



MALAYSIA

Realising the potential of radioligand therapy: a national call to action

May 2025

This project is led by The Health Policy Partnership (HPP) with guidance from a multidisciplinary group of experts. HPP has full editorial control of all outputs and is guided by experts with the aim of reflecting a consensus position. The project is supported with funding by Novartis.

The
**Health Policy
Partnership**

[research, people, action]



About this report

This policy narrative has been developed following consultation with national experts in radioligand therapy delivery, and seeks to provide an evidence-based overview of the key challenges that must be addressed to enhance radioligand therapy readiness at a national level. In addition, it provides policymakers and health system leaders with recommendations to improve effective implementation of radioligand therapy and, ultimately, support delivering the best-quality care for people with cancer.

To assess the current implementation of radioligand therapy in Malaysia, the authors of this report convened an advisory group of national experts in nuclear medicine and oncology to guide the development of the policy narrative. Insights were gathered through a series of interviews and a workshop, and combined with desk-based research to identify policy and system barriers and associated recommendations.

Funding disclaimer







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Executive summary

Radioligand therapy is a precision medicine that, if effectively implemented, has the potential to significantly improve cancer care and outcomes.

Cancer is a substantial global burden; it was the third leading cause of death in 2021, resulting in almost 10 million deaths.¹ The incidence of cancer is growing,² but new, targeted precision approaches – such as radioligand therapy – have the potential to provide more effective treatment options with fewer side effects.¹³⁴ A considerable level of

investment and research into radioligand therapy is ongoing, with more than 320 clinical trials around the world exploring the therapeutic application of radiopharmaceuticals in a range of cancers.⁵

There are more than
320
ongoing clinical trials
around the world

This momentum is paving the way for demand to increase significantly in the next 20 years.

It is therefore vital that health systems have the ability to rapidly and sustainably adapt to integrate this innovative technology into care.

Effectively integrating radioligand therapy into standard care could play a key role in achieving key cancer targets in Malaysia.

In 2021, cancer had the third highest mortality rate in Malaysia and had been among the top five causes of death for the previous 20 years.¹⁶ This led to the development of a national target to reduce overall cancer mortality by a third by 2030. The country is also aiming to decrease morbidity and improve quality of life for people with cancer and their families or loved ones.⁶

The incidence of cancer is growing

In 2021, the disease caused almost
10 million deaths



In 2021, cancer had the
3rd highest mortality rate
in Malaysia





This report has identified the key barriers to implementing radioligand therapy effectively in Malaysia. To address these barriers, policymakers are encouraged to:

- **review clinical and cost-effectiveness assessments within the Ministry of Health medicines formulary**, using local and international expertise to ensure the assessments are fit for purpose and access to the therapy is equitable.
- **integrate the use of multidisciplinary teams into the delivery of radioligand therapy** to ensure equitable and comprehensive care from diagnosis to treatment and ongoing support.
- **enable nuclear services to be expanded sustainably and equitably across Malaysia**; this should include exploring public–private partnerships to bolster the widespread implementation of radioligand therapy.
- **encourage the recognition of nuclear pharmacy as a specialised area** to help with expanding the number and capacity of radiopharmacists trained to support the delivery of radioligand therapy.
- **develop a strategy to support the long-term, consistent supply of medical radioisotopes across Malaysia**; this would promote the equal distribution of production facilities throughout the country and increase opportunities for investment.
- **establish a formalised joint regulatory committee that brings together representatives from the National Pharmaceutical Regulatory Agency (NPRA) and the Medical Radiation Surveillance Division (MRSD)** to streamline review processes and develop validated protocols to support the efficient expansion of radioligand therapy.
- **raise awareness of radioligand therapy among physicians by offering cross-disciplinary continuing medical education (CME)**, and support nuclear medicine physicians to provide practical training to junior colleagues.
- **create a joint oncology and nuclear medicine board** with input from key societies and the Ministry of Health; the board could develop guidelines, set standards for multidisciplinary teams and share research to guide the use of radioligand therapy.
- **use accredited private hospitals to help deliver practical experience to physicians studying nuclear medicine**, and engage with higher education providers and the Malaysian Society of Nuclear Medicine & Molecular Imaging to understand how to overcome barriers surrounding indemnity for this training.



An introduction to radioligand therapy

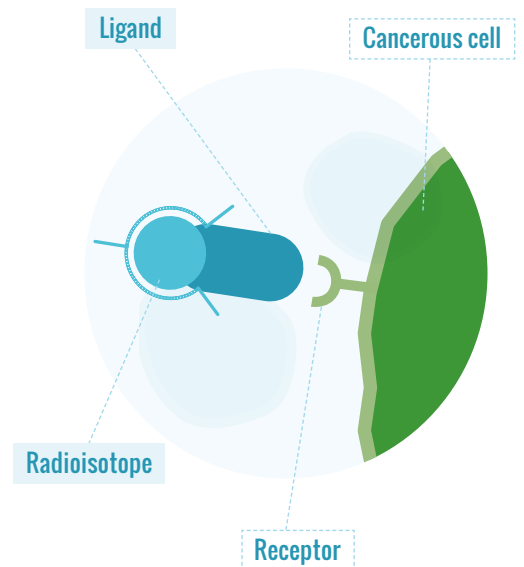
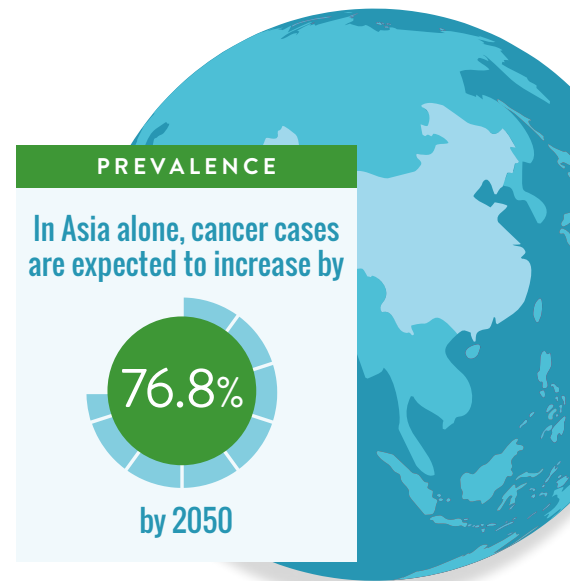
The global prevalence and cost of cancer is immense, and continues to grow, but our ability to tackle it is improving.

Cancer was the third leading cause of death in 2021, when it led to almost 10 million deaths globally.¹ In Asia alone – the continent with the highest prevalence of cancer – it is estimated that there will be 7.5 million additional new cases of cancer by 2050, an increase of 76.8% from 2022.⁷ However, while the incidence of cancer continues to grow, so does the number of available treatments and innovations.

Radioligand therapy is a targeted treatment with huge potential to improve cancer care. The therapy is made up of two parts: a ligand that identifies cancer cells, and a radioisotope that delivers radiation.⁸ The process allows radiation to target cells anywhere in the body.^{3,4} Because the radiation works over short distances and can be directed specifically to cancer cells, the treatment is generally well tolerated and has less impact on healthy cells than other treatments, such as chemotherapy.⁴ Additionally, radioligand therapy has been proven to improve survival rates and quality of life, as well as slow disease progression, meaning that the treatment can have a significant positive impact on people's lives.⁹⁻¹¹ Radioligand therapy is currently licensed in several countries for use in certain types of neuroendocrine neoplasms (NENs) and prostate cancer.¹²⁻¹⁶

However, the mechanism by which the therapy works is not specific to any particular tumour type, meaning it could be applied to many other cancers.

Investment and research are paving the way for a large increase in demand for radioligand therapy in the next 20 years. Recognition of its potential has led to significant investment; there are more than 320 ongoing clinical trials around the world exploring the therapeutic application of radiopharmaceuticals in a range of cancers.⁵ Given the potential of this research to identify new applications for radioligand therapy, demand is expected to surge.





As demand increases, so too will the need to build readiness for the implementation of radioligand therapy to ensure equitable access. Readiness is the ability of a health system to rapidly and sustainably adapt policies, processes and infrastructure to support the integration of new therapies, as outlined in the Radioligand Therapy Readiness Assessment Framework (see *Appendix*).¹⁷ Identifying the policy and health system barriers to the implementation of radioligand therapy allows for more effective long-term planning and resource allocation to build readiness and provide equitable access to radioligand therapy services.

BOX 1. Defining radioligand therapy

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



The potential of radioligand therapy in Malaysia

Cancer rates are consistently high in Malaysia, resulting in national commitments to reduce mortality.

In 2021, cancer resulted in more than 31,000 deaths in Malaysia, making it the third leading cause of death.¹ It had been among the top five causes of mortality for the previous 20 years.⁶ To tackle this, the Malaysian Ministry of Health (MoH) developed the National Strategic Plan for Cancer Control Programme 2021–2025 (NSPCCP); one of the programme’s targets is to reduce overall cancer mortality by one third by 2030, in line with the United Nations’ Sustainable Development Goals.^{6,18} The plan also aims to decrease morbidity and improve the quality of life for people living with cancer and their families or loved ones.⁶

In 2021,

31,000

deaths were caused by cancer in Malaysia

Integrating radioligand therapies into standard care in Malaysia could be central to achieving these goals, but currently nuclear medicine services are limited and variable; however, there are national plans to address this.

In Malaysia, radioligand therapy is delivered through nuclear medicine services; 35 sites in the country have a nuclear medicine department or unit,¹⁹ and only six of these are public MoH hospitals. MoH hospitals typically receive almost 75% of hospital admissions,²⁰ they are commonly used by people who lack adequate health insurance and those who cannot afford private medical treatment, as well as pensioners and government workers.^{19,21} Only two MoH hospitals are equipped with in-house positron emission tomography (PET) scanners, and hence have the ability to provide the imaging needed for radioligand therapy to treat neuroendocrine tumours and prostate cancer.²²⁻²⁴ There are no MoH nuclear medicine services on the east coast of Peninsular Malaysia,^{6,22} although there are two private facilities equipped with single-photon emission computed tomography (SPECT) capabilities, which can provide limited radioligand therapy services.²⁵

Of the 35 sites in the country that have a nuclear medicine department or unit,

only 6 sites



are public hospitals.



Some hospitals only provide outpatient services, while others may have up to 28 beds available for inpatient procedures.²² This means the types of nuclear medicine therapies available to people in Malaysia can vary depending on where they live. The NSPCCP includes an ambition to address this inequality by equipping regional nuclear medicine facilities with diagnostic and therapeutic inpatient and outpatient services, as well as PET and SPECT scanners.⁶

Radioligand therapy in Malaysia involves a variety of specialists; however, the use of multidisciplinary teams (MDTs) is not standardised across services, which can result in variations in care. MDTs – who are often used in the delivery of radioligand therapies – may involve oncologists, nuclear medicine physicians, surgeons and radiologists, along with the primary team, such as urologists or endocrinologists.^{21 26} Regional guidelines state that MDTs should be a feature of radioligand therapy care; this approach is used in public hospitals, such as the National Cancer Institute and Hospital Kuala Lumpur, but it is not an established practice in all hospitals.^{19 21 27 28}

BOX 2. Setting up and running an effective multidisciplinary team

MDT care is the gold standard for the management of people with cancer. It can facilitate collaboration between specialists and improve outcomes.^{29 30} Below are some ways to implement an effective MDT:^{31 32}

- Install an MDT coordinator responsible for:
 - identifying which specialists to include on the team
 - scheduling regular meetings and streamlining patients for discussion (patient stratification)
 - identifying the mandatory aspects of care that should be discussed at each MDT meeting
- Task the MDT coordinator with establishing and managing a referral system, recommending patients, and providing the team with patient information and case files
- Establish management guidelines to ensure consistent approaches to treatments.



Although radioligand therapy has been available as a treatment option in Malaysia for some time, it is not subsidised, which can result in high out-of-pocket costs. Radioligand therapy is not included in the MoH medicines formulary, and therefore is not subsidised by the government.^{21 33} Individuals eligible for the treatment must either have private medical insurance or pay out of pocket.^{21 26 34} Data from the region have demonstrated that high out-of-pocket costs for treatments can lead to devastating outcomes; 75% of people with cancer have experienced financial catastrophe or death within one year of their diagnosis – and these outcomes are significantly more common among people with a lower household income.³⁵

Although international guidelines have been adapted for local populations, it could be beneficial to develop national guidelines for the wider implementation of radioligand therapy – particularly as more cancers are likely to be managed through this treatment in the future. The Malaysian Oncological Society was involved in adapting the European Society of Medical Oncology guidelines for prostate cancer to meet the needs of an Asian population.²⁷ Alongside this, the Malaysian Chapter of the Asia-Pacific Neuroendocrine Tumours Society has published treatment guidelines.²⁸ Both sets of guidelines recommend radioligand therapy as a treatment option for prostate cancer and neuroendocrine tumours.^{27 28} However, the lack of published national guidelines for the treatment of prostate cancer or neuroendocrine tumours may result in inconsistent treatment and care.³⁶

Opportunities to advance the implementation of radioligand therapy in Malaysia



Maintaining engagement between the government and physicians may provide wider access to radioligand therapy and support decisions around subsidisation



Understanding system-wide barriers and embracing public–private hospital collaboration could broaden access to radioligand therapy services



Increasing awareness and understanding of radioligand therapy among healthcare professionals could support expanded access



Recognising specialist status for healthcare professionals involved in radioligand therapy would help combat workforce shortages



Developing policy that secures a consistent supply of radioisotopes may help future-proof access to this treatment



Encouraging the joint regulation of radioligand therapy could support more streamlined implementation

Maintaining engagement between the government and physicians may provide wider access to radioligand therapy and support decisions around subsidisation



WHAT IS THE CURRENT CONTEXT?

Radioligand therapy in Malaysia is mostly funded through private insurance or paid out of pocket. People without private medical insurance are required to pay directly to access radioligand therapy, as it is not currently included in the MoH medicines formulary and is not subsidised by the government. This can lead to inequitable access.^{26 21} To be included in the medicines formulary (commonly known as the blue book), each new treatment must be reviewed and approved through a budget impact assessment and a value-based assessment that then allows hospitals to procure the treatment.^{21 26 33}

Public funding is sometimes available for radioligand therapy; however, it is not guaranteed and insurance limitations are becoming more common, which can further limit access. For people without insurance or who are unable to cover the cost of radioligand therapy, public hospitals may be able to fund the treatment with their own budget or apply to the MoH for financial support.²¹ Applications are reviewed by a technical committee to assess affordability and sustainability; the process can often take several months.²¹ While these applications are not required in private hospitals – insurance and out-of-pocket funding are more common there – the high cost of and rising demand for radioligand therapy are making it more difficult to successfully convince insurance companies that an individual requires this treatment.²¹ The NSPCCP also notes that there are ceilings to insurance coverage for cancer treatment, and that these may be a barrier to the broader implementation of radioligand therapy.⁶

NGOs are an alternative avenue for funding radioligand therapy, but the level of support available is limited. An organisation called National Cancer Council Malaysia, known as MAKNA,³⁷ helps provide access to cancer treatments for people from households within the lowest 40%-income bracket.²¹ Physicians usually make a request to the organisation, on behalf of the patient, justifying the need for the treatment and explaining the costs.²¹ However, as demand and costs for radioligand therapy have risen, NGOs are not able to provide as much support as they used to.³⁴ For example, people with neuroendocrine tumours require multiple rounds of treatment with PRRT, but NGOs may only provide funding for the first cycle of treatment.³⁴



WHAT CAN BE DONE?

Direct communication between physicians and the MoH about increasing access to radioligand therapy could address disparities in access and advance subsidisation. Health technology assessments, which include a pharmacoeconomic evaluation, are required to determine which treatments are included in the medicines formulary and this often relies on pharmaceutical companies to submit an application.²¹ These applications could be supported by repeated requests for MoH funding from physicians to provide radioligand therapy and – coupled with increased levels of direct engagement by this group – may help to boost awareness about the therapeutic importance of this treatment.²¹ Should the therapy become subsidised, disparities in access could be reduced significantly as radioligand therapy would no longer require out-of-pocket payments from people without private health insurance.

Understanding system-wide barriers and embracing public–private hospital collaboration could broaden access to radioligand therapy services



WHAT IS THE CURRENT CONTEXT?

There are a limited number of nuclear medicine services in Malaysia, and most focus on diagnostic nuclear medicine. Only 35 in 355 hospitals have nuclear medicine services; of these, only 6 are MoH hospitals, meaning there is limited access to these services for individuals without insurance or who cannot afford to pay out of pocket.^{19 22 38} Due to limited infrastructure supporting a comprehensive delivery of nuclear medicine services, most centres focus on diagnostic nuclear medicine rather than therapeutics, and they do not all have the scanners needed to deliver radioligand therapy.^{21 22 34} This has resulted in an inability to meet demand – particularly in public hospitals – as well as reported reticence to publicise the potential of radioligand therapy in case the hospitals do not have the capacity to support more patients.^{19 21}

The distribution of nuclear medicine services is uneven, which is resulting in inequalities in access to radioligand therapy. The majority of centres are located in the central or northern regions of Peninsular Malaysia – in Penang, Klang Valley, Kuala Lumpur and Putrajaya.²¹ While the provision of nuclear medicine services in the southern part of the peninsula is slowly developing, there are no MoH nuclear medicine services on the east coast, and Borneo only has two centres (both with minimal therapeutic provision), resulting in inequitable access to services.^{6 21 34} Although the government offers financial support for the travel costs incurred by people from Borneo who are seeking treatment, it does not cover other expenses.²¹

WHAT CAN BE DONE?

Undertaking a system-wide evaluation of the delivery requirements for radioligand therapy may help future-proof expansions in access. The MoH committed to each region having at least one comprehensive nuclear medicine centre that can deliver both diagnostics and therapeutics.^{19 21} With increases in demand expected for radioligand therapy,¹⁹ a system-wide review could identify initial priority areas and help ensure services are expanded sustainably and cost-effectively. The review could include the economic costs of not expanding access, as well as workforce numbers, service provision and demand.

The creation of public–private partnerships could help broaden the delivery of radioligand therapy. Public–private partnerships are long-term contracts to provide healthcare facilities, equipment or services.³⁹ Some evidence has shown that public–private partnerships can improve diagnosis, length of hospital stay, referral rates, mortality rates and patient satisfaction.⁴⁰ Partnerships such as these could be an opportunity for a pilot project that enables private patients to receive radioligand therapy closer to their homes in public hospitals that may have the required infrastructure but not a full-service set-up.²¹ Once evaluated, this approach may help provide a pathway to the wider-scale implementation of radioligand therapy. It may also help the government fully understand the long-term economic implications of these services.

CASE STUDY 1. Hub-and-spoke by the British Nuclear Medicine Society

As proposed by the British Nuclear Medicine Society, a hub-and-spoke model of service provision is one way to increase equitable access to radioligand therapy.^{41 42} 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 capacity and expertise from the central hub to deliver high-quality services.⁴³ People on low incomes may be eligible for financial help with travel costs to access specialist services.⁴⁴

This model could be replicated in Malaysia to provide equitable access and meet future demand for radioligand therapy.

CASE STUDY 2. Increasing imaging infrastructure in Spain⁴⁵

In 2013, there was a regional discrepancy in the number of PET scanners per inhabitant, meaning people in some regions did not have access to appropriate care. Some regions had as many as 3.11 PET scanners per 1 million inhabitants, while others had as few as 0.48.

To address this discrepancy and improve care, a review looked at the age of existing medical equipment. The review resulted in a report calling for improved infrastructure across the health system, and highlighted the need to prepare for increased radioligand therapy. As the same time, the Spanish government was granted EU funding for new, high-tech equipment that would help address the recommendations in the report.

The government consulted with medical societies and gathered information about regional needs from local governments to inform equipment distribution. From 2020 to 2022, the number of PET scanners in Spain grew from 88 to 115 (a 30.6% increase).⁴⁶ This led to a rise in the number of scans; 58,039 more scans took place in 2022 than in 2020 (a 26.0% increase).⁴⁷



BOX 3. Delivering care via public–private partnerships

Public–private partnerships can take many forms; the most common in a healthcare setting are:⁴⁸

- infrastructure-based models, where the private partner is contracted to design, build, finance and maintain healthcare facilities; this is the most common form of private–public partnership in healthcare globally
- models where the private partner is contracted to deliver discrete clinical services; this is commonly used in India and Southeast Asia
- integrated models, where the private partner is contracted to design, build, finance and operate facilities, and deliver non-clinical and clinical services.

In practical terms, these models are used regularly; for instance, during the COVID-19 pandemic, the NHS used private healthcare provider Bupa to deliver cancer services. Through this partnership, Bupa was able to perform over 700 surgeries, 647 of which were time-critical cancer surgeries, and provide outpatient services to almost 200 individuals. The partnership also allowed facilities to share staffing resources to support the cancer patients.⁴⁹

Increasing awareness and understanding of radioligand therapy among healthcare professionals could support expanded access



WHAT IS THE CURRENT CONTEXT?

There is low awareness of radioligand therapy among oncologists, which may result in patients not being referred for the treatment. Radioligand therapy is included in the postgraduate training syllabus for clinical oncology; however, with the fast expansion of this treatment modality, oncologists may find it difficult to keep pace with each new development.²¹ Awareness can also vary depending on whether oncologists work in a hospital that provides radioligand therapy services. Oncologists who work in hospitals that offer these treatments have greater awareness of radioligand therapy than oncologists who work in hospitals that do not.²¹ Unfortunately, a lack of information and awareness among oncologists may also contribute to delays in referral and treatment, which could ultimately affect patient outcomes.²¹

University education in radioligand therapy does not provide the practical experience needed to effectively deliver high-quality care. Undergraduate medical training in Malaysia does not include radioligand therapy or the role of nuclear medicine in clinical management.²⁵ This may be due to the limited number of universities that provide an undergraduate medical programme and have a nuclear medicine facility.^{21,25} There is a postgraduate programme on nuclear medicine that is delivered by the Universiti Sains Malaysia through a four-year master's programme in nuclear medicine.^{21,26} However, education about radioligand therapy currently focuses on the theoretical aspects of the treatment as it is difficult to provide students with practical experience because there are so few sites (just six MoH hospitals) that can deliver radioligand therapy.^{21,26} Clinicians often receive this practical experience in placements abroad once they have completed the programme; however, this often takes place in other countries, including the UK or Australia, which can provide greater exposure to the practical delivery of nuclear medicines.^{21,34}

Nuclear pharmacy is not uniformly recognised as a specialist area across different hospitals, which may result in fewer pharmacists training in this area. Pharmacists in Malaysia can be supported to obtain a master's degree in nuclear pharmacy, and can then be recognised by the National Pharmaceutical Regulatory Agency (NPRA) as subject matter experts in radiopharmaceuticals.²¹ However, this opportunity is not available to pharmacists who work outside of MoH hospitals; this restricts the pool of recognised nuclear pharmacy expertise.²¹ Additionally, because of a decline in the number of nuclear

pharmacy lecturers, plans for future undergraduate pharmacy curriculums indicate education on nuclear pharmacy will be limited.²⁵ This may lead to reduced awareness of nuclear pharmacy among young pharmacist trainees and consequently an insufficient workforce to meet future demand.

WHAT CAN BE DONE?

Establishing opportunities for spreading awareness of radioligand therapy across a broad range of physicians is key to improving access. The provision of cross-disciplinary continuing medical education (CME) that includes oncologists, nuclear medicine physicians and other referring physicians could create opportunities to improve understanding of which patients are suitable for referral into radioligand therapy.²¹ Encouraging nuclear medicine physicians to attend and present at conferences for associated specialities may also support this, and enable oncologists, urologists, endocrinologists and others to keep up to date with advances in radioligand therapy treatments.^{21,26} A key activity that would support spreading awareness is the development of a joint oncology and nuclear medicine board, which may involve the Society of Nuclear Medicine and the Malaysian Oncological Society with an MoH representative. The board could help guide the implementation of radioligand therapy as a treatment option, develop clinical practice guidelines that include clinical indications for radioligand therapy, set standards for MDTs, and take the lead in providing proactive knowledge and research updates.²¹

Private hospitals may have the capacity to support wider practical experience during nuclear medicine training in Malaysia. Accredited private facilities could provide practical training as part of the postgraduate nuclear medicine training programmes to address the limited opportunities at public hospitals.²¹ There are more private than public hospitals with nuclear medicine services. So offering more opportunities to gain practical training experience in these settings may help address the shortage of physicians with this level of experience and allow them to remain in Malaysia for the duration of their training.^{21,22} There are potential indemnity issues around this approach, but including representatives from the MoH in the development of a pilot programme could clarify issues before they arise.²¹

The development of a nationwide policy could support wider recognition of nuclear pharmacy as a specialised area. This would allow radiopharmacists to have access to higher education in nuclear pharmacy regardless of whether they work in private or MoH hospitals. It may also help attract more pharmacists to this specialised area, which could in turn encourage universities to keep nuclear pharmacy in the undergraduate curriculum, and generate wider interest.²¹



Clinical trials are another avenue that could increase awareness and access to radioligand therapy before wide-scale integration into routine clinical practice. Increasing the number of and participation in clinical trials could provide valuable experience, enhancing technical knowledge in patient selection, dosimetry, imaging, and therapy integration into clinical practice. Clinical trials also promote local expertise and contribute to understanding the safety and efficacy of new radiopharmaceuticals, fostering further research in the field.⁵⁰

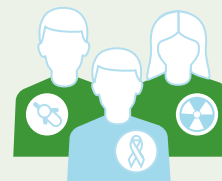


CASE STUDY 3. The Radioligand Therapy Academy: increasing awareness among healthcare professionals⁵¹

The Radioligand Therapy Academy, an online resource, seeks to increase knowledge of the therapy around the world and advance its integration into cancer care. The academy offers virtual and in-person courses, providing healthcare professionals with the opportunity to upskill in the field of radioligand therapy. This can in turn help increase referrals.

Without formal training on radioligand therapy in Malaysia, healthcare professionals may benefit from participating in courses such as those offered by the academy to gain expertise and address knowledge gaps.

Recognising specialist status for healthcare professionals involved in radioligand therapy would help combat workforce shortages



WHAT IS THE CURRENT CONTEXT?

There are relatively few nuclear medicine specialists in Malaysia and many of them work in private hospitals, which may be limiting the service provision in public hospitals. Malaysia has a comparatively low number of specialist nuclear medicine physicians (0.002 per 100,000 population⁵² vs., for example, 0.02 in Germany and 0.019 in Australia);^{53 54} there are only 67 in the country,³⁴ although there are also radiologist physicians and internal medicine physicians who sub-specialise in nuclear medicine.²⁵ Some of the factors contributing to the shortage of experienced nuclear medicine physicians in public hospitals include: high unsubsidised treatment costs, which mean that individuals cannot afford to pay for the treatment, so it takes place less often; limited access to in-depth practical postgraduate training; and inadequate opportunities for nuclear medicine physicians to gain experience in radioligand therapy. Private hospitals, on the other hand, tend to have more people with cancer being treated with radioligand therapy; hence, nuclear medicine physicians in these hospitals gain more experience.⁵⁰

Many nuclear medicine physicians are moving away from public hospitals to work in the private sector; this may exacerbate inequalities in accessing radioligand therapy. An increasing number of nuclear medicine physicians and oncologists are leaving public hospitals to work in private hospitals.²¹ Healthcare professionals in MoH hospitals have high workloads, often resulting in a high staff turnover.⁶ The larger salaries paid by private hospitals are drawing away specialists with the expertise to deliver innovative medicines;²¹ this has particularly been the case with oncologists.⁶ The trend threatens the ability of public hospitals to deliver treatments such as radioligand therapy, and may create a two-tiered health system where only people who can afford care in private hospitals are able to access this type of treatment. To help address this issue, the MoH has developed a policy that allows physicians from public hospitals to work in private hospitals one day a week.²¹

More radiopharmacists are needed to meet future demand, but limited recognition of nuclear pharmacy may be restricting expansion. Pharmacists trained in radiopharmaceutical preparation are central to the delivery of radioligand therapy and to ensuring product quality, safety and efficacy.⁵⁵ However, they receive less recognition than nuclear medicine physicists, who often receive more advanced training.²⁵ Additionally, the Malaysian Pharmacists



Society does not recognise nuclear pharmacy as a specialised area,⁵⁶ which could be discouraging trainee pharmacists from pursuing this area of interest and subsequently limiting the number of radiopharmacists.²¹

WHAT CAN BE DONE?

Encouraging the recognition of nuclear pharmacy as a specialised area and enhancing training for nuclear medicine specialists may boost interest and expand workforce numbers. One of the objectives of the NSPCCP is to build the cancer workforce and strengthen human capital development.⁶ Meeting this objective may involve providing more opportunities for practical training and by default, should radioligand therapy receive subsidisation, this would also provide more exposure to these medicines in public hospitals. Additionally, to meet the long-term requirements of radioligand therapy, any increase in the number of nuclear medicine physicians must be matched by a rise in the number of radiopharmacists.²¹ Building recognition of radiopharmacists – and of nuclear pharmacy as a specialism in its own right – through national societies could also help entice more pharmacists into this area, ensuring nuclear medicine services can be expanded sustainably to meet the increases in demand that are expected.



CASE STUDY 4. **European Association of Nuclear Medicine INSPIRE programme: tackling workforce challenges**⁵⁷

The European Association of Nuclear Medicine has developed the Initiatives in Nuclear Medicine to Support Professional Interest and Recruitment in Europe (INSPIRE) programme to address shortages in the workforce.

The objective of the programme is to attract nuclear medicine workers by approaching students, schools, universities and other stakeholders. INSPIRE engages younger generations through social media, offers in-person experience in nuclear medicine, and promotes the appeal of working in the field.

Similar projects could be replicated in other countries, including Malaysia, to boost the nuclear medicine workforce and support the long-term implementation of radioligand therapy.

Developing policy that secures a consistent supply of radioisotopes may help future-proof access to this treatment



WHAT IS THE CURRENT CONTEXT?

The domestic production of radioisotopes for radioligand therapy is not high enough to meet demand, so they are primarily imported.

Radiopharmaceuticals for PET scans are manufactured locally using medical cyclotrons, but therapeutic radionuclides are primarily imported because the manufacturing infrastructure in Malaysia, including the research reactor and cyclotron facilities, lacks the capability to produce them. There are only five low-energy cyclotrons in the country; they are not evenly spread out,²¹ and there are no comprehensive facilities in Borneo.⁵⁰ Should a person require a PET scan to facilitate radioligand therapy in this region, there would be high costs associated with transporting the radiopharmaceuticals.²¹ The importation of radioisotopes into Malaysia can be beset by delays; they can take up to four weeks to arrive, by which time a patient's condition may have worsened and they may no longer be eligible for treatment.¹⁹

Access to radioisotopes can be challenging, primarily due to supply chain constraints. Previously, the Malaysian Nuclear Agency supplied radioisotopes to hospitals.²¹ However, private hospitals now negotiate their own contracts with vendors, while the MoH negotiates radioisotope supply contracts on behalf of all public hospitals.²¹ In cases of supply disruptions for radioisotopes, institutions are often left with limited options and must reduce their caseloads to match available supply.⁵⁰ This ultimately restricts access to radioligand therapy.¹⁹ To address this, it will be essential to consider diversifying procurement channels and introducing more flexible regulations to enable hospitals to source supplies during shortages or disruptions. At the same time, encouraging improvements in local production capacity could provide a more sustainable and reliable supply of radioisotopes.

WHAT CAN BE DONE?

To address the import issues and limited domestic supply, a centralised nuclear pharmacy facility is being established. A proposal to provide radiopharmaceuticals across Malaysia was approved by the MoH and the Ministry of Finance in 2022.²¹ The facility will be based at the National Cancer Institute and house cyclotrons with a higher capability to produce radioisotopes that can be used for radioligand therapy, such as Lutetium-177.²¹ Private hospitals with additional cyclotrons are also investigating the possibility of



producing and supplying further radioisotopes for PET imaging.²¹ However, clear system and demand mapping needs to be undertaken to prevent oversupply, which may result from higher production outputs.²¹

Building a cyclotron that could supply the East Malaysian states would be essential to ensuring that establishing regional nuclear centres is cost effective. The cost of transporting radiopharmaceuticals to Borneo is high,²¹ so a dedicated cyclotron that has the ability to produce them locally may reduce expense. Broadening the distribution of radioisotope production across Malaysia will be a key component of fulfilling the national commitment to more equitable access.⁶

The production of radiopharmaceuticals could also come from outside the established healthcare infrastructure, and there may be opportunities for investors to set up cyclotron and imaging facilities in Malaysia. This could help secure a level of production that can meet demand, remove hurdles around importation, and bring additional investment to the country.²¹ Setting up these facilities outside of major urban areas may also increase physicians' access to PET scans and broaden access to radioligand therapy.²⁶

Developing a policy that focuses on securing a consistent supply of radioisotopes is also essential for the sustainable growth of radioligand therapy and future-proofing services. The process of developing this policy could involve the Malaysian Nuclear Agency and the MoH engaging with national experts in radioligand therapy and nuclear medicine to discuss key challenges and opportunities around national production vs. importation.²¹



CASE STUDY 5. Supporting the development of a radioligand policy framework in Europe⁵⁸

The Stakeholder Political Alliance for Radioligand Cancer Therapies (SPARC-Europe), a policy initiative launched in 2020, aims to build a comprehensive environment for radioligand therapy. It does this by providing expert knowledge and guidance to support policymakers in implementing radioligand therapy and increase accessibility to this treatment for people living with cancer.

The goal of SPARC-Europe is to:

- highlight the need to integrate innovative medicines into health systems
- support the development of guidance for implementing radioligand therapy
- overcome geographical inequalities in access to these medicines
- guide the development of education and training programmes for healthcare professionals in the field of radioligand therapy.

Encouraging the joint regulation of radioligand therapy could support more streamlined implementation



WHAT IS THE CURRENT CONTEXT?

Overlapping regulation of the import of radioligand therapy into Malaysia is creating delays in access, which need to be addressed. The import of radioligand therapy into Malaysia requires approval by both the NPRA and the MRSD of the MoH, as well as customs clearance and import permits.^{21,26} Overlapping regulation managed by independent bodies has led to delays in accessing the treatment; it can take up to three weeks from the physician deciding to treat an individual with radioligand therapy to being able to administer it.²¹ Radioligand therapy is also classified as an investigational product in Malaysia, for use in clinical trials, meaning that permission and clearances must be sought for each dose, every time a person receives it. This can exacerbate the delays in access significantly.^{21,26} Delays due to the long regulatory process are attributed to a lack of formalised communication between the agencies and the need for a joint protocol that would enable improved regulatory oversight.³⁴ To try to address this, the NPRA and the MRSD recently met to discuss streamlining processes and ensuring regulations align.³⁴

Delays and restrictions in obtaining licenses to treat people with radioligand therapy can limit the use of innovative medicines. Before physicians can import radioligand therapy into Malaysia to treat their patients, each nuclear medicine centre must obtain a license to provide the treatment.²¹ However, accessing these licenses is becoming more difficult. This may be due to limited awareness of the latest radiopharmaceuticals among the responsible regulatory authorities, which can result in a lack of clarity as to why these medicines are needed.²¹ Ultimately, this could risk limiting the ability to introduce new, innovative, and potentially more effective radiopharmaceuticals into Malaysia, and hamper local research and clinical trials.

Regulation is not standardised for licensed and unlicensed radioligand therapy, potentially leading to variations in quality and safety assessments. Currently, both licensed and unlicensed radioligand therapy are available in Malaysia. Licensed therapies require import from abroad, while some unlicensed therapies can be manufactured domestically.^{21,26} Licensed and unlicensed radioligand therapy undergo different evaluation processes,²¹ which may contribute to disparities in implementation and care standards.



WHAT CAN BE DONE?

Establishing a formalised joint regulatory committee may help ensure clear communication, streamline protocols and align regulation. Bringing together representatives from the NPRA and the MRSD who can combine cross-agency services – including providing licences to centres and reviewing permits to import – may expedite many of the processes that are creating delays.²¹³⁴ The development of a formalised protocol could also support the assessment and review of new, innovative medicines. Additionally, consolidating regulation could ensure that all radioligand therapies, whether licensed or unlicensed, undergo the same rigorous quality and assurance assessments, and could therefore reduce the risk of variable safety standards.



Recommendations for action

Radioligand therapy is an innovative, potentially life-changing therapy for people with cancer. In Malaysia, innovative treatments – including radioligand therapy – will be a crucial tool for reaching the national target of reducing mortality by a third by 2030, and improving cancer outcomes and quality of life. While many of the recommendations in this report will require collaboration between different organisations, the role of the government in advancing these recommendations cannot be understated. By taking decisive action, the government can drive improvements in cancer treatment that benefit the entire Malaysian population. Other countries are already proactively adapting their health sectors to embrace these new technologies; therefore, it is vital for Malaysia to join this global momentum, prioritising high-quality cancer care and implementing policies that foster innovation and accessibility. The authors of this report have developed a series of recommendations, guided by a multidisciplinary advisory group, that can contribute to Malaysia becoming an innovation hub through successfully implementing radioligand therapy.

WE CALL ON RELEVANT POLICYMAKERS AND DECISION-MAKERS TO:

-  **review clinical and cost-effectiveness assessments within the MoH medicines formulary,** using local and international expertise to ensure the assessments are fit for purpose and access to the therapy is equitable.
-  **integrate the use of MDTs into the delivery of radioligand therapy** to ensure equitable and comprehensive care from diagnosis to treatment and ongoing support.
-  **enable nuclear medicine services to be expanded sustainably and equitably across Malaysia;** this should include exploring public–private partnerships to bolster the widespread implementation of radioligand therapy.
-  **encourage the recognition of nuclear pharmacy as a specialised area** to help with expanding the number and capacity of radiopharmacists trained to support the delivery of radioligand therapy.
-  **develop a strategy to support the long-term, consistent supply of medical radioisotopes across Malaysia;** this would promote the equal distribution of production facilities throughout the country and increase opportunities for investment.
-  **establish a formalised joint regulatory committee that brings together representatives from the NPRA and the MRSD** to streamline review processes and develop validated protocols to support the efficient expansion of radioligand therapy.
-  **raise awareness of radioligand therapy among physicians by offering cross-disciplinary CME,** and support nuclear medicine physicians to provide practical training to junior colleagues.
-  **create a joint oncology and nuclear medicine board** with input from key societies and the MoH; the board could develop guidelines, set standards for MDTs and share research to guide the use of radioligand therapy.
-  **use accredited private hospitals to help deliver practical experience to physicians studying nuclear medicine,** and engage with higher-education providers and the Malaysian Society of Nuclear Medicine & Molecular Imaging to understand how to overcome barriers surrounding indemnity for this training.

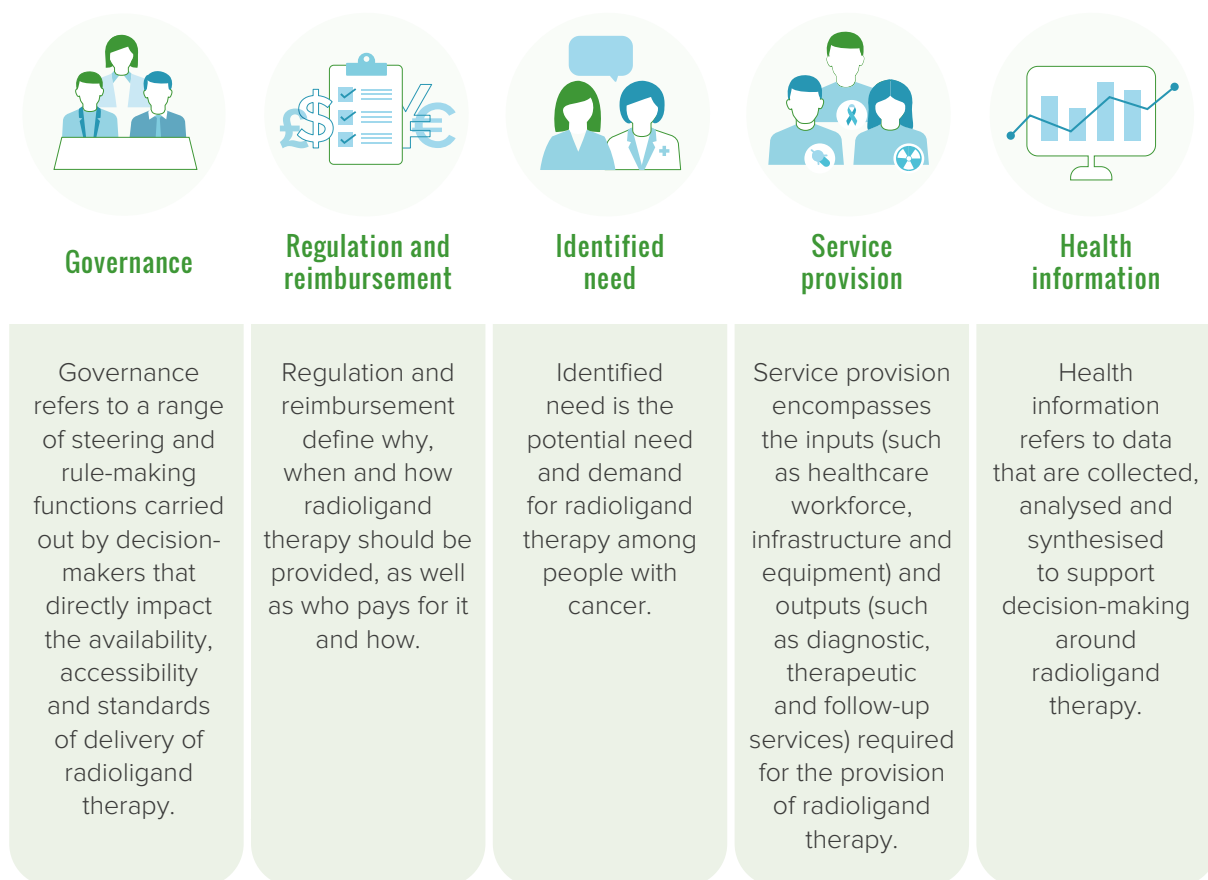
Appendix

The Radioligand Therapy Readiness Assessment Framework used to guide the research for this policy narrative was developed by HPP to evaluate national health systems' progress in integrating radioligand therapy.¹⁷ The framework allows those using it to take a systems-based approach to assessing the level of readiness in their country across five key domains (*Figure 1*), with the aim of identifying gaps in capacity and supporting more effective long-term planning and resource allocation.

The framework's development was guided by a multi-stakeholder international advisory group made up of nuclear medicine specialists, oncologists, urologists and patient representatives, and has been endorsed by the European Association of Urology, the European Neuroendocrine Tumor Society and the Oncidium Foundation.

Previous applications of the framework have been carried out in the US, the UK and South Korea.

Figure 1. The five domains of the Radioligand Therapy Readiness Assessment Framework





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