership
16. International Agency for Research on Cancer. 2024. Estimated number of new cases from 2022 to 2045, Both sexes, age [0-85+]. Available from: https://gco.iarc.fr/tomorrow/en/dataviz/bars?mode=population [Accessed 10/11/24]
17. Wait S, Han D, Muthu V, *et al.* 2017. Towards sustainable cancer care: Reducing inefficiencies, improving outcomes—A policy report from the All.Can initiative. *J Cancer Policy* 13: 47-64
18. World Health Organization. 2010. *Monitoring the building blocks of health systems: A handbook of indicators and their measurement strategies.* Geneva, Switzerland
19. The Health Policy Partnership. 2021. *Radioligand therapy readiness assessment framework.* London: HPP
20. Maser B, Force LM, Friedrich P, *et al.* 2020. Paediatric Oncology System Integration Tool (POSIT) for the joint analysis of the performance of childhood cancer programs and health systems. *J Cancer Policy:* 10.1016/j.jcpo.2019.100208
21. Flux G, Buscombe J. 2021. BNMS position statement on molecular radiotherapy : Nuclear Medicine Communications. *Nucl Med Commun* 42(10): 1061-63
22. Buscombe J. 2020. The future of molecular radiotherapy services in the UK. *Clin Oncol:* 10.1016/j.clon.2020.11.012
23. Herrmann K, Giovanella L, Santos A, *et al.* 2022. Joint EANM, SNMMI and IAEA enabling guide: how to set up a theranostics centre. *Eur J Nucl Med Mol Imaging* 49(7): 2300-09
24. United Nations. 2021. Goal 9: Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation. Available from: https://sdgs.un.org/goals/goal9#targets_and_indicators [Accessed 10/10/24]
25. United Nations. 2021. Goal 3: Ensure healthy lives and promote well being for all at all ages. Available from: https://sdgs.un.org/goals/goal3 [Accessed 10/10/24]

26. Lezotre P-L. 2014. Introduction. In: Lezotre P-L, ed. *International Cooperation, Convergence and Harmonization of Pharmaceutical Regulations*. Oxford: Elsevier Inc

27. Department of Health and Social Care. 2022. Healthcare regulation: deciding when statutory regulation is appropriate. Available from: https://www.gov.uk/government/consultations/healthcare-regulation-deciding-when-statutory-regulation-is-appropriate/healthcare-regulation-deciding-when-statutory-regulation-is-appropriate [Accessed 10/10/24]

28. Dixon J. 2005. *Regulating Health Care: The Way Forward*. London: The King's Fund

29. International Atomic Energy Agency. 2023. *Nuclear and radiation safety - Resolution adopted on 29 September 2023 during the 13th plenary meeting*. Vienna: IAEA

30. European Commission. SAMIRA Action Plan. Available from: https://energy.ec.europa.eu/topics/nuclear-energy/radiological-and-nuclear-technology-health/samira-action-plan_en [Accessed 10/10/24]

31. The Health Policy Partnership. 2021. *Health system readiness for radioligand therapy in the US: Regulation and reimbursement*. London: HPP

32. Organisation for Economic Co-operation and Development. 2022. *Value-based providers' payment models: understanding where and under which conditions they work*. Paris: OECD

33. Schaefer NG, Huang P, Buchanan JW, *et al.* 2011. Radioimmunotherapy in non-Hodgkin lymphoma: opinions of nuclear medicine physicians and radiation oncologists. *J Nucl Med* 52(5): 830-38

34. Schaefer NG, Ma J, Huang P, *et al.* 2010. Radioimmunotherapy in non-Hodgkin lymphoma: opinions of U.S. medical oncologists and hematologists. *J Nucl Med* 51(6): 987-94

35. Berenson A. 2007. Medicare cuts payout on 2 cancer drugs. *The New York Times*. Available from: https://www.nytimes.com/2007/12/07/business/07drug.html [Accessed 24/10/24]

36. European Commission. 2023. European Cancer Imaging Initiative. Available from: https://digital-strategy.ec.europa.eu/en/policies/cancer-imaging [Accessed 10/10/24]

37. Cufer T, Kosty MP. 2023. ESMO/ASCO Recommendations for a Global Curriculum in Medical Oncology Edition 2023. *ESMO Open*: 10.1016/j.esmoop.2023.101631

38. European Cancer Organisation. 2. Information. Available from: https://www.europeancancer.org/content/the-code-information.html [Accessed 22/10/24]

39. Council of Europe Steering Committee for Human Rights in the Fields of Biomedicine and Health. 2023. *Guide to health literacy: contributing to trust building and equitable access to healthcare*. Strasbourg: Council of Europe

40. World Health Organization. Health system governance. Available from: https://www.who.int/health-topics/health-systems-governance#tab=tab_1 [Accessed 04/10/24]

41. World Health Organization. 2022. *Health System Performance Assessment - A framework for policy analysis*. Geneva: World Health Organization

42. Australasian Association of Nuclear Medicine Specialists. 2022. *Re-indexation of nuclear medicine-related items on the Medicare Benefits Schedule (MBS)*. Balmain: AANMS

43. Arztestellen. 2023. Facharzt-Weiterbildung Nuklearmedizin: Dauer, Inhalte, Perspektiven. Available from: https://aerztestellen.aerzteblatt.de/de/redaktion/facharzt-weiterbildung-nuklearmedizin [Accessed 24/10/24]

44. Bezak E, Damilakis J, Rehani MM. 2023. Global status of medical physics human resource - The IOMP survey report. *Phys Med* 113: 10.1016/j.ejmp.2023.102670

45. Kelly D, Lankshear A, Wiseman T, *et al.* 2020. The experiences of cancer nurses working in four European countries: A qualitative study. *Eur J Oncol Nurs* 49: 10.1016/j.ejon.2020.101844

46. Cancer Nurses Society of Australia. 2023. *Cancer Nursing Workforce Survey*. Gabbadah: CNSA

47. Trapani D, Murthy SS, Boniol M, *et al.* 2021. Distribution of the workforce involved in cancer care: a systematic review of the literature. *ESMO Open* 6(6): 100292

48. Organisation for Economic Co-operation and Development. 2024. Healthcare Resources. Available from: https://data-explorer.oecd.org/vis?tenant=archive&df[ds]=DisseminateArchiveDMZ&df[id]=DF_HEALTH_REAC&df[ag]=OECD&dq=..&lom=LASTNPERIODS&lo=5&to[TIME_PERIOD]=false [Accessed 10/10/24]

49. Organisation for Economic Co-operation and Development. 2023. OECD Health Statistics 2023: Definitions, Sources and Methods - Hospital employment. Available from: https://stats.oecd.org/wbos/fileview2.aspx?IDFile=9af49c74-e685-424e-ae5e-e18f4a3392a4 [Accessed 10/10/24]

50. IQVIA Institute for Human Data Science. 2023. *Succeeding with innovation: the state of radioligand therapy readiness in Europe*. London: IQVIA

51. Organisation for Economic Co-operation and Development. Healthcare Resources: Medical technology. Available from: https://stats.oecd.org/index.aspx?queryid=30184 [Accessed 04/10/24]

52. Beyer T, Czernin J, Freudenberg L, *et al.* 2023. A 2022 international survey on the status of prostate cancer theranostics. *J Nucl Med* 64(1): 47-53

53. Electronic Medicines Compendium. 2023. Lutathera® 370 MBq/mL solution for infusion. Available from: https://www.medicines.org.uk/emc/files/pil.12723.pdf [Accessed 11/10/24]

54. Northwestern Memorial Hospital. 2022. *PLUVICTO*. Chicago: Northwestern Medicine

55. Ambroggi M, Biasini C, Del Giovane C, *et al.* 2015. Distance as a barrier to cancer diagnosis and treatment: review of the literature. *The Oncologist* 20(12): 1378-85

56. United States Nuclear Regulatory Commission. 2007. *Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator - NUREG-1556*. Rockville: U.S. NRC

57. Australian Radiation Protection and Nuclear Safety Agency. 2023. *Review and assessment manual*. Yallambie: ARPANSA

58. International Atomic Energy Agency. 2009. *Release of patients after radionuclide therapy*. Vienna: IAEA

59. National institute for Health and Care Excellence. 2022. NICE processes and methods - economic evaluation. Available from: https://www.nice.org.uk/process/pmg36/chapter/economic-evaluation [Accessed 18/03/24]

60. National Institute for Health and Care Excellence. 2024. *Annual Report and Accounts 2022/23*. London: NICE

61. Hicks RJ, Kwekkeboom DJ, Krenning E, *et al.* 2017. ENETS consensus guidelines for the standards of care in neuroendocrine neoplasms: peptide receptor radionuclide therapy with radiolabelled somatostatin analogues. *Neuroendocrinology* 105(3): 295-309

How to measure health system readiness for radioligand therapy

KEY PERFORMANCE INDICATORS

Please cite this report as:

Melson C, Morgan L. 2024. *How to measure health system readiness for radioligand therapy: key performance indicators*. London: The Health Policy Partnership

The Health Policy Partnership