



# Health Technology Assessment of Radiotheranostics in Developing Countries

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# Radiotheranostics





- ❑ Radiotheranostics combines molecular imaging (primarily PET and SPECT) with targeted radionuclide therapy, typically with radionuclides that emit  $\alpha$ -,  $\beta$ - or auger-radiation.
- ❑ Radiotheranostics, which integrates diagnostic imaging and targeted radionuclide therapy, is revolutionizing precision medicine.
- ❑ *The objective of this presentation is to evaluate the adoption of radiotheranostics in lower-income countries, analyzing cost-effectiveness, accessibility, and regulatory frameworks, and identifying sustainable strategies to bridge the gap between high and low-income settings and enhance global healthcare equity.*

**Table 1:**

Summary of radiotheranostics for cancer treatment

	Ligand	Therapeutic isotope	Imaging isotope	Target	Manufacturer	Disease	Clinical trial phase or approval date
Iodine	None	<sup>131</sup> I	<sup>124</sup> I, <sup>131</sup> I	NaI symporter	Curium, GE Healthcare	Thyroid cancer	NA
Dotatate (Lutathera)	Peptide	<sup>177</sup> Lu	<sup>68</sup> Ga, <sup>111</sup> In	SS2R	Adacap (Novartis)	Neuroendocrine tumours	Approved, 2018
Satoreotide tetraxetan	Peptide	<sup>177</sup> Lu	<sup>68</sup> Ga	SS2R	Ipsen	Neuroendocrine tumours, small-cell lung cancer, and breast cancer	Phase 1 and 2
PSMA-617	Small molecule	<sup>177</sup> Lu	<sup>68</sup> Ga, <sup>18</sup> F	PSMA	Adacap (Novartis)	Castration-resistant prostate cancer	Phase 3
Lexidronam (Quadramet)	None	<sup>153</sup> Sm	<sup>99</sup> Tc, <sup>18</sup> NaF	New bone formation	Lantheus	Bone metastases	Approved, 1997
Radium223 (Xofigo)	None	<sup>223</sup> Ra	<sup>99</sup> Tc, <sup>18</sup> NaF	Calcimimetic	Bayer	Prostate cancer and bone metastases	Approved, 2012
Strontium89 (Metastron)	None	<sup>89</sup> Sr	<sup>18</sup> NaF	New bone formation	GE Healthcare	Bone pain	Approved, 1990
Ibritumomab tiuxetan (Zevalin)	Antibody	<sup>90</sup> Y	None	CD20	Spectrum Pharmaceuticals	Relapsed or refractory low-grade, follicular, or transformed B-cell non-Hodgkin lymphoma	Approved, 2002
Tositumomab (Bexxar)	Antibody	<sup>131</sup> I	<sup>124</sup> I, <sup>131</sup> I	CD20	GlaxoSmithKline	Low-grade, transformed low-grade, or follicular large-cell lymphoma	Approved, 2003; withdrawn, 2014
Iobenguane (Azedra)	Antibody	<sup>131</sup> I	<sup>123</sup> I, <sup>124</sup> I	Norepinephrine transporter	Progenics	Pheochromocytoma and Paraganglioma	Approved, 2018
Apamistamab (Iomab-B)	Antibody	<sup>131</sup> I	None	CD45	Actinium Pharmaceuticals	Bone marrow ablation	Phase 3
Lilotomab satetraxetan (Betalutin)	Antibody	<sup>177</sup> Lu	None	CD37	Nordic Nanovector	Indolent non-Hodgkin lymphoma, follicular lymphoma, diffuse large B-cell lymphoma	Phase 1 and 2
Omburtamab	Antibody	<sup>131</sup> I	None	CD276	Ymabs Therapeutics	Neuroblastoma, CNS metastases, and small-round-cell tumour	Phase 2 and 3
3BP-227	Small molecule	<sup>177</sup> Lu	<sup>177</sup> Lu	NTSR1	Ipsen	Pancreatic ductal adenocarcinoma, colorectal cancer, and gastric cancer	Phase 1
FAPi	Small molecule	<sup>90</sup> Y, <sup>231</sup> Bi, or <sup>212</sup> Pb	<sup>68</sup> Ga, <sup>18</sup> F	FAP	Sofie Biosciences	Pancreatic ductal adenocarcinoma, colorectal cancer, and head and neck cancer	Compassionate use (Germany)
Pentixather	Peptide	<sup>177</sup> Lu or <sup>90</sup> Y	<sup>68</sup> Ga	CXCR-4	Pentixapharm	Multiple myeloma and lymphoma	Compassionate use
Glass microspheres	None	<sup>90</sup> Y	None	Tumour vessels (angiogenesis)	BTG (Boston Scientific)	Hepatocellular carcinoma	Approved, 2000
Resin microspheres	None	<sup>90</sup> Y	None	Tumour vessels (angiogenesis)	Sirtex	Hepatocellular carcinoma and liver metastases	Approved, 1998
Microspheres	None	<sup>166</sup> Ho	<sup>166</sup> Ho	Tumour vessels (angiogenesis)	Terumo	Hepatocellular carcinoma and liver metastases	Phase 2

The list shows common radiotheranostics, but is not comprehensive. The availability and development of radiotheranostics varies between countries. NA=not applicable. SSR2=somatostatin receptor type 2. PSMA=prostate-specific membrane antigen. NTSR1=neurotensin receptor type 1. FAPi=fibroblast-activated protein inhibitor. FAP=prolyl endopeptidase FAP. CXCR-4=C-X-C chemokine receptor type 4.

	<h2>STRENGTHS</h2>	<ul style="list-style-type: none"> <li>• Evidence-based medicine supports clinical decisions.</li> <li>• Investment in radiotheranostics is growing.</li> <li>• Advances in radiopharmacy drive innovation.</li> <li>• Cancer genomics enables personalized treatment.</li> </ul>
	<h2>WEAKNESSES</h2>	<ul style="list-style-type: none"> <li>• Lack of global NM recognition.</li> <li>• Human resource shortages hinder progress.</li> <li>• Service complexity limits widespread adoption.</li> <li>• High costs restrict patient access.</li> </ul>
	<h2>OPPORTUNITIES</h2>	<ul style="list-style-type: none"> <li>• Non-communicable diseases increase demand.</li> <li>• Expanding nuclear medicine industry investment.</li> <li>• New curriculum and research advancements.</li> <li>• International collaborations boost regional production.</li> </ul>
	<h2>THREATS</h2>	<ul style="list-style-type: none"> <li>• Competing specialties challenge nuclear medicine.</li> <li>• High costs reduce treatment affordability.</li> <li>• Regulatory and reimbursement instability.</li> <li>• Supply shortages disrupt service delivery</li> </ul>



# Current Landscape of Radiotheranostics for Health Technology Assessment

- ❑ Findings reveal significant disparities in access to radiotheranostics between high-income and low-income nations. Industrialized countries benefit from well-established infrastructure, continuous research funding, and trained professionals.
- ❑ In contrast, developing nations struggle with affordability, lack of specialized personnel, regulatory hurdles, and fragmented healthcare systems.
- ❑ Successful models of radiotheranostics integration in resource-limited settings highlight the importance of international collaboration, technology-sharing programs, and innovative financing mechanisms.
- ❑ Initiatives such as public-private partnerships, international training collaborations, and cost-effective technology adaptations show promise in improving accessibility.
- ❑ Policy makers must focus on creating favorable regulations, investing in workforce development, and ensuring sustainable funding mechanisms.

# HTA of Radiotheranostics: Developing vs. Industrialized Countries

HTA	Industrialized Countries	Developing Countries (LMICs)
Clinical Evidence	Robust clinical trials, established protocols	Limited trials, reliance on external data
Cost-Effectiveness	Formal economic evaluations, reimbursement pathways	Sparse cost-effectiveness data, budget constraints
Infrastructure	Advanced imaging (PET/SPECT), isotope production facilities	Scarcity of equipment, limited access to radiopharmaceuticals
Regulatory Framework	Mature HTA bodies (e.g., NICE, CADTH), clear approval processes	Fragmented or nascent HTA systems, weak regulatory oversight
Human Resources	Specialized workforce, continuous training	Shortage of trained professionals, brain drain
Ethical & Social Equity	Patient-centered care, informed consent, equity policies	Urban-rural disparities, low awareness, limited ethical oversight
Environmental Safety	Strict radioactive waste protocols	Inadequate disposal systems, environmental risks
Stakeholder Engagement	Multi-stakeholder HTA committees, public consultations	Limited engagement, top-down decision-making



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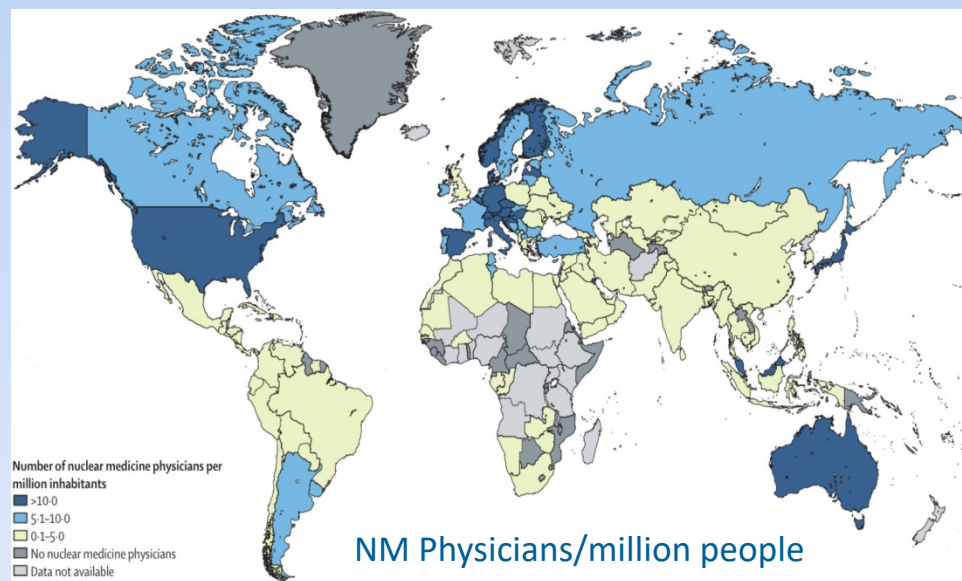
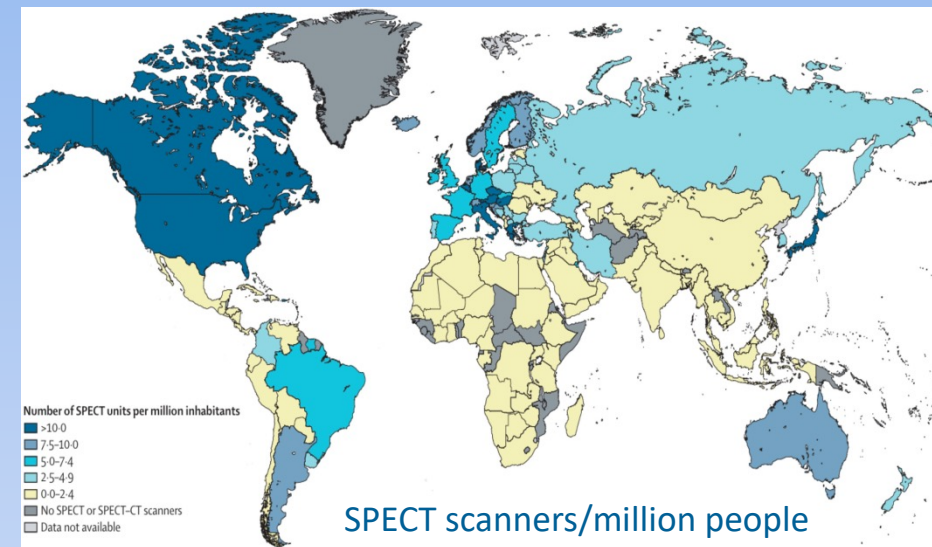
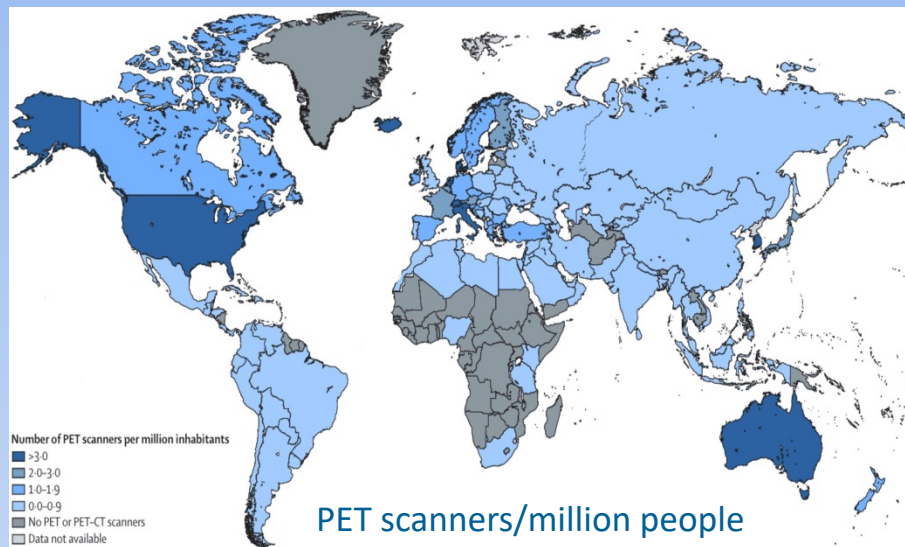
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# Global Overview of Radiotheranostics Facilities

## Equipment and NM Physicians



Source: [Implementation of Radiotheranostics: Challenges, Barriers, and IAEA-Driven Strategies for Sustainable Access](#) - ScienceDirect



# Recommendations and Policy Implications

## Policy

## Implication

Health System Planning

HTA integration ensures evidence-based prioritization of radiotheranostic services

Budget Allocation

Cost-effectiveness data guides efficient resource use and long-term savings

Equity & Access

HTA supports policies that reduce disparities in cancer care

Innovation Adoption

Facilitates responsible uptake of emerging technologies

Global Collaboration

Encourages harmonized standards and shared learning across borders



# Recommendations for HTA of Radiotheranostics in LMICs

## Strengthen HTA Institutional Capacity

- ❑ Establish national HTA agencies or integrate HTA units within Ministries of Health.
- ❑ Train multidisciplinary teams in clinical evaluation, health economics, and ethical analysis.
- ❑ Promote regional HTA networks to share expertise and resources.

## Develop Context-Specific Evaluation Frameworks

- ❑ Tailor HTA methodologies to reflect local epidemiology, health system constraints, and cultural values.
- ❑ Include equity and ethical dimensions, especially for high-cost technologies like radiotheranostics.

## Enhance Data Infrastructure

- ❑ Invest in cancer registries, imaging databases, and treatment outcome tracking.
- ❑ Collaborate with international partners to access clinical trial data and real-world evidence.

## Promote Sustainable Financing Models

- ❑ Explore pooled procurement, public-private partnerships, and donor support for radiotheranostic infrastructure.
- ❑ Integrate HTA findings into reimbursement and pricing decisions to ensure affordability.

## Foster Regulatory Harmonization

- ❑ Align radiopharmaceutical approval processes with international standards
- ❑ Create fast-track pathways for essential technologies with proven clinical benefit.

## Engage Stakeholders and Communities

- ❑ Include patients, clinicians, and civil society in HTA deliberations to ensure transparency and relevance.
- ❑ Build public awareness around nuclear medicine safety and benefits.

## Monitor Environmental and Safety Protocols

- ❑ Implement strict guidelines for radioactive waste disposal and facility safety.
- ❑ Encourage eco-friendly isotope production and lifecycle assessments

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# Infrastructure Investment

## Prioritizing Essential Equipment

Investing in basic radiotherapy machines; reliable diagnostic imaging modalities.

## Establishing Regional Centers of Excellence

Creating specialized centers with advanced capabilities to serve wider geographic areas.

## Upgrading Facilities

Modernizing existing facilities; improving electrical and mechanical infrastructure.



# Workforce Development

## Training Programs

Developing training programs for oncologists, radiologists, nuclear medicine physicians, physicists, and technicians.

## International Collaboration

Partnering with institutions in industrialized countries for training and mentorship.

## Retention Strategies

Incentivizing healthcare professionals to remain in underserved areas.





# Policy and Regulatory Frameworks

## National Cancer Control Plans

Integrating radiotherapy and diagnostics into national cancer control strategies.

## Standardized Guidelines

Developing clear guidelines for referral, diagnosis, and treatment.

## Funding Mechanisms

Establishing sustainable funding mechanisms to support infrastructure and workforce development.



# Future Research

## Further HTA for Radiotheranostics studies

Promoting further HTA studies in developing countries to guide decision-making.

## Impact Evaluation

Monitoring and evaluating the impact of interventions to improve access to radiotherapy and diagnostics.

## Implementation Research

Applying implementation research to identify barriers and facilitators to implementing evidence-based practices.



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# Conclusion

- ❑ The implementation of radiotheranostics varies significantly between industrialized and developing nations due to disparities in technology, infrastructure, and funding.
- ❑ A structured approach involving education, investment, and international collaboration is key to overcoming disparities.
- ❑ Establishing cost-effective technologies, improving training programs, and fostering regulatory reforms will facilitate equitable healthcare improvements worldwide.

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