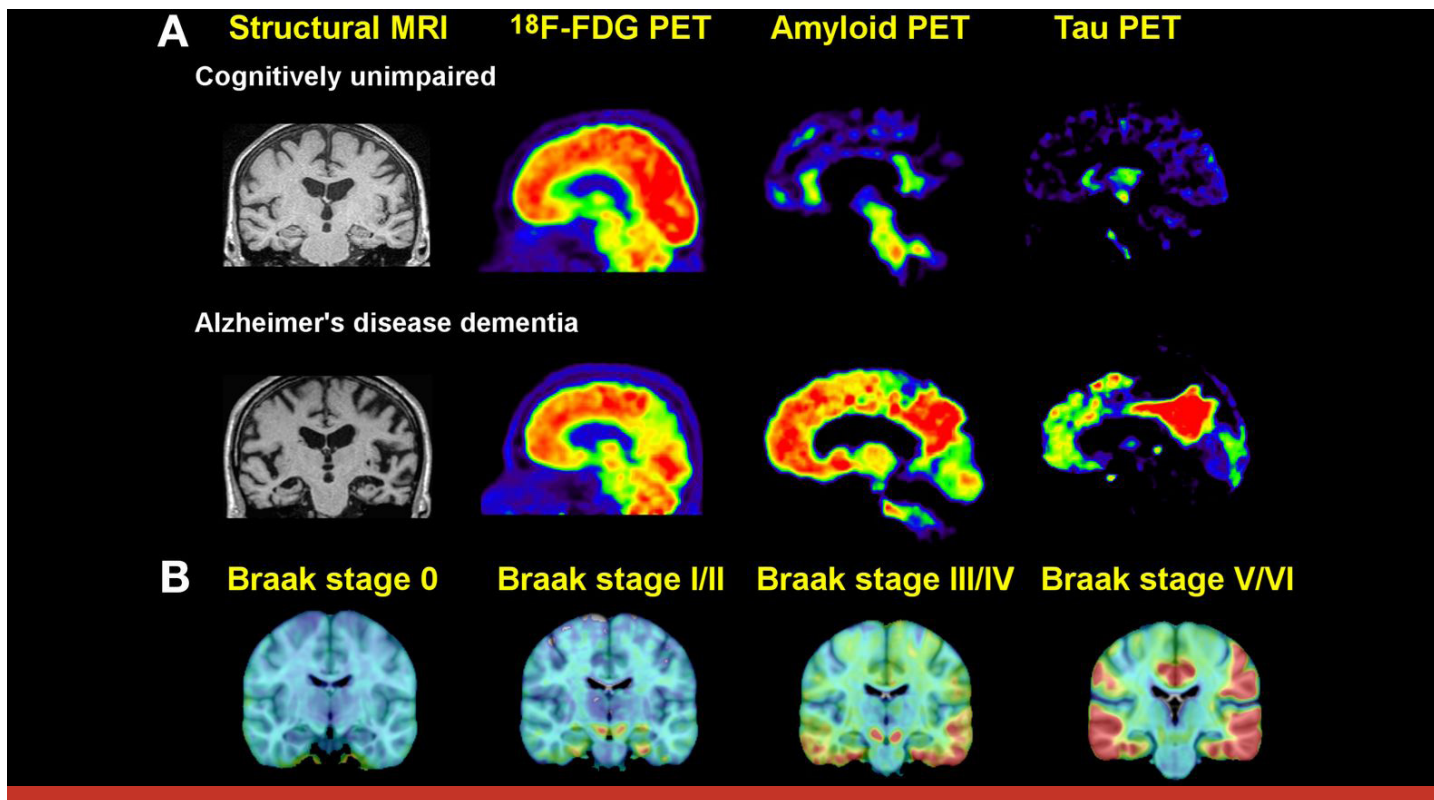


VALUE INITIATIVE



Advancing Nuclear Medicine: Key Developments in Radiopharmaceuticals and Alzheimer's Diagnostics

Satoshi Minoshima, MD, PhD, FSNMMI - Chair in the Department of Radiology and Imaging Sciences at the University of Utah; Former President of the SNMMI and Founder and Chair of the SNMMI Value Initiative Industry Alliance

As the founder of the SNMMI Value Initiative, I'm excited to share some significant updates that are reshaping our field. Two major developments stand out: the recent breakthroughs in Alzheimer's disease diagnostics and treatments and CMS issued an initial ruling to unbundle diagnostic radiopharmaceuticals. These changes not only impact our industry but also promise to improve patient care in profound ways.

Progress in Alzheimer's Diagnostics and Treatments

We're seeing exciting advancements in the fight against Alzheimer's disease, thanks in large part to nuclear medicine. Over the past few years, we've witnessed the FDA approval of new PET tracers that allow us to image amyloid plaques and tau tangles in the brain—key indicators of Alzheimer's. These tools have revolutionized how we diagnose disease, making it possible to identify it earlier and more accurately.

But progress doesn't stop there. The development of new treatments, particularly disease-modifying therapies like anti-amyloid antibodies, is offering new hope for patients. Nuclear medicine is playing a crucial role here both in

research and clinical applications. PET imaging provides a non-invasive way to detect abnormal protein depositions in the brain, help diagnose patients who likely benefit from treatments, and monitor how these treatments are working over time.

The combination of improved diagnostics and emerging therapies is changing the landscape of Alzheimer's care. We're moving toward a future where we can not only detect the disease earlier but also potentially alter its course, giving patients and their families more options and hope than ever before.

Unbundling Radiopharmaceuticals: A Game-Changer

For years, the nuclear medicine community has been pushing for CMS to unbundle radiopharmaceuticals from the Ambulatory Payment Classification (APC) system. On July 10, 2024, the Centers for Medicare & Medicaid Services (CMS) proposed Medicare payment rates for hospital outpatient and Ambulatory Surgical Center (ASC) services. The Calendar Year (CY) 2025 Hospital Outpatient Prospective Payment

Continued on page 9. See [Advancing Nuclear Medicine](#).

Crystal Clear: Unlocking the Ideal Imaging Length for Whole-Body PET/CT

Joshua Wiley, CNMT, PET

An article by United Imaging, an SNMMI Value Initiative Industry Alliance Leadership Circle Partner

Total-body PET/CT which covers the entire patient body in one bed position, such as the uEXPLORER®, represented a significant advancement in imaging technology, addressing many clinical and research needs while also presenting new challenges. However, the adoption of this technology is not without obstacles. The cost of these systems is higher due to the amount of crystal required for their construction. There are also practical considerations related to the physical size of the scanner which can fit in most but not all PET/CT suites. Therefore, United Imaging considered clinical needs, technical specifications, room sizing, and cost in developing a whole-body system.

When considering the necessary specifications for whole-body PET/CT systems, capable of scanning from head to mid-thigh in a single bed position, it is necessary to have a look at the average heights of the adult population. The median heights—178.4 cm for males and 164.7 cm for females¹—indicate that a significant portion of the patient population may not be fully covered in a single scan with a scan range of half a total-body system (100 cm). (Figure 1) This is especially true as you consider that sensitivity drops off at the edge of the field of view over the head and pelvic regions. This limitation can lead to the need for multiple scanning passes, which introduces potential for registration errors and increases overall scan time. The uMI Panorama™ GS addresses this issue effectively with its long axial field of view of 148 cm, allowing for coverage from the vertex to the mid-thigh in most individuals.

For total-body and whole-body PET systems, technical challenges need to be overcome to address parallax, scatter, randoms to have detector efficiency across a larger axial field of view (AFOV) and manage the substantial data they generate.

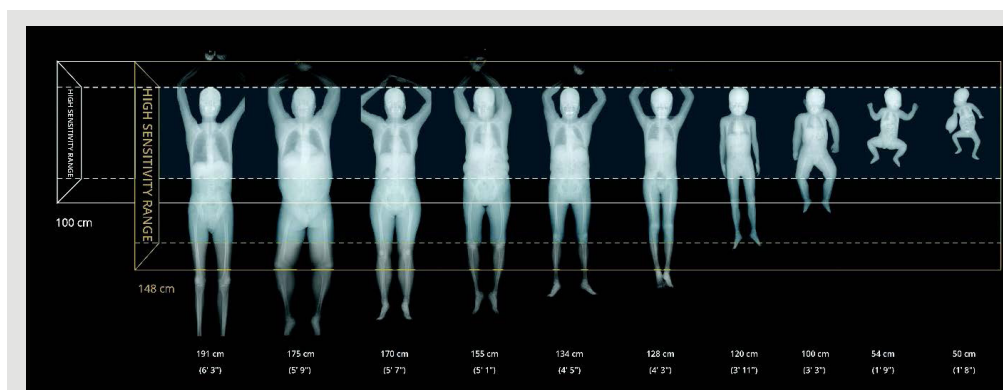


Figure 1. Patient sizes with high sensitivity range of half a total-body system 100 cm and a 148 cm system.

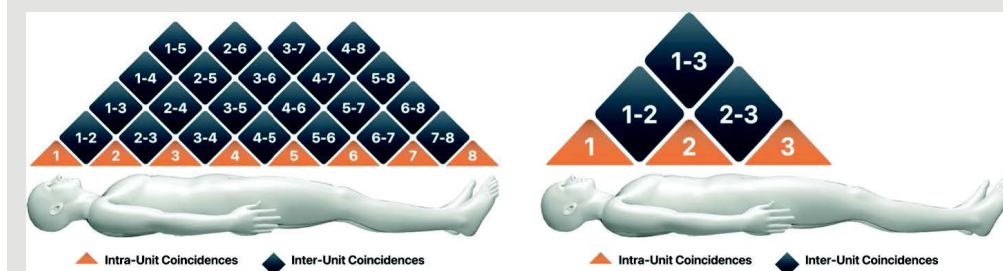


Figure 2. Relationship of inter-unit coincidences and intra-unit coincidences for total-body 194 cm and whole-body PET 148 cm systems.

Additionally, utilizing high angle line of responses which would degrade the PET image; at the same time, we need to collect as many events as possible to increase the sensitivity of the system. For the 194 cm system uEXPLORER, this was managed utilizing the line of response from every 5 inter-unit coincidences of detectors. For the 148 cm uMI Panorama GS we utilize a new uExcel Digital PET detector, specifically designed for long axial field of view systems utilizing 3 inter-unit coincidences of detectors. The new detector increases the amount of readout bandwidth and optimizes position data with 100% crystal to SiPM coverage. (Figure 2) The uMI Panorama GS was also designed to fit in a standard PET/CT room which increases access to more facilities.

A long axial field of view significantly impacts clinical workflows and patient comfort. By enabling most of the body to be scanned in a single

position, it reduces the need for patient repositioning, which not only minimizes discomfort and stress for patients but also reduces the risk of motion artifacts that can compromise scan quality. This aspect is particularly beneficial for patients who may experience pain or have difficulty remaining still for long periods. Additionally, new clinical and research opportunities are possible with the ability to visualize tracer movement in real time over the body. (Figure 3)

From an economic and operational perspective, digital whole-body PET/CT systems offer benefits with shorter scan times which improve the throughput of medical imaging facilities. This allows more patients to be scanned each day, thus improving access to critical diagnostic procedures. The increase in system sensitivity allows for a reduction in the injected dose of radioactive tracers needed for patients scans and can also reduce costs associated with

Continued on page 3. See *Crystal Clear*.

Value Initiative Reflections and Memories

By Matt Shah, Vice President, Global Sales & Marketing, Siemens Healthineers and Terri Wilson, President, Blue Earth Diagnostics

It has been a pleasure to be a part of the SNMMI Value Initiative since its initial days in 2017 and see it grow from the two founding companies (Siemens Healthineers and Blue Earth Diagnostics) to now over thirty-five companies. Founded over a coffee chat in discussions with Satoshi Minoshima (Prof. and chair of Radiology/Imaging Sciences, University of Utah), Jim Williams (CEO, Siemens Molecular Imaging), Virginia Pappas (CEO, SNMMI), Jonathan Alles (CEO, Blue Earth Diagnostics), it has become a pioneering model on how industry, academia, and society members can collaborate to push forward the scientific, regulatory, and patient access topics.

With investments of >\$11 million, The Value Initiative has led to achievements across multiple domains in Research & Discovery, Quality of Practice, Workforce Planning & Lifelong Learning, Outreach, and Advocacy. The collaborative work has enabled research scholarships for young molecular imaging scientists, the creation of Theranostics centers of excellence & dosimetry certification programs, development of imaging quantification & standardization initiatives, improved awareness of Molecular Imaging procedures via national media, and to the recent proposal by CMS to separately pay for certain diagnostic radiopharmaceuticals to improve and preserve patient access to them.

Most importantly, the Value Initiative has allowed the broader nuclear medicine community to come together, create a vision for the future, and develop a roadmap of initiatives to drive the field forward. “Collaboration” is the one word, as referenced in the top chart, that best illustrates the spirit of the initiative.

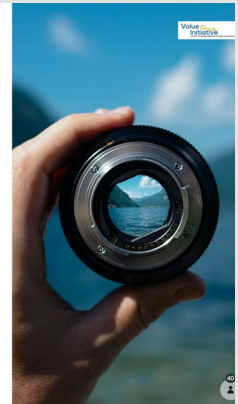
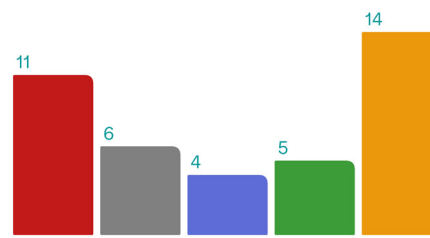
The Value Initiative has a lot more work to do as the field of Nuclear Medicine is helping to drive innovations in radiopharmaceuticals, imaging equipment, advance software and artificial imaging to address unmet clinical needs. Continued academic, industry, and society collaboration will be key to ensure Molecular Imaging reaches its potential.

What one word describes the Value Initiative to you?

60 responses:



Which of these domains of the Value Initiative is currently your primary focus?



Crystal Clear Continued from page 2.

tracer materials. The adoption of scanners with true whole-body imaging like United Imaging’s can lead to significant cost savings and operational efficiencies, while simultaneously improving patient care.

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- Images courtesy of The First People’s Hospital of Kunshan, CHN

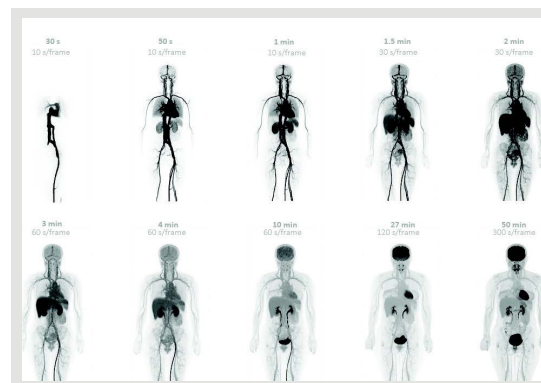


Figure 3. ¹⁸F-FDG, 6.72 mCi (249 MBq), single bed, 1-hour dynamic scan³

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ANNUAL MEETING

Assessing the Value of MPI Modalities for the Diagnostic of CAD. Results of Systematic Literature Review and Meta-Analysis

By Arturo Cabra, MsC – Health Economics and Outcomes Research Lead, GE HealthCare, Pharmaceutical Diagnostics

Background.

The current landscape for diagnosing Coronary Artery Disease (CAD) includes a combination of non-invasive, invasive, functional, and structural modalities, each of which possesses its own diagnostic accuracy and cost. The choice of diagnostic method depends on the patient's risk factors, symptoms, clinical scenario, and the availability of modalities. Nuclear-based myocardial perfusion imaging (MPI) modalities, such as SPECT and PET, currently serve as gatekeepers for invasive coronary angiography (ICA).

To date, no published systematic literature reviews (SLR) have collated evidence on healthcare resource utilization (HCRU) and clinical outcomes following PET- and SPECT-MPI to inform economic evaluation for PET compared to SPECT-MPI for diagnosing CAD. In a 2024 study published in the Journal of Medical Economics¹, a group of researchers aimed to consolidate and analyze the evidence to bridge the gap between research and evidence-informed decision making related with HCRU and downstream cardiac outcomes following PET- and SPECT-MPI in CAD. Exploratory meta-analyses of clinical outcomes were performed to complement the analysis.

Analysis.

Despite the initial identification of 791 articles that meet the PICO Criteria (Problem/Population, Intervention, Comparison, Outcome), just a limited number of studies (71) were considered for inclusion and data extraction. The results of the analysis revealed that often clinical studies and economic evaluations do not capture (or link) all pertinent outcome parameters (i.e., diagnostic performance, HCRU, and cardiac events, together) or the articles report individual parameters: diagnostic performance, downstream HCRU, and cardiac outcomes as individual non-related variables (Figure 1).

Findings.

Results indicated that PET-MPI led to higher early and late rates of invasive procedures, such as coronary angiography and revascularization, compared to SPECT-MPI, but had lower rates of repeat testing. Additionally, the incidence of acute myocardial infarction was lower with PET-MPI, although this difference was not statistically significant (Table 1).

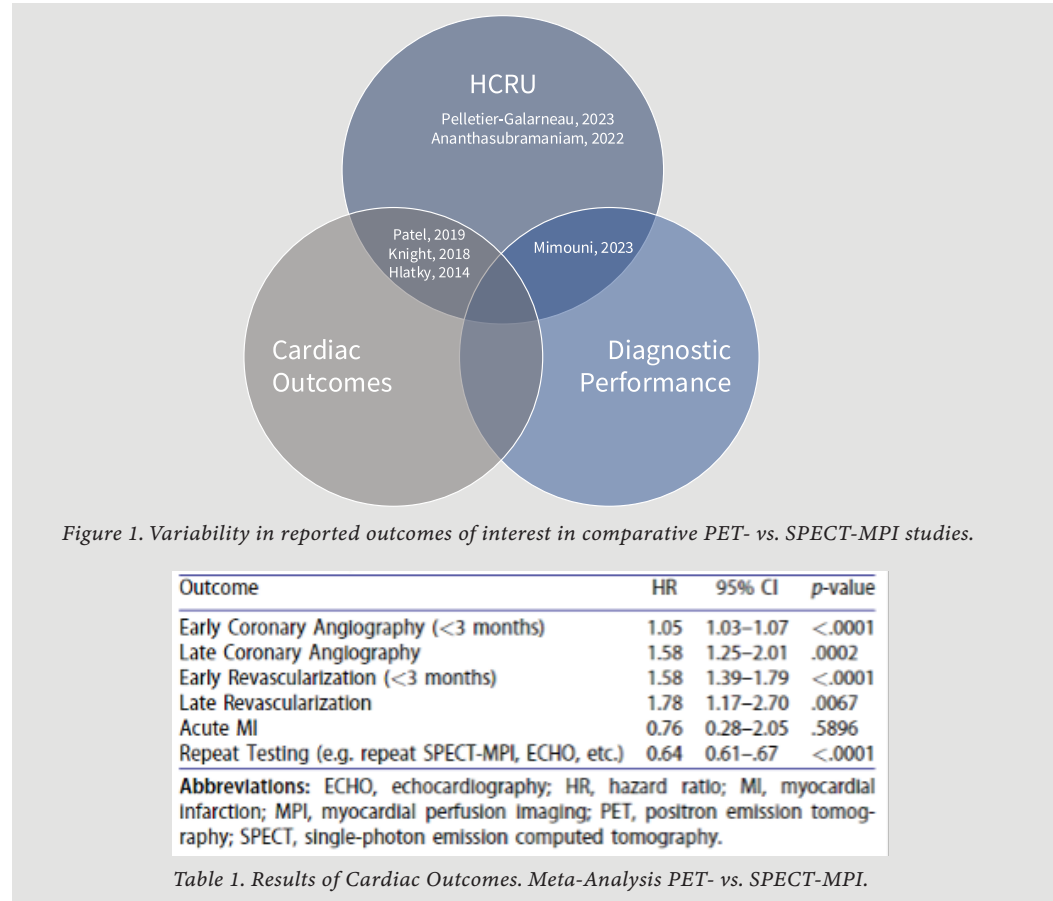
Significance of Research.

The article highlights the gaps in the literature related to outcomes associated with CAD diagnostic modality since current evidence often does not comprehensively link diagnostic performance with downstream HCRU and clinical outcomes, hindering the full

understanding of the economic impacts associated with these modalities.

The results of this research will support the development of a framework to inform future economic evaluations of PET- and SPECT-MPI and provide HCRU and cardiac event estimates that can inform future models.

¹Ferko N, Priest S, Almualllem L, Walczyk Mooradally A, Wang D, Oliva Ramirez A, Szabo E, Cabra A. Economic and healthcare resource utilization assessments of PET imaging in Coronary Artery Disease diagnosis: a systematic review and discussion of opportunities for future economic evaluations. J Med Econ. 2024 Jan-Dec;27(1):715-729. doi: 10.1080/13696998.2024.2345507. Epub 2024 May 6. PMID: 38650543.



2024 Awards – Alternative Diagnostic Pathways in Prostate Cancer

Research: Evaluation of Alpha- versus Beta-Particle Targeted Radiotherapy for Treatment of PSMA Heterogeneous Prostate Cancer
Award Amount: \$100,000



Dr. Jason Lewis Ph.D. - Memorial Sloan Kettering Cancer Center

- Uses a model of PSMA heterogeneous prostate cancer to identify optimal targeted radiotherapy treatments.
- They hypothesize that alpha particle treatments such as [²²⁵Ac] Ac-PSMA-617 will be more efficacious than beta particle treatments ([¹⁷⁷Lu]-Lu-PSMA-617) in this resistant phenotype, due to their increased cytotoxicity.
- This grant will support the graduate work of Rachel Payne.

Thank you to Telix for supporting this grant.

2024 Awards – Innovator’s Grant

Research: Targeted Radiovaccination for Castration Resistant Prostate Cancer
Award Amount: \$100,000



Labros Meimetis Ph.D - University of Wisconsin-Madison

- This application seeks to develop a new therapeutic paradigm to overcome resilience to treatment in mCRPC patients from the tumor microenvironment and heterogeneity using a targeted therapeutic radiometal and an immunostimulant payload.

Thank you to ERF, the SNMMI Board of Directors, and many individual donors for supporting this grant.

2024 Awards – Community-Based Theranostics

Research: Establishing centralized dosimetry process with peripheral SPECT/CT image acquisition within an expanding RPT program throughout the Mountain West
Award Amount: \$100,000



Nichole M. Maughan PhD and Dustin Boothe MD – Intermountain Healthcare

- This grant focuses on implementing a standardized process for imaging with a large geographic reach and a centralized process for dosimetry processing and analysis so that they can improve patient access to high-quality, personalized patient management and radiopharmaceutical therapies.

Thank you to Oliver Buck, Udo J. Vetter, and ITM corporation for supporting this grant.

Standardized template for clinical reporting of PSMA PET/CT scans

An article by Telix, an SNMMI Value Initiative Industry Alliance Principal Member Partner

By Shadi A. Esfahani¹ · Michael J. Morris² · Oliver Sartor³ · Mark Frydenberg^{4,5} · Stefano Fanti⁶ · Jeremie Calais⁷ · Neha Vapiwala⁸

This abstract Received: 18 March 2024 / Accepted: 21 July 2024

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Abstract

Purpose Accurate diagnosis and staging of prostate cancer are crucial to improving patient care. Prostate-specific membrane antigen (PSMA)-targeted positron emission tomography with computed tomography (PET/CT) imaging has demonstrated superiority for initial staging and restaging in patients with prostate cancer. Referring physicians and PET/CT readers must agree on a consistent communication method and application of information derived from this imaging modality. While several guidelines have been published, a single PSMA PET/CT reporting template has yet to be widely adopted. Based on the consensus from community and academic physicians, we developed a standardized PSMA PET/CT reporting template for radiologists and nuclear medicine physicians to report and relay key imaging findings to referring physicians. The aim was to improve the quality, clarity, and utility of imaging results reporting to facilitate patient management decisions.

Methods Based on community and expert consensus, we developed a standardized PSMA PET/CT reporting template to deliver key imaging findings to referring clinicians.

Results Core category components proposed include a summary of any prior treatment history; presence, location, and degree of PSMA radiopharmaceutical uptake in primary and/or metastatic tumor(s), lesions with no uptake, and incidentally found lesions with positive uptake on PET/CT.

Conclusions This article provides recommendations on best practices for standardized reporting of PSMA PET/CT imaging. The generated reporting template is a proposed supplement designed to educate and improve data communication between imaging experts and referring physicians.

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⁸ Department of Radiation Oncology, University of Pennsylvania, Philadelphia, PA, USA



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Article and References

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Linz study. Data will inform the design of a pivotal registration trial for TLX101.

TLX66 (90Y-besilesomab) is an investigational therapy for bone marrow conditioning for hematopoietic stem cell transplantation. TLX66 has been evaluated in approximately 100 patients as an immunotherapy and in combination with low-dose chemotherapy conditioning regimens.¹² A recently published Phase I study demonstrated that bone marrow conditioning can be enhanced with TLX66, with all 14 patients who received allogeneic transplants achieving sustained complete responses.¹³

For patients with advanced or metastatic soft tissue sarcoma, TLX300 (therapy; administered in combination with doxorubicin) and TLX300-CDx (89Zr-olaratumab; companion diagnostic) are being developed as an antibody-based theranostic pair targeting growth factor receptor alpha, a tyrosine kinase receptor involved in fibrogenesis.¹⁴

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Advancing Nuclear Medicine Continued from page 1.

System (OPPS) and ASC Payment System Proposed Rule is published annually and will have a 60-day comment period, which will end on September 9, 2024. The final rule will be issued in early November.

So, what will this mean for us?

In the past, radiopharmaceuticals used in diagnostic imaging were bundled together with the imaging procedure itself under one payment. This often resulted in under-reimbursement for these critical agents, which in turn stifled innovation and limited patient access to advanced diagnostic tools. With an unbundling policy, radiopharmaceuticals could be reimbursed separately, which better reflects their true value.

This impending change will be a win-win. Providers could receive appropriate compensation for the use of high-cost radiopharmaceuticals, and patients will likely see increased access to the latest diagnostic technologies. For our industry alliance, this also means that companies can invest more confidently in the development of new radiopharmaceuticals, knowing that there's a clear pathway to reimbursement.

For those of us who have been advocating for this change, it will be a significant milestone that highlights the growing recognition of nuclear medicine's value in healthcare.

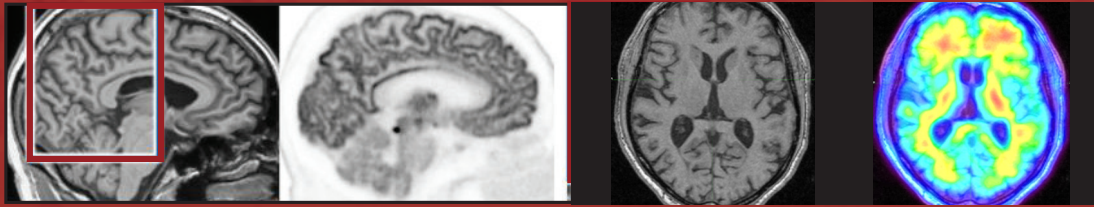
Looking Ahead

These developments—the breakthroughs in Alzheimer's diagnostics and treatments and the likely unbundling of radiopharmaceuticals—underscore the critical role that nuclear medicine plays in modern healthcare. As we look to the future, the SNMMI Value Initiative Industry Alliance will continue to support these advancements, advocate for policies that reflect the true value of our work and encourage innovation that benefits patients worldwide.

We're at an exciting juncture in our field, and I'm confident that with continued collaboration and dedication, we can drive even more progress and deliver greater value to those we serve.



Satoshi Minoshima, MD, PhD, FSNMMI
Chair in the Department of Radiology and Imaging Sciences
at the University of Utah;
Former President of the SNMMI and Founder and Chair
of the SNMMI Value Initiative Industry Alliance



BRAIN IMAGING RESOURCE GUIDE

The **Society of Nuclear Medicine and Molecular Imaging (SNMMI)** provides a comprehensive collection of resources for nuclear medicine and molecular imaging professionals. These resources include Appropriate Use Criteria and Procedure Standard documents, reader training courses, videos for technologists, and other educational materials for brain imaging scans. The SNMMI is continually updating and expanding these resources to support the delivery of high-quality patient care and advancing the understanding and management of patients with neurological issues.



Gero-Theranostics

By Jean-Luc Urbain, MD, PhD, FASNC – Past President CANM, President-Elect SNMMI; John Prior, MD, PhD – President SSMN; Andrew Ross, MD – Immediate Past President CANM; Francois Lamoureux, MD – President CANM

Nuclear Medicine & Theranostics

As the 21st century dawned, nuclear medicine faced a bleak outlook. The advent of clinical ultrasonography, computerized tomography, and magnetic resonance seemed to overshadow our field's relevance, while a dearth of investments in novel radiopharmaceuticals and relying on decades old Anger physics cast a shadow over its future.

Yet, through a series of remarkable developments intertwined with the human genome projects and the explosion of the omics knowledge and technologies, coupled with the relentless determination of pioneers, nuclear medicine has undergone a profound and fantastic resurgence. Today, it stands poised to play a pivotal role in patient management, particularly in oncology, marking a turning point marked by a shortage of nuclear professionals unprecedented in our history.

Central to this renaissance is the discovery and clinical application of a new class of radiopharmaceuticals known as Theranostics. Coined by John Funkhouser in 1998, Theranostics represents a revolutionary fusion of therapeutic and diagnostic modalities. Under Funkhouser's leadership as CEO of PharmaNetics, this vision crystallized into a paradigm-shifting approach that was intending to blend therapeutics and diagnostics seamlessly.

Nuclear Theranostics, epitomized by the use of a single target binding agent to both diagnose and treat specific diseases, has sparked immense enthusiasm within the nuclear medicine community. With approximately 90 companies currently engaged in developing precision medicine radiopharmaceuticals, market analyses indicate exponential financial growth for the specialty in the years ahead. Forecasts indicate a seismic shift from an imaging-centric specialty to a therapeutic focus, with nuclear medicine projected to transition from an 85% imaging specialty to a 60-70% therapeutic specialty.

While Nuclear Theranostics have already made significant inroads in managing neuroendocrine tumors, prostate cancers, and select thyroid cancers, their integration of diagnostic and therapeutic components represents just the beginning of the concept of Theranostics. Across diverse fields, from Nano Theranostics to Magnetic Theranostics and Immuno-Theranostics, researchers are harnessing the power of integrated platforms to tackle a spectrum of diseases, spanning from degenerative and systemic disorders to infectious diseases.

In essence, the revitalization of nuclear medicine through Theranostics heralds not only a renaissance within our field but also a broader revolution in precision medicine and patient management fueled by relentless innovation and collaborative research.

GeroScience

The progress in socioeconomics, living standards, medicine, and public health has heralded a remarkable era of increased lifespan worldwide. Over centuries, life expectancy

has nearly doubled from the early 19th century, a testament to humanity's strides in healthcare and societal development.

While aging itself isn't a disease, it significantly heightens the risk of various acute and chronic conditions, including cardiovascular disease, diabetes, cancer, arthritis, and degenerative disorders (Figure 1). Gerontology, coined by Ilya Ilyich Mechnikov in 1903, encompasses a broad spectrum of disciplines, addressing the societal, psychological, cognitive, and biological dimensions of aging's impact on older adults.

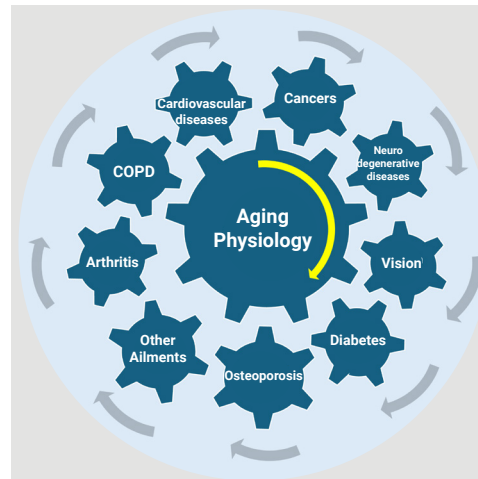


Figure 1. GeroScience: Illustration of aging related conditions/diseases

Recognizing the pivotal role of aging research, the National Institute on Aging (NIA), established by the U.S. Congress in 1974, has been at the forefront. In 2012, Drs. Felipe Sierra and Ronald Kohanski catalyzed the NIH-wide Geroscience initiative, consolidating efforts to understand the genetic, molecular, and cellular biology processes that underpins aging.

GeroScience endeavors to unravel the intricate mechanism of aging, viewing it as a primary driver of age-related diseases. Geroscientists delve into the fundamental physiological, pathophysiological and biological processes associated with aging, aiming to develop interventions that mitigate age-related ailments and enhance overall well-being in older populations (Figure 2).

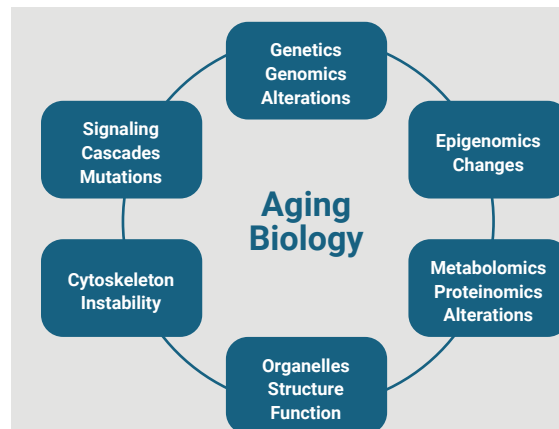


Figure 2. GeroScience: Aging biology processes snapshot

Continued on page 12. See [Gero-Theranostics](#).

By probing the molecular and cellular intricacies of aging, GeroScience is poised to accelerate our understanding of aging and revolutionize approaches to age-related healthcare. This interdisciplinary pursuit unites researchers across diverse fields, forging pathways to address the multifaceted challenges posed by an aging worldwide population, with the ultimate aim to foster healthier and more fulfilling lives for older adults.

GeroScience, Nuclear Medicine and Theranostics

The intersection of GeroScience, nuclear medicine, and Theranostics represents a promising frontier in understanding and managing age-related conditions and diseases. As people worldwide are living longer, addressing age-related health challenges becomes increasingly urgent. GeroScience, as a field, seeks to unravel the underlying genetic, molecular, and cellular mechanisms driving aging and age-related diseases.

Nuclear medicine, with its ability to visualize and treat diseases at the molecular level, offers a unique toolset for GeroScientists to delve into the intricacies of aging processes. The development and utilization of nuclear diagnostic and therapeutic Theranostics further enhance this capability, enabling precise detection and targeted treatment of age-related conditions (Figure 3).

Additionally, nuclear medicine techniques can assist Gerontologists in patient management by providing personalized diagnostic and therapeutic strategies tailored to individual molecular profiles. This targeted approach enhances treatment efficacy and patient outcomes, ultimately improving quality of life for older adults.

Conclusion

As the fields of GeroScience, Nuclear Medicine, and Theranostics continue to evolve, their integration holds great promise for advancing our understanding of aging and transforming the landscape of age-related healthcare. By synergizing these disciplines, researchers and clinicians can pave the way for innovative approaches to promote healthy aging and address the complex health challenges associated with growing older.



Figure 3. 18-FDG PET scintigraphy performed on a 62-year old patient for suspicion of a pulmonary tumor showing in fact a diffuse joint inflammatory process related to a psoriatic arthritis



Jean-Luc Urbain, MD, PhD, FASNC



John Prior, MD, PhD



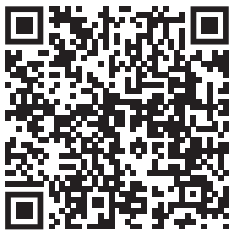
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