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OVERVIEW ON THE CURRENT IMPLEMENTATION OF HEALTH TECHNOLOGY ASSESSMENT IN THE HEALTHCARE SYSTEM IN HUNGARY

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Objectives: Our objectives were to assess the current implementation of health technology assessment (HTA) in Hungary and to identify country-specific patterns of challenges and potential improvements.
Methods: We applied a structure that can be used to create HTA implementation roadmaps to evaluate various issues regarding HTA implementation. A comprehensive description of the Hungarian HTA system is presented according to relevant literature and experiences of the authors.
Results: By investigating eight components of HTA implementation, we identified the most important strengths and weaknesses of the Hungarian system. More specifically, we were mainly focusing on the emergence of HTA capacity, the establishment and current role of Department of HTA, the complex process of decision making, the quality elements developed in the near past, and the activity of Hungarian experts at international collaborations.
Conclusions: We concluded that there is a sophisticated methodological and educational basis for HTA in Hungary. A permanent focus on capacity building and changes to the reimbursement procedure can further improve transparency and the scientific basis of decision making in the country.

Keywords: Health technology assessment, Central and Eastern Europe, Hungary, HTA implementation

Hungary is a Central and Eastern European (CEE) country with a population of 9.9 million. Similarly to most states in the region, the general health status is significantly worse compared with Western European countries according to several indicators, for example, life expectancy, standardized death rate where the main causes of death are diseases of the circulatory system or malignant neoplasms (1). Hungary has a mandatory public health insurance system which is financed through taxes and social insurance contributions by employers and employees. Health services are granted to all citizens with only a few exceptions. The main payer in the country is the National Institute of Health Insurance Fund Management (NHIF). Private health insurance and privately owned hospitals remain to have only a marginal role in Hungary while informal payments (i.e., under the table gratuities) represent a significant contribution to the system (2).

The NHIF uses various reimbursement methods for selected health technologies with mandatory HTA criteria. There are two main reimbursement categories for retail pharmaceuticals. In the case of indication-dependent reimbursement, prescriptions can be issued only by specialists in clearly defined indications, while products receiving normative reimbursement can be prescribed by all practicing physicians. The level of reimbursement may vary (50 percent, 70 percent, 90 percent, and 100 percent in the first category and 0 percent, 25 percent, 55 percent, and 85 percent in the latter), where the percentage depends on the severity of the illness (3). These categories are combined with internal price referencing methods, including therapeutic and generic reference pricing. Hospital medicines are reimbursed through Diagnostic Related Groups (DRGs) or directly purchased by the NHIF through a central tendering system. Patients may also get reimbursement for those high-priced pharmaceuticals that are not on the regular reimbursement list through a special budget allocated on an individual basis by considering equity principles.

Hungary has had an important role in CEE in terms of developing and implementing novel health policy methods in the past few decades. For instance, Hungary was among the first countries in the region who implemented a DRG system for financing hospitals in 1993 (4). HTA related activities also date

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Table 1. Eight Elements of HTA Implementation According to Kaló et al (8)

Element	Main component(s)
HTA capacity building	- Education
HTA funding	- Financing critical appraisal of technology assessment
	- Financing health technology assessment (i.e., HTA research)
Legislation on HTA	- Legislation on the role of HTA process and recommendations in decision-making process
	- Legislation on organizational structure for HTA appraisal
Scope of HTA implementation	- Scope of technologies
	- Depth of HTA use in pricing and/or reimbursement decision of health technologies
Decision criteria	- Decision categories
	- Decision thresholds
	- Multi criteria decision analysis
Quality and transparency of HTA implementation	- Quality elements of HTA implementation
	- Transparency of HTA in policy decisions
Use of local data	- Requirement of using local data in technology
	- Access and availability of local data
International collaboration	- International collaboration, joint work on HTA (joint assessment reports) and national/regional adaptation (reuse)
	- International HTA courses for continuous education on HTA

back to 1993, and its institutionalization also has more than a decade of history (5).

Optimal implementation of HTA can support decision makers to make their choices based on transparent scientific criteria. It is important to note that, due to transferability issues, HTA analyses cannot be used across countries without local adjustment (6;7). The main objective of implementing HTA in Hungary has always been to support the national decision-making process.

Our study attempts to summarize the HTA implementation process in Hungary with special focus on the country-specific attributes of the developed system. In addition, we propose to identify the challenges of the current situation and potential areas for improvement.

METHODS

For describing the current status of implementation and for identifying future challenges, we applied a previously developed structure that can be used to scrutinize HTA implementation roadmaps (8). The authors of the HTA implementation roadmap collected feedback and input from relevant stakeholder groups in an iterative process. The development of the structure was informed by a pragmatic literature review of current HTA practices in CEE countries that included reviewing the gray literature, such as Web pages of Ministries of Health and HTA bodies in each CEE country (8). This structure investigates eight elements of HTA implementation: capacity building, HTA funding, HTA legislation and governance, scope of HTA implementation, decision criteria, quality and transparency of HTA implementation, use of local data, and international collaboration. The eight elements and their components can be seen in detail in Table 1.

IMPLEMENTATION OF HTA IN HUNGARY

Capacity Building

In most cases, the number of HTA experts in CEE countries is less than it is in Western European countries. Capacity building has always been in the focus of various Hungarian HTA experts who started teaching HTA-related courses at several universities across the country. In Hungary, the number of institutions offering such courses has increased during the past decades, and today students can receive education in HTA at several universities in Budapest and in regional centers. Forms of HTA education can range from 1-week short courses to graduate or post-graduate programs. In fact, Hungary is the only CEE country with a full 2-year international master program in health economics (9). The number of trained professionals exceeded 200 in 2010 (10), and the number continues to grow ever since.

Hungary has also got an active Health Economics Association since 2003 which became the ISPOR Hungary Chapter in 2007. The association organizes monthly meetings centered around various presentations and a 2-day annual conference providing platform for scientific discussions and networking. Membership of the chapter has been growing

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continuously, and its structure is well balanced between younger and more experienced HTA professionals, and people coming from the academic, public, and private sectors.

HTA Funding (Critical Appraisal and HTA Research)

In Hungary, pharmaceutical and medical device manufacturers have to pay a process fee for the submission of pricing and reimbursement dossiers, which also covers the critical appraisal process of submitted HTA documents. The fee for pharmaceutical submissions has been set to 1.5 million Hungarian Forints (~5,000 Euros) (11).

Limited public funds are available for conducting HTA research; HTA evidences are mainly limited to pricing and reimbursement submissions of pharmaceuticals and medical devices. However, there is no budget for the revision of previous HTA recommendations and consequent reimbursement decisions, developing HTA methodologies, or conducting HTA for health technologies not marketed by private manufacturers (such as surgical interventions or public health programs). A more efficient implementation and knowledge transfer would require more public investment, which may eventually lead to better allocation of resources.

HTA Legislation and Governance (Organizational Structure and the Role of HTA in the Decision-Making Process)

Critical appraisals of HTA submissions are conducted by the Department of HTA. The Department was established in 2004 and is currently part of the National Institute of Pharmacy and Nutrition (OGYÉI), which is a national regulatory organization of pharmaceuticals, and it also conducts methodical and research initiatives in Hungary, independently from the NHIF. The Department of HTA critically evaluates the reimbursement submissions of pharmaceuticals since 2004, simple medical devices such as therapeutic appliances since 2007, and complex medical devices such as hospital technologies since 2010. The HTA process in Hungary is the most detailed and sophisticated in the case of pharmaceuticals that constitutes the majority of the workload delivered by the Department of HTA. During recent years, the Department evaluated 80 to 100 submissions annually. The number of employees at the Department of HTA has stayed between 10 and 15 during the past decade.

Hungary has a quite complex decision-making process for pricing and reimbursement of pharmaceuticals. The NHIF forwards the reimbursement dossiers submitted by manufacturers (i) to those NHIF department(s), which may potentially cover the reimbursement of the new technology; (ii) to the Medical Professional College to clarify the role of the technology in the clinical guidelines; and (iii) the Department of HTA to critically appraise the method of quantifying the health gain, cost-effectiveness ratio, and the budget impact. These three bodies evaluate the submission and, thereafter, their representatives present their opinion and discuss recommendation about reimbursement at the Health Technology Assessment Committee (HTAC) meeting. The HTAC makes its final opinion, which is forwarded to the Director-General of the NHIF to make the final decision, or if modification of regulations is required, to Health Secretariat at the Ministry of Human Capacities. The process is simplified in the case of medical devices intended for personal use by patients, with no HTAC meeting taking place, and only the Department of HTA and the NHIF being involved in the process.

In 2013, a new element, central tenders, was introduced in the case of high-cost innovative drugs that are given in inpatient care and their use is strictly monitored. In the case of these pharmaceuticals, the HTAC meeting is followed by another committee meeting, where the representatives of the State Secretariat of Health and the Ministry of National Economy are involved in the decision-making process to discuss potential implications on state budget. The general decision-making process can be seen in detail in Figure 1.

Scope of HTA Implementation (Scope of Technology and Depth of HTA Use)

The Hungarian decision-making process requires the use of HTA since 2004 (10). It is mandatory for the manufacturers to support their claims for reimbursement with evidence, proving clinical efficacy, safety, and cost-effectiveness of their products. All analyses should be adapted to the Hungarian settings and should follow the current Hungarian pharmacoeconomic guideline as much as possible (3).

If the submission is only aimed at accepting minor modification of the packaging of the product, or for example in the case of generic drugs, HTA is not required and a simplified procedure can be applied in which the NHIF makes the decision on reimbursement without involving other bodies in the process. When a manufacturer wants a new pharmaceutical to be reimbursed, or for example when it wants to increase the price of an already reimbursed drug, or when a manufacturer wants its drug to be reimbursed in a new indication, the use of HTA is mandatory.

Decision Criteria

The medical and therapeutic value, safety, cost-effectiveness, reference prices, budget impact, and other special criteria of pharmaceutical products are being discussed during the two aforementioned confidential committee meetings. The representatives of the manufacturer can also be involved in the discussion; however, they have to leave the meeting before the discussion ends with a vote regarding the opinion of the committee on the reimbursement of the product.

With medical devices and other technologies, the process is similar to the one in the case of pharmaceuticals, and since 2010, a multicriteria decision analysis (MCDA) was introduced by the NHIF for these devices and technologies (12).

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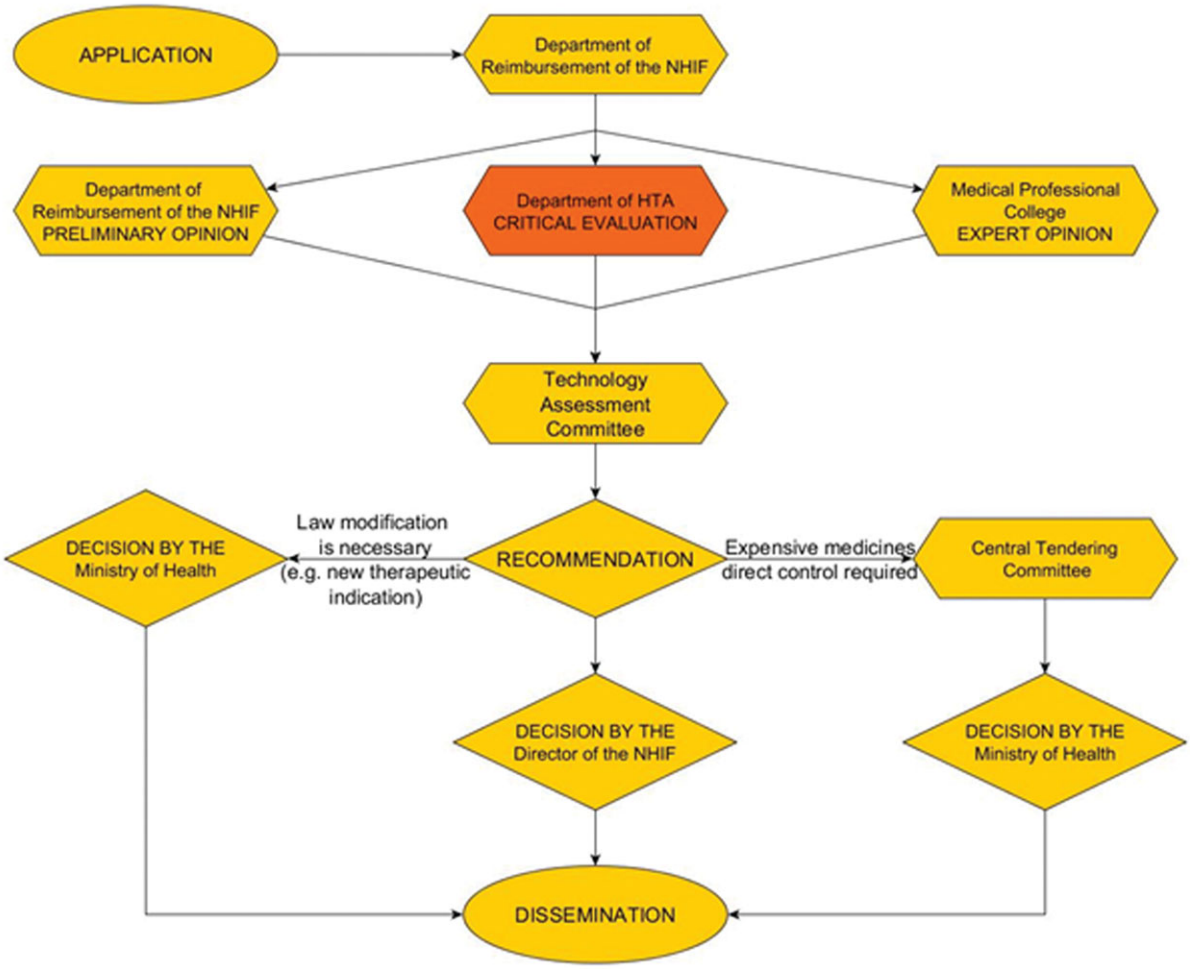

Figure 1. The general decision-making process in Hungary in the case of reimbursement of pharmaceuticals.

This scoring system evaluates the technology by six main dimensions. Until now, the effective application or the relevance of the method has not been published; therefore, it is difficult to address the effect of MCDA tool in Hungary.

Quality, Timeliness, and Transparency of HTA Implementation

The Hungarian Health Economics Association also plays an important role in publishing methodological papers related to HTA, most notably the Hungarian Health Economics Guideline was first published in 2003 and was renewed in 2013. The guideline describes the requirements of conducting a proper HTA analysis in great detail (13).

Hungarian experts also published a methodological checklist for the critical appraisal of HTA analyses (14). The checklist has ninety-one questions that cover a wide range of potential methodological issues from eleven main topics, including comparator selection, efficacy, effectiveness, costs, sensitivity analysis, methodological approach, transparency, and interpretation.

Currently, it is not mandatory for manufacturers of pharmaceuticals to include their health economic models in the reimbursement submissions. If the manufacturer chooses not to submit its model, they can present it to the employees of the Department of HTA under the supervision of the NHIF. The critical appraisals conducted by the Department of HTA are strictly confidential and cannot be published according to internal regulations. Only the manufacturer that applied for the reimbursement, the members of the HTAC, and certain employees of the NHIF can have access to the reports. The current process allows only 43 days for the Department of HTA to conduct the critical appraisal of pharmaceutical and 30 days for medical device submissions. The possibility to have consultations with manufacturers, clinicians, and patient groups is limited due to time pressure and/or internal regulations and processes. These factors may heavily affect the quality of analyses conducted by the Department.

Use of Local Data

It should be noted that certain elements of international HTA reports are transferable, but adjustment to local data is absolutely necessary (15). Some inputs for HTA analyses, for example data from clinical studies is transferable, and thus researchers can avoid duplication of work across countries.

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Meanwhile, local monetary values and data regarding the general framework of the healthcare and reimbursement system should be collected locally. As the Department of HTA conducts only critical appraisal of submitted HTA dossier, they do not have access to the source HTA documents (e.g., global value dossiers, economic models before local adaption) prepared by international teams on behalf of manufacturers; therefore, they cannot directly evaluate their transferability. However, the Department of HTA tries to validate assumptions in the submitted HTA dossier by benchmarking available information at EUnetHTA database or Web sites of international HTA agencies (16).

According to the methodological guidelines for economic evaluations, calculation of treatment costs should be based on local data (13).

In Hungary, limited accessibility to accurate patient databases or registries and delays in the revision of medical guidelines can have a negative impact both on the HTA research and the critical appraisal. For instance, estimating the number of potential patients can be difficult, especially in cases where the manufacturer wants its product to be reimbursed only in a specific subgroup of patients. Eventually, it may be complicated to conduct a realistic budget impact analysis which is often the most important criteria of reimbursement.

International Collaboration

The Department of HTA has also been an active participant of several international projects. For example, it has been involved in the development and pre-application of the EUnetHTA Core Model, development of methodological guidelines, early dialogues, and several other projects within the EUnetHTA Joint Action 1 and 2 (17). The Department was also involved in the MEDEV Committee on medicine evaluation and in the SEED Consortium that focused on early dialogues with manufacturers of pharmaceuticals and medical devices.

FUTURE CHALLENGES AND DEVELOPMENT POTENTIAL OF HTA IN HUNGARY

Based on our comprehensive description above, first we identified the major challenges that HTA experts may face in Hungary, then we listed those areas where we think Hungary has good potential for improvement.

Challenge: Limited Accessibility of Pricing Information for the Department of HTA

The Hungarian healthcare reimbursement system remains complex, and for pharmaceuticals, risk-sharing agreements (e.g., price-volume agreements) are mandatory between the NHIF and the manufacturers (18). This leads to the situation where the official list price of new products and the price that NHIF actually pays for the drugs can differ. The details of these confidential price reductions are not shared with the Department of HTA, although comparing the list prices or using them for economic evaluations and budget impact analyses can limit the meaningfulness of HTA conclusions.

Challenge: Retention of Personnel at Department of HTA

The fluctuation of employees working at the Department of HTA is still very high especially when compared with other governmental bodies in Hungary. In many cases, the employees leave the Department and join pharmaceutical or HTA consultant companies after they reach senior status, which leads to a permanent need for capacity building.

Challenge: Transparency

As of today, neither the HTA submissions by manufacturers nor the conclusions of the critical evaluations of HTA reports are published. This practice highly reduces the transparency of the evaluation process of pharmaceuticals and medical devices.

Improvement: Re-evaluation

In Hungary, HTA is not used for the re-evaluation of already reimbursed products or disinvestment decisions. Re-evaluation would ensure improved evidence base of policy decisions, but it would necessitate further capacity building and additional financial resources.

Improvement: Mandatory Submission of Models

Transparency, usefulness, and the thoroughness of critical appraisals conducted by the Department of HTA could be improved significantly by making the submission of the health economic models mandatory.

Improvement: Budget Allocation

Increased public funding could be used to extend HTA to health technologies not marketed by private manufacturers, for methodological improvement of HTA and for horizon scanning or introducing revision of previous reimbursement decisions (7). These new tasks may necessitate increased personnel at the Department of HTA or active collaboration with academic centers.

CONCLUSIONS

It should be highlighted that countries need to focus on identifying and formulating their own values, health policy objectives, and constraints to develop their own HTA systems. Decision makers should be aware that creative and consistent implementation processes deliver success over the years (8).

During the past decade, Hungarian HTA experts focused on strengthening the methodological basis of HTA in the country with publishing guidelines, checklists, and maintaining an active HTA environment. A great variety of HTA educational programs are present in Hungary, and Hungarian HTA experts are

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maintaining strong international relations with their colleagues from other countries.

Even though HTA plays an integral role in the decision-making process, the budget-based approach can overshadow its usability because the true objective of HTA is to help decision makers to maximize health gains by allocating the available budget most efficiently and it may also violate the objectivity of HTA process (7).

Several challenges still remain. The potential improvement of the current decision-making process includes publishing the HTA analyses to some extent, making submissions of the health economic models mandatory, and improving the information-sharing between the NHIF and the Department of HTA. These steps together with a permanent focus on capacity building can improve transparency and contribute to the scientific basis of decision making in the country.

In conclusion, the Hungarian HTA system can rely on the strong methodological and educational background in the country. Some further improvements regarding the process of decision making could help the local HTA system to achieve its full potential.

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

REFERENCES

1. European Health for All database (HFA-DB). World Health Organization Regional Office for Europe. https://data.euro.who.int/hfadb/ (accessed December 10, 2015).
2. Gaál P, Szigeti Sz, Csere M, Gaskins M, Panteli D. Hungary health system review. *Health Syst Transit*. 2011;131-266.
3. 32/2004. (IV. 26.) Decree of the Ministry of Health and Social Affairs [Hungarian]. https://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0400032.ESC (accessed December 10, 2015).
4. Babarczy B, Gyenes P, Imre L. 25 years of the DRG-based health-financing system in Hungary. (Article in Hungarian). *Orv Hetil*. 2015;156:1155-1164.
5. Gulácsi L, Brodszky V, Péntek M, Varga S, Vas G, Boncz I. History of health technology assessment in Hungary. *Int J Technol Assess Health Care*. 2009;25(Suppl 1):120-126.
6. Gulácsi L, Boncz I, Drummond M. Issues for countries considering introducing the "fourth hurdle": The case of Hungary. *Int J Technol Assess Health Care*. 2004;20:337-334.
7. Kolasa K, Kalo Z, Zah V, Dolezal T. Role of health technology assessment in the process of implementation of the EU Transparency Directive: Relevant experience from Central Eastern European countries. *Expert Rev Pharmacoecon Outcomes Res*. 2012;12:283-287.
8. Kaló Z, Gheorghe A, Huic M, Csanádi M, Kristensen FB. HTA implementation roadmap in Central and Eastern European countries. Manuscript accepted for publication in Health Economics. (2015).
9. Description of "MSc in Health Policy Planning and Financing" course at Eötvös Loránd University. https://old.tatk.elte.hu/studies/master-programs-isomis/health-economics-msc (accessed December 10, 2015).
10. Kaló Z, Bodrogi J, Boncz I, et al., on behalf of ISPOR Hungary Chapter. Capacity building for HTA implementation in middle-income countries: The case of Hungary. *Value Health Reg Issues*. 2013;2:264-266.
11. Gulácsi L, Rotar AM, Niewada M, et al. Health technology assessment in Poland, the Czech Republic, Hungary, Romania and Bulgaria. *Eur J Health Econ*. 2014;15(Suppl 1):S13-S25.
12. Endrei D, Molics B, Ágoston I. Multicriteria decision analysis in the reimbursement of new medical technologies: Real-world experiences from Hungary. *Value Health*. 2014;17:487-489.
13. The Technical Guideline for the Making of Health-Economic Analyses by the Ministry of Human Resources Egészségügyi Közlöny 2013/ 3. 1314-1334. https://www.hbcs.hu/uploads/jogszabaly/1479/fajlok/EEMI_szakmai_iranyelve.pdf (accessed December 10, 2015).
14. Inotai A, Pékli M, Jóna G, Nagy O, Remák E, Kaló Z. Attempt to increase the transparency of fourth hurdle implementation in Central-Eastern European middle income countries: Publication of the critical appraisal methodology. *BMC Health Serv Res*. 2012;12:332.
15. Kaló Z, Landa K, Doležal T, Vokó Z. Transferability of National Institute for Health and Clinical Excellence recommendations for pharmaceutical therapies in oncology to Central-Eastern European countries. *Eur J Cancer Care (Engl)*. 2012;21:442-449.
16. Drummond M, Augustovski F, Kaló Z, et al. Challenges faced in transferring economic evaluations to middle income countries. *Int J Technol Assess Health Care*. 2015;31:442-448.
17. Szerencsés V. Európai együttműködés és magyar részvétel az egészségügyi technológia-értékelés terén [Hungarian]. IME Egészség-Gazdaságtan Különszám 2014 Dec. 47-50.
18. 2006. XCVIII. Decree of the Hungarian Parliament [Hungarian]. https://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0600098.TV. (accessed February 12, 2016).

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