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EDITORIAL

Model-based cost-effectiveness studies in nuclear medicine: an unavoidable fact of life

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This editorial briefly introduces the key principles of health technology assessment (HTA) and health economic modelling. It does not aim to provide a comprehensive tutorial on health economic modelling, as such tutorials are available elsewhere [1–3], but it contributes to providing the nuclear medicine and molecular imaging community with a better insight into the dynamics between clinical practice and resource-constrained European healthcare systems. As appropriate health economic analyses require knowledge of modelling methods and of the clinical context, collaboration between healthcare professionals, statisticians and HTA experts is crucial. By working together, we ensure that nuclear medicine procedures are not only clinically beneficial but also optimised to both improve patient care and resource allocation. In this editorial, we reflect on applications of cost-effectiveness studies in nuclear medicine from 1998 to 2025, to show both the opportunities and challenges related to health economic modelling in this field.

Introduction to HTA and health economic modelling

HTA is a structured and evidence-based approach used to evaluate health technologies. The International Network of Agencies for Health Technology Assessment (INAHTA) defines HTA as a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose of HTA is to inform decision-making in order to promote an equitable, efficient, and high-quality health system. The health technology can be a diagnostic test, device, medicine, vaccine, procedure, programme or system. The dimensions of value for the health technology are assessed by examining the intended and unintended consequences of using a health technology compared to relevant existing alternatives. These dimensions include clinical safety and effectiveness, costs and economic implications, ethical, social, cultural and legal issues, organisational and environmental aspects, as well as wider implications for the patient, relatives, caregivers, and the population. HTA is increasingly recognised

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as a valuable multidisciplinary process for decision and policy makers in establishing and monitoring the accessibility, pricing and reimbursement of health technologies.

Health economics is a subfield within the HTA domain focusing on comparing the health and economic value of competing investment options, particularly within a context of scarce resources and limited healthcare budgets. Because every euro can only be spent once, the key question becomes how to allocate resources most effectively. Health economics is not primarily about cost savings, or cost reduction, but rather about *how* to best spend the available limited healthcare budget to maximise population health outcomes [4]. This also means accounting for opportunity costs, that is, recognising that deciding to fund a particular healthcare strategy or innovation implies that we cannot fund other strategies or innovations, and therefore do not receive the benefits those alternatives could provide. Health economists use a range of methods including cost-benefit, cost-effectiveness and cost-utility analyses to systematically and transparently evaluate cost and health outcomes, helping to inform evidence-based decisions [5].

Cost-effectiveness can be studied alongside randomised controlled trials (RCTs) or by using health economic simulation models. As diagnostic RCTs are rare and may have a limited follow-up duration, simulation modelling becomes unavoidable [6]. RCTs are also not always necessary as there are other methods to collect data, but they may provide the most unbiased estimates on effectiveness and costs of therapeutic decisions based on specific diagnostic tests. It may take a long time to gather enough follow-up data to ensure further events are unrelated to upfront decisions. By the time the data is available, the diagnostic approach or therapy may have been improved or replaced in such a way that the data is already outdated [7]. At the same time, simulation models evaluating novel diagnostics will, in general, require more extensive clinical evidence than those assessing therapeutics [8]. It requires an investment in collecting the clinical data on how new imaging techniques, radiopharmaceuticals or therapeutic agents are used and lead to (changes in) therapeutic effectiveness, patient management and survival [9]. The advantage is that simulation models can reflect uncertainty in evidence and variability in clinical practices and patient populations. This flexibility helps in understanding the robustness of expected patient outcomes and costs under different scenarios.

Developing and validating simulation models can be a complex process, especially when addressing complex clinical care pathways such as those found in oncology, which may require substantial time and expertise. However, simpler models, when appropriately aligned with the decision problem, can offer valuable insights with fewer assumptions and greater transparency. Balancing feasibility and completeness is a key challenge in model development, and the appropriate level of complexity should be guided by the nature and complexity of the decision problem itself. Importantly, modellers have flexibility in choosing simpler or more complex approaches depending on the context, and there is considerable value in keeping models simple where possible [10]. Rather than aiming for maximal detail, modellers may benefit from a structured approach that carefully weighs the trade-offs between model complexity, data availability, and the clarity and usability of results. In some cases, a simpler model may be more robust, easier to communicate and better suited to inform decision-making. In others, especially where multiple interdependent procedures or treatment sequences are involved, a more extensive model may be warranted. Ultimately, the objective is to ensure that the model is fit for purpose, neither under- nor over-specified for the decision problem at hand [11]. Once a model is established, it can be updated and re-used to assess new evidence, explore different scenarios and adapt to varying healthcare settings [12].

Cost-effectiveness studies in nuclear medicine in 1998: underutilisation

It was Sanjiv Sam Gambhir, the late professor and chair of radiology at the Stanford School of Medicine, a pioneer in molecular imaging, who already wrote in 1998 that cost-effectiveness studies were underutilised by nuclear medicine researchers and misunderstood by many clinicians [13]. Studies simply focused on cost components without considering clinical effectiveness. Imaging professionals lacked a complete understanding of how the results of an imaging study could influence individual patients' treatment planning and outcomes. Another frequent misunderstanding was failing to recognise that costs should encompass all costs involved in patient management, not just those up to and including imaging. A solid understanding of patient care pathways is essential to identify how molecular imaging can cost-effectively support patient outcomes.

Cost-effectiveness studies in nuclear medicine in 2010: evidence generation

By 2010, the role of molecular imaging in clinical practice had taken a big leap forward. An increasing number of studies highlighted how molecular imaging, especially [^{18}F]FDG PET/CT, could help medical specialists better stratify patients, paving the way for more personalised care and improved outcomes. The strongest evidence of [^{18}F]FDG PET/CT advantages over conventional imaging options

came from malignant lymphoma and head and neck cancers [14, 15]. While [^{18}F]FDG PET/CT diagnostic value was well-supported in multiple cancers since 2010, there was often insufficient evidence to accurately assess clinical utility and cost-effectiveness in these cancers [16–20]. Typically, the nuclear medicine and molecular imaging community identified decision problems, or opportunities, from their daily clinical practice. However, realising the full potential of these insights depends on the willingness to invest in generating the required supporting clinical evidence. There was a need for prospective, longitudinal and randomised controlled clinical trials comprising high patient numbers [21, 22]. With such data in hand, models may demonstrate how advances in molecular imaging and nuclear medicine support improving patient management and outcomes.

From diagnostic accuracy to therapeutic effectiveness and patient outcome to cost-effectiveness

Accurate imaging is a powerful tool, but on its own does not improve patient outcome. Its true value lies in enhancing clinical decision-making by enabling medical specialists to select the most effective therapy and avoid futile therapeutic options. That is why imaging techniques should be evaluated not just for how well they detect disease, but also for how they contribute to improving patient outcomes and whether they offer good value for money [23, 24]. In personalised cancer care, imaging can detect tumour activity at an early stage, opening the door to treatment in a stage when therapies with curative intent are still an option and potentially less costly [25]. However, if the available treatments are limited or ineffective, even the most advanced imaging may not lead to better outcomes and thus justify its cost.

Specifically in the field of theranostics, where diagnostic imaging and targeted therapy are based on the same molecular targets, both the clinical value of molecular imaging and treatment effectiveness are highly interconnected [26]. The treatment itself may involve a radioligand therapy (RLT) or a targeted non-radionuclide approach, for instance an antibody-drug conjugate. Diagnostics enable personalised, image-guided treatments that can improve outcomes by ensuring therapies are better matched to individual patients. In practice, the diagnostic phase often involves radionuclide imaging to visualise and quantify how a therapeutic agent distributes throughout the body (and over time). This setup allows clinicians to assess in advance whether the therapy is likely to reach and treat the tumour, improving patient selection [27, 28], or upfront evaluation (and potential improvement) of different treatment conditions [29].

Cost-effectiveness studies in nuclear medicine in 2025: the opportunities

The last 15 years have seen nuclear medicine undergo a metamorphosis driven by quasi-simultaneous rapid developments in technology and radiopharmacy. The introduction of hybrid or multimodality imaging contributed to the significant improvement of the technical efficacy and diagnostic accuracy of SPECT- and PET-imaging, while developments in radioisotope production and radiochemistry have led to exponential growth in molecular imaging and RLT. Molecular imaging stands out as a significant area of development, with effective routine use of [^{18}F]FDG PET/CT in many malignancies and novel use of PSMA PET/CT in high-risk prostate cancer patients [30, 31]. Despite molecular imaging having seen remarkable advancements providing more of a functional or metabolic dimension to understanding disease compared to traditional imaging in oncology, cardiovascular disease, neurology, inflammation and infectious diseases, its adoption into daily clinical practice has remained limited compared to conventional imaging techniques such as CT and MRI. This is largely due to upfront investments required for infrastructure, equipment and highly specialised personnel. Similarly, RLT-related costs require upfront investments in equipment and infrastructure, safety compliance, waste management and staff augmentation and training [32].

Reimbursement decisions and clinical guidelines on national level, but also implementation decisions at hospital level are increasingly informed by cost-effectiveness studies. Though, cost-effectiveness studies are rarely the sole basis for such decisions. At the national level, cost-effectiveness studies are often used to justify reimbursement decisions by demonstrating that initial investments may lead to improved outcomes or long-term cost savings [33, 34]. Similarly, clinical guidelines may incorporate structured and transparent reporting of economic evidence to support recommendations, and to be published in peer-reviewed journals [35]. At the hospital level, the use of cost-effectiveness studies is growing, particularly as hospitals face pressure to manage high-cost innovations. Nearly half of the respondents in a recent survey conducted across 28 countries reported performing hospital-based HTA, mainly in larger hospitals with more than 500 beds [36]. However, practical frameworks to guide decisions in hospital-based HTA units remain limited [37, 38]. Many of these assessments are context-specific and often unpublished, making them less visible in the literature.

Healthcare organisations are increasingly seeking structured approaches to evaluate value for money. While cost-effectiveness studies are not always decisive, they are becoming an important method in the broader

decision-making process. In the remainder of this editorial, we therefore list certain challenges of conducting cost-effectiveness studies. We focus specifically on simulation modelling, given its relevance to the evaluation of nuclear medicine diagnostics and therapies.

Cost-effectiveness studies in nuclear medicine in 2025: the challenges

Justifying the upfront investments for molecular imaging and RLT requires robust evidence of their long-term health benefits or cost savings. However, such evidence is often scarce, and when available, it may already be outdated due to the rapid pace of innovation. Moreover, molecular imaging and RLT frequently lack a standardised approach and multiple technologies may exist for the same molecular target. This variability complicates the selection of comparators and cost inputs. Simulation models used for cost-effectiveness analyses can rapidly become complex if different in parallel or sequential diagnostics, radiopharmaceuticals or therapeutic agents are involved, adding up to a combined diagnostic accuracy and predictive value for the group of tests. Empirical data on the diagnostic performance of groups of tests and the impact of combined tests on therapeutic effectiveness, patient management and survival are often missing, or evidence is taken from studies with a relatively small sample size [39] and retrospective study design [40].

Diagnostic tests are inherently prone to false-positive and false-negative results, which may lead to futile interventions or delayed treatment. These diagnostic errors should be explicitly modelled as they affect both patient outcomes and healthcare costs [41]. A major challenge arises when moving from diagnostic accuracy studies to evaluations of therapeutic effectiveness: without a valid reference test, we lose the ability to distinguish true from false test results. Diagnostic errors go unrecognised but have already driven patient management. This complicates modelling efforts, as we cannot observe how outcomes would change if patients had been treated based on the correct test result. In oncology, this problem is even greater because there is a frequent absence of a gold standard, making it difficult to validate test results and fully assess the impact of diagnostic inaccuracies.

Patient perspectives, preferences and adherence are increasingly recognised as critical information for imaging and treatment choices. Increased patient confidence can substantially impact decisions and quality-of-life of patients [42]. While simulation models are primarily used to evaluate long-term survival and quality-of-life, they also have the potential to capture impact on workflow and staffing efficiency, and the environmental footprint of radiopharmaceuticals, scanners and therapeutic agents. These aspects include the costs from production to delivery, hospital care and waste management. However, methods to systematically incorporate this information into simulation models are still underdeveloped. Importantly, simulation outcomes can vary significantly across healthcare settings due to differences in patient populations, clinical practices, care pathways, legislation, reimbursement structures, and logistics such as production and transport. To tailor models to specific countries or regions, real-world evidence is essential. More context-specific real-world evidence, such as data from population registries, can help ensure that models reflect actual clinical practice rather than idealised scenarios [41].

Conclusions

This editorial has presented both challenges and opportunities facing molecular imaging and therapy in 2025. Moving forward, a strong interdisciplinary approach is needed to support the implementation of cost-effective innovations in the nuclear medicine field. This vision echoes Sanjiv Sam Gambhir's 1998 call to systematically and transparently demonstrate the cost-effectiveness of nuclear medicine imaging and therapies [13], and builds on the evidence base that began to grow meaningfully around 2010 [14, 21, 22]. It is, therefore, the time to strengthen collaboration among medical professionals, (bio)statisticians and HTA specialists, to generate the clinical and economic evidence needed to demonstrate that molecular imaging and nuclear medicine are not only clinically effective but also contribute to the affordability and sustainability of healthcare systems. To turn innovation into impact, robust model-based evaluations demonstrating cost-effectiveness should be regarded as a fundamental part of future research in nuclear medicine.

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Declarations

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