



## Editorial

## Health technology assessment and economic evaluation: Is it applicable for the traditional medicine?

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## ABSTRACT

Gaps between limited health resources and expanding health service demands are emerging to be more and more prominent, which extremely generate the cost-effective strategies for scientific policy-making in the context of healthcare. As a systematic approach and solid tool to promote healthcare system more efficient and sustainable, health technology assessment (HTA) could provide multi-dimensional evidences comprising effectiveness, safety, economic implications, ethical, social, cultural and legal issues, in which economic evaluation is an important and unique part for optimizing decision-making. After decades of development, HTA has formulated a set of systematic theories, methods and procedures based on modern medicine. Meanwhile, as an important component of medicine system across the world, traditional medicine (TM) originates from knowledge, skill, and practices based on the theories, beliefs, and experiences indigenous to different traditional cultures. Yet whether current theory and method system of HTA is applicable for TM is necessary to be explored and investigated. In principle, the general steps and methods of HTA could be basically applicable to TM, except for the PICO structuring, cost measurement, and supportive clinical evidence and information collection in economic evaluation. Therefore, these three challenging problems need to be focused and addressed in future HTA for TM.

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## 1. Introduction

Health technology assessment (HTA) is a field of scientific research to inform policy and clinical decision-making on the introduction and use of health technologies. In the present context, health technology commonly includes *drugs, devices, medical and surgical procedures* used in healthcare delivery, the *knowledge* associated with this, as well as *organizational and support systems*, within which healthcare is provided. According to the WHO's global survey on HTA,<sup>1</sup> 80% countries had a formal HTA process to inform decision-making, in which they systematically collected data and considered the impacts of a particular health technology or intervention. Meanwhile, about half had legislative requirements to formalize the incorporation of the results of HTA in healthcare decision-making, as well as two thirds had established national HTA organization or department, unit or committee to produce HTA reports for the Ministry of Health (MOH). Additionally, the

survey also revealed that shortage of qualified human resources appeared to be a key barrier for producing and using HTA evidences to inform decision-making.

HTA provides a bridge between research and decision-making, including policy and clinical decision-making. It provides evidence-based information to help make decisions on the selection and utilization of health technologies (including emerging new technologies), to promote efficient and appropriate health resource allocation, and to control costs while maximizing value for patients and the healthcare system. HTA has been gaining recognition internationally and has played an increasingly important role in health policy-making. HTA organizations can be found in many countries, from developed countries to developing nations, such as the National Institute for Health and Care Excellence (NICE) in the United Kingdom, the Swedish Council for Technology Assessment in Health Care, the Canadian Agency for Drugs and Technologies in Health (CADTH), the Medicare Services Advisory Committee (MSAC) in Australia, and the Veterans Affairs Technology Assessment Program (VATAP) in the United States.

HTA systematically examines the technical performance, safety, cost-effectiveness, organizational implications, social consequences,

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legal and ethical considerations of the application of a health technology.<sup>2</sup> Its main purpose is to inform technology-related policy-making in health care, and thus improve the uptake of cost-effective new technologies and prevent the adoption of technologies that are of doubtful value for the health system.<sup>3</sup>

Traditional Medicine (TM), belonging to health technologies, is the sum total of the knowledge, skill, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.<sup>4</sup> As an important component of the world medical system, HTA and evidences for TM should be fully emphasized when making relevant clinical and policy decisions. However, HTA on TM has not received widespread attention across the whole world currently. Few official institutions claim that they conduct HTA for TM, as well as less published literature reporting HTA results on TM. This paper focuses on the review of HTA development status in Asia, HTA new definition, and key characteristics and procedures of economic evaluation for health technology, and explores the underlying applicability and challenges of HTA and economic evaluation for TM.

## 2. HTA in Asia

In Asia, many countries are catching up HTA with their local adaptation for policy-making.<sup>5</sup> The establishment of the HTAsiaLink network in 2011 has been catalytic in driving the growth and strengthening HTA capacity across the region.<sup>6</sup> The network includes thirty-four HTA organizations from seventeen member countries or regions, including Singapore, Malaysia, Philippines, Vietnam, China, South Korea, Thailand and Taiwan (China).<sup>7</sup>

South Korea became the first Asian country to officially implement HTA to inform reimbursement decisions and introduced the positive list system (PLS) in 2006, which includes a formal HTA process for new drugs. The agency responsible for reimbursement decisions is the Health Insurance Review and Assessment Service (HIRA), which acts independently but is under the supervision of the Ministry of Health and Welfare. In 2008, the National Evidence-based healthcare Collaborating Agency (NECA) was established to conduct HTA research, and in 2010, the HTA processes pertaining to procedures and diagnostics were transferred from HIRA to NECA.<sup>8</sup>

In Thailand, HTA plays an important role in evidence-based healthcare decision making with the leading HTA agency, Health Intervention and Technology Assessment Program, Department of Health, Ministry of Public Health. In Thailand, HTA has been formally integrated into coverage decisions, including in the development of the National List of Essential Medicines and the Universal Health Coverage Scheme benefits package.<sup>9</sup>

In Japan, HTA has gradually played a vital role in incorporating new drugs into medical insurance. Commonly, new drugs without existing comparator could be included in medical insurance immediately after approval by the Pharmaceutical and Medical Devices Agency (PMDA), and the initial medical insurance payment price determined by manufacturers or markets based on cost-plus to cover the pharmaceutical development costs.<sup>10,11</sup> During the first two years of new pharmaceuticals enrolled in medical insurance, HTA will be conducted, and renegotiation will be adopted based on the HTA results to determine the new payment prices for relevant new drugs at the end of the second year.<sup>8,12</sup> Before 2016, Japan did not have a complete HTA mechanism, yet in 2012, HTA was discussed how to be introduced and applied in Japan due to the Japanese government began to emphasize the important function of HTA to inform policy-making, rather than only formulate evidence-based clinical practice guidelines. Since a three-year HTA

pilot program to assess cost-effectiveness was introduced in April 2016, cost-effectiveness analysis of HTA has emerged to be promoted in Japan.<sup>8</sup>

In China, HTA was introduced to China in 1980s and developed at academic universities, yet has gradually been attracting Chinese government attention and influencing decision-making since 2010s. With the full emphasis from all sectors of society on HTA, the Chinese government has issued a series of supporting and guiding policies to encourage and explore the application of HTA in decision-making. Particularly, the National Health Commission (NHC) and National Healthcare Security Administration (NHSA), two key ministries governing the health system in China, have demonstrated clear progress in incorporating HTA to policy-making. NHSA (and its predecessor, the Ministry of Human Resources and Social Security (MHRSS)) has included HTA or pharmacoeconomic evaluation evidences and procedures in the National Reimbursement Drug List (NRDL) updating since 2017.<sup>13</sup>

## 3. New definition of HTA

In 2020, HTA definition was updated by HTAi and INAHTA. Health technology assessment (HTA) is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system.<sup>14</sup> Regarding to the value, it interprets that the dimensions of value for a health technology may be assessed by examining the intended and unintended consequences of using a health technology compared to existing alternatives. These dimensions often include clinical effectiveness, safety, costs and economic implications, ethical, social, cultural and legal issues, organizational and environmental aspects, as well as wider implications for the patient, relatives, caregivers, and the population.<sup>15</sup> The overall value may vary depending on the perspective taken, the stakeholders involved, and the decision context. In this updated definition, it highlights the key word of “value” to incorporate all evaluation elements and dimensions, while it gives interpretation of comprehensive dimensions and perspectives.

Economic evaluation is one of backbones of HTA, which assesses the cost-effectiveness of health technology, and it tries to meet decision-making needs, balancing increasing health care needs due to new health technology and providing appropriate health services (including technology) in the context of limited health resources. So it would reflect multi-facet value, not only clinical value but also economic value, such as value for money or affordability.

## 4. Economic evaluation

According to *Methods for the Economic Evaluation of Health Care Programmes*, Economic evaluation seeks to inform the range of very different but unavoidable decisions in health care.<sup>16</sup> It has two features, dealing with both the inputs and outputs, which can be described as the costs and consequences, and concerning itself with choices with tradeoff of inputs and outputs. The definition of economic evaluation is as the *comparative analysis of alternative courses of action in terms of both their costs and consequence*.<sup>16</sup> Economic evaluation is not commissioned by “cost-saving”, and it aims to achieve the efficiency of additional costs.

Many types of health care decisions/choices can be addressed through economic evaluation. Policy makers, clinicians, public health workers, and patients, are looking for choices or recommendations, for example, alternative clinical strategies for a given condition: transplantation versus dialysis for renal failure; alternatives in the timing of interventions: introduction of hypertension screening or health promotion programs; alternative locations for

care: inpatient versus home or community care; alternative programs aimed at different conditions: COVID-19 immunization versus coronary care units or ECMO equipped; alternatives in scale or size of a program: expansion of a screening program from high risk individuals to everyone.

## 5. Economic evaluation's key procedures

### 5.1. Economic evaluation's perspective should be carefully determined at the beginning of the study

There are several perspectives normally, patients, health system, payer, and societal. The key to identify one or more perspectives is related to measurement of costs and consequences. For example, health care claims at a hospital are paid by a health insurance schemes, out-of-pockets by patients, or even other sources, so the measurement of costs is different due to different perspectives. Since HTA is always serving for reimbursement decision, payer perspective is very common, but it might not capture the whole picture of costs. Societal perspective comprehensively covers health-care, non-health, productivity, intangible costs and beyond, and it is challenging in study design, data collection and analysis protocol. So the identification of the perspective of the study and relating this to the costs is very important.

### 5.2. Categories of costs should be defined well according to the economic evaluation purpose with appropriate time horizon

Costs are classified as direct medical costs, direct non-medical costs, indirect costs and intangible costs.<sup>17</sup> Direct medical costs are mainly occurred for health services in healthcare setting, such as outpatient or inpatient costs, costs for pharmaceuticals, tests, radiological procedures, surgery, procedures, and services, etc. These are the costs that are traditionally counted as health care expenditures and represent the outlays that contribute to the portion of the gross national product spent on health care. Direct non-medical costs are mainly expenses for transportation, accommodation, nutrition, family care, home aides or others during seeking health services but do not involve purchasing medical care. Indirect costs are related to morbidity and mortality costs, such as unpaid assistance, days lost from work, decreased productivity due to health issues. Indirect morbidity costs may occur because of being absent from work, because of a decreased earning ability when working, or because of long-term disability that necessitates a change in type of work. Human capital approach is applied to measure productivity costs. Intangible costs represent another category of costs and are difficult to measure. These are the costs of pain, suffering, grief, and the other non-financial outcomes of disease and medical care. In cost-utility analysis, intangibles may be measured to some extents, such as QALYs.

Cost analysis is not only an exercise about whose costs to consider but also a choice of time period, time horizon. Analytic time horizon is the period over which the costs and consequences of health outcomes that occur as a result of the intervention are considered. In short-term, outpatient or inpatient costs are measured in quantity of services; in medium-term, those costs are collected in a time period, such as one year, which reflects costs for all related; and in long-term, costs are incorporated for life-cycle. The length of time horizon is related to purpose of economic evaluation, and the long term life-course costs could capture all possible positive and negative effects and their costs, and could present the long term inputs against their outputs. The time period for the cost data collection must be contemporaneous with the time period for which clients are served. In general, the time period should be long enough to avoid any secular patterns.

Estimating costs have three steps, identifying resources used, measuring the resources used and placing a monetary value on the resources used.

### 5.3. Appropriate types of analysis should be deliberately selected, including cost-effectiveness analysis (CEA), cost-benefit analysis (CBA) and cost-utility analysis (CUA)

Different types of analysis are determined according to the purpose of the study, and are classified by measurement of consequences of analysis, effectiveness using indicators for a single or similar health outcome of long term effects (such as life years) or short term effects (such as surrogate indicators, blood pressure, % of cholesterol reduction, cases of DVT detected, episode-free days), benefit representing transfer of health consequence into monetary value, and utility using long term life years weighted by corresponding utility or quality of life. (Table 1).

Cost-benefit analysis forces an explicit decision about whether the cost is worth the benefit by measuring both in the same units, so it could be applied to one intervention without any comparison.

### 5.4. Economic evaluation's PICO should be carefully structured

PICO represents that P-population or patients, I-intervention, C-comparison, O-outcome. There are several challenging questions before the evaluation is conducted:

- Have we included all of the important interventions which reasonably competitive with each other?
- How will we decide how the disease is usually diagnosed or treated?
- Is the clinical setting relevant and target population appropriate?
- Are we competing two different interventions or different levels of a single intervention? (marginal or incremental)
- Have we selected a set of outcomes to analyze, such as progress free survival (PFS) or overall survival (OS) for an intervention for a cancer?

To conduct an economic evaluation, we must identify all the possible alternatives to the treatment or intervention we are analyzing, and identify the current best treatment as the control rather than placebo or bad/outdated one. In some cases, a pharmaceutical company prefers to select a weak comparison to justify the new treatment seems to be better, so selection of the comparison should be carefully discussed and decided among stakeholders.

### 5.5. Economic evaluation should be supported by solid clinical evidence

It is important for evaluators to learn about the disease, such as symptoms, complications, transmission, and treatment, to chart out the course of the disease and its development, and to list the data elements needed, available or not. In order to get clinical evidence, a specific RCT or any kind of literature review could be employed. If a meta-analysis or a systematic review could demonstrate some clinical effectiveness, it is highly recommended. In one of checklists for quality control of economic evaluation, *Consolidated Health Economic Evaluation Reporting Standards (CHEERS)*,<sup>18</sup> it presents single study-based or synthesis-based estimates check point. For single study-based estimates, the research team should describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness evidence. For synthesis-based estimates, it should describe fully the methods used for identification of included studies and synthesis of clinical effectiveness evidence.

### 5.6. Economic evaluation should specify the discount rate or time preference

The discount rate is related to the value along with the time. A dollar that an individual receives this year is worth more than a dollar that will be received 10 years from now. So the discount rate should be adjusted for costs if it is over 1 year. In any consideration of costs, it is important to note when they are incurred. Nominal costs in the future are likely to be higher simply because of inflation, and these future inflated costs need to be corrected to their equivalent value at the time the decision is being made. Simultaneously, effects occurring in the future should be discounted. If not discounted for effects, it could lead to inconsistencies in reasoning. Leaving effects undiscounted leads to quite impossible conclusions.

Both costs and benefits should be discounted to account for the consequences of time, using the following formulas:

$$\begin{aligned} \text{Costs} &= \sum \text{costs}_t / (1+i)^t \\ \text{Benefits} &= \sum \text{benefits}_t / (1+i)^t \\ i: & \text{discount rate; } t: \text{the } t \text{ th year} \end{aligned}$$

### 5.7. Economic evaluation should employ a decision-analytical model

While conducting economic evaluation, many types of models are used for measuring or simulating cost-effectiveness ratios, including decision tree model, Markov model and partition survival model. Decision tree is widely used in economic evaluation, especially in short term period, but it is not suitable for chronic diseases with long-term prognoses. The Markov model could deal with decision problems, health states transitioning with time cycle (month, or year). For cancer therapy, partition survival model is very common. Any specific type of decision-analytical model selected should be justified for its rationale. Providing a figure to show model structure is strongly recommended, and all main assumptions underpinning the model should be demonstrated.

### 5.8. Economic evaluation's finding should be presented as incremental cost-effectiveness ratios (ICER)

ICER compares the relative effect of multiple programs or interventions. The ratio of the difference in costs between two alternatives to the difference in effectiveness between the same two alternatives ( $\Delta C/\Delta E$ ).

$$\text{ICER} = (\text{TC}_a - \text{TC}_b) / (E_a - E_b)$$

Normally, there are four scenario based on cost-effectiveness comparison. First, cost difference is decreased while effect difference is improved, which is dominated by the intervention. Second, cost difference is increased while effect difference is declined, which is definitely cost-ineffective. Third, cost and effect differences are simultaneously increased, then ICER is one of approaches to evaluate cost-effective compared to a predefined threshold. Fourth, cost and effect differences are both decreased, and it is also needed to evaluate.

Threshold is helpful to determine if the technology is cost-effective or not. However, it is explicitly released in some countries, but not clear in other countries. In UK, the general threshold is £20,000-£30,000 /QALY, but it is increased for some kinds of therapies to cancer. In China, it is not clearly set and released, but commonly using 1–3 times GDP per capita instead.

### 5.9. Economic evaluation should undertake sensitivity analysis to demonstrate the robustness of the evaluation

Sensitivity analysis determines the degree to which the uncertainty could influence conclusions about the economic impact

of clinical decisions. When undertaking a sensitivity analysis, we should identify the uncertain parameters, and specify the plausible range based on reviewing the literature, consulting expert opinion, and using a specific confidence interval around the mean. There are several methods for sensitivity analysis, one-way, multi-way, threshold and scenario analysis.

### 5.10. Interpretation of economic evaluation or policy translation should be carefully integrated other factors

Economic analysis is a valuable tool in decision making, but it is only one factor. Other social, ethical, political, and legal considerations should be combined with the economic analysis to reach a final decision about the value of an intervention or treatment.

## 6. HTA and economic evaluation for traditional medicine (TM)

Traditional medicine has a long history. It is the sum total of the knowledge, skill, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.<sup>4</sup> The WHO Traditional Medicine Strategy 2014–2023 was developed and launched in response to the World Health Assembly resolution on traditional medicine (WHA62.13). One of the strategic objectives is to promote universal health coverage by integrating TM services into health care service delivery and self-health care.<sup>4</sup>

There are many kinds of TM, including Traditional Chinese Medicine (TCM). TCM is a general term for different national medicine in China which reflects the ancients' comprehending and viewpoints on life, health and disease in China. The theoretical basis of TCM originates from the thought and theories of Holism of Human Beings and Universe, Yin-Yang, Five Phases, Mutual Generation and Restriction, Concept of Holism, and Syndrome Differentiation and Treatment. Over thousands of years, the theoretical system of TCM has been continuously improved and made a great progress in clinical practice, with the technical methods of being more and more abundant.<sup>19</sup>

In China, the activities related to Evidence-based Medicine (EBM) for TCM are more visible, and HTA activities are emerging. Yang et al.<sup>19</sup> summarized that "HTA in TCM is facing important development opportunities. On the other hand, due to TCM's uncertain clinical efficacy, lack of clinical efficacy evaluation system of TCM, insufficiency of basic evidence and information and lack in qualified professional talents for HTA in TCM, the development of HTA in TCM is also facing severe challenges." So the evidence for TCM's clinical effectiveness seems to be the key issue, if aligned with EBM principles, design, and methodologies. Then the economic evaluation applicable for TCM sounds to be significant, if economic evaluation approach fitting the TCM context. The TCM prescription normally includes 10–20 herbs, and it is prescribed by the TCM doctor and it is adjusted based on patients' characteristics and doctors' experience. So the costs vary a little bit each time, and the effectiveness changes in different settings.

In 2020, the Chinese national reimbursement drug lists by the national medical insurance authority included the new 119 kinds of drugs, including 40 kinds of Chinese patent medicines. Among them, Niu Huang Qingxin pill and other 10 varieties were directly included, while Xiaoer Niu Huang Qingxin powder and other 30 varieties were included through economic evaluation and budget impact analysis negotiation. Further, six kinds of proprietary Chinese medicine exclusive drugs with 1 billion RMB annual sales amount per single drug were successfully negotiated to reduce the price, such as Kanglaite injection, Kangai injection, salvianolate for injection, Danhong injection, Lanqin oral liquid and bailing capsule.



After the negotiation, the six kinds of Chinese patent medicines' average price decreased by 43.46%. So it demonstrates that China has started to implement economic evaluation in TCM, and it could push the evolution of TCM.<sup>20,21</sup>

In terms of the main evaluation dimensions of HTA, economic implications could be the most challenging aspect of the applicability for TM. The key procedures for economic evaluation referred above are deliberated as follows.

#### (1) Gaps on PICO structuring

Except for some standardized TM prescriptions (e.g., Kampo in Japan, TCM classical prescriptions), most of TM prescriptions normally comprising 10–20 herbs, and the number and dosage of herbs vary between different individuals owing to the prescriptions usually being adjusted based on patients' characteristics and doctors' experience, thus the "Intervention" is not easy to be determined for structuring explicit PICO in TM economic evaluation. In addition, the definition of TM indication is not the same as chemical medicine and biologics, which usually refers to a type of disease classified by its traditional medical theories. For instance, TCM's indication is divided into *Chinese medicine symptom*, as a result, the selection of comparators is relatively difficult for the chemical drugs and biologics without specific indications completely matched with TCM. Furthermore, clinical effectiveness evaluation indicators and methods of TM are not scientifically established based on specific medicine theories, and the biochemical examination indicators are usually regarded as alternative outcomes of TM interventions, which just reveal the short-term clinical effectiveness that could not manifest the whole effectiveness of TM techniques. Therefore, how to elect feasible indicators to fully reflect the effectiveness of interventions needs to be emphasized and explored in HTA for TM.

#### (2) Challenges of cost measurement

Comparing with modern medicine, such as chemical drugs, the costs of TM are more difficult to collect exactly, since that almost every TM prescription or procedure (e.g., TCM prescription, Acupuncture, Tuina) has unique drug number, dosage or treatment procedure based on the specific symptom and characteristics of the patient at each visit, which determines the cost of TM treatment per patient per visit varies substantially. In order to accurately measure the cost of TM treatments, expanding sample size to oversee the probability distribution of cost to obtain better estimation value of cost, instead of over-reliance on the prior probability distribution of cost originated from modern medicine. Besides, TM therapies are mainly self-priced by providers, which makes it difficult to evaluate the unit cost of specific TM items. Moreover, the price or cost of TM could not be obtained from public sources as a result of relevant TM price information is withheld by independent healthcare providers.

#### (3) Lack of supportive clinical evidence and information

Robust clinical evidence and information are the basis of HTA and economic evaluation. Due to lack of attention to TM clinical research for a long time in the past, evidence of TM efficacy, effectiveness, and utility is extremely few, especially lacking high-quality clinical research evidence, which severely hinders the development and application of HTA for TM. Additionally, double uncertainty of clinical effectiveness for TM is quite prominent, namely that the effectiveness/efficacy is not only determined by TM, but also depends on the healthcare provider or operator, which makes it challenging to evaluate the net effectiveness/efficacy caused by TM. What's more, TM is often combined with chemical medications or biologics in clinical scenarios, which is not easy to measure the true effect of TM.

## 7. Conclusion

TM refers to a variety of medical knowledge systems with long history in countries and regions around the world that have been independently developed before modern medicine. It is necessary to conduct HTA for TM, and to evaluate its cost-effectiveness to justify its value since TM is still widely used and has important impacts on human health for their unique advantages in disease prevention, chronic diseases treatment and recovery. This paper summarizes the key points in conducting economic evaluation, including perspectives, costing, type of analysis, PICO, clinical evidence, discounting, decision-analytic model, ICER, sensitivity analysis and reporting interpretation. In terms of the main evaluation dimensions of HTA, economic evaluation could be the most challenging aspect of the applicability for TM.

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## Conflict of interests

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## Ethical statement

Not applicable.

## Data availability

Data sharing is not applicable to this article as no new data were created or analyzed in this article.

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**Table 1**  
Comparison among different methods of economic evaluation.

| Consequences | Analytic methods  | Applications                                   |
|--------------|---|--|
| Stary value  | Single outcome: intermediate (e.g., blood pressure); long term, (e.g., life years gained)                                       | Similar diseases, treatment, or indicator      |
| Stary value  | Multiple outcomes combined into weighted index (e.g., QALYs)  | Compare different diseases or treatments       |
| Stary value  | Assigning money value to different health status. Methods including willingness to pay, contingent valuation, conjoint analysis | Compare different diseases or treatments, espe |

  

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