



# 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

|                                    | <b>Ligand</b>  | <b>Therapeutic isotope</b>                               | <b>Imaging isotope</b>              | <b>Target</b>                 | <b>Manufacturer</b>      | <b>Disease</b>   | <b>Clinical trial phase or approval date</b> |
|------------------------------------|----------------|--|-------------------------------------|-------------------------------|--------------------------|--|--|
| 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, 2007                               |
| Radium223 (Xofigo)                 | None           | <sup>223</sup> Ra  | <sup>99</sup> Tc, <sup>18</sup> NaF | Calcimimetic                  | Bayer                    | Prostate cancer and bone metastases  | Approved, 2013                               |
| Strontium89 (Metastron)            | None           | <sup>89</sup> Sr   | <sup>18</sup> NaF                   | New bone formation            | GE Healthcare            | Bone pain  | Approved, 1998                               |
| 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                                      |
| Lilotumab 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. NTR1=neurotensin receptor type 1. FAPI=fibroblast-activated protein inhibitor. FAP=prolyl endopeptidase FAP. CXCR-4=C-X-C chemokine receptor type 4.



# 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.

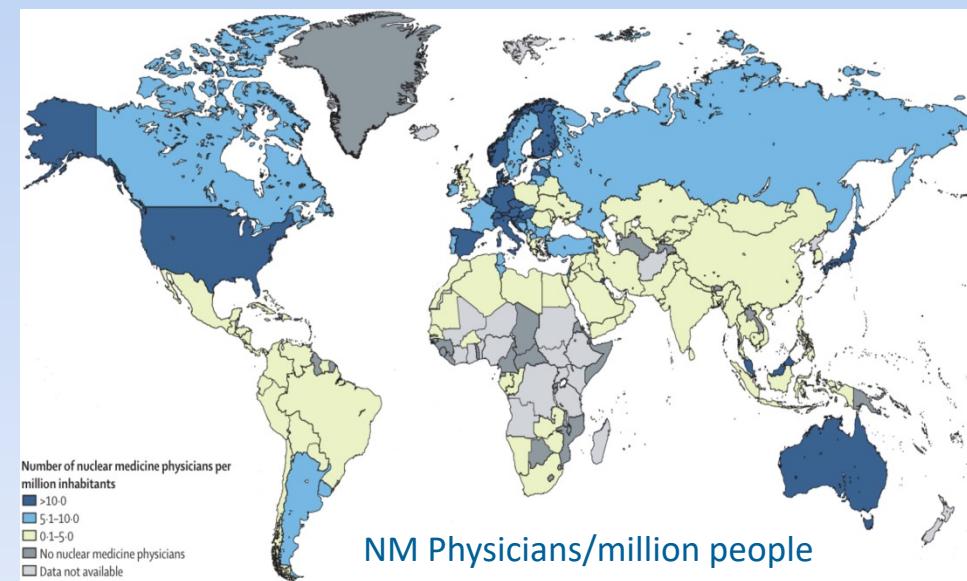
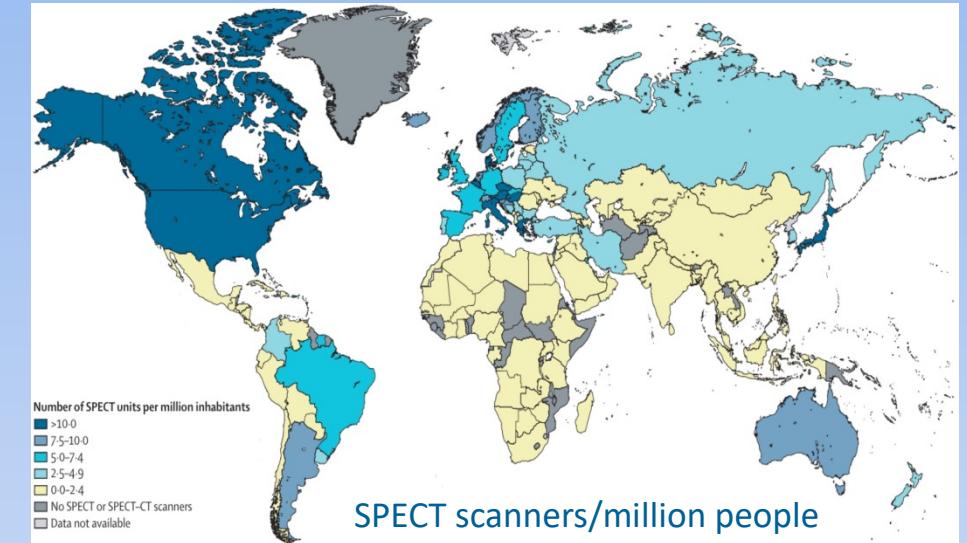
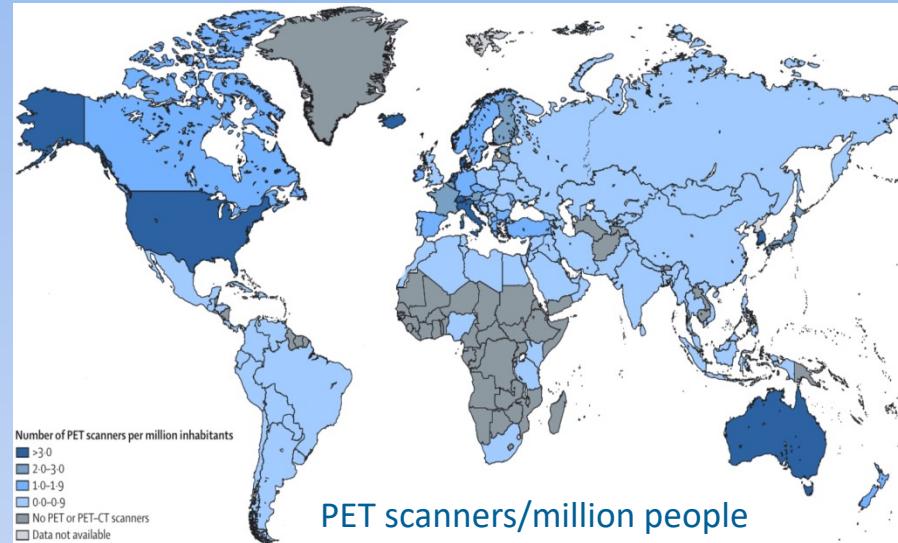
# HTA of Radiotheranostics: Developing vs. Industrialized Countries

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



# Global Overview of Radiotheranostics Facilities

## Equipment and NM Physicians



# Recommendations and Policy Implications

## Policy

## Implication

Health System Planning

HTA integration ensures evidence-based prioritization of radiotherapeutic 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.



# 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.

## References

- Radiotheranostics in oncology: current challenges and emerging opportunities. Lisa Bodei. *Nature Reviews Clinical Oncology*. volume 19, pages: 534–550 (2022)
- Radiotheranostics: a roadmap for future development. Ken Herrmann. *Lancet Oncol*. 2020 Mar;21(3):e146–e156. doi: [10.1016/S1470-2045\(19\)30821-6](https://doi.org/10.1016/S1470-2045(19)30821-6)
- Implementation of Radiotheranostics: Challenges, Barriers, and IAEA-Driven Strategies for Sustainable Access. Akram Al Ibraheem. <https://doi.org/10.1053/j.semnuclmed.2025.07.005>
- Strengthening health technology assessment for cancer treatments in Europe by integrating causal inference and target trial emulation. Heiner C. Bucher. *The Lancet Regional Health- Europe* 2025;52: 101294 Published Online 9 April 2025 <https://doi.org/10.1016/j.lanepe.2025.101294>
- Similarities and Differences in Health Technology Assessment Systems and Implications for Coverage Decisions: Evidence from 32 Countries. Volume 6, pages 315–328, (2022)
- A Roadmap For Systematic Priority Setting And Health Technology Assessment (Hta) A Practical Guide For Policy Action In Low- And Middle-income Countries
- Global Expert Panel Releases Good Practices Guidance for Developing or Updating Health Technology Assessment Guidelines. Jan 14, 2025
- Technical guidance for Health Technology Assessment in low-and middle-income countries Developed by the Global Health Cluster for use in international projects and collaboration March 2023