Comparative Analysis of Economic Evaluation Frameworks for AI-Based Digital Health Technologies Across Four HTA Systems:

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Introduction

To support value-based adoption of AI-enabled digital health technologies, many HTA agencies have begun integrating economic evaluation—including cost-effectiveness and budget impact analyses—into their decision-making frameworks.
As AI-based medical technologies continue to enter the Korean market, early-stage assessment becomes increasingly critical. This study explores whether established economic evaluation frameworks from international HTA systems can be incorporated into Korea's Scientific Advice (SA) program, which provides early guidance on evidence generation and regulatory alignment for innovative health technologies.

Method

We conducted a structured review of AI-related HTA reports and economic evaluation frameworks from four jurisdictions: NICE (UK), CADTH (Canada), ICER/PHTI (US), and SBU (Sweden). A total of 18 reports were included—12 from Canada, 4 from the UK, and 1 each from the US and Sweden. The reports were assessed for their use of economic modeling, QALY-based metrics, real-world evidence (RWE), clinically relevant endpoints, and population specification—key components of value-based decision making.

Table 1. Overview of HTA Databases from Major International Agencies

Institution	DB
Canada's Drug Agency	CDA-AMC
National Institute for Health & Clinical Excellence	NICE
Institute for Clinical and Economic Review	ICER
Swedish Agency for Health Technology Assessment and Assessment of Social Service	SBU
International HTA	INAHTA

For the case study, official manuals available on each HTA agency's website were first reviewed to identify relevant procedures and guidelines. Subsequently, published methodological guidelines were collected and analyzed. To examine the current status of AI-based health technology assessments, agency websites were searched for AI-related guidance documents, and additional HTA reports were identified using the INAHTA database and Google. The search applied the keywords "Artificial Intelligence (AI)," "Deep Learning," "Machine Learning," and "Cost-Effectiveness."

Result

Each HTA agency has developed its own guidelines and manuals to support context-specific economic evaluations. Based on these manuals, agencies conduct economic analyses reflecting their national healthcare systems.
The UK demonstrated relatively active use of economic evaluations, with four AI-based technologies incorporated into NICE guidance. In Canada, most HTA reports relied on systematic reviews, providing limited economic evidence. In the United States, one digital diabetes management report was identified under the ICER–PHTI digital health assessment framework, which incorporated elements of economic evaluation.

Sweden assessed AI-based mammography as cost-effective within its dual-reader system; however, the generalizability of these findings may be limited in contexts such as Korea, where comparable clinical practices are not in place.

Table 2. International Comparison of Health Insurance and Economic Evaluation Systems

contents	Canada (CDA-AMC)	United Kingdom (NICE)	United States (ICER)	Sweden (SBU)
Healthcare system	Jointly operated by federal and provincial governments; provincial autonomy in standard setting; government-managed, organized, and funded system; publicly financed universal coverage (Medicare).	National Health Service (NHS)	Public health insurance (Medicare, Medicaid, CHIP, and special programs); private insurance; uninsured population	National Health Service (NHS); universal public insurance financed by national and local taxation
overview	Provides information to decision-makers on drugs, medical devices, and diagnostic tools to support reimbursement and policy decisions.	Conducted by NICE, a public institution (National Institute for Health and Care Excellence	Independent organization performing cost-effectiveness and value-based analyses to inform pricing and reimbursement decisions	Conducts HTA within the National Health System; results are published and used as reference data
Economic Evaluation Procedures	1) Define problem 2) Select evaluation type 3) Identify target population 4) Choose appropriate comparators 5) Conduct literature review 6) Define time horizon 7) Develop and validate model 8) Perform sensitivity analysis 9) Submit structured report 10) Resource use and cost reporting 11) Uncertainty analysis	1) Define clinical question 2) Compare intervention with current practice 3) Evaluate health outcomes 4) Analyze cost-effectiveness using QALYs 5) Conduct sensitivity and scenario analyses 6) Review by expert committee 7) Stakeholder consultation 8) Recommendation finalized by appraisal committee	1) Define research problem 2) Design decision model 3) Collect relevant data 4) Analyze cost and outcomes 5) Report findings including budget impact	1) Set evaluation scope 2) Conduct systematic review 3) Assess cost-effectiveness 4) Use validated tools 5) Interpret and report economic findings
outcome	Supports reimbursement and policy decisions; facilitates evidence-based decision-making; results published via CADTH/ICER reports	Provides cost-effectiveness results in ICER per QALY gained	Presents economic metrics such as: Cost per QALY, Cost per life-year gained, and Cost per consequences	No separate economic modeling results are reported
Application of Results	Results inform clinical and health policy decisions, including pricing, coverage, and use recommendations	Recommendations guide clinical practice and NHS adoption decisions	Provides insights for value-based pricing and resource allocation but not binding for reimbursement	Used as regional reference data for healthcare policy and practice

Table 3. Status of AI-Based Health Technology Assessments (HTA) in Major Countries

contents	Canada (CDA-AMC)	United Kingdom (NICE)	United States (ICER)	Sweden (SBU)
Current Status of AI Technology Assessments	12 AI-related HTA reports published (as of June 2024); developing AI-based evaluation frameworks and promoting standardization across provinces.	4 reports published (as of June 2024); 80+ AI projects supported through national programs such as the AI in Health and Care Award	1 AI-related HTA identified (Digital Diabetes Management Solutions); part of the digital health assessment framework.	1 AI-based HTA published (AI mammography for breast cancer screening); evaluated as cost-effective within the dual-reader system.
Use Cases	Focused on medical imaging, diagnostic tools, and predictive analytics for chronic disease management.	Applications in diagnostics, workflow optimization, and clinical decision support systems.	Focused on digital health and chronic disease management applications.	AI applied in cancer screening and diagnostic imaging.
Summary	Leading in framework development and methodological standardization for AI-integrated HTA.	Actively institutionalizing AI evaluation within national HTA; strong governance and evidence-based leadership.	Early-stage adoption; integrating AI assessment with economic modeling under the ICER–PHTI framework.	Limited but robust evaluations; findings context-specific to Sweden's clinical infrastructure.

Conclusion

Context-specific economic modeling is essential for assessing emerging technologies. Integrating economic evaluation into Korea's Scientific Advice (SA) process could support early value assessment and strategic planning for AI-based health technologies, while providing a foundation for broader application across diverse interventions.

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