International Journal of Research in Medical Sciences
Sanjeyan N et al. Int J Res Med Sci. 2026 Oct;14(10):4942-4951
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012
DOI: https://dx.doi.org/10.18203/2320-6012.ijrms20263578

Review Article

Theranostics: integrating molecular imaging and targeted therapy for precision medicine across oncology and beyond

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Received: 15 August 2026
Accepted: 18 August 2026

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ABSTRACT

To review the principles, mechanisms, clinical applications, safety considerations, challenges and future perspectives of theranostics. Literature from peer-reviewed journals, clinical trials and authoritative sources was reviewed. Theranostics integrates molecular imaging and targeted therapy, demonstrating significant benefits in neuroendocrine tumors, prostate cancer, lymphoma and emerging non-oncologic diseases. Theranostics represents a cornerstone of precision medicine and is expected to expand further with advances in artificial intelligence, nanotechnology and novel radiopharmaceuticals.

Keywords: Theranostics, Precision medicine, Radiotheranostics, Nanotheranostics, Phototheranostics, PET imaging

INTRODUCTION

Theranostics represents a transformative paradigm in modern biomedical science, integrating diagnostics and therapy into a unified, patient-specific framework. By combining the ability to visualize disease markers with the capability to deliver targeted interventions to those same molecular sites, theranostics advances the core mission of precision medicine-delivering the right treatment to the right patient at the right time. The conceptual foundation of theranostics originates from early nuclear medicine approaches that used paired diagnostic and therapeutic radioisotopes. However, over the last two decades, improvements in molecular imaging, nanotechnology, and photomedicine have expanded the concept into a broad and sophisticated scientific field with diverse applications in oncology, neurology, cardiology, and regenerative medicine. Today, three major technological branches-radiotheranostics, nanotheranostics, and phototheranostics-collectively support the rapid growth of image-guided, personalized treatment strategies.

In clinical practice, theranostics has become especially prominent in oncology, where tumor heterogeneity poses challenges to traditional therapeutic strategies. Many tumors differ significantly in receptor expression, vascular characteristics, metabolic pathways, and immune profiles. Theranostic imaging enables clinicians to visualize these differences before initiating therapy, ensuring that only patients with adequate target expression and favorable biodistribution receive specific targeted therapies—a process often referred to as "image-based patient selection" or "molecular profiling through imaging".[1] This markedly reduces unnecessary toxicity and resource utilization when compared to non-targeted systemic treatments.

The following sections provide an integrated overview of radiotheranostics, nanotheranostics, and phototheranostics, focusing on mechanistic principles,

technological evolution, and clinical relevance-without discussing individual approved agents or commercial formulations.

Radiotheranostics is the most established branch of theranostics and is built on the pairing of diagnostic and therapeutic radionuclides that bind to the same molecular target. The diagnostic radionuclide, typically a positron- or gamma-emitting isotope, is used to image the distribution of the ligand-target interaction, determine the extent of disease, and assess therapeutic suitability. The therapeutic isotope, often an alpha- or beta-emitter, delivers cytotoxic radiation precisely to the targeted tissues. Because both imaging and therapy rely on the same biologically active vector—such as a peptide, small molecule, or antibody-the biodistribution and pharmacokinetics are consistent across diagnostic and therapeutic phases. This ensures predictable organ dosimetry, enhanced safety, and reliable treatment planning.[2,3,4]

A notable frontier in radiotheranostics is the development of alpha-particle emitters. Alpha radiation exhibits high linear energy transfer (LET) and short tissue penetration, allowing extremely potent tumor cell kill with minimal collateral damage. This property makes alpha emitters especially suitable for micrometastatic disease and radioresistant tumors. While challenges such as radionuclide availability and recoil chemistry persist, alpha therapy remains a major research focus.[5] Overall, radiotheranostics provides a mature and clinically proven framework that continues to evolve with improved targeting, higher-resolution imaging, and next-generation radionuclide chemistry.

Nanotheranostics integrates therapeutic and imaging modalities within engineered nanoscale platforms, typically ranging from 1-200 nm. These nanosystems may incorporate chemotherapy agents, nucleic acids, immunomodulators, photosensitizers, or thermal agents. At the same time, they can be labeled or constructed from materials that enable imaging via MRI, PET, SPECT, optical imaging, or photoacoustics. The ability to co-deliver therapeutic and imaging components within a single structure makes nanotheranostics highly versatile.

The most important conceptual advantage of nanotheranostics is the capacity for multifunctionality. Nanoparticles can be synthesized to include multiple therapeutic cargos, multi-modal imaging probes, surface ligands for active targeting, and physicochemical properties that enable controlled release. This modularity enables the design of platforms that respond to specific microenvironmental stimuli such as pH, enzyme activity, redox conditions, or hypoxia. By exploiting these stimuli, nanotheranostic systems can release therapeutic payloads selectively within diseased tissue while minimizing systemic exposure.[6] Tumor targeting in nanotheranostics can be mediated by both passive and activemechanisms. Passive targeting relies on the enhanced permeability and retention (EPR) effect, which enables nanoparticles to accumulate in tumors due to leaky vasculature and poor lymphatic drainage. Although the EPR effect has been widely utilized, it is increasingly understood that its magnitude varies across tumor types, stages, and patient-specific physiology. Consequently, active targeting strategies are being developed to improve specificity. These approaches include conjugating nanoparticles with antibodies, peptides, aptamers, or small molecules that bind selectively to tumor receptors or microenvironmental markers.[7,8]

Material innovations continue to push nanotheranostics forward. For example, iron oxide nanoparticles enable MRI-based monitoring, gold nanoparticles support optical and thermal imaging, and carbon-based nanostructures provide high loading capacity for both imaging and therapeutic components. Nanoparticle-mediated combination therapy-such as chemo-photothermal, chemo-gene, or dual-PDT/PTT systems-offers synergistic pathways to overcome drug resistance and tumor heterogeneity.[9]

Phototheranostics brings together light-based diagnostic imaging and targeted therapy using photoresponsive agents that can be activated by specific wavelengths, most commonly in the near-infrared (NIR) region. Two primary therapeutic mechanisms dominate this field: photodynamic therapy (PDT) and photothermal therapy (PTT). These can be combined with imaging modalities such as fluorescence imaging, optical coherence tomography, and photoacoustic imaging.[10]

PTT involves agents that convert absorbed light energy into heat, resulting in localized hyperthermia that selectively damages targeted tissue. Nanostructures with strong NIR absorption-such as gold nanostructures, semiconducting polymers, or carbon-based materials-are commonly used as PTT mediators. Imaging guidance, particularly through fluorescence or photoacoustic imaging, ensures that thermal treatment is applied only when adequate nanoparticle concentration is achieved, minimizing injury to surrounding tissue.[11]

An important advantage of phototheranostics is its ability to provide spatial and temporal precision. The therapeutic effect is localized to the illuminated area, allowing millimeter-scale control of tissue destruction. This precision is ideal for surface and near-surface malignancies, including skin, head and neck, gynecological, and gastrointestinal tumors. Fluorescence-guided surgery combined with intraoperative phototherapy has shown promise in enhancing surgical margin visualization and reducing residual disease.[12]

PRINCIPLE OF THERANOSTICS

Theranostics operates on the principle of integrating diagnostics and therapy into a unified, patient-centered approach, enabling highly personalized medicine by

matching diagnostic and therapeutic agents to the unique molecular profile of each patient. This approach ensures that therapies are tailored to the specific characteristics of the disease, maximizing efficacy while minimizing side effects. Theranostic agents are designed to target specific molecular markers, allowing for precise localization of disease sites, real-time monitoring of treatment response, and dynamic adjustment of therapy based on imaging data. The multidisciplinary nature of theranostics involves collaboration among various specialists-such as nuclear medicine physicians, oncologists, radiopharmaceutical scientists, and medical physicists-to optimize patient care, ensure regulatory compliance, and provide continuous education and monitoring throughout the treatment process. By combining advanced imaging with targeted therapy, theranostics revolutionizes precision medicine, offering improved outcomes through individualized, evidence-based treatment protocols.[13,14]

MECHANISM OF THERANOSTICS

The mechanism of theranostics is a stepwise, highly targeted process that integrates molecular imaging and therapy for precision medicine. The process begins with the selection of a disease-specific biomarker-such as a receptor or protein that is overexpressed in cancer or other diseases. A radiopharmaceutical agent is then designed, combining a targeting molecule (like a peptide or antibody) with a radionuclide. In the diagnostic phase, a radionuclide suitable for imaging (such as gallium-68 or fluorine-18) is attached to the targeting agent and administered to the patient. The agent binds to the target cells, and advanced imaging techniques like PET or SPECT scans are used to visualize the location and extent of the disease.

If the imaging confirms the presence of the target, the patient proceeds to the therapeutic phase. Here, a different radionuclide with therapeutic properties (such as lutetium-177 or iodine-131) is attached to the same targeting agent. This therapeutic agent delivers targeted radiation directly to the diseased cells, maximizing destruction of abnormal tissue while sparing healthy cells. The entire process is monitored in real time, allowing clinicians to assess treatment response and adjust dosing or strategy as needed, ensuring optimal outcomes and minimizing side effects.[15]

This dual approach enables highly individualized treatment, as each patient's therapy is based on their specific molecular profile and imaging results. Theranostics is particularly effective in cancers like neuroendocrine tumors and prostate cancer, but its applications are expanding to other diseases such as neurodegenerative disorders and cardiovascular conditions. By combining diagnostics and therapy into a single, coordinated strategy, theranostics represents a major advancement in precision medicine.[16]

RADIATION TYPES IN THERANOSTICS

β-particle emission

β-particle emission is the most widely used type of radiation in theranostics due to the high availability of suitable radionuclides. These particles are negatively charged and have a low linear energy transfer (LET), which means they deposit energy over a longer range (2-12 mm, or 20-120 cell lengths). This longer travel distance enables a "crossfire" effect, where both targeted and adjacent tumor cells are irradiated, making β-emitters particularly effective for treating larger tumor masses. Common examples include lutetium-177 (^{177}Lu), iodine-131 (^{131}I), and yttrium-90 (^{90}Y). The biological effect of β-particles is primarily through the generation of reactive oxygen species, which cause DNA single-strand breaks. However, their efficacy may be reduced in hypoxic (low oxygen) tumor environments because the repair mechanisms are oxygen-dependent.[17]

α-particle emission

α-particle emission involves positively charged particles that are much larger and heavier than β particles. These particles have a very high LET (~80 keV/μm) and travel only a short distance (50-100 μm, or one to three cell lengths). The high LET results in irreparable double-strand DNA breaks, making α-emitters more cytotoxic and especially effective for small tumors and micrometastases. α-particles are oxygen-independent, so they remain effective even in hypoxic tumor microenvironments. Examples of α-emitters used in theranostics include actinium-225 (^{225}Ac) and radium-223 (^{223}Ra). The biological effects include stronger immune responses (abscopal effect) and greater ionization, which minimize collateral damage to healthy tissues.[18]

IMAGING TECHNIQUES USED IN THERANOSTICS

Positron emission tomography

Positron emission tomography (PET) is a highly sensitive nuclear imaging technique that uses positron-emitting radiotracers such as fluorine-18 (^{18}F) or gallium-68 (^{68}Ga) to visualize metabolic and molecular activity in tissues. In theranostics, PET scans are performed to detect the presence and distribution of disease-specific targets, such as overexpressed receptors on cancer cells. The images help clinicians select suitable patients for targeted therapy and monitor the effectiveness of treatment by assessing changes in tracer uptake over time. PET is especially valuable for cancers like neuroendocrine tumors and prostate cancer, where specific molecular markers are targeted for both diagnosis and therapy.[19]

Single-photon emission computed tomography

Single-photon emission computed tomography (SPECT) employs gamma-emitting radiotracers, most commonly technetium-99m (^{99}mTc), to create three-dimensional images of organ function and disease. In theranostics, SPECT is used to assess blood flow, organ function, and the presence of disease, especially in cardiac, neurological, and oncological applications. The functional data from SPECT helps in diagnosis, therapy planning, and monitoring the response to targeted treatments. SPECT is often paired with anatomical imaging (such as CT) to provide more precise localization of disease.[20]

Magnetic resonance imaging

Magnetic resonance imaging (MRI) provides high-resolution anatomical images by detecting signals from hydrogen nuclei in the body's tissues. In theranostics, MRI is frequently combined with nanoparticle-based contrast agents that enhance the visualization of tumors and other pathological changes. This approach is particularly useful for assessing the size, location, and extent of tumors, as well as for monitoring treatment response. MRI is non-ionizing and offers excellent soft tissue contrast, making it ideal for repeated imaging and for guiding interventions in theranostics.[21]

Optical imaging (fluorescence and bioluminescence)

Optical imaging techniques, including fluorescence and bioluminescence, use light-emitting agents to track biological processes in real time. In theranostics, these methods are used to visualize drug distribution, tumor progression, and surgical margins. Fluorescence imaging is often employed during surgery to guide tumor resection, while bioluminescence is used in preclinical research to study disease mechanisms and therapeutic efficacy. These techniques are especially valuable for their high sensitivity and real-time capabilities, though their depth of penetration is limited compared to other modalities.

Multimodal imaging (PET-MRI, PET-CT)

Multimodal imaging integrates the strengths of different imaging techniques, such as PET-MRI and PET-CT, to provide both functional and anatomical information in a single scan. PET-MRI combines the metabolic insights of PET with the superior soft tissue contrast of MRI, while PET-CT merges PET's molecular data with CT's anatomical detail. These hybrid approaches are essential in theranostics for precise lesion characterization, accurate staging of disease, and monitoring of treatment response. Multimodal imaging enables clinicians to tailor therapies to individual patients and improve outcomes through comprehensive diagnostic information.[22]

CLINICAL APPLICATIONS IN ONCOLOGY

Malignant pheochromocytoma and paraganglioma

Malignant pheochromocytoma and paraganglioma are rare neuroendocrine tumors characterized by overexpression of the norepinephrine transporter (NET), which enables selective uptake of metaiodobenzylguanidine (MIBG) radiopharmaceuticals. For diagnostic imaging, I-123 MIBG is used due to its favorable gamma emission and low radiation burden, providing high sensitivity (82-88%) and specificity (70-84%) for detecting both primary and metastatic lesions, making it a cornerstone for staging and patient selection for targeted therapy. I-123 MIBG scintigraphy is especially valuable for assessing the extent of disease and guiding further management decisions.

For therapeutic intervention, I-131 MIBG is administered to deliver targeted beta radiation to tumor cells expressing NET. High-specific-activity I-131 MIBG has demonstrated efficacy in controlling disease progression in patients with metastatic or unresectablepheochromocytoma and paraganglioma, with multicenter trials confirming its safety and benefit in improving survival and symptom control, especially in advanced cases. The theranostic approach, using I-123 MIBG for diagnosis and I-131 MIBG for therapy, allows for personalized treatment planning and monitoring, highlighting the integration of imaging and targeted radionuclide therapy in the management of these challenging tumors.[23]

Neuroendocrine tumors

Neuroendocrine tumors (NETs) are a heterogeneous group of neoplasms that arise from neuroendocrine cells distributed throughout the body, most commonly in the gastrointestinal tract and pancreas, but also in the lungs and other organs. These tumors can be functional (producing hormones causing clinical syndromes) or non-functional, and they range from indolent to highly aggressive, with variable clinical presentations and prognoses.

For NETs, theranostics is a cornerstone approach, leveraging the overexpression of somatostatin receptors (SSTR) on tumor cells. This allows for both precise imaging and targeted therapy using radiolabeled somatostatin analogs. Ga-68 DOTATE and Ga-68 DOTATOC PET/CT are now the preferred diagnostic tools for detecting, staging, and selecting patients for therapy due to their superior sensitivity and specificity compared to older agents like In-111 Pentetreotide. For treatment, Lu-177 DOTATATE and Lu-177 DOTATOC are the primary agents for peptide receptor radionuclide therapy (PRRT), demonstrating significant efficacy in controlling disease progression and improving survival in advanced NETs. Y-90 DOTATATE and Y-90 DOTATOC are also used, especially for larger or more

aggressive tumors, due to their longer beta-particle range, and combination therapy has shown synergistic benefits in some studies.[24]

B-cell non-Hodgkin malignant lymphoma

B-cell non-Hodgkin malignant lymphoma (NHL) is a type of hematologic malignancy characterized by abnormal proliferation of B-lymphocytes. These tumors often express the CD20 antigen, which serves as a key target for theranostic approaches using radiolabeled monoclonal antibodies.

In-111 IbritumomabTiuxetan is used for diagnostic imaging, allowing visualization of CD20-positive lymphoma lesions and helping to select patients for targeted radioimmunotherapy. Pre-therapy imaging with In-111 IbritumomabTiuxetan is performed to confirm tumor targeting and assess biodistribution before administering therapeutic doses. Y-90 IbritumomabTiuxetan is approved for the treatment of relapsed or refractory CD20-positive follicular B-cell NHL. It delivers targeted beta radiation to lymphoma cells, resulting in high response rates and improved progression-free survival, particularly in indolent lymphomas. I-131 rituximab and Lu-177 rituximab are also under investigation as alternative therapeutic options, with Lu-177 rituximab showing promise in preclinical and early clinical studies for relapsed/refractory B-cell NHL due to its favorable radiation profile and targeted delivery.[25]

Bone metastasis

Bone metastasis refers to the spread of cancer cells to the bone, often resulting in increased bone turnover and pain. Detection and management of bone metastases rely on theranostic approaches that combine diagnostic imaging and targeted radionuclide therapy. Tc-99m bone scan (using Tc-99m MDP or similar bisphosphonates) is the standard diagnostic tool for detecting bone metastases. It identifies areas of increased osteoblastic activity, which are characteristic of bone metastases, and has higher diagnostic performance than conventional imaging methods, often changing patient management plans.

Sr-89 is a beta-emitting radionuclide used for palliative therapy in bone metastases. It is concentrated in bone areas with high turnover, delivering targeted radiation to metastatic lesions and providing significant pain relief with a favorable safety profile. Sm-153 EDTMP is another beta-emitting agent used for pain palliation in bone metastases, especially in prostate and breast cancers, and is well-tolerated with effective pain relief. Ra-223 is an alpha-emitting radiopharmaceutical approved for metastatic castration-resistant prostate cancer with bone metastases. It delivers high linear energy transfer radiation to bone lesions, prolonging survival and improving quality of life, with a distinct mechanism and safety profile compared to beta-emitters.

These agents enable a theranostic approach for bone metastasis, where diagnostic imaging with Tc-99m bone scan guides therapy selection, and targeted radionuclide therapy with Sr-89, Sm-153 EDTMP, or Ra-223 provides palliation and disease control.[26]

Castration-resistant prostate cancer

Castration-resistant prostate cancer (CRPC) is an advanced stage of prostate cancer that no longer responds to standard hormone therapy. Prostate-specific membrane antigen (PSMA) is highly expressed in CRPC cells, making it an ideal target for theranostic approaches. Ga-68 PSMA and F-18 PSMA PET/CT are the primary imaging modalities for detecting CRPC lesions. Ga-68 PSMA PET/CT is particularly sensitive, capable of identifying metastatic disease even at very low PSA levels, and is highly effective for restaging and monitoring treatment response in CRPC patients. F-18 PSMA PET/CT offers similar diagnostic accuracy and is increasingly used in clinical practice for its favorable imaging characteristics.

Lu-177 PSMA radioligand therapy (RLT) is FDA-approved for PSMA-positive metastatic CRPC, delivering targeted beta radiation to tumor cells and resulting in significant PSA response rates and improved progression-free survival. Ac-225 PSMA RLT is an emerging alpha-emitter therapy, showing high efficacy in heavily pretreated CRPC patients with substantial antitumor effects and manageable toxicity, including xerostomia and mild hematologic side effects. Both Lu-177 and Ac-225 PSMA therapies are transforming the management of advanced CRPC by offering targeted, personalized treatment options with improved outcomes. These theranostic strategies enable precise patient selection, effective disease monitoring, and targeted therapy, significantly advancing the care of patients with castration-resistant prostate cancer.[27]

NON-ONCOLOGIC AND EMERGING APPLICATIONS OF THERANOSTICS

Theranostics is rapidly expanding its reach beyond traditional oncology applications, demonstrating significant potential in the diagnosis and treatment of a wide range of non-oncologic diseases. This innovative approach is transforming patient management in cardiovascular, neurological, autoimmune, and inflammatory conditions by integrating advanced imaging with targeted therapies.

Cardiovascular diseases

In cardiovascular medicine, theranostic strategies are being used to address conditions such as atherosclerosis, cardiac amyloidosis, and myocardial inflammation. Molecular imaging techniques like PET and MRI allow clinicians to visualize molecular changes in the heart, facilitating early detection and precise diagnosis. By

combining imaging findings with targeted therapies, these approaches enable more effective monitoring and personalized treatment plans, ultimately improving patient outcomes.

Neurological disorders

Theranostics is making strides in the field of neurology, offering new hope for patients with neurodegenerative diseases such as Alzheimer's disease, Parkinson's disease, and multiple sclerosis. Advanced imaging modalities provide detailed views of neuroanatomy and functional connectivity, allowing for early detection and precise diagnosis. Targeted therapeutic interventions, guided by these imaging findings, are being developed to address the underlying molecular changes in the brain, paving the way for more effective and personalized treatments.

Autoimmune and inflammatory diseases

Theranostic approaches are also being applied to autoimmune and inflammatory diseases, including rheumatoid arthritis, sarcoidosis, and inflammatory bowel disease. Radioligand therapies and targeted imaging agents are used to diagnose and treat these conditions, improving the precision and efficacy of interventions. For example, anti-TNF-alpha therapy, when combined with molecular imaging, allows for the monitoring and optimization of treatment in rheumatoid arthritis, leading to better patient outcomes.

Other emerging applications

Beyond these areas, theranostics is being explored for infections such as osteomyelitis and other inflammatory conditions. The use of radiopharmaceuticals and targeted therapies is enabling more accurate diagnosis and effective treatment of these diseases, highlighting the versatility and potential of theranostic approaches in non-oncologic settings.[28,29,30]

SAFETY CONSIDERATIONS IN THERANOSTICS

Theranostic agents require careful assessment of safety, pharmacokinetics, and dosimetry to optimize their therapeutic index and minimize adverse effects. Key considerations include ADME (absorption, distribution, metabolism, and excretion), off-target effects, organ toxicity, and radiation safety issues. Patient-specific dosimetry is critical for tailoring therapeutic doses to maximize efficacy while minimizing risks to healthy tissues.

Safety, pharmacokinetics, and dosimetry

Theranostic agents are rigorously evaluated for safety through preclinical and clinical studies, focusing on biodistribution, toxicity, and pharmacokinetics. Regulatory agencies such as the FDA require comprehensive imaging and therapeutic validation, toxicity profiling, and pharmacokinetic/pharmacodynamic (PK/PD) studies to ensure agents are safe for human use. These evaluations help identify potential cytotoxicity, immunogenicity, and long-term safety risks. Efficient clearance and biocompatibility are essential to minimize systemic toxicity and ensure that agents do not accumulate in off-target organs.[31]

ADME and off-target effects

ADME studies are crucial for understanding how theranostic agents are absorbed, distributed, metabolized, and excreted. These agents are designed for targeted delivery to minimize off-target effects, but some may still accumulate in healthy tissues, leading to organ toxicity. For example, renal and bone marrow toxicity are common concerns with radiopharmaceuticals. Off-target deposition can result in prolonged retention and increased radiation exposure, necessitating careful selection and optimization of agents to reduce these risks.[32]

Organ toxicity and radiation safety

Radiation safety is a major concern in theranostics due to the use of ionizing radiation. Organ toxicity, particularly in the kidneys and bone marrow, is closely monitored. Dosimetry calculations are used to estimate the absorbed dose to critical organs and ensure that therapeutic activities remain within safe limits. Patient-specific dosimetry allows for personalized dose optimization, which can improve therapeutic outcomes and reduce the risk of adverse effects.

Patient-specific dosimetry and optimization

Patient-specific dosimetry involves calculating the absorbed dose to tumors and critical organs based on individual imaging data. This approach allows for the optimization of therapeutic activities, ensuring that patients receive the most effective dose while minimizing toxicity. Recent clinical trials have demonstrated improved safety and efficacy when patient-specific dosimetry is used, highlighting its importance in the clinical application of theranostic agents.[33]

REGULATORY, MANUFACTURING AND ECONOMIC CONSIDERATIONS OF THERANOSTICS

Theranostics is not only a scientific and clinical advancement but also faces significant regulatory, manufacturing, and economic challenges that must be addressed for its successful implementation and global adoption.

Manufacturing challenges

Manufacturing theranostic agents requires specialized facilities such as cyclotrons and research reactors, as well

as skilled personnel. The production capacity for key radionuclides like technetium-99 m and lutetium-177 must keep pace with the growing demand, but supply chain issues and the high cost of infrastructure can limit availability. Ensuring consistent quality and safety during production involves rigorous process validation, equipment certification, and ongoing staff training. These requirements add to the complexity and cost of manufacturing theranostic agents.

Economic considerations

The economic landscape of theranostics is shaped by substantial upfront investments in technology, infrastructure, and staff training. The cost of licensing, maintaining specialized facilities, and managing radioactive waste further adds to the financial burden. Reimbursement systems for theranostic treatments are often complex, requiring simultaneous approval for both diagnostic and therapeutic components. However, successful implementation of theranostics can lead to long-term cost savings by improving treatment efficiency and reducing ineffective therapies. This makes theranostics a potentially cost-effective approach in the long term, despite the initial high costs.[34,35]

CHALLENGES AND LIMITATIONS

Theranostics faces several challenges and limitations that impact its widespread adoption and effectiveness in clinical practice. Key issues include complex dosimetry requirements, infrastructure and resource limitations, regulatory hurdles, workforce shortages, and the need for multidisciplinary collaboration.

Dosimetry and technical challenges

Accurate dosimetry in theranostics is time-consuming and difficult, and the value of patient-specific dosimetry in optimizing therapeutic activity remains uncertain. Differences in radiobiological effects and biodistribution between radionuclides complicate dose estimation and extrapolation from external beam radiotherapy. The short half-life of diagnostic radionuclides means that biodistribution data may not fully reflect long-term therapeutic effects, limiting the precision of treatment planning.[36]

Infrastructure and resource limitations

Theranostic services require specialized infrastructure, such as PET/CT scanners, cyclotrons, and dedicated isolation rooms, which are costly and not widely available, especially in developing countries. Maintenance of equipment and availability of radiopharmaceuticals are additional barriers. The scarcity of trained professionals and high staffing costs further limit access to theranostic care, particularly in low- and middle-income countries.[37]

Regulatory and economic barriers

Regulatory approval and reimbursement for theranostic agents can be slow and inconsistent, hindering their adoption. High costs for licensing, infrastructure, and staff training make it difficult for many centers to establish and sustain theranostic programs. Insurance coverage and reimbursement issues also restrict patient access to these advanced treatments.[38]

Workforce and multidisciplinary collaboration

There is a global shortage of professionals trained in theranostics, and a lack of collaboration between medical specialties can lead to confusion and suboptimal patient management. Effective theranostic practice requires multidisciplinary teams, but communication gaps and limited participation in tumor boards or clinical meetings can impede optimal care.[39]

Off-target effects and safety concerns

Theranostic agents may accumulate in off-target organs, leading to organ toxicity and adverse effects. Careful selection and optimization of agents are necessary to minimize these risks. Radiation safety is also a major concern, requiring strict protocols for staff and patient protection.[40]

FUTURE OF THERANOSTICS

The future of theranostics is marked by rapid advancements in imaging technology, radiopharmaceutical development, artificial intelligence, and personalized medicine. These innovations promise to revolutionize the diagnosis and treatment of cancer and other diseases, offering greater precision and improved patient outcomes.

Expanding therapeutic targets

Theranostics is moving beyond traditional oncology applications to target a broader range of diseases, including autoimmune, cardiovascular, and neurological conditions. The development of new radiopharmaceuticals and targeted agents will allow for more specific and effective treatments across multiple therapeutic domains.[41]

Artificial intelligence and radiomics

The integration of artificial intelligence (AI) and radiomics is expected to enhance diagnostic accuracy and treatment planning. AI-powered algorithms can analyze large datasets from imaging and clinical records, enabling the prediction of disease progression and treatment response. Radiomics provides quantitative imaging biomarkers, supporting personalized medicine and patient stratification.[42]

Multimodal imaging and nanotechnology

Future theranostic platforms will feature multimodal imaging capabilities, combining PET, SPECT, MRI, and optical imaging for comprehensive disease assessment. The advent of nanotechnology will enable the design of multifunctional nanoparticles that can deliver both imaging and therapeutic payloads with remarkable precision.[43]

Clinical trials and regulatory evolution

Ongoing and future clinical trials will explore expanded indications for existing theranostic agents and develop new ones. Regulatory frameworks are evolving to address the unique challenges of theranostics, ensuring patient safety and efficacy while facilitating rapid translation into clinical practice.

Accessibility and affordability

Efforts are underway to make theranostic technologies more accessible and affordable, especially in low- and middle-income countries. Portable and cost-effective imaging devices, along with telemedicine and AI-powered diagnostic tools, are being developed to bring advanced theranostic care to underserved populations.44

CONCLUSION

Theranostics stands at the forefront of a new era in medicine, fundamentally changing how diseases are diagnosed and treated by combining advanced imaging with targeted therapy. This approach allows for highly personalized care, as treatments are matched to the unique molecular characteristics of each patient's disease, ensuring greater precision and effectiveness. The integration of cutting-edge imaging modalities—such as PET, SPECT, MRI, and optical imaging—enables clinicians to visualize disease processes in real time, monitor treatment response, and adjust therapeutic strategies as needed.

Patient-specific dosimetry is a cornerstone of theranostics, allowing for the optimization of therapeutic doses to maximize efficacy while minimizing risks to healthy tissues. However, challenges remain, including the complexity of dosimetry calculations, limited availability of specialized infrastructure, regulatory hurdles, and the need for multidisciplinary collaboration. Despite these obstacles, continuous advancements in radiopharmaceuticals, nanotechnology, and artificial intelligence are driving the field forward. These innovations promise to enhance diagnostic accuracy, expand therapeutic options, and make theranostic care more accessible and affordable, particularly in underserved regions.

Looking ahead, theranostics is expected to play a pivotal role in the evolution of precision medicine. The development of new agents, expanded clinical applications, and the integration of AI and multimodal imaging will further refine and broaden the impact of theranostic approaches. As these technologies mature and become more widely available, theranostics will continue to revolutionize patient care, offering improved outcomes and a higher quality of life for individuals worldwide.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: Not required

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Cite this article as: Sanjeyan N, Yuvaraj C, Naveen kumar S, Balakrishnan S, Suban M. Theranostics: integrating molecular imaging and targeted therapy for precision medicine across oncology and beyond.. Int J Res Med Sci 2026;14:4942-51.