

Bridging Gaps for Radioligand Therapy: Policy Priorities for Scaled Implementation

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Abstract

Background

Radioligand therapy (RLT) represents a transformative advancement in precision cancer treatment, improving outcomes of patients with advanced cancers. Despite growing clinical evidence demonstrating favorable benefit-risk profiles of RLTs, outdated regulatory frameworks continue to restrict patient access. This report aims to bridge the critical gap between scientific evidence and policy implementation by providing actionable recommendations that enable healthcare systems to optimize RLT delivery while maintaining safety standards.

Methodology

This broad analysis examined regulatory frameworks, clinical guidelines, and real-world implementation data across multiple healthcare systems, focusing on countries with stringent hospitalization requirements (e.g., Germany, Japan) and those applying evidence-based protocols (e.g., United Kingdom, United States). Evidence was assessed using the RLT Readiness Assessment Framework^(a) across seven focus areas to identify policy gaps and implementation challenges.

Key Findings

Current policies perpetuate historical precedents rather than reflecting contemporary evidence. Hospitalization requirements vary widely across countries, from 1-4 hours in the United States to 72-96 hours in Japan, driven by policy choices rather than medical necessity. Systemic policy gaps were identified across seven domains: (1) fragmented governance creating conflicting safety standards; (2) infrastructure concentrated in urban centers and without systematic planning to meet future demands; (3) radiation safety protocols inconsistent with current risk-benefit profiles of RLTs; (4) workforce shortages; (5) health technology assessment and payment systems inadequate to capture the full value of RLT, thereby penalizing efficient care delivery; (6) absence of real-world evidence collection mechanisms; and (7) limited stakeholder awareness of RLT safety and efficacy. The economic impact is substantial: evidence-based 24-hour discharge protocols could increase patient throughput by 67% compared to current 48-72-hour requirements, expanding access while maintaining safety. International best practices from Belgium, Italy, Switzerland, and the United Kingdom demonstrate that evidence-based reform is both feasible and beneficial.

Interpretation

Coordinated reforms in post-treatment discharge criteria, payment models, and RLT-specific assessment frameworks can simultaneously improve patient outcomes, enhance system efficiency, and expand equitable access to breakthrough treatments.

Keywords: Health Policy; Patient Access; Precision Oncology; Health Technology Assessment; Real-World Evidence; Global Health Systems; Radioligand Therapy.

Background

Radioligand therapy (RLT) represents a major advance in targeted cancer treatment, delivering radiation directly to tumors

while sparing healthy tissue [1-3]. Compared with chemotherapy, which is systemic and toxic, [4-6] or external beam radiation therapy (EBRT), which irradiates broader areas from outside the

body, RLT offers a more precise and tolerable option that improves patient safety [7,8].

Advances in targeted radionuclide therapy (TRT) have further refined RLT into an accurate, effective, and well-tolerated therapeutic option, with, for example, Lutetium-based (^{177}Lu) therapies, combining predictable pharmacokinetics with improved benefit-risk profile [9-11].

Evidence from Phase III clinical trials [4,12] and real-world evidence confirm the efficacy, favorable benefit-risk profile with improved cost-effectiveness of RLT [4,13-15]. Standardized fixed-dose treatment regimens simplify and broaden applicability across diverse health systems, including those with limited resources [16-18]. Radiation exposure to the public and healthcare workers after RLT remains minimal and well below established safety thresholds, typically as low as two chest x-rays [19,20].

Yet, despite the growing global cancer burden, RLTs are currently available for only two indications [21]:

- Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)
- metastatic CastrationResistant Prostate Cancer (mCRPC)

Outdated and inconsistent policies affect RLT expansion across different domains, from discharge criteria, [19,22-24] to infrastructure requirements, [9] and radioactive waste management protocols, [24] among others. Most strikingly, hospitalization requirements vary from discharge within hours, in some countries, to others imposing up to 96 hours of inpatient isolation (see Table 1). These divergences reflect policy choices rather than medical necessity and create unnecessary barriers, resulting in inequities in patient access.

This report aims to bridge the gap between clinical evidence and policy by providing actionable recommendations to expand equitable access to RLT by strengthening health system readiness, optimizing care models, and supporting safe and sustainable implementation.

Table 1: Post-RLT Hospitalization Requirements Across Select Countries

Country	Care Setting	Discharge Time Post- RLT	Regulatory Rationale
Canada [22,25]	Outpatient	1-4 hours**	Institutional protocols usually follow the recommended dose constraint of 5 mSv per episode to relatives, visitors, and caregivers set by the International Commission on Radiological Protection and the US Nuclear Regulatory Commission (NRC).
Germany [22,26,27]	Inpatient	≥48 hours	Radiation Protection Directive mandates 48h minimum based on radioactive excretion patterns (>90% elimination occurs within this period). Earlier discharge must be reported to the authorities. <i>Discharge criteria: dose rate <1 mSv/year at 2-meters distance.*</i>
Japan [22,24]	Inpatient	72-96 hours	Ministry of Health, Labor and Welfare guidelines prioritize retained activity levels over fixed time constraints, focusing on radioactive excretion. <i>Discharge criteria: dose rate ≤0.005 mSv/h (5 μSv/h) at 1-meter distance.</i>
Switzerland [28]	Inpatient	20 hours	A collaborative policy reform between the Swiss Federal Office of Public Health/ Bundesamt für Gesundheit (BAG) and the Swiss Society of Nuclear Medicine (SGNM), replaced the previous 3-night hospitalization mandate with a two-night minimum requirement for patient discharge.
United Kingdom [22]	Outpatient: 80% Inpatient: 20%	Outpatient: 3-4 hours	Risk-stratified approach balancing patient volumes with safety: low-risk patients receive outpatient care after the first cycle; high-risk patients (comorbidities, travel burdens, inadequate home shielding) remain inpatient throughout treatment.
United States [22,29]	Outpatient	1-3 hours**	NRC permits discharge based on demonstrated low γ-radiation emission from ^{177}Lu -PSMA-617 patients (0.023 mSv/h at 1m after four hours) - significantly lower than ^{131}I therapy levels. <i>Discharge criteria: dose rate <5 mSv at 1-meter distance.</i>

*Dose limit rate of <1 mSv/year originates from European Council Directive 2013/59/Euratom & International Commission on Radiological Protection (ICRP) directives.

**Depending on institutional protocol.

Methodology

This report employed a broad approach to synthesize evidence on RLT radiation safety and hospitalization optimization. The methodology was designed to provide a structured assessment of current practices, identify policy gaps, and develop evidence-

based recommendations for improving RLT accessibility while maintaining safety standards.

Research Design

The analysis used a narrative synthesis approach, integrating findings from diverse data sources to build a comprehensive

picture of today's RLT landscape. This method accommodated the varied nature of available evidence, from clinical trial data to regulatory documents, independent reports, and real-world practice patterns. Multiple sources were cross-referenced to ensure findings were reliable and valid, with results organized using the RLT Readiness Assessment Framework across seven focus areas [30].

Data Collection and Analysis Methods

Literature Review

The analysis drew on a structured review of current evidence on RLT, focusing specifically on radiation safety, healthcare system readiness, and hospitalization practices. Searches of PubMed, Google Scholar, and institutional repositories used targeted keywords including 'radioligand therapy', 'hospitalization', 'radiation safety', and 'health system readiness'. Given the rapidly evolving nature of RLT evidence, no date restrictions were applied to capture the most current developments.

The review also examined recent analyses commissioned by third parties, summarizing their findings in alignment with the broader evidence base. These sources were selected for the breadth and solidity of their research designs, which integrated different research methodologies to generate complementary insights across diverse contexts that enriched the overall evidence base.

Source prioritization focused on materials that examined new evidence in the context of next-generation RLT, and health system implementation needs. Relevant data, frameworks, and

recommendations underwent thematic synthesis to support discussions on optimizing RLT access while maintaining radiation safety.

Evidence Analysis

Policy gaps and challenges underwent identification through thematic analysis of the evidence collected. This analytical approach enabled a comprehensive assessment of policy barriers across multiple dimensions and identified practical reform opportunities that policymakers can implement in their national contexts. The specific focus areas that emerged from this analysis are presented in the Key Findings section.

Key Findings

This section includes the main findings organized according to the seven focus areas and their corresponding policy gaps:

1. Governance and policy frameworks
2. Health system readiness and capacity
3. Radiation safety
4. Workforce development and training
5. Financing, reimbursement, and economic assessment
6. Evidence generation and data infrastructure
7. Stakeholder education and awareness

Table 2 provides a summary of the policy impact of each of the seven focus areas.

Table 2: Overview of the policy impact of each focus area

Focus Area	Policy Impact
Governance and policy frameworks	Regulatory fragmentation and lack of harmonization create a patchwork of radiation safety, dosimetry, and waste management standards and guidelines that sometimes override available evidence, forcing healthcare systems to choose between regulatory compliance and optimal patient care.
Health system readiness and capacity	Infrastructure bottlenecks and geographic inequities deny treatment access to eligible patients, while outdated hospitalization protocols waste 67% of existing capacity that could serve additional patients safely and effectively. [24]
Radiation safety	Current radiation safety protocols force patients into unnecessarily extended hospitalizations based on outdated risk assessments, when contemporary evidence demonstrates that RLT may result in radiation exposure levels comparable to everyday activities such as air travel.
Workforce development and training	Workforce shortages and fragmented training programs create critical bottlenecks that could delay RLT access for eligible patients, while certification requirements sometimes taking up to a year limit the rapid scaling of the RLT workforce needed to meet growing demand.
Financing, reimbursement, and economic assessment	Current reimbursement models often discourage hospitals from adopting evidence-based protocols by creating financial incentives that may override clinical and safety considerations, ultimately posing barriers to optimal patient care.
Evidence generation and data infrastructure	Critical evidence gaps prevent healthcare systems from assessing whether extended hospitalization protocols align with patient safety requirements and quality of life (QoL) considerations, perpetuating reliance on historical precedents rather than contemporary outcomes data.
Stakeholder education and awareness	Limited awareness among policymakers, patients, and healthcare professionals about the improved risk-benefit profiles of RLT perpetuates outdated treatment protocols and regulatory approaches, creating unnecessary barriers to patient access and optimal care delivery. [31]

Governance and Policy Frameworks for RLT

Fragmented governance frameworks result in patients with similar cancer diagnoses receiving dramatically different treatment experiences - from same-day discharge to mandatory 96-hour hospital stays - based solely on geography rather than medical need. While international frameworks such as the International Atomic Energy Agency (IAEA) Basic Safety Standards and the European Council Directive 2013/59/Euratom provide foundational radiation protection and operational requirements, [32,33] the absence of harmonized implementation guidelines allows each country to interpret these standards differently, creating a regulatory patchwork that prioritizes historical risk perceptions and conservative interpretations of risk-benefit profiles over patient welfare. This fragmentation directly contradicts the goals established by the IAEA, which in its 2023 resolution urged Member States to strengthen nuclear and radiation safety infrastructure, scientific capabilities, and international cooperation [34].

Critical Gaps in Policy and Policy Implementation

- Lack of updated, evidence-based radioprotection guidelines reflecting actual ¹⁷⁷Lu-based RLT risk-benefit profiles.
- Limited integration of RLT in national and regional cancer-care frameworks despite growing clinical importance and lack of dedicated committees or working groups at the national level to guide RLT's safe use in health systems.
- Across countries, there is no uniform, patient-centered approach to post-RLT treatment assessment that informs discharge decisions, with most relying solely on radiation safety as the primary criterion.
- Lack of dedicated, harmonized regulations for the local small-scale radiopharmaceutical preparation, leading to inconsistent implementation of Good Manufacturing Practices and potentially regional quality variability.
- Conflicting guidance on dosimetry requirements despite clinical evidence supporting fixed-dose protocols.
- Lack of appropriate regulations for standardized radiopharmaceutical waste disposal.
- Insufficient patient and patient advocacy group involvement in RLT policy development processes.

Health System Readiness & Capacity for RLT

Health system readiness and infrastructure capacity represent critical determinants of equitable RLT access, with current limitations creating significant barriers to treatment availability across healthcare settings. The delivery of RLT requires specialized theranostics infrastructure encompassing radiation-

shielded treatment rooms, secure radiopharmaceutical storage areas, dose calibrators, radioligand imaging capabilities (e.g., 68Ga/18F-PSMA PET, 99mTc-PSMA SPECT/scintigraphy) and comprehensive waste management systems. These capabilities are often concentrated in urban areas, forcing patients to travel long distances or cross borders for treatment [31].

Economic modeling of hospital operations demonstrates that reducing hospitalization from 48- to 72-hour protocols to 24 hours could increase patient throughput by 67%. This would enable typical 3-bed facilities to treat 612 patients annually instead of 367, while maintaining equivalent safety standards [24]^(b). However, healthcare systems continue operating under divergent approaches that limit access. In Germany and Japan, RLT is typically administered in inpatient settings using shielded rooms with attached washrooms, following conservative radiation safety protocols. In contrast, Australia and the United States routinely administer RLT on an outpatient basis, with patients discharged once radiation levels fall below 0.023 mSv/h at 1 meter; typically within four hours p.i. [9,35,36] Outpatient care is often delivered in standard nuclear medicine or infusion rooms, offering greater flexibility and efficiency, especially in high-demand settings.

Critical Gaps in Policy and Policy Implementation

- Absence of systematic health system readiness assessments and data-driven capacity planning, particularly in resource-constrained settings.
- Bottlenecks in PSMA-PET/CT imaging capacity and other modalities of tumor expression assessment creating cascading delays in the RLT treatment pathway.
- Lack of harmonized infrastructure requirements and standards across healthcare systems.
- Underdeveloped referral networks resulting in geographic inequities and delayed treatment access.
- Insufficient strategic investment in RLT infrastructure relative to projected demand and clinical benefits.

Radiation Safety

Radiation safety is one of the central concerns in RLT scale-up and implementation. Research confirms that modern RLT technologies result in exposure levels well below safety thresholds requiring extended inpatient stays mandated in several countries (see Table 1). The clinical safety and efficacy of Lu-based treatments have been well established through landmark trials such as NETTER-1 [37] and VISION, [38] while evidence on radiation safety continues to accumulate. Studies report that discharging patients 48 hours after receiving an average dose of 6.3 gigabecquerel (GBq) resulted in a maximum public exposure dose of just 0.294 mSv, well below the 1 mSv/year limit

(a) The Radioligand Therapy Readiness Assessment Framework, developed by the Health Policy Partnership with an international expert advisory group, evaluates how well RLT is integrated into health systems and what is needed for its successful adoption in cancer care.

(b) These are based on several assumptions related to the treatment capacity such as the number of beds.

recommended by international guidelines [19]. When patients are released 24 hours p.i., the expected public dose remains well below this limit [19]. Additional research demonstrates that radiation levels measured at 1 meter from patients had already fallen below 0.030 mSv/hour within 4-6 hours p.i., a threshold deemed safe for release [23]. These empirical measurements significantly diverge from the conservative discharge requirements widely practiced across countries, which fail to reflect the improvements in the risk-benefit profiles of RLTs.

Critical Gaps in Policy and Policy Implementation

- Lack of harmonized radiation exposure thresholds for patients, caregivers, healthcare professionals, and the public across regions during and after treatment.
- Absence of radiation safety exposure thresholds specific to RLTs that reflect their actual risk-benefit profile and support evidence-based discharge criteria.

RLT Workforce Development & Training

Workforce development and training are critical enablers of effective RLT implementation across healthcare systems [25]. The delivery of RLT depends on a multidisciplinary team of healthcare professionals, each with specialized competencies, whose coordination directly affects patient access, care quality, and healthcare system readiness. RLT practitioners encompass nuclear medicine physicians, urologists, oncologists, radiologists, nurses, pathologists, radiation safety officers, medical physicists and hospital administrators each contributing uniquely to the patient journey from diagnosis and referral to treatment and follow-up.

Current workforce limitations create cascading access barriers across the treatment pathway. With 21% of the nuclear medicine workforce in Europe expected to retire within five years, [39] and certification for handling radioactive materials typically requiring one year for untrained staff, healthcare systems face a growing gap between clinical demand and available expertise [24]. Simultaneously, safety guidelines mandate strict limits on staff radiation exposure - for example, nurses can attend approximately 110 sessions of ^{177}Lu -PSMA-617 per year [23,24] to remain within the 1 mSv/year exposure limit defined by EURATOM [19]. Post-treatment patient exposure also contributes to the 1 mSv limit, [25] posing remarkable limitations and human resources management challenges, especially in settings with severe limitation in workforce and resources.

Critical Gaps in Policy and Policy Implementation

- Lack of harmonized, specialized training programs for RLT practitioners across all healthcare disciplines involved in patient care.
- Limited availability of multidisciplinary teams and

coordination frameworks for RLT delivery.

- Inadequate systematic workforce planning mechanisms for RLT healthcare professionals.

RLT Financing, Reimbursement, & Economic Assessment

An economic analysis revealed that hospital financial outcomes vary dramatically based on hospitalization duration due to the underlying payment models. These financial pressures frequently conflict with clinical evidence and patient welfare, creating systematic barriers to optimal care delivery. Payment systems can either support or undermine evidence-based practice adoption, with profound implications for both healthcare system efficiency and patient access to life-extending treatments [24].

Estimates from financial modeling of RLT administration in a standard 3-bed facilities showed that reducing hospitalization from 48- to 72-hour protocols to 24-hour protocols generate annual hospital profits of approximately €510,700 (~US\$600,800) in Germany and JPY224 million (~US\$1.53 million) in Japan, while simultaneously enabling treatment of significantly more patients [24].

However, the financial impact varies significantly due to prevailing reimbursement mechanisms. Under Germany's Diagnosis-Related Group (DRG) system, hospitals anticipate a 20% reduction in reimbursement rates with shortened stays yet maintain profitability through increased patient volume. Conversely, Japan's Diagnosis Procedure Combination (DPC) model, which combines per-diem payments with procedure-specific fees, creates more favorable financial situation for reduced hospitalization [24].

The cost structure analysis reveals that the predominant expense component of RLT is the radiopharmaceutical itself, which amounts at JPY6.2 million for six treatment cycles in Japan. Variable costs associated with extended stays contribute additional, unnecessary treatment expenses, further limiting system capacity and creating inefficiencies that could be eliminated with the implementation of evidence-based protocols [24].

Critical Gaps in Policy and Policy Implementation

- Current reimbursement structures penalize evidence-based hospitalization protocols which allow for earlier discharge.
- Absence of RLT-specific HTA frameworks capturing full value propositions and facilitating value-driven reimbursement.
- Limited real-world economic evidence validating the theoretical efficiency gains of reduced hospitalization for RLT.
- Lack of consideration for patients' financial burden associated with extended hospitalization for RLT treatment.

RLT Evidence Generation & Data Infrastructure

Healthcare systems lack the real-world data (RWD) generation mechanisms needed to prove that shorter hospitalizations are safe, perpetuating outdated policies despite growing clinical and radiation safety evidence.

Despite specialized assessment tools such as the Functional Assessment of Cancer Therapy-Radionuclide Therapy (FACT-RNT) being developed to monitor relevant symptoms and toxicities in radiopharmaceutical trials, [40] implementation in routine practice remains sporadic. Critically, no prospective studies have systematically evaluated whether 24-hour, 48-hour, or 72-hour hospitalization protocols result in differential outcomes for patient safety, QoL, or healthcare system efficiency. Without integrated data systems linking diagnostic imaging results, treatment records, post-treatment monitoring, and long-term follow-up outcomes, policymakers cannot assess the full clinical and economic impact of different RLT delivery models.

Critical Gaps in Policy and Policy Implementation

- Limited availability of Real-World Evidence (RWE) for RLT.
- Insufficient policy and funding support for rigorous research into differential outcomes for patient safety, QoL, or healthcare system efficiency of different hospitalization protocols.
- Limited consideration for patient perspective and preferences.
- Absence of policy requirement to systematically collect, analyze, and share post-marketing RLT usage data, including radiation exposure metrics, safety incidents, and compliance with radiation protection standards.

Stakeholder Education & Awareness

Robust stakeholder education and public awareness are critical enablers for equitable and safe RLT implementation across healthcare systems. Despite growing therapeutic relevance and demonstrated clinical benefits, global understanding of RLT - particularly among policymakers, patients, and caregivers - remains limited [25]. This knowledge gap affects not only informed decision-making but also regulatory support, societal perception, and the successful transition toward evidence-based care delivery models.

Policymakers often have limited awareness of the full value and benefits of RLT, particularly regarding improved risk-benefit profiles of the most recent RLT treatments, like the Lu-based RLTs, and minimal post-treatment risk to the public. Similarly, patients and caregivers may not fully understand RLT's safety and efficacy compared to conventional treatments, or the importance

of adhering to radiation safety precautions post-discharge. This creates hesitancy, hindering treatment acceptance and limiting the shift toward shorter hospitalization models that could benefit both patients and healthcare systems [31].

Public and patient education is essential for any transition toward reduced post-RLT hospitalization. Comprehensive guidance must be provided to patients and caregivers regarding radiation safety measures, including avoiding prolonged close contact with vulnerable individuals (e.g., pregnant women, infants), safely managing waste, [41] and understanding the excretion kinetics of isotopes like ¹⁷⁷Lu-PSMA-617 [24,25,42].

Critical Gaps in Policy and Policy Implementation

- Insufficient awareness and understanding among the general public and key stakeholders, including policymakers, healthcare professionals and patients, regarding the value and benefits of RLT and radiation safety post-RLT administration.

High-Level Recommendations

Based on the policy gaps identified across seven focus areas and a comprehensive review of evidence, the following strategic recommendations provide actionable guidance for policymakers and other stakeholders to optimize RLT implementation while maintaining safety standards:

Governance and Policy Frameworks for RLT

- **Establish global coordination mechanisms:** Facilitate the creation of a multi-stakeholder technical task force under IAEA leadership, including European Association of Nuclear Medicine (EANM), national radiation authorities, leading radiation academic and research institutions, and oncology societies, to advance risk-based radioprotection frameworks that reflect the actual risk-benefit profiles of RLT.
- **Develop evidence-based discharge criteria:** Promote global consensus on updated discharge methodologies that incorporate individual risk assessment and balance radiation safety with patient-centered outcomes.

Example: The United Kingdom successfully transitioned to outpatient treatment for most patients based on evidence and clinical leadership (see Best Practices in Appendix 1) [24,28].

- **Integrate RLT into national cancer frameworks:** Support health ministries in recognizing RLT as integral to cancer care and establishing national RLT advisory committees for its integration into national cancer control plans (NCCPs).

Example: Belgium developed a national RLT plan through multistakeholder collaboration (see Best Practices in Appendix 1) [43].

- **Harmonize regulatory approaches:** Facilitate collaboration at the global level between multisectoral stakeholders and regulatory agencies to standardize small-scale radiopharmaceutical preparation regulations and establish suitable, evidence-based radiopharmaceutical waste management protocols.

- **Include patient voices in policy development:** Create structured mechanisms for patient advocacy group involvement in the RLT policymaking to ensure transparency, trust, and alignment with patient needs.

Health System Readiness & Capacity for RLT

- **Develop readiness assessment frameworks:** Develop systematic health system evaluation tools with data-driven capacity planning to ensure equitable access to RLT, particularly in resource-constrained settings.

- **Implement systematic capacity monitoring:** Develop and adopt systematic methodologies to assess and track imaging capacity bottlenecks over time, with data collected globally to assess progress and inform capacity planning decisions.

- **Establish minimum infrastructure standards:** Promote global consensus on basic minimum infrastructure requirements, focusing on essential elements for safe and effective RLT delivery adaptable to local resource contexts in low- and middle-income countries (LMICs).

- **Support the establishment of an international multistakeholder coalition:** that supports existing efforts and provides countries with practical guidance to scale up RLT capacity, including facility requirements, technical assistance, and referral network development.

- **Build the economic case for investment:** International Organisations and academic institutions involved in RLT should partner to develop the economic case for global investments in RLT and advocate for inclusion in the scope of multilateral development banks, bilateral aid institutions, and other international financing mechanisms.

RLT Workforce Development & Training

- **Support integration of workforce assessment into readiness frameworks:** Ensure that critical resources developed for countries to assess their RLT readiness include comprehensive healthcare workforce capacity and training evaluations to facilitate systematic assessment of workforce capacity gaps.

- **Develop comprehensive training guidance:** Ensure that international multistakeholder coalition guidance for RLT capacity scaling includes detailed healthcare workforce requirements, skill specifications, and frameworks for developing

education curricula and recurrent training opportunities.

Example: Europe's INSPIRE Program provides a proactive, system-wide approach to workforce sustainability (see Best Practices in Appendix 1) [39].

- **Support training material development:** Facilitate collaboration between international Organisations, academic institutions, and funding agencies to develop education and training materials that support countries in scaling up RLT capacity.

Radiation Safety

- **Develop comprehensive safety protocols review:** Collaborate with leading international organisations such as the Organisation for Economic Co-operation and Development (OECD), Nuclear Energy Agency (NEA) and key RLT stakeholders to develop a comprehensive review report on radiation safety protocols implemented by frontrunner countries (UK, US, Australia), including detailed analyses of lessons learned and actionable guidance for adaptation to different national contexts.

- **Create permanent coordination mechanisms:** Support the establishment of a Standing Radiation Safety Coordination Group under IAEA auspices, modeled on European Heads of Medicines Agencies or African CDC to enable structured dialogue and cooperation among national regulators and implementing agencies.

- **Create awareness-raising materials:** Promote the development of evidence dissemination materials through multistakeholder coalitions highlighting progress in the RLT field - particularly the evolving benefit-risk profile of RLTs - to strengthen stakeholder understanding and prepare for evidence-based policies.

RLT Financing, Reimbursement, & Economic Assessment

- **Support appropriate payment models:** Advocate for the development and implementation of payment models that accelerate RLT integration and favor cost-containment, through evidence-based discharge criteria.

Example: Switzerland conducted pilot projects assessing 20-hour admission feasibility and revised incentive schemes to remove systemic barriers (see Best Practices in Appendix 1) [28].

- **Establish specialized HTA frameworks:** Support development of theranostics-specific evaluation criteria capturing diagnostic and therapeutic value, healthcare system capacity gains, and patient QoL improvements within integrated evaluation frameworks.

Example: Belgium created the Technical Council for Radioisotopes as an independent evaluation body (see Best Practices in Appendix 1) [43].

- **Advocate for standardized economic data collection:** Support requirements for healthcare institutions to capture comprehensive economic outcomes, including direct costs, system capacity improvements, and patient QoL measures under different hospitalization scenarios.
- **Support patient financial impact research:** Advocate for prospective programs comparing economic outcomes between traditional extended hospitalization and evidence-based early discharge protocols across multiple healthcare systems.

RLT Evidence Generation & Data Infrastructure

- **Create global RLT research coordination mechanisms:** Advocate for the establishment of research coordination mechanisms under the leadership of the IAEA, World Health Organization, or Organisation for Economic Co-operation and Development/Nuclear Energy Agency to define global research priorities, harmonize data collection protocols, and synthesize real-world evidence and patient-reported outcomes.
- **Support the development of innovative financing for research:** Explore options to secure financing for evidence-generation through blended models leveraging: (i) international development bank allocations under health systems innovation frameworks; (ii) voluntary member state contributions for nuclear medicine capacity-building; and (iii) strategic philanthropic partnerships with global health donors (e.g., Bill & Melinda Gates Foundation, Wellcome Trust, Gavi-style consortia). Explore innovative options such as a Radiopharmaceutical Innovation Fund for multi-country implementation research.
- **Expand safety research in diverse settings:** Prioritize evidence generation across LMICs and proactively disseminate findings to support scalable protocol adoption.

Stakeholder Education & Awareness

- **Support targeted awareness campaigns:** Partner with leading patient advocacy Organisations to design RLT-focused sessions at major patient engagement events highlighting the improvements in the risk-benefit profiles of RLT.
- **Engage scientific and policy publications:** Work through multisectoral stakeholder coalitions to ensure systematic inclusion of RLT content in high-reach journals and professional

networks, raising awareness among decision-makers, payers, and healthcare professionals.

- **Promote country-specific material development:**

Co-develop tailored awareness resources with advocacy groups, clinical leaders, and communication specialists for use at national and subnational levels.

Conclusion

Radioligand therapy (RLT) faces a policy paradox: strong clinical evidence supports its safety and efficacy, yet outdated regulations and misaligned incentives continue to restrict access. Instead of evidence gaps, barriers stem from institutional inertia, excessive hospitalization requirements, and fragmented frameworks that strain health system capacity, inflate costs, and slow adoption. These inefficiencies also delay the generation of real-world data that could further strengthen the case for reform, perpetuating a cycle of limited access.

Experiences from focus countries show that policy change is possible when regulators prioritize contemporary evidence over precedent. Their approaches highlight key enablers of progress: evidence-based regulatory alignment, active clinical leadership, multi-stakeholder engagement, financial reform, and structured implementation guidance. To achieve sustainable integration, immediate priorities include forming an IAEA-led task force to modernize global radioprotection frameworks, conducting readiness assessments to address workforce and infrastructure gaps, and adopting evidence-based discharge criteria to enable shorter, safer hospital stays. Medium-term reforms should integrate RLT into NCCPs, harmonize regulatory standards, and align payment systems to support efficient and equitable delivery.

Financial Declaration

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Appendices

Appendix 1: Best Practices

Several countries have successfully navigated the complex challenges associated with RLT implementation, offering valuable lessons in policy innovation and system readiness. The following examples demonstrate how different healthcare systems have successfully implemented evidence-based RLT policies, overcoming regulatory barriers and optimizing patient care delivery. These cases provide concrete evidence that policy reform is both feasible and beneficial, offering practical models for other countries to adapt to their specific contexts.

Switzerland

Switzerland transformed its hospitalization requirements through collaborative policy reform between the Federal Office of Public Health (BAG) and the Swiss Society of Nuclear Medicine (SGNM). The previous 3-night hospitalization mandate was replaced with flexible protocols following a systematic pilot project that demonstrated safety and feasibility. New regulations implemented in 2024 eliminated the financial incentives for the minimum hospital stay of three nights and legally mandated a 2-night (48 hours) hospital stay for ¹⁷⁷Lu-therapies. A pilot study was started by BAG and SGNM to evaluate discharge after 20 hours. Implementation was supported through patient radiation protection leaflets developed by BAG and SGNM [28].

- **Key success factors:** Strong professional advocacy by SGNM and key opinion leaders, regulatory receptiveness, evidence-based pilot testing, and coordinated financial incentive reform.
- **Main Stakeholders:** Federal Office of Public Health (BAG), Swiss Society of Nuclear Medicine (SGNM), Swiss Association of Physicians (FMH), key opinion leaders, and hospitals.

United Kingdom

The United Kingdom transformed RLT delivery from inpatient to outpatient models through evidence-based protocol implementation. King's College Hospital pioneered the transition, supported by 2019 audit data demonstrating equivalent safety outcomes. Most centers now use day-case models with discharge guided by radiation thresholds (<25 µSv/h at 1m) rather than time-based requirements [28]. The transition addressed healthcare capacity pressures while improving patient experience. Today, 80% of RLT is outpatient-based, [22] demonstrating successful system-wide transformation.

- **Key Success Factors:** Clinical leadership, audit-supported evidence generation, risk-stratified protocols, and healthcare capacity optimization priorities.
- **Main Stakeholders:** National Health Service (NHS) centers, King's College Hospital, Medicines and Healthcare products Regulatory Agency (MHRA), clinical researchers, and patient groups.

United States

Federal guidance enables evidence-based outpatient protocols through clear regulatory frameworks. Nuclear Regulatory Commission (NRC) rules permit discharge when exposure limits remain below 5 mSv, typically achieved within 1-3 hours post-treatment [22,29,44]. The approach prioritizes actual radiation exposure data over historical precedents, supported by robust evidence demonstrating low dose rates following administration [22,29].

- **Key Success Factors:** Clear federal guidance, evidence-based safety thresholds, institutional implementation flexibility, and systematic safety monitoring.
- **Main Stakeholders:** Nuclear Regulatory Commission (NRC), hospital systems, medical physicists, and clinical researchers.

Italy

Legislative reform shifted from time-based to risk-based discharge criteria through comprehensive policy change [44]. The 2020 Legislative Decree 101 eliminated mandatory hospitalization except for high-dose iodine-131 therapies, implementing individual risk assessment protocols with 6-hour minimum monitoring. Discharge involves radiometric evaluation and personalized safety protocols. Nationwide guidelines ensure standardized application across facilities [45].

- **Key Success Factors:** Legislative support, evidence-based risk stratification, national professional collaboration, and systematic implementation guidance.

- **Main Stakeholders:** Italian Ministry of Health, Italian Association of Nuclear Medicine (AIMN), Italian Association of Medical Physics (AIFM), Italian Scientific Institutes for Research, Hospitalization and Healthcare (IRCCS), and radiation protection specialists.

Japan

Payment system adaptation supported evidence-based protocol transition from inpatient to hybrid care models. Initial Xofigo® administration under traditional inpatient settings evolved to outpatient therapy as clinical confidence grew. The Diagnosis Procedure Combination (DPC) system financially rewards shorter stays, aligning economic incentives with evidence-based protocols. This experience also highlighted the critical role of workforce development and infrastructure planning [24].

- **Key Success Factors:** Payment system alignment, institutional adaptation flexibility, clinical confidence building through experience.

- **Main Stakeholders:** Hospitals, payer agencies, Ministry of Health, and nuclear medicine departments.

Belgium

A dedicated reimbursement framework helped overcome financing barriers through targeted policy innovation. The Technical Council for Radioisotopes (TCRI) within national healthcare institute National Institute for Health and Disability Insurance (INAMI-RIZIV) specifically addresses RLT reimbursement challenges. Belgium became the first country in the European Union to reimburse ¹⁷⁷Lu-PSMA-617 (Pluvicto®) in April 2024, following national RLT plan development with multi-stakeholder input [43].

- **Key Success Factors:** Dedicated institutional infrastructure, early stakeholder alignment, multi-stakeholder planning processes, early reimbursement pathway establishment, and integrated capacity development support.

- **Main Stakeholders:** TCRI, RIZIV/INAMI, hospitals, oncologists, nuclear medicine physicians, radiopharmaceutical suppliers, patient organizations, and regulatory authorities.

Inspire Program (Europe)

The European Association of Nuclear Medicine (EANM) launched INSPIRE in 2024 as a comprehensive workforce development initiative addressing anticipated nuclear medicine professional shortages. The program employs a three-pillar strategy: awareness outreach to attract new professionals, hands-on educational experiences for skill development, and innovation to modernize training pathways. Implementation leverages digital engagement platforms and targeted grant schemes supporting national initiatives and student engagement programs [39].

- **Key Success Factors:** Proactive workforce planning, multi-modal educational approaches, digital platform utilization, and coordinated national implementation support.

- **Main Stakeholders:** EANM, national nuclear medicine societies, universities, student associations, patient groups, and industry partners.

Appendix 2: Key Terms and Concepts

Diagnosis-Related Group (DRG)

A patient classification system that groups hospital cases into categories based on clinical conditions and procedures that are expected to require similar hospital resources. Under DRG-based payment systems, hospitals receive a fixed payment for each patient case within a specific DRG category.

Diagnosis Procedure Combination (DPC)

A Japanese hospital payment system that combines elements of per-diem and fee-for-service reimbursement. Under DPC, hospitals receive a daily fixed payment that covers basic hospital services, with decreasing rates for longer stays, plus additional fees for specific procedures and expensive medications. This hybrid approach aims to balance cost control with appropriate compensation for resource intensive treatments.

Discharge Criteria

Specific measurable parameters, for RLT primarily radiation dose rates, that must be met before a patient can be safely released from medical supervision. These criteria typically specify maximum admissible radiation exposure levels at defined distances from the patient (e.g., ≤ 0.005 mSv/hour at 1 meter in Japan, or < 1 mSv/year at 2 meters in Germany). Discharge criteria vary significantly between countries, directly impacting hospitalization duration and healthcare system capacity needs.

Dosimetry

The scientific discipline concerned with the measurement, calculation, and assessment of ionizing radiation doses received by the human body. In RLT context, dosimetry encompasses both radiation protection dosimetry (measuring external radiation exposure to healthcare workers and the public) and therapeutic dosimetry (calculating radiation doses delivered to tumors and healthy organs).

Fixed-dose Protocol

A standardized treatment regimen where all eligible patients receive the same predetermined amount of radiopharmaceutical activity, regardless of individual characteristics such as body weight, tumor burden, or organ function.

Health Technology Assessment (HTA)

A multidisciplinary process that systematically evaluates clinical effectiveness, cost-effectiveness, and broader impact of health technologies, including medicines, medical devices, and procedures. HTA bodies analyze scientific evidence to inform coverage and reimbursement decisions, considering factors such as comparative effectiveness, budget impact, and societal values.

Multidisciplinary Team (MDT)

A collaborative group of healthcare professionals from different specialties who work together to plan and deliver comprehensive patient care. In RLT, the MDT typically includes urologists or uro-oncologists, medical or clinical oncologists, nuclear medicine physicians, radio pharmacists, medical physicists, specialized nurses, and radiation safety officers. The MDT reviews patient cases, determines treatment eligibility, coordinates care delivery, monitors treatment response, and manages adverse events, ensuring that complex treatment decisions incorporate diverse clinical perspectives.

Millisievert (mSv)

The mSv (millisievert) is a unit of ionizing radiation dose. It is a subunit of the sievert (Sv), which is the International System of Units (SI) measurement used to express the biological effect of ionizing radiation on human tissue. One millisievert is one-thousandth of a sievert ($1 \text{ mSv} = 0.001 \text{ Sv}$). The sievert measures the “effective dose” of radiation, which means it quantifies the risk of biological harm from an absorbed dose, considering both the type of radiation and the varying sensitivities of different tissues and organs in the body. The mSv is commonly used because a full sievert is a very large dose and rare outside of accidents or medical treatment; typical medical and environmental exposures are often in the range of microsieverts (μSv) or millisieverts (mSv) [46].

Post-infusion (p.i.)

The time immediately following the intravenous administration of a radioligand therapy agent. This period is critical for radiation safety considerations as the patient’s body contains the highest levels of radioactivity, with gradual elimination occurring primarily through renal excretion. Radiation exposure measurements during the post-infusion period (e.g., 4 hours p.i., 24 hours p.i.) inform discharge decisions and safety protocols.

Radioligand Therapy (RLT)

A precision cancer treatment modality that combines targeted molecular therapy with therapeutic radiation. RLT consists of three components: i) a ligand that binds target receptors and/or other biomarkers with high affinity; ii) a chelator and linker that enable the attachment of a radionuclide to the ligand, and iii) a radionuclide/radioisotope that enables the visualization or treatment of tumor

lesions. This approach enables selective irradiation of cancer cells while minimizing exposure to healthy tissues, offering therapeutic benefits for patients with advanced cancers.

Real-World Evidence (RWE)

Clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of real-world data collected outside the controlled environment of clinical trials. RWE sources include electronic health records, claims databases, patient registries, and patient-reported outcome measures. For RLT, RWE provides insights into treatment patterns, effectiveness in diverse patient populations, long-term risk-benefit profiles, and healthcare resource utilization, complementing clinical trial data and informing policy decisions.

Theranostics

An integrated approach to personalized medicine that combines diagnostic imaging and targeted therapy using the same or similar molecular targeting vectors. In this paradigm, a diagnostic radiopharmaceutical (e.g., ^{68}Ga -PSMA for PET imaging) first identifies whether a patient's tumor expresses the target of interest, followed by a therapeutic radiopharmaceutical (e.g., ^{177}Lu -PSMA) that delivers treatment to the same target.

Theranostics Infrastructure

The specialized facilities, equipment, and systems required for the safe and effective delivery of theranostic procedures. Essential components include radiation-shielded treatment rooms with dedicated ventilation systems, secure radiopharmaceutical storage areas, dose calibrators and radiation monitoring equipment, waste management systems for radioactive materials, imaging equipment (PET/CT, SPECT/CT), and information systems for scheduling and tracking. Infrastructure requirements vary based on local regulations and service delivery models (inpatient vs. outpatient).

Appendix 3: Glossary of acronyms

CT: Computed Tomography; DPC: Diagnosis Procedure Combination; DRG: Diagnosis-Related Group; EANM: European Association of Nuclear Medicine; EBRT: External Beam Radiation Therapy; EMA: European Medicines Agency; EURATOM: European Atomic Energy Community; FACT-RNT: Functional Assessment of Cancer Therapy-Radionuclide Therapy; GBq: Gigabecquerel; GEP-NETs: Gastroenteropancreatic Neuroendocrine Tumors; HTA: Health Technology Assessment; IAEA: International Atomic Energy Agency; LMICs: Low- and middle-income Countries; ^{177}Lu : Lutetium-177; mCRPC: Metastatic Castration-Resistant Prostate Cancer; MDT: Multidisciplinary Team; MDTs: Multidisciplinary Teams; MHRA: Medicines and Healthcare products Regulatory Agency; MTBs: Multidisciplinary Tumor Boards; mSv: Millisievert; mSv/h: Millisieverts Per Hour; μSv : Microsievert; NETs: Neuroendocrine Tumors; NRC: Nuclear Regulatory Commission; OECD: Organisation for Economic Co-operation and Development; PET: Positron Emission Tomography; PET/CT: Positron Emission Tomography/Computed Tomography; p.i.: post-infusion; PSA: Prostate-Specific Antigen; PSMA: Prostate-Specific Membrane Antigen; QoL: Quality of Life; RLT: Radioligand Therapy; RWD: Real-World Data; RWE: Real-World Evidence; SGNM: Swiss Society of Nuclear Medicine; SNMMI: Society of Nuclear Medicine and Molecular Imaging; SPECT-CT: Single Photon Emission Computed Tomography; Sv: Sievert; TRT: Targeted Radionuclide Therapy; WHO: World Health Organization.

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