Global Landscape of Artificial Intelligence in Health Technology Assessment: Trends, Governance, and Emerging Practices

MSR96

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Introduction

- Artificial Intelligence (AI) and machine learning (ML) are increasingly being integrated into health technology assessments (HTAs) to enhance systematic reviews, real-world evidence generation, and economic modelling, with potential to improve efficiency and evidence quality[1,2]
- However, adoption remains uneven across agencies, creating uncertainty for global HTA submissions and highlighting the need to assess the current landscape of AI acceptability and use[3]

Objective

- To provide a comprehensive overview of AI/ML adoption, guidance, and governance across international HTA agencies

Methods

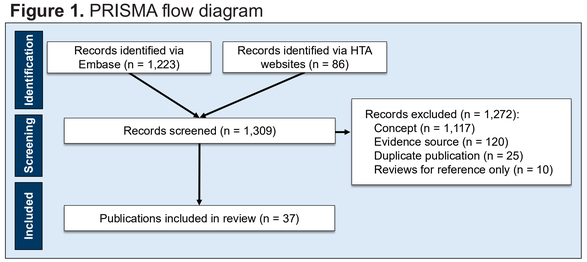
- A targeted literature review of HTA websites[#] was conducted to identify guidance documents, policy statements, and opinions on use of AI and ML in United States (US).* Canada, Europe including EUnetHTA/JCA, and Asia-Pacific
  - Initial HTA website searches along with supplementary search of Embase, bibliographies of previous reviews, and gray literature were performed on December 11, 2024,[4] and updated on October 1, 2025, to capture newly available evidence
- Publications on AI/ML approaches recommended/accepted/used by HTA agencies across therapeutic area were identified using PCC framework (Population, Concept, Context)[5]

Results

Publication Selection

- Review included 37 publications (n=37; **Figure 1**), comprising evidence identified in the previous review[4] and newly retrieved records: 36 from HTA agency websites and 1 from Embase
  - The Embase record was a NICE paper on AI/ML in screening

Figure 1. PRISMA flow diagram



Publication Characteristics

- Ten HTA agencies provided AI/ML guidance (**Figure 2 and 3**), mainly from CDA-AMC (Canada; n=7),[6-12] followed by HAS (France; n=6),[13-18] NICE (UK; n=6),[19-24] IQWiG (Germany; n=6),[25-30] FIMEA (Finland; n=4),[31-34] NIPH (Norway; n=3),[35-37] EUnetHTA[α]/JCA (Europe; n=2),[38,39] KCE (Belgium; n=1),[40] PBAC (Australia; n=1),[41] and INESSS (Canada; n=1)[42]

Figure 2. Included publications on use of AI/ML by HTA agencies

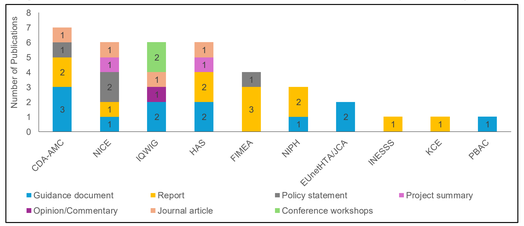
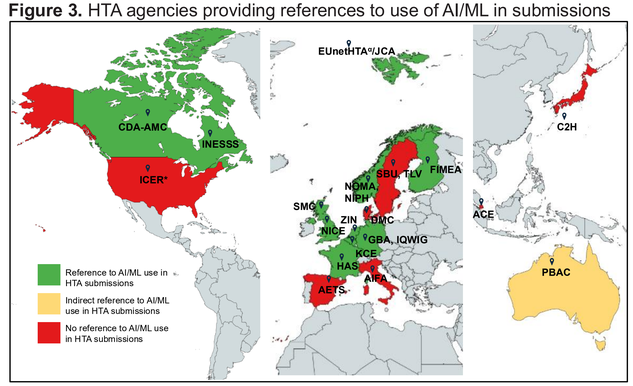


Figure 3. HTA agencies providing references to use of AI/ML in submissions



Results (continued)

HTA agencies are acknowledging AI/ML in submissions, particularly for literature reviews and evidence synthesis (n=17), real-world evidence generation (n=9), economic modeling (n=3), and indirect treatment comparison (n=3); Seven HTA agencies are adopting AI/ML for internal use

	NICE	CDA-AMC	NIPH	IQWiG	EUnetHTA[α]/JCA	HAS	KCE	FIMEA
Literature Review and Evidence Generation	AI/ML in search & screening; ML classifiers to expedite study identification;[19] **"human-in-the-loop"**;[20] ethical, technical, and regulatory compliance emphasized[20]	AI for search strategy, automated data extraction,[8,11] *Position statement **augment human efforts** and updated AI definition aligned with Canadian AI governance*[11]	*Dedicated ML implementation for search and screening;*[35] *semi-automated data extraction and LLM exploration*[37]	ML filters/classifiers allowed[25] *with demonstrated sensitivity; cautious adoption*[26]	Endorses validated study filters (≥95% sensitivity); supports RCT classifiers[39]	*Developing AI trust framework;*[15] monitoring automation tools;[13,14] *cautious stance*[15]	*Evaluated AI across full SLR lifecycle; flags reproducibility risks of semantic search*[40]	No formal guidance reported
Health Economic Modelling	AI/ML for model construction, calibration, parameter estimation, simulation optimization, report generation;[20,22,23] *human oversight emphasized and proposed initial best-practice principles*[23]	*Aligns with NICE; AI supports dataset interrogation, model building, calibration, simulation optimization*[11]	No formal guidance reported					
Real-World Evidence	AI/ML for RWD extraction, curation, feature selection for causal inference; must comply with RWE reporting standards[20]	*AI for structured data, population selection, causal effect estimation;*[11] method choice remains investigator-driven[6,7]	*Exploring generative AI for registry tabular extraction*[37]	Permission granted for RWD use in AI/ML analyses[29]	No formal guidance reported			*Evaluated AI vs traditional Adverse Drug Reaction processing*[32]
Indirect Treatment Comparison	LLM prompts for code generation in network meta-analysis[20]	*Mirrors NICE;*[11] growing interest in ChatGPT and similar AI platforms to support systematic review processes, but emphasizes cautious use[10]	No formal guidance reported		ML/statistical models may support propensity score estimation[38]	No formal guidance reported		
For Internal Purposes	AI for efficiency, accuracy, quality; staff upskilling;[20] automation in COVID-19 surveillance[24]	Evaluation instrument for AI search tools;[10] tool assessment for fit-for-purpose applications (but only **under human supervision**);[12] *staff training*[11]	*Active ML infrastructure and workforce development*[36]	*Ongoing tool evaluations*[30] *and expert forums*[28]	No formal guidance reported	*Emphasizes staff training;*[16] *identified 49 AI initiatives across 25 HTAs*[17]	*Promotes shared repositories and responsible AI guidance*[40]	Internal RWD/AI/ML network;[31] *Internal automation rollout and staff training*[33]

INESSS evaluated GPT-4 for literature screening, finding a ranking strategy with 100% sensitivity and reasonable specificity;[42] PBAC referred Cochrane Handbook, which highlights AI tools like RCT Classifier and Screen4Me for streamlining study selection of RCTs.[41] No relevant documents were found for the Netherlands (ZIN), Scotland (SMC), Italy (AIFA), Spain (AETS), Sweden (SBU, TLV), Denmark (DMC), Singapore (ACE), or Japan (C2H). No guidance documents were identified for ICER (US).*

Italicized text highlights new updates compared with previously published information in the ISPOR 2026 poster (MSR109 Artificial Intelligence Integration in Health Technology Assessments: A Review of Global Policies and Practices).

Structured guidance | **Exploratory Stage** | **No/limited guidance**

Real Time Example And Key Takeaways

Real Time Examples

- TA962 used a Natural Language Processing model to conduct systematic literature review update[43]
- TA1071 used AI-assisted searches to identify treatment effect modifiers[44]

AI/ML Adoption

- Comprehensive guidance for literature reviews: AI tools for systematic reviews are well-developed
- Guidance for other HEOR applications remains limited

Human Oversight

- "Human in the loop" is strongly advocated
- Automation is feasible for structured tasks (screening, data extraction), but modeling and reasoning tasks require human judgment

Limited Internal Efficiency Gains

- Despite timeline pressures, AI is rarely used to accelerate HTA processes
- Suggests cautious adoption where quantitative reasoning and regulatory compliance are critical

Conclusions

- AI/ML adoption in HTAs is expanding but remains uneven across agencies. NICE and CDA-AMC currently provide the most structured policy direction, while many other agencies are still in early or exploratory stages.
- To enable scalable and trustworthy implementation, the field needs standardized frameworks, stronger cross-agency collaboration, and continuous evaluation to ensure transparent, ethical, and harmonized use of AI/ML across HTA processes.

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[#] HTA Agencies of Interest: Agency for Care Effectiveness (ACE); Agencia de Evaluación de Tecnologías Sanitarias (AETS); Agenzia Italiana del Fármaco (AIFA); Canada's Drug Agency (CDA-AMC); Center for Outcomes Research and Economic Evaluation for Health (C2H); Danish Medicines Council (DMC); European Network for Health Technology Assessment (EUnetHTA); Finnish Medicines Agency (FIMEA); Gemeinsamer Bundesausschuss (GBA); Haute Autorité de Santé (HAS); Institute for Clinical and Economic Review (ICER)*; Institut National d'Excellence en Santé et Services Sociaux (INESSS); Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG); Joint Clinical Assessment (JCA); Belgium Health Care Knowledge Centre (KCE); National Institute for Health and Care Excellence (NICE); Norwegian Institute of Public Health (NIPH); Norwegian Medical Products Agency (NOMA); Pharmaceutical Benefits Advisory Committee (PBAC); Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU); Scottish Medicines Consortium (SMC); Dental and Pharmaceutical Benefits Agency (TLV); Zorginstituut Nederland (ZIN).

* ICER is an independent, nonprofit organization without statutory HTA status or formal regulatory or reimbursement authority, but was included in this review as the closest functional equivalent to an HTA agency in the United States.

[α] EUnetHTA officially ceased operations in September 2023.

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Disclosures

Eon Ting, Matthew Badin, Vivian Vuong, Thomas Haugli-Stephens, and Johanna Jacob are employees and/or shareholders of AstraZeneca. Nishu Gaind, Mir-Masoud Pourrahmat, Luka Ivkovic, and Mir Sohail Fazeli are employed by Evidinno Outcomes Research Inc.

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