

Challenges and Best Practices for the Japan Health Technology Assessment Pilot Program

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KEY POINTS

Health technology assessment (HTA) processes continue to expand globally.

Authorities developing new HTA processes should draw inspiration from the approaches taken by existing HTA bodies, adapted to regional circumstances.

These guiding principles may be helpful for Japan, which is in the process of developing and establishing their own HTA.

To guide health technology policy decisions, countries often rely on health technology assessments (HTAs). HTAs typically involve the evaluation of a medical technology's impacts, but can be operationalized for different purposes, depending on the needs and policies of a country. For decades, countries such as the United Kingdom, Canada, and Australia have used HTAs to inform resource allocation. In the new climate of healthcare cost concerns, a wave of countries without formal HTAs, such as Japan, Costa Rica, and Argentina, are implementing their own processes.

process that evaluates drugs and medical devices post-launch based on clinical and economic benefits relative to a comparator.[2]

Launched in 2016, the HTA pilot phase evaluated 7 previously reimbursed drugs and 6 medical devices. The results of the HTA evaluation will be reflected directly by a price revision, but only a portion of the price can be adjusted via the HTA review. Four other factors, including social impact and ethics, may be considered during the appraisal process, each assigned a 5% weight. Although the results of this pilot have

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For countries developing their own HTA systems, the variability in HTA purpose and structure can make identifying optimal aims and processes challenging. For example, high- and upper-middle income countries tend to use HTA to guide reimbursement and coverage decisions; lower income countries tend to use HTA for planning and budgeting.[1] In this piece, we discuss some common challenges and best practices for burgeoning HTAs to consider, particularly those that may be applicable to Japan, which is completing a pilot of their proposed HTA process. As the third-largest economy in the world, the results and subsequent implementation of Japan's HTA has significant implications for HTA processes around the world.

HTA PILOT PROGRAM IN JAPAN

Japan has the world's longest life expectancy and ranks highly across a number of health metrics. Its universal healthcare system, which provides insurance and comprehensive care to all citizens, has contributed significantly to these health achievements. Like all health systems, however, Japan's system has faced rising healthcare expenditures and budgetary constraints. The Japanese Ministry of Health, Labour, and Welfare's (MHLW) Central Social Insurance Medical Council (Chu-I-Kyo) has developed an HTA

not been disclosed publicly, Japan aims to formally launch their HTA in April 2019.

COMMON CHALLENGES FOR NEW SYSTEMS AND PROCESSES OF HTA

The first step in establishing an HTA is to determine the policy decisions that the HTA should inform. These decisions depend on many public health and economic factors, such as healthcare coverage. Since Japan's health system covers all medications, their HTA will inform pricing adjustments. Regardless of the purpose, however, all HTAs face similar start-up considerations.

ESTABLISHING GOOD PROCESSES AND METHODOLOGIES

Creating a new HTA requires developing a scientific framework for evaluating new technologies and a process for conducting these evaluations. Best practices and guidelines continue to evolve as the evidence base grows and new scientific techniques are innovated.[3] However, the core of high-quality economic and policy research remains constant, meaning that HTAs must define the appropriate interventions, populations, comparators, outcomes, and time horizon to ensure the evaluations are appropriate for the relevant policy decisions. The MHLW has commissioned and published guidelines for cost-effectiveness analyses,[2] developed by

Japanese health economists, although the process for feedback and refinement is unclear.

DEFINING A COST-EFFECTIVENESS THRESHOLD

HTAs commonly rely on cost-effectiveness thresholds, or the cost for each additional unit of the outcome where “cost-effectiveness” or reasonable value is anticipated. This benchmark could also be conceived as a measure of the opportunity cost of the health outcomes for the marginal intervention that must be relinquished to provide resources for a new intervention.[4] Typically, quality-adjusted life years (QALY)—a measure of life-extension and quality of life—are used as the unit of outcome.

Since cost-effectiveness thresholds can inform whether a technology has “low” or “high” value, establishing the appropriate value is essential. There are no universally accepted values, but some fall in the range of one to three times gross domestic product (GDP) per capita. In the United States, for example, the conventional willingness-to-pay range has been \$50,000 to \$150,000 USD, and in the United Kingdom, it has been closer to \$25,000 per QALY.[5] In both countries, thresholds may be higher for treatments targeting certain diseases or populations. Japan’s currently selected threshold of JPY5M falls within the lower end of the range; however, the function of the threshold could be considered conceptually different as a starting point for price revisions, instead of as a benchmark for coverage decisions.

BUILDING CAPACITY

In addition to the scientific methodology, developing a rigorous HTA also requires identifying and allocating human and financial resources to support the process. Securing and retaining these resources can be challenging, especially for countries without well-established HTA programs.[1] Engaging global experts during the HTA development process can help ensure that human resources are experienced and knowledgeable.

STAKEHOLDER BUY-IN

When not executed according to sound principles, HTA could be viewed skeptically as an attempt to limit patient access or a lever for government price negotiation. Involving a range of stakeholders, such as patients, providers, manufacturers, and scientific experts in the development process can support the credibility of an HTA.

THE HTAS OF TOMORROW

Developing an HTA has the potential to improve public health and societal welfare significantly; however, there is no “one-size-fits-all” approach, due to country-specific needs, resources, and policies. For example, Australia does not use an explicit willingness-to-pay threshold in their decision making and publishes the decisions of the Pharmaceutical Benefits Advisory Committee on the internet without disclosing the details of the economic analyses.[6] The United Kingdom’s National Institute for Health and Care Excellence (NICE), while building primarily on drug manufacturers’ submissions, often commissions an independent academic center to prepare evaluations for consideration by the technology appraisal committee.[7]

Countries establishing new HTAs, like Japan, have the opportunity to identify components of existing processes that best align with the objectives of their health system. As these processes have evolved globally, so have the needs of the health systems they serve. In the current climate of seeking value and quality in care and making

decisions based on a body of evidence, the following practices could be helpful for nascent HTAs.

TRANSPARENT PROCESSES AND DECISION MAKING

Many HTA guidelines recommend transparent processes and decision making for the evaluation of new medical technologies. [1,8] Transparency can ensure appropriateness of the approaches selected, build greater confidence in the results, and allow for greater participation of all stakeholders, including manufacturers, providers, and patients.

REAL-WORLD DATA INCORPORATION

Randomized controlled trials remain the gold standard for evidence of efficacy and safety for new medical technologies. However, there is growing interest in incorporating real-world data, given differences in patient populations and behavior between the controlled setting of clinical trials and the real world.

MULTISTAKEHOLDER ENGAGEMENT

There has also been a growing recognition of the limitations of conventional economic methods to measure the true value of new medical technologies. For example, a treatment’s nonclinical benefits, such as reduced caregiver burden and improved productivity, are often not included in standard economic evaluations. Confirming that key stakeholders, particularly patients, are included can help ensure that the full benefits of a treatment are evaluated.

Through the implementation of its HTA pilot, Japan’s MHLW has taken an important first step in developing a scientifically based system that can inform the optimal use of its limited resources. As Japan and other countries establish new HTA processes, support from global experts in HTA will be valuable to ensure that lessons learned from other countries can be leveraged and operationalized. ●

Financial support for this research was provided by Gilead to Precision Health Economics, a life sciences consulting firm. In addition to their academic positions, Drs. Børllum Kristensen, Igarashi, and Neumann are consultants to Precision Health Economics. Dr. Goldman is a founder and consultant to Precision Health Economics.

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Additional information

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