

## SEMINAR

# Current status of health technology assessment research in Japan

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## ABSTRACT

Health technology assessment (HTA) is implemented in the decision-making process for the reimbursement and pricing of drugs and medical devices around the world. This study presented the trend and characteristics of HTA research in Japan and worldwide. HTA research increased since the 2010s. Cancer was a prominent subject and the Markov model was a major analytical model in HTA research both globally and in Japan. In Japan, osteoporosis was a more popular topic, but there were fewer surgical research and review articles compared to the global trend. Since Japanese articles on HTA were much fewer than those from the United States, the United Kingdom, and China, various types of HTA research should be encouraged in Japan to promote product innovation and optimize medical expenditures.

## KEY WORDS

cost-benefit analysis, cost-effectiveness, health technology assessment

## INTRODUCTION

Health technology assessment (HTA) for cost-effectiveness evaluation is implemented in the decision-making process for the reimbursement and pricing of drugs and medical devices [1, 2]. HTA systematically assesses the properties and effects of health technology to determine its value at different points in its lifecycle [3]. HTA research, thus, focuses on patient-centered outcomes (e.g., quality-adjusted life year) and cost-effectiveness (e.g., incremental cost-effectiveness ratio) [4]. In non-Japanese countries, HTA is often used for the first evaluation to determine the reimbursement and prices of drugs and medical devices [2].

The Japanese government started using HTA in 2016 for biennial price revision, but not for the first evaluation. The assessment is targeted at drugs and medical devices that fulfill certain selection criteria; specifically, the Central Social Insurance Medical Council (*Chuikyō*)

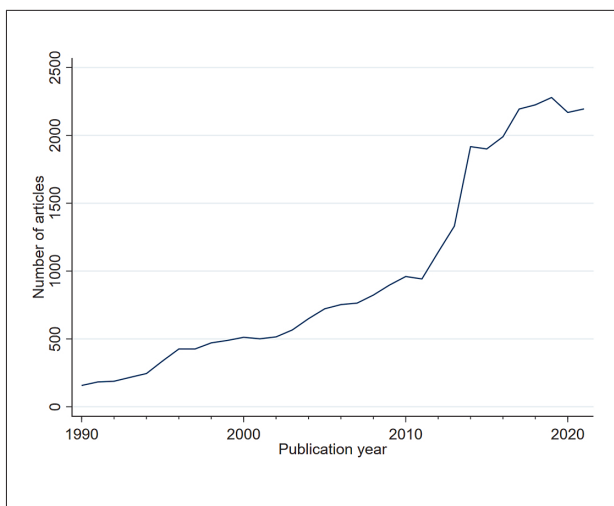
selects drugs and medical devices that have high premiums due to their previous pricing and are achieving massive sales currently to undergo price revision through HTA [5]. By initially charging high premiums on innovative products and reducing their prices by price revision through HTA two years later, the Japanese government aims to promote the accelerated innovation of new innovative products and optimize medical expenditures. After a product is selected for HTA, a cost-effectiveness analysis is conducted based on the Japanese official guideline [6].

Despite the implementation of HTA for the repricing of drugs and medical devices, research on cost-effective analysis in Japan is still lacking compared to other countries. Thus, this study aimed to clarify the trend and characteristics of cost-effectiveness analysis research in the world and Japan.

## GLOBAL TRENDS IN HEALTH TECHNOLOGY ASSESSMENT RESEARCH

We searched PubMed for HTA research using cost-effectiveness analysis between 1990 and 2021 around the world, including Japan. The trend of research articles is shown in **Fig. 1**. The number of articles increased rapidly since the 2010s presumably because many international organizations (e.g., the United Nations and the World Health Organization) began focusing on HTA for country-level evidence-based policy decision-making for designing universal health coverage systems in the early 2010s [7].

We conducted further searches by categorizing research by major theme, disease, analytic model, and country. We added the “focused term”[Title/Abstract] to the aforementioned search term; for example, (“cost-effectiveness”[Title] OR “cost-benefit analysis”[MeSH Major Topic]) AND “Cancer”[Title/Abstract]. The number of articles on various topics was found to be increasing (**Figs. 2a** and **2b**); cancer was the most popular topic among diseases. This could be attributed to the increase in costly anti-cancer treatments. The Markov model, which is suitable for modeling chronic diseases [8], seemed to be used most frequently in HTA research (**Fig. 2c**). The use of the partitioned survival model was increasing recently, since this model is useful for HTA of interventions for advanced or metastatic cancers [9]. HTA research was conducted dominantly in the United Kingdom and the United States of America (**Fig. 2d**). The number of articles increased gradually since the estab-



**Fig. 1** The number of articles on health technology assessment in PubMed

Search term: “cost-effectiveness”[Title] OR “cost-benefit analysis” [MeSH Major Topic]

lishment of the HTA associations: the United Kingdom set up the National Institute for Clinical Excellence in 1999 [4], and the United States of America established the Patient-Centered Outcomes Research Institute in 2010 [10]. Further, the number of articles in China was growing rapidly since the establishment of the National Centre for Evaluation of Medicines and Health Technologies as a national HTA agency in 2018 [11]. In contrast, in Japan, although the government established the Center for Outcomes Research and Economic Evaluation for Health in 2018 [12], HTA research in this region had hardly increased.

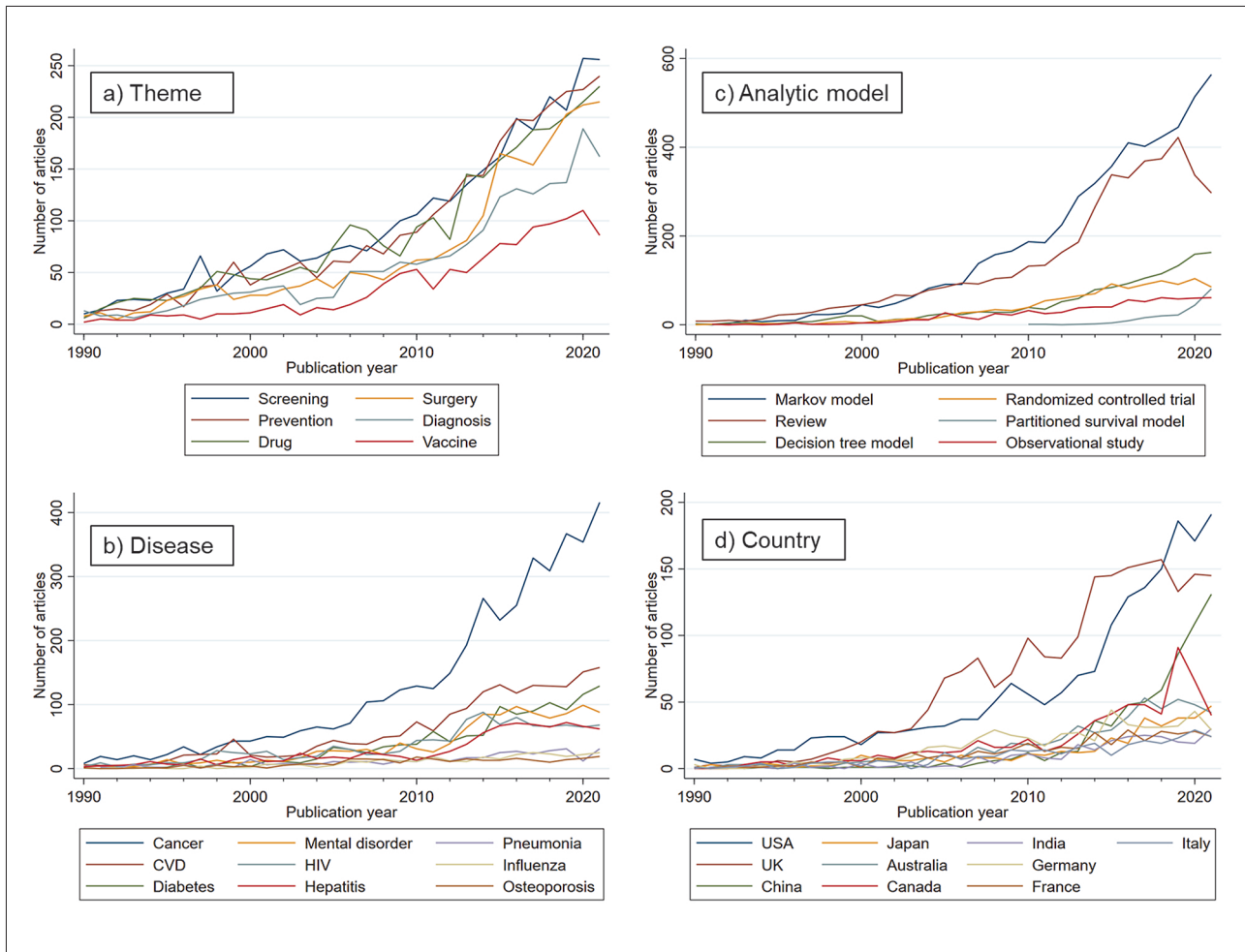
## CHARACTERISTICS OF HEALTH TECHNOLOGY ASSESSMENT RESEARCH IN JAPAN

We searched PubMed for HTA research conducted between 1990 and 2021 in Japan. The search term was similar to that for worldwide trends; for example, (“cost-effectiveness”[Title] OR “cost-benefit analysis”[MeSH Major Topic]) AND “Japan”[Title/Abstract] AND “Cancer”[Title/Abstract].

Screening was the most prevalent technique (19%) of HTA research in line with the world trend (**Table 1**). Since screening is a process of identifying affected individuals in the general population, it can rarely offer individual benefits such as life expectancy gain; therefore, its public benefits such as cost-effectiveness would likely be examined even in Japan, where HTA research is still uncommon. While HTA research on surgery was increasing globally, along with research on drugs, research on surgery (7.5%) in Japan is stagnant at only two-thirds of the amount of research on drugs (13%). There is potential to increase HTA research on surgery in Japan.

Consistent with the global trend, cancer was a prominent subject of HTA research in Japan, accounting for approximately a quarter of total HTA research publications. The second highest number of studies have focused on cardiovascular diseases (8.6%), which is also consistent with the global trend. Nevertheless, HTA research on osteoporosis, which is rarely conducted in the world, was the third most published in Japan (4.6%). Since Japan has the longest life expectancy among women in the world [13], osteoporosis in elderly women would be a hot topic in HTA research. There were few studies on human immunodeficiency virus in Japan compared to the global trend (0.6%) presumably, as its prevalence in East Asia was estimated to be still low [14].

Regarding analytical models, the Markov model was common (38%) considering the global trend. However,



**Fig. 2** The number of articles on health technology assessment in PubMed categorized by major theme, disease, analytic model, and country

Abbreviations: CVD, cardiovascular disease; HIV, human immunodeficiency virus

Search term: ("cost-effectiveness"[Title] OR "cost-benefit analysis"[MeSH Major Topic]) AND "focused term"[Title/Abstract]

| Table 1 Characteristics of 347 health technology assessment research studies in Japan |          |                        |          |                             |          |
|---|----------|------------------------|----------|-----------------------------|----------|
| Theme   | n (%)    | Disease                | n (%)    | Analytic Model              | n (%)    |
| Screening   | 67 (19)  | Cancer                 | 89 (26)  | Markov model                | 131 (38) |
| Drug  | 46 (13)  | Cardiovascular disease | 30 (8.6) | Review                      | 34 (9.8) |
| Prevention  | 35 (10)  | Osteoporosis           | 16 (4.6) | Decision tree model         | 30 (8.6) |
| Surgery   | 26 (7.5) | Hepatitis              | 15 (4.3) | Randomized controlled trial | 14 (4.0) |
| Vaccine   | 25 (7.2) | Diabetes               | 12 (3.6) | Observational study         | 9 (2.6)  |
| Diagnosis   | 20 (5.8) | Influenza              | 9 (2.6)  | Partitioned survival model  | 8 (2.3)  |
|   |          | Mental disorder        | 8 (2.3)  |                             |          |
|   |          | Pneumonia              | 6 (1.7)  |                             |          |
|   |          | HIV                    | 2 (0.6)  |                             |          |

Abbreviation: HIV, human immunodeficiency virus  
 Search term: ("cost-effectiveness"[Title] OR "cost-benefit analysis"[MeSH Major Topic]) AND "Japan"[Title/Abstract] AND "focused term"[Title/Abstract].

compared to the number of review articles worldwide following the Markov model, the number of review articles in Japan was considerably lower (9.8%). This indicated that original articles were mainstream in HTA research in Japan. Additionally, few original articles were available for review. Indeed, while nearly 150 HTA studies are published annually in the United Kingdom, the United States of America, and China, Japan had few publications—approximately 40 articles are published in Japan per year even recently. Thus, to promote product innovation and optimize medical expenditures in Japan, various types of HTA research, including review research, should be encouraged.

## CONCLUSIONS

HTA research has been increasing particularly since the 2010s. Cancer was a prominent subject of HTA research and the Markov model was a major analytic model in the world and Japan. In Japan, osteoporosis was a more common research topic, while surgical research and review articles were fewer considering the global trend. Despite the implementation of HTA for price revision and the establishment of a specialized agency, the number of research articles on HTA in Japanese has hardly increased.

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