SCOPING REVIEW / EARLY HEALTH TECHNOLOGY ASSESSMENT

Value Frameworks and Methodologies of Early Health Technology Assessment

A synthesis of 30 framework-oriented studies

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30	8	5	2000-2026
INCLUDED STUDIES	VALUE DIMENSIONS	DECISION OBJECTIVES	FRAMEWORK EVIDENCE

01 / CONTEXT

Why evaluate earlier?

Traditional HTA often enters after clinical development or market entry. Early HTA moves evaluation upstream, when product design, target population, evidence plans and investment choices can still change.

Working definition
Prospective assessment of a conceptual or developing health technology's potential value to inform development, research and investment decisions.

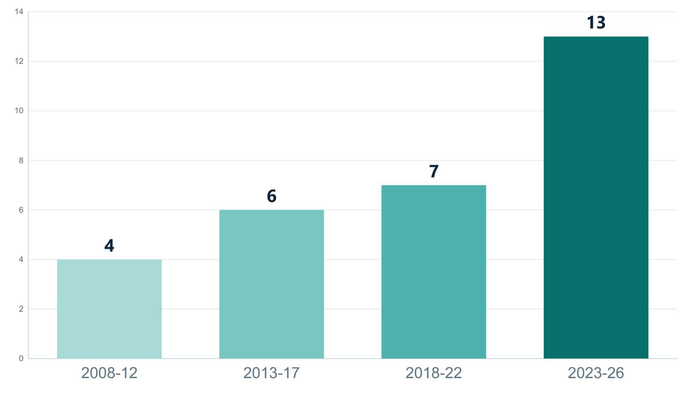
02 / METHODS

Scoping review design

- Five databases: PubMed, Web of Science, CNKI, WanFang Data and VIP
- Framework-oriented reviews, conceptual models, consensus work and policy analyses
- Two independent reviewers, with discussion or a third reviewer for disagreements
- Descriptive induction, open coding and thematic integration
- Reporting informed by PRISMA-ScR

03 / EVIDENCE BASE

The literature accelerated after 2022



13 of 30 studies were published in 2023-2026.

05 / MAIN FINDING

An eight-dimensional value framework

The first six dimensions recurred across multiple independent studies. The final two represent emerging extensions from recent system-level frameworks.

1. **Unmet need and problem definition** — Epidemiology / gap analysis
   Disease burden, service gaps and care-pathway bottlenecks
2. **Clinical value and patient benefit** — Target product profile / scenarios
   Performance thresholds, safety, subgroups and quality of life
3. **Economic value, payment and pricing** — Early modelling / headroom
   Cost effectiveness, willingness to pay, headroom and budget impact
4. **Organizational and implementation value** — Process modelling / feasibility
   Workflow fit, learning curve, training cost and readiness
5. **Stakeholder preferences and adoption** — MCDA / DCE / consultation
   Payer, clinician, patient and developer conditions for uptake
6. **Uncertainty and evidence gaps** — Sensitivity / scenario / VoI
   Decision risk, parameter sensitivity and priorities for research
7. **Equity and accessibility** — Equity scoring / stratification — EMERGING EXTENSION
   Geographic access, vulnerable groups and system capability
8. **Diffusion, scaling and system integration** — Maturity / scale-up assessment — EMERGING EXTENSION
   Adoption maturity, transferability and long-term sustainability

07 / APPLICATION AND SCOPE

Technology-specific priorities

Diagnostics and high-risk devices
Clinical pathway redesign, diagnostic performance thresholds, downstream treatment allocation and workflow fit.

Digital mental health and radiology AI
Payer definition, service integration, buyer value proposition, payment models and strategic pricing.

Drug repurposing
For candidate medicines: data access, intellectual property, regulatory coordination and a viable development case.

Precision medicine and cancer genomics
Equity, infrastructure capacity, study representation, ethical issues and cross-system scaling.

Also represented: general health technologies and hospital technology / organizational innovation.

08 / EVIDENCE GAPS

What the field still needs

- Consistent terminology and clearer conceptual boundaries
- Explicit matching of methods to concept, prototype and early clinical stages
- Transparent reporting of rapid and policy-facing assessments
- Empirical evidence that Early HTA changes development or access outcomes
- Stronger integration of ethics, equity and implementation

09 / POLICY RELEVANCE

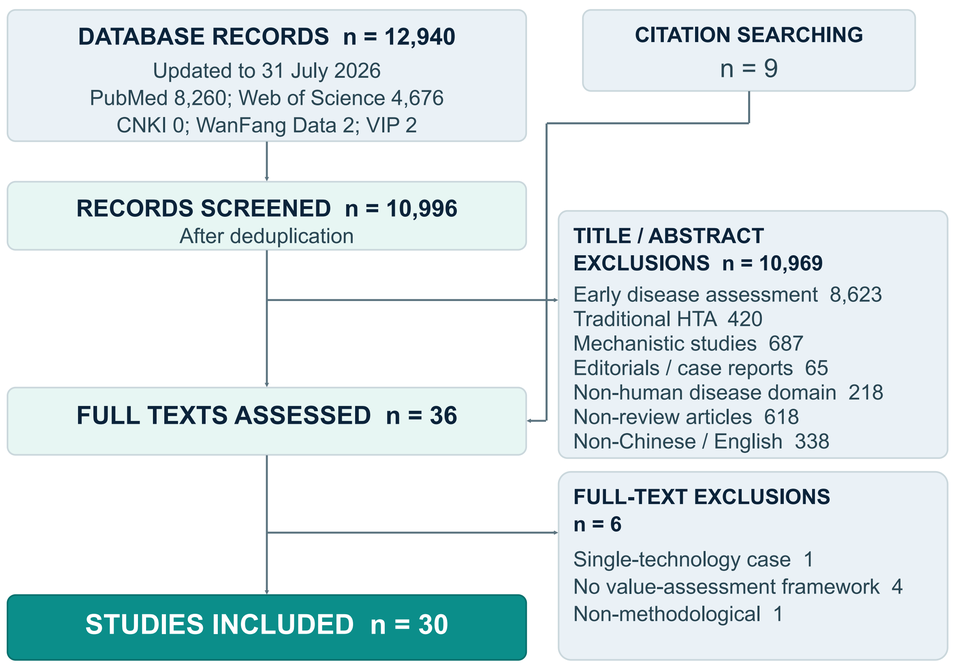
Priorities for China

- Define how Early HTA connects with regulatory review, hospital access, reimbursement and evidence-generation mechanisms
- Pilot innovative medicines, in vitro diagnostics and digital health technologies
- Develop a Chinese case repository, reporting standard and links to real-world evidence and payment pilots

06 / STUDY SELECTION AND METHOD SYNTHESIS

Study selection and decision methods

A. Literature selection



B. Methods follow the decision objective

1. **Define the problem**
   Epidemiology, care-pathway analysis and gap analysis
2. **Estimate potential value**
   Early cost-effectiveness modelling, headroom and budget impact
3. **Identify value conditions**
   MCDA, stakeholder input and discrete choice experiments (DCE)
4. **Design the next study**
   Value of information, performance thresholds and scenario analysis
5. **Support conditional adoption**
   Rapid review, simplified modelling and lifecycle analysis

Thematic synthesis across 30 included studies

A living model supports iterative decisions

Evidence, performance, price and implementation assumptions evolve with the technology. The model guides stop/go decisions, product refinement and evidence generation throughout development.

CONCLUSION

Early HTA has moved beyond early cost-effectiveness modelling. It now tests whether a technology can create value, under which clinical, economic and implementation conditions, and what evidence should be generated next.

The practical unit is an iterative decision supported by a living model.