# Ethical AI Deployment in HEOR

MSR192

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**KEY MESSAGE**

**HEOR needs its own ethical AI standard, one built around the realities of economic modelling, HTA, and population-level decision-making. Unethical AI in HEOR doesn't just produce bad research, it determines who gets access to life-changing treatments.**

## BACKGROUND

Artificial intelligence (AI) is increasingly applied in health economics and outcomes research (HEOR) to support real-world evidence generation, economic modeling, and payer and health technology assessment (HTA) decision-making. [1] However, ethical AI principles are not often widely discussed and existing guidelines may not fully address ethical risks specific to HEOR, where AI outputs influence pricing, reimbursement, and population-level access to care.

Existing health-sector guidance already emphasizes that AI in health should be governed with ethics and human rights at the center of design, deployment, and use, and identifies core principles including protecting autonomy, promoting well-being and safety, ensuring transparency, fostering responsibility and accountability, ensuring inclusiveness and equity, and promoting responsive and sustainable AI systems. [2,3]

## OBJECTIVE

1. Review existing ethical frameworks and guidelines for AI deployment in HEOR
2. Develop a HEOR-specific ethical framework for AI deployment with methodological and governance considerations relevant to economic evaluation and HTA decision contexts
3. Assess ethical risks across the HTA lifecycle, including data characteristics, transparency practices, reproducibility, and governance structures that influence downstream economic and access outcomes
4. Synthesize guidance from international health AI ethics, HTA agency position statements, real-world evidence standards, and economic evaluation reporting standards relevant to HEOR submissions

## METHODS

### Desk Research and Expert Feedback

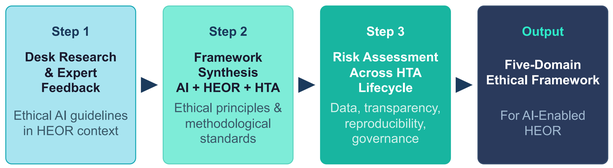
Conducted a brief desk research and collected expert feedback on ethical guidelines related to use of AI in HEOR.

### Conceptual Framework Development

Drafted a conceptual framework synthesizing ethical AI principles, HEOR methodological standards, and HTA evidence requirements.

### Risk Assessment Across HTA Lifecycle

Ethical risks were assessed across the HTA lifecycle with particular attention to data characteristics, model objectives, transparency practices, reproducibility, and governance structures that influence downstream economic and access outcomes.




## FRAMEWORK OVERVIEW

### Five-Domain Ethical Framework for AI-Enabled HEOR

A comprehensive framework addressing the unique ethical challenges of AI deployment in health economics and outcomes research was developed which was later used to map various HEOR activities to relevant ethical priority areas (Fig:1).

**1 Bias and Equity Assessment**

Though predictive accuracy is important, bias and equity should also be assessed based on downstream economic and access implications.

**2 Decision Auditability**

Transparency should be operationalized as decision auditability, enabling traceability of data provenance, assumptions, and modeling choices relevant to HTA review. [2]

**3 Reproducibility**

Reproducibility represents ethical concerns in HEOR, given the persistence of pricing and coverage decisions over time.

**4 Data Governance**

Robust data governance is required to address privacy and consent challenges associated with large, linked datasets.

**5 Accountability and Monitoring**

Clear accountability and post-deployment monitoring are necessary to identify indirect ethical harms manifested through access and coverage outcomes.

### Ethical Framework Domain Coverage

| | Problem Formulation | Data Acquisition | Model Development | Validation | Evidence Synthesis | HTA Submission | Post-Deployment Monitoring |
|---|---|---|---|---|---|---|---|
| Bias & Equity | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | |
| Decision Auditability | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | |
| Reproducibility | | | ✓ | ✓ | ✓ | ✓ | |
| Data Governance | ✓ | ✓ | ✓ | ✓ | | | |
| Accountability | | | | | | ✓ | ✓ |

✓ Domain active at this stage
Not a primary focus at this stage

Fig 1:Ethical framework to be considered at various stages of HEOR workflow

## RESULTS

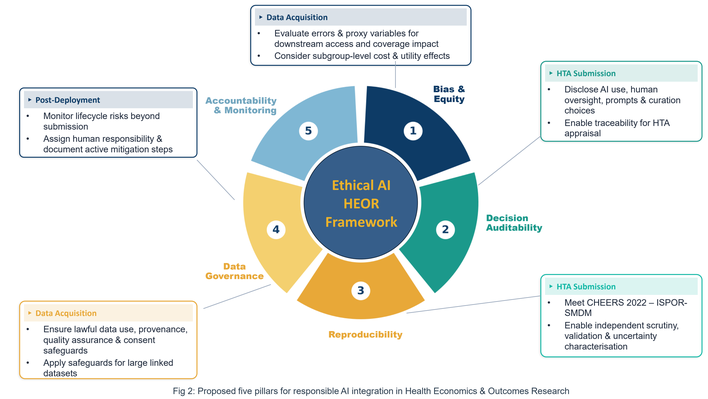



Fig 2: Proposed five pillars for responsible AI integration in Health Economics & Outcomes Research

**5**
Ethical Domains

**HTA**
Lifecycle Coverage

**AI+HEOR**
Specific Framework

## DISCUSSION

### Key Findings

Integrating economic impact, auditability, objective alignment, and governance into ethical evaluation can support more trustworthy AI-enabled HEOR evidence and more transparent reimbursement and policy decision-making.

## CONCLUSIONS

This study proposes a HEOR-specific five-domain ethical framework that addresses:

- Bias and equity in economic and access outcomes
- Decision auditability for HTA transparency
- Reproducibility for persistent policy decisions
- Data governance for privacy and consent
- Accountability and post-deployment monitoring

**References:**

1. Additional ISPOR Working Group Report (2024). Value in Health. DOI: 10.1016/j.jval.2024.10.3846
2. World Health Organization. Ethics and governance of artificial intelligence for health. Geneva: WHO; 2021.
3. Canada's Drug Agency (CDA-AMC). Position Statement on the Use of AI in the Generation and Reporting of Evidence. 2025.

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