Qualitative Analysis of Recent New Health Technology Assessment Cases and Evaluation Trends for the Adoption of Novel Technologies (Key insights from NECA HTA Reports)

HTA72

Jinhee, Moon[1] MPH**, Sungwon, Jung**[1] PhD.
1. Vantive Korea, Seoul, Republic of Korea.

BACKGROUND

- Rapid technological advances have increased the demand for timely adoption of clinically meaningful medical innovations
- Need for early access of new technologies is increasing, but the needs for robust evaluation of safety, effectiveness, and evidence generation have been intensified in parallel
- In Korea, new health technology assessment (nHTA) conducted by the Evidence-based Healthcare Collaborating Agency (NECA) serves as a key gatekeeper prior to clinical adoption and reimbursement

OBJECTIVE

- To understand nHTA process and recent trends in submitted technologies, evaluation outcomes, and implications for the adoption of advanced medical technologies in Korea by conducting qualitative analysis with the HTA cases

METHODS

- Data source: Publicly disclosed information on the NECA website including nHTA evaluation status and assessment results (HTA reports).
- Scope of the analysis: Medical technologies classified in "Procedure and intervention" category and submitted to NECA for nHTA between Aug 2023 and Dec 2025
- Data collection and Variables: Information is extracted on review status, outcomes, key evaluation parameters related to safety and effectiveness, the sub-committee meetings and those compositions.

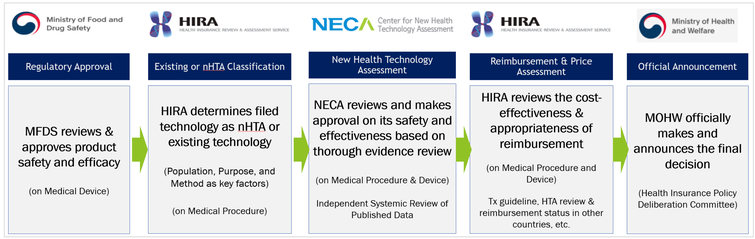
RESULTS

I. Overview of nHTA process and Outcomes

- **Pathway for Innovative Technology in the Korea Healthcare System:** Once regulatory approval is secured, new technology must undergo independent evidence-based evaluation process by NECA to demonstrate safety and effectiveness. This is followed by reimbursement assessment conducted by the Health Insurance Review and Assessment Service (HIRA), prior to final adoption into the healthcare system.

- Total applications between Aug 2023 to Dec 2025 were 73 cases, 56 (77%) case were completed and 17 (23%) cases still under review. (17 cases (65%) still under review among 2025 applications)
- Among completed evaluations (56 cases), only 46% (26 cases) were confirmed as new technology (new technology with safety and effectiveness accepted)

[Conceptual process of introduction of innovative health technology in Korea]



[nHTA application status and outcomes]

(case)

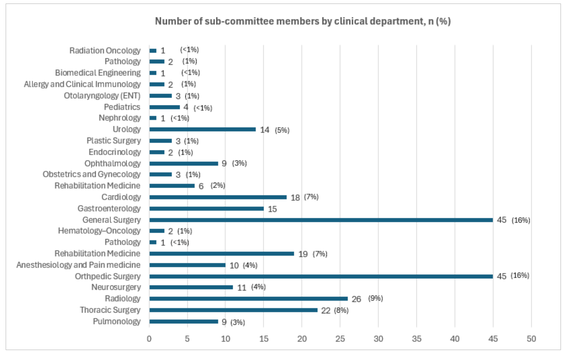
nHTA Status				Evaluation Result		
Year of Application	Application	Completed	In Process	New technology "accepted"	Research stage "not accepted"	Other * Category
2023. Aug~	16	16	-	10	6	-
2024	31	31	-	10	14	7
2025	26	9	17	6	2	1
Total	73	56	17	26	22	8

**Other category: withdrawal, rejections, and re-classification as non nHTA category*

II. Therapeutic Area Trends of Technologies Submitted for HTA Review

- The distribution of disease areas was varied based on the clinical expertise represented within sub-committee. Overall, technologies most frequently involved were: Orthopedic Surgery (16%), General Surgery (16%), and Radiology (9%).
- Except for ophthalmology, sub-committees were composed of 3-4 clinical specialties, reflecting the multidisciplinary nature of technology assessment. Including Evidence-based medicine specialty, committees generally consist of 7 members from relevant specialties.

[Disease area of new health technologies* (subcommittee composition by specialty)]



**Technologies limited to Procedure and intervention category*

III. Evaluation Trends and Implications for the Adoption of Novel Technologies

- **Trends in new technology submissions**:
  - ➢ Recent innovations increasingly drive incremental improvements in existing therapeutic options, expand solutions addressing remaining clinical needs, and leverage technological advances, to enhance patient experience during treatment through less invasive interventions, or to support clinicians in clinical decision-making and procedural workflows.

- **Level of Clinical Effectiveness Evidence:**
  - ➢ Clinical evidence for new technologies showed wide variation, ranging from RCT to case reports, resulting in a broad spectrum of evidence quality. While the required level of evidence differed across cases, stronger evidence such as RCT was often expected for decision, particularly for technologies targeting severe or high-risk conditions.
  - ➢ Beyond study design, consistency of clinical outcomes across studies played a key role in evaluation, and magnitude of clinical benefit vs comparators are also the key required evidences.
  - ➢ Consensus among experts, textbooks, and clinical practice guidelines were also referenced in decision-making.

- **Characteristics of Key Evaluation Endpoint (clinical factors for decision making)**
  - ➢ Safety evaluation focuses on identifying adverse events directly related to the technology. Technologies are generally accepted when observed safety risks are comparable to existing alternatives or considered clinically manageable.
  - ➢ Effectiveness endpoints vary by disease area, and are evaluated in multiple dimensions, including technical performance, clinical outcomes, short- and long-term endpoints, healthcare utilization, and patient quality of life. The importance of each endpoint depends on the primary therapeutic goal, with greater emphasis on mortality if it is used in patients in life-threatening conditions.

- **Key Implications for Evidence Generations and Policy-Decision Making**
  - ➢ Early and strategic evidence planning, supported by well-designed studies and aligned with HTA expectations, is essential for industry to enable timely adoption of novel technologies.
  - ➢ More flexible, patient-centered evaluation approaches are need for technologies addressing severe or high-unmet-need conditions, especially where clinical options are limited, as over-reliance on hard outcomes alone may delay access to clinically valuable innovations.

CONCLUSIONS

- Recent nHTA trends highlight increasing complexity in the evaluation of innovative technologies. These findings emphasize the importance of flexible assessment frameworks and well-structured evidence generation pathways to support timely and patient-centered adoption.

REFERENCES New health technology assessment reports by NECA. Accessed from: https//nhta.neca.re.kr

CONTACT INFORMATION Jinhee Moon (jinhee.moon@vantive.com) Sungwon Jung (Sungwon.jung@vantive.com)