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Health Technology Assessment of the Medical Devices: A Case Study from the Czech Republic

Jana Rozmarinová[1], Barbora Říhová[2]

Abstract

Health technology assessment (HTA) has become the systematic evaluation of health technology's properties and effects that inform decision-makers. The implementation and expansion of HTA can contribute to slowing down burgeoning healthcare costs. In the Czech Republic, elements of HTA are quite standardly used in pharmacoeconomics, but questions arise on the use of HTA of medical devices. The theoretical framework developed is followed by a case study of the Czech Republic to assess whether the use of HTA of medical devices in the Czech Republic is implemented. This study uses publicly available resources, mainly public health acts and public notices related to HTA. We examined the institutionalisation of HTA for medical devices (HTA applied only at a selected area of medical devices) in the Czech Republic and compared Czech's HTA principles of medical devices to the HTA Core Model. It was found that the HTA process used for medical devices is very limited in the Czech Republic. Our data show that HTA was officially established, but in reality, the medical devices have not been assessed following HTA principles.

Keywords:
health technology assessment, healthcare costs, medical devices

Introduction

The main feature of healthcare funding during the last few decades is the rapid growth in the costs of healthcare over the decades. There is no exception to this development in the Czech Republic. In the meantime, a policy to improve healthcare funding problems and imbalances should be implemented. Health technology as-

1 Masaryk University, Faculty of Economics and Administration, Brno, Czech Republic.

2 Masaryk University, Faculty of Medicine, Brno, Czech Republic.

sessment (HTA) is a tool which includes a number of activities applying systematic methods of scientific inquiry to the evaluation and use of healthcare technologies to gain value for money in healthcare. This instrument can help to improve the healthcare budget imbalances. The evaluation can focus on all impacts of particular healthcare technology, including its clinical, ethical, social, legal, and economic implications. In general, the evaluation of efficiency and effectiveness in the public sector has a long tradition in the literature (Lamovsek and Klun 2020). This paper examines the substantial issues of HTA and its institutionalisation related to medical devices in the Czech Republic.

The paper's objective is to introduce the Czech effort to implement HTA methods on selected kinds of medical devices.

To achieve the research goal, the first part of the paper introduces the main theoretical findings concerning the topic of increasing expenditures in healthcare in general, especially the relation between technological improvement and healthcare expenditures. Here HTA is presented as one of the tools for measuring the cost-efficiency of healthcare services. The paper continues with the Czech development of HTA for medical devices. The article's critical part is a case study that presents the current system of monitoring the effectiveness when entering medical devices to the Czech Republic's reimbursement process.

Literature (Friedberg et al. 1999, Gulácsi et al. 2014) shows that HTA has an essential role in the public finance of healthcare concerning cost savings. However, HTA is a frequent topic of international studies; there have only been a few studies in the Czech Republic seeking solutions for such a phenomenon (Gulácsi et al. 2014). We attempt to fill this gap in the research and show the progress of HTA in the Czech Republic in the field of medical devices. The paper's core research problem is to reflect the Czech situation in the HTA of medical devices.

HTA is a tool for improving the imbalances and problems in health systems through the systematic evaluation of properties, effects, and the impact of health technology (Goodman 2004). The objective is to provide a synthesis of the best available evidence to support policy decisions (Mueller et al. 2017). Persuasive arguments exist for using HTA as an analytical tool for informed decision-making on health technologies (Garrido et al. 2008; Hartz and John 2009; Garrido et al. 2010).

When researching academic publications, it is evident that medical devices' economic evaluation is frequently overlooked, and the discussion on HTA for medical devices is quite rare. However, some studies cover this HTA issue (Drummond et al. 2009; Siebert et al. 2002; Kirisits and Redekop 2013; Cookson and Hutton 2003; Tarricone et al. 2014, Ramsay et al. 2001; Tarricone et al. 2017; Ciani et al. 2016 Taylor and Iglesias 2009). There are many reasons why HTA methodology of medical devices should be examined separately (in contrast to HTA methodology of drugs). Most of the reasons are based on the actual differences between pharmaceuticals and medical devices.

The studies' results mostly point out that the critical issue is the existence of a learning curve when evaluating medical devices (Drummond et al. 2009; Tarricone et al. 2017; Ramsay et al. 2001). The most emphasised and most frequent issues were:

- the fact that the devices often have multiple purposes (Drummond et al. 2009; Kirisits and Redekop 2013);
- the absence of randomised controlled trials (Tarricone et al. 2014; Cookson and Hutton 2003; Drummond et al. 2009; Taylor and Iglesias 2009; Rosina et al. 2009);
- the importance of the close connection between the device and its user (Siebert et al. 2002, Taylor and Iglesias 2009).

Furthermore, the device costs often comprise both procurement costs (including associated infrastructure) and running costs, including maintenance and consumables (Tarricone et al. 2014). The particular recommendations on dealing with HTA medical devices result from the project EUnetHTA or MedtechHTA (EUnetHTA Joint Action 2; Tarricone et al. 2017).

Background

Before we can evaluate the development of the HTA of medical devices in the Czech Republic, we need to characterise the general trends in healthcare, which result in the need for HTA. To fully understand the changes that have occurred in healthcare, it is essential to understand the general demographic trends and the dynamic technological changes that have taken place in the health sector.

The healthcare expenditure represents a relatively substantial part of public spending in the Czech Republic. Its GDP proportion is steadily rising at higher rates than the gross domestic product in most OECD countries. The following table (see Table 1) shows healthcare expenditures as a percentage of GDP in the Czech Republic in recent years. The increasing trend is evident from this table.

A similar development can be seen in other countries in the Visegrad Group: Slovakia 5.3 % (2000) and 6.7 % (2018), Poland 5.3 % (2000) and 6.3 % (2018) except for a relatively stable development in Hungary 6.8 % (2000) and 6.7 % (2018), (OECD, Health expenditure and financing 2021).

Therefore, healthcare expenditure is attracting attention from many economists, who offer two main explanations for high and rising healthcare costs: the rapid diffusion of new technologies and the population ageing (Sorenson et al. 2013). Technological innovations are considered to be the primary driver of rising healthcare costs, although the main problem is that not all innovations have resulted in cost-effective solutions (Mueller et al. 2017).

Improved healthcare technologies generally increase healthcare expenditures. The greater availability of such technologies is associated with greater per capita use and higher spending on healthcare services (Bodenheimer 2005). The new healthcare technologies enable more patients to be cured, improve patients' quality of life, and shorten treatment durations. However, we are facing a conflict between available sources and technological improvement. Moreover, a general demographic trend towards a longer life expectancy and the declining fertility rates of the Czech Republic population add pressure to healthcare and its funding.

The trend of enormously increasing healthcare costs thanks to technological innovations and demographic ageing has led to a more accurate evaluation of benefits medical technologies concerning their prices. Economic evaluations enable decision-makers to maximise the benefits (health effects) from a given quantity of resources and recommend effective treatments (Banta and Jonsson 2009).

Table 1
Healthcare expenditures in the Czech Republic as a percentage of GDP

Year	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
Expenditures (%)	5.7	5.9	6.2	6.5	6.4	6.3	6.2	6.0	6.3	7.2
Year	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**
Expenditures (%)	6.9	6.9	7.0	7.7	7.6	7.2	7.1	7.1	7.5	7.8

Source: Health expenditure and financing, OECD (2021)

The most crucial mission of HTA is to provide data to public policymakers to enable them to carry out informed decision-making in the healthcare sector. The word "technology" in the context of HTA is used in a broad sense, and health technology is an intervention that can be used to promote health or in prevention, diagnostics, and treatment of acute or chronic disease, or for rehabilitation. It includes drugs, medical devices, diagnostic and therapeutic methods used in the clinical practice and assessed within public health or healthcare facilities.

The field of HTA was systematically developed in the United States, where the Office of Technology Assessment published its first report on the subject in 1976. The first country in which HTA was formalised, and the mandatory guidelines for health economic evaluations were issued, was Australia in 1992. There were similar mandatory guidelines issued in Canada, Finland, the Netherlands, Portugal, the USA, and the UK (Hjelmgren et al. 2001).

HTA began to spread to the rest of the world in the late 1980s, with the Swedish Council on Technology Assessment in Health Care. Over the next twenty years, HTA spread to nearly all European countries (Banta and Jonsson 2009).

The majority of EU Member States have HTA agencies that provide information for policy decisions. The primary aim of HTA agencies is to produce HTA reports, which the decision-makers use to plan their informed, evidence-based reimbursement decision.

When considering Central and Eastern Europe (CEE), countries that share a common past with a series of reforms since 1989 took steps to improve their health systems (Medveď et al. 2005; Kaló et al. 2016). The healthcare reforms are conducted with the objectives to rationalise costs, to make health services more available, and to increase the quality of health services (Vitezić et al. 2019). After 2000, health technology assessment became part of these efforts, and a significant increase in HTA-related activities for decision-making purposes in CEE appeared. Today, there are many guidelines and research studies dedicated to HTA, and governments are mandating agencies to issue national policy guidelines on the use of drugs and medical devices. The Agency for Polish Health Technology Assessment (AHTAPol) was established in 2005 and published its first HTA guidelines in 2007, the Office of Health Technology Assessment (OHTA) was established in 2004 in Hungary and was renamed the Technology Appraisal Head Department (TAHD) in 2012, and an HTA unit was set up within the Ministry of Health in Romania in 2012. Reimbursement decisions from other countries, mainly from the National Institute for Health and Care Excellence (NICE), are considered in these countries (Gulácsi et al. 2014).

HTA has broadened out into many countries, but in many of these it is not so commonly used as to contain an assessment of a wide range of health technologies (not only drugs but medical devices and medical and surgical procedures) over a long period. The majority of HTA has been conducted on pharmaceuticals rather than other technologies, such as medical devices (Cookson and Hutton 2003). On the other hand, there are countries that Canada, Switzerland, Austria or Hungary can serve as examples for; here HTA has been fully developed for many categories of HTA.

Data and methodology

The first part of the analysis reviews the documents related to the institutionalisation of HTA in the Czech Republic. We used published studies and publicly available papers to reflect the development of the Czech HTA of medical devices.

The analytic part of our paper includes publicly available data for a particular medical device category. This category of devices includes expensive medical devices with a price above 5 million without VAT. This fact also remains to be the limit of this research. In general, the medical device portfolio includes a wide range of 500,000 items (from surgical gloves to orthopaedic implants or pacemakers (Peter et al. 2020). Our paper covers those described above due to limited implementation of HTA for medical devices in the Czech Republic.

Specifically, our analysis is based on Ministry of Health materials. For comparing the HTA Core Model (as a model of best practice) with the Czech rules for decision-making on medical devices (MD) two independent experts in HTA were consulted. The particular elements of Czech rules are compared to the model of best practice. The HTA Core Model (Lampe et al. 2009) is chosen as a model of best practices. It is a model developed by EUnetHTA, and even the ministry itself refers to this model in the ministry's proclamation.

Finally, we used publicly available data, the applications, assessment tables, decisions and rationale concerning the medical devices' purchase with the purchase price higher than 5,000,000 CZK. These data have been manually collected since they are available as pdf documents. The next step was the data tabulation and selection according to the purpose. The goal was to quantify the number of HTA-based decisions.

Moreover, in the context of the analyses performed, one term needs to be defined, the medical device. According to the European Union (EU) directive 93/42/EEC, "medical device" means "any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease (resp. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; control of conception) and which does not achieve its principal intended action in or on the human body by pharmacological immunological or metabolic means, but which may be assisted in its function by such means", for example, ranging from e.g. cardiac pacemaker, surgical gloves, diagnostic test kits to magnetic resonance imaging (MRI) scanner (Council directive 93/42/EEC).

Results

HTA of medical devices in the Czech Republic – a look at the institutionalisation

For many reasons[3], the healthcare markets tend to be significantly influenced by the state across health systems worldwide. Because of these properties, there is a generally shared agreement among experts that healthcare is at least in part a collective good that cannot be solely the individual responsibility of the citizens (Nemec et al. 2015). The healthcare system in the Czech Republic is no exception to this, and the state's participation in healthcare is very significant. The state's role is represented by universal mandatory health insurance in the Czech Republic. In the case of economically inactive citizens (children, retired and the unemployed), the payments to the system are made by the state. Currently, the share of the state insured persons in the Czech Republic population reached 55.8 % in 2019, the percentage of payments for state insured was nearly 21.7 % in 2019 (MoH, 2019). The legal background is based on Act 20/1966; basic principles are solidarity and equal healthcare availability. Moreover, one of the essential elements of the Czech health system are the state's university hospitals.

Under socialism, the implementation and purchase of new medical technologies was based solely on a political decision in Czechoslovakia. Under the communist regime, it was usual for a political decision to predetermine any economic resource allocation. With the end of the communist era and the opening up of the borders for purchasing medical technologies, the Czech Republic lacked the professional capacity and methods to decide on the cost-effectiveness of purchasing and implementing new technologies and became vulnerable to seemingly beneficial offers of companies delivering medical devices (MD). The cost-benefit calculations were not undertaken, nor were there any calculations published on the effectiveness of medical procedures (Lawson and Nemec 1998), while at the same time, those countries with a market economy, when planning the implementation of new technologies, were evaluating new investments and their utilisation.

The Czech Republic has made considerable progress in the HTA for pharmaceuticals since that time (the obligatory requirements based on cost-utility analysis

3 The core common agreement among economic theories is that healthcare should not be the responsibility of individuals and the role of the state is desirable (Feldstein1993). The reason is that the healthcare market has a very specific structure, which was described in 1963 by Arrow, who emphasised the reasons why healthcare tends to be a market where the state has an important role. The informational asymmetry is a common feature of healthcare; moreover, the condition of the healthcare market is influenced by the uncertainty that recovery from illness is as unpredictable as its occurrence and demand is irregular and unpredictable. An example of the externalities typically present on the healthcare market is the spread of communicable diseases (Arrow 1963); the year 2020 and the coronavirus crisis reaffirms this long-valid statement by Arrow.

as a method for the assessment, the willingness-to-pay threshold is implicitly set to 3 times the GDP per capita).

Nevertheless, there has been little interest in the HTA of medical devices in the Czech Republic, even though the medical device industry is one of the most dynamic healthcare areas in the Czech Republic (Gajdošová 2018). Some effort was made during Minister of Health Leos Heger's time from July 2010 to July 2013. The tender for HTA methodology was managed with a bid price of 240,000 CZK (approximately 8,900 EUR). The resulting Czech HTA methodology consisted of three main parts: a general introduction describing general HTA, a manual for applicants (evaluators), and a manual for opponents. The two manuals which defined the HTA analysis formalities were considered the essential process components (Ministry of Health 2013). Still, the whole project came to a halt in July 2013 following the Petr Necas government's sudden resignation.

Directions towards a formalised HTA for MD deteriorated under the next Minister of Health, Nemecek (in office from January 2014 to November 2016). The pressure on the need to control the high costs of purchasing medical devices persisted. The new administration created an advisory committee for evaluating requests from individual providers (especially hospitals) for purchasing medical devices over 5,000,000 CZK (185,000 EUR), in other words, with no relation to the policy of the previous minister. Minister Nemecek established an advisory commission called "The Commission for the Evaluation and Allocation of Medical Devices" ("MD Committee"). The MD Committee's methodology used a multicriteria evaluation, although the methods of HTA were not implemented in its decisions. Minister Nemecek mentioned that HTA is one possible way of evaluating new medical devices, and HTA methods would probably be implemented in the commission's methodology later. The Czech HTA professional community frequently criticised the commission with three main arguments being put forward:

1. The decisions are made based on documents that are not publicly available. Only the final opinions were published (supported, rejected or postponed) (Nemec et al. 2021).
2. The assessment phase is wholly omitted.
3. The proposal submitted to the MD committee is not obligatory.

The future of HTA also remained uncertain under Minister of Health Miloslav Ludvik during his short time in office (from December 2016 to December 2017), where he did not mention HTA as a priority. The current minister, Adam Vojtech (in office since December 2017), has criticised the previously established "MD Committee", and has promised that HTA elements will be incorporated into the board's decision-making process (minister's claim from January 2018, Ministry of Health 2018). Despite this promise, the methodology's features are still not part of the decision-making process. The commission's work focuses on the regional

availability of devices in areas with worse access to devices for patients (the specific details follow from the paper's analytical part).

From Table 2, we can conclude that the Czech experience with HTA for medical devices is low, with the Czech Republic being one of those countries where HTA has not been fully implemented. On the contrary, a methodology for the evaluation of drugs is used from 2013 on (SUKL). A typical feature of the current state of HTA for medical devices is performed and discussed in more detail in the next chapter.

Monitoring of the effectiveness of the medical devices – a Czech case study on the selected category of MD

The Czech system's current setting of monitoring the effectiveness when medical devices enter the reimbursement (namely those with a purchase price higher than CZK 5 million excluding VAT) results from the Order of the Minister of Health No. 29/2019. The current MD Committee assesses applications for the location and operation of instrumentation paid from public health insurance funds through services provided on them or the purchase of instruments with a subsidy from the state budget (MoH 2018). This commission's task is primarily to assess the effectiveness of the acquisition of instrumentation and services performed here, covered by public health insurance. If the healthcare provider wants to operate in the regime of payments from public health insurance, this commission has to authorise it. Through this mechanism, the ministry regulates the charges for the services performed with the device. This primary feature of the commission remains the same as the previous commission and "the old rules".

Minister of Health Vojtech (in office until September 2020) criticised the commission-set rules by the previous minister and subsequently changed the rules for decision-making and the commission's composition by Order No. 29/2019. The minister gave two reasons for this step, the non-transparency of the previous system and the non-application of HTA principles in the commission's rules (MoH, 2018).

The minister also presented the inclination to the principles of HTA in the government's programme statement of 27 June 2018 (Vlada, 2018). In this document, he states the promise of "introducing a transparent system for the entry of new technologies and services into public health insurance payments, based on the principles of health technology assessment, cost-effectiveness assessment and with an emphasis on patient benefits" (Government of the Czech Republic 2018).

The ministry undertook it to publish all documents relating to the commission's decision-making, including the minutes of meetings, applications, and decisions, to increase the transparency of the device committee's decision-making. The minister announced that the commission's decision-making procedures should be in line with the principles of HTA. This thesis was also incorporated into the commission's procedure rules (Rules of Procedure of the Commission, Article 1, point 7 states, "In the case of new types of devices …, the Commission uses the principles

Table 2
History of HTA of medical devices in the Czech Republic (Author, based on document analysis)

HTA for drugs (pharmacoeconomics)	HTA for medical devices
2006–2009 Minister of Health Julinek	
Professional information about pharmacoeconomics Became available in the Czech Republic (ČFES)	Basic information
January 2009–May 2009 Minister of Health Filipiova	
ČFES – optional guidelines for pharmacoeconomics	HTA for medical devices is not mentioned as a policy priority
May 2009–June 2010 Minister of Health Juraskova	
	HTA for medical devices is not mentioned as a policy priority
June 2010–July 2013 Minister of Health Heger	
2012 – the methodology for pharmacoeconomics is prepared **February 2013 – SÚKL issued mandatory methodology for pharmacoeconomics**	Ministerial directive no. 6/2012 "HTA in the system of public health insurance" The HTA Council was established Tender for HTA methodology Pilot tests of the suggested methodology Issue of "Implementation of HTA in CR" document
2013–2014 Minister of Health Holcat	
Methodology for pharmacoeconomics standardly used	Period of stagnation
2014–2016 Minister of Health Nemecek	
	HTA is not mentioned as a policy priority **MD committee was established (HTA methodology is not implemented in its decision**) ČFES – optional guideline for HTA of MD
2016–2017 Minister of Health Ludvik	
Methodology for pharmacoeconomics standardly used	Period of stagnation
2017– Present Minister of Health Vojtech	
Methodology for pharmacoeconomics standardly used	Criticism of the MD committee New rules for MD committee (č. 25/2019), some **elements of HTA are applied**

Source: Author, based on sources

of the health technology assessment process based on analyses according to the current European HTA guidelines."

The rules that entered into force with the new order classify devices into three categories:

- Category I (Renewal of an existing device of an identical type in the same location and operated by the same provider);
- Category II (Devices that are part of the system of reimbursement from health insurance after 1 January 2018);
- Category III (Devices not yet covered by health insurance).

The HTA principles are not applied to categories I and II; instead, decisions are based on the local and temporal availability of a device for patients. The only class with HTA principles is Category III, according to the Ministry of Health.

The entire process of the entry of devices into the reimbursement mechanism commences with collecting candidates' applications, gathered by the commission secretary. The secretary subsequently passes them to two independent evaluators, who carry out the evaluation using an evaluation table (see Table 3) and provide an opinion with a recommendation. The emphasis is placed on the geographical location and whether the device is part of a specialised care centre's technical equipment.

Table 3
Table for evaluators – questions

	Yes	No	Weight of criterion
Is the device part of the technical equipment of a specialised care centre?			25
Does the geographical location of the device meet the requirements of Government Regulation No. 307/2012 Sb.?			25
Demographic location of the device: Is the number of devices in the region (based on the population) lower than expected?			20
Use of existing devices: Does the applicant have a similar device, and to what extent is it used?			15
Use of the newly acquired device: Is the expected number of medical procedures higher than the average in the CR?			15
Purchase recommended (YES/NO)			

Ministry of Health (2018)

Then the meeting of the commission is held. The Commission acts and evaluates the applications received according to detailed criteria, on the basis of which it reaches the standpoint. The criteria stipulated in the Rules of Procedure and their

links to the categories (1 to 3) are shown in Table 4. Category 3 contains criteria that represent the HTA component in the Czech system of the entry of devices in the market. The applicant fills in the application, which is divided according to these criteria. Voting takes place during a meeting of the commission, where the members may (but need not) follow the recommendation resulting from the evaluators (see Table 3) and meeting criteria (see Table 4).

Table 4
Criteria for assessment of medical devices (Category I–III) – from official statement

Criterion	Category I	Category II	Category III
1. Technical specification	✔	✔	✔
2. A need in the region	✔	✔	✔
3. A need in the individual healthcare provider	✔	✔	✔
4. Medical benefit for the patient	x	x	✔
5. Availability of HTA assessment from abroad	x	x	✔
6. Existence, quality, and result of HTA evaluation in the CR	x	x	✔
7. Existence of diagnostic-therapeutic standards	x	x	✔
8. Instrument network in the region	✔	✔	✔
9. Budget impacts on health insurance funds	✔	✔	✔
10. Unit acquisition cost for a specific device, including accessories	✔	✔	✔
11. Financial resources for the acquisition of a new device	✔	✔	✔
12. Proposed purchase price within the market research	✔	✔	✔
13. Personnel ensuring the operation of the device	✔	✔	✔

Source: Author own compilation, based on Ministry of Health (2018)

Table 5 compares the best practice model HTA CoreModel with HTA elements in the Czech rules. The table shows a limited application of HTA methods in comparison with the best practice model. In the case of new devices, the Czech system of HTA does not meet even the shortened model's essential requirements for accelerated HTA use ("Rapid HTA").

Table 5
HTA Core Model Domains and their comparison with the Czech new rules for MD committee

		HTA Core Model Domains	Rules for MD committee with HTA elements
Full HT	**Rapid Relative Effectiveness**	1. Health problem and current use of technology	yes
		2. Description and technical characteristics of technology	yes
		3. Safety	no
		4. Clinical effectiveness	no
		5. Costs and economic evaluation	limited (budget impact only)
		6. Ethical analysis	no
		7. Organisational aspects	to some extent
		8. Patients and social aspects	no
		9. Legal aspects	no

Source: Based on Lampe et al. (2009) and the medical devices rules (MoH, 2018)

The number of applications evaluated in Category III (a class with HTA elements) is presented in Table 6. The table shows the numbers of applications in each category for 2018 and 2019. Three medical devices were evaluated in class III: a CT simulator, a mass spectrometer, and a heart transport system. Since 11 April 2018, when the commission held its first meeting under the newly modified rules, three sessions were held: 11 April 2018, 27 June 2018, 24 October 2018. In 2018, the commission evaluated 48 applications for device placement since introducing the new rules, 32 applications of which in Category I, 15 applications (31 %) in Category II, and one application in Category III (3 % of the total). The same data were selected and presented in the table for 2019, and only two applications were evaluated in the HTA mode.

Applications by initiators (most often hospitals) and the committee commission's opinion are available on the Ministry of Health's website. The statement also includes a completed evaluation table, the outcome of the commission's decision-making, and the decision rationale. Where a device is not recommended, the explanation is more extensive.

The most common reasons for a refusal to place a device are a failure to provide the personnel capacity for the device's operation in the medical facility, the geographical distribution of devices, or a combination of these two reasons.

Table 6
The numbers of applications in each category for 2018 and 2019

	Criterion	No. of applications	Recommended	Not recommended	Postponed
2018	I	32	27	0	5
	II	11	6	5	0
	III	**1**	**1**	0	0
2019	I	123	122	0	1
	II	31	20	7	3
	III	**2**	**2**		

Processed according to Ministry of Health of the CR (2018)

Discussion

When studying HTA development in various states, one can identify a broad set of processes to reach a valid methodology for HTA and find the widely shared opinion that the need for HTA due to increased expenditures in healthcare is desirable. In the chapter on the Czech Institutional context, we have described the development of HTA in the Czech Republic. The government health policy's efforts to move Czech HTA for MD forward failed (Table 2, June 2010–July 2013 Minister of Health Heger). The inconsistency of two successive governments caused it, what one minister started, the other did not finish and moved in the opposite direction by not using the elements of HTA when deciding on medical devices. In 2019 Minister of Health Vojtech set the new rules for the MD committee with HTA principles. Many questions arise concerning the current development of the HTA for medical devices with new regulations for the Czech device commission.

To answer the research question, the real frequency of applying the methodology for Category III is the most significant finding. Although the Ministry of Health has undertaken to use HTA elements, these have been institutionally limited to Category III devices. As a result, HTA elements are barely reflected in the process of decision-making on the acquisition of medical devices. Only three devices were evaluated in Category III until the end of 2019 (Table 6). That means that only three medical devices have been assessed with Czech HTA since the new rules of the commission (promising HTA use) came into force (whole number of applications 200 during 2018 and 2019). After a more detailed examination of the applications, we see that points concerning HTA are very brief; they are only statements on the availability of foreign HTAs and information on the availability of HTA studies conducted in the Czech Republic. A comparison of the Czech system, which contains the elements of HTA for medical devices with the best

practice methodology, the HTA Core Model (also because the Ministry of Health itself had acknowledged that model in its statements), clearly shows that HTA is not applied to Category III either.

HTA is a much broader category, and the Czech system works with its elements to a limited extent. The most significant difference is that HTA contains a tremendous amount of evidence from the literature. It draws on a comprehensive search of the current state – epidemiological, clinical and safety data, and legal, social, and ethical aspects, including its pharmacoeconomic analysis from the environment where the method will be implemented, etc. All this is missing in local conditions of institutionalisation. A few brief sentences in the Czech incorporation of HTA for the MD committee that have nothing to do with evidence-based medicine, are far from meeting the primary objectives of HTA. Therefore, the main difference is the supporting documents' quality; only a few HTA-related points are submitted to the MD committee, but that is not an HTA study. From the ministry's point of view, the question remains whether the HTA of medical devices is resolved with that. Although not having contributed to the application of the HTA, the ministry's efforts have improved transparency. They have been guided by the principles of accessibility and equality in access to healthcare. The applications and the decisions, including rationale, are publicly available to the Czech Republic citizens. Therefore, this ministry endeavour, i.e. the new rules for the decision-making of the MD committee, is a step forward (also, in particular, compared to the previous state of the MD committee in the period from 2014 to the date of validity of the new rules), but HTA still is not included.

Conclusions

This paper describes and discusses the development and use of HTA for a selected category of medical devices in the Czech Republic. The sufficiently systemised HTA for MD and its implementation into the decision-making process has been lacking (even if elements of HTA are quite standardly used in pharmacoeconomics). In HTA development, we encountered the problem that cabinet reshuffles and ministerial drifts do not contribute to consistent HTA development in the Czech Republic.

Our paper's core part presented the currently selected MD category entry system into the Czech reimbursement system. It can be pointed out that the Czech Ministry of Health has not entirely met the objectives it had set in the area of HTA. Although Minister Vojtech presented himself as a great supporter of HTA, in institutionalising decision-making on medical devices, he focused entirely on new devices, which the MD committee encounters rarely. Moreover, where his commission evaluates these new devices, HTA is only a marginal element during decision-making. We demonstrated that the Czech Republic government (and the

Ministry of Health) did not stand by their proclamations from the government's program statement (to use HTA in deciding on the purchase of medical devices, which in reality is not underway, as our results clearly show).

Our results linked to the description of the development of HTA for MD in the Czech Republic and the findings related to the research question lead us to conclude that whenever the Czech central government tried to implement the HTA for medical devices, its effort failed.

Therefore, it is time to consider what can be done about the glaring irrationalities in the current system of entering new costly technologies into reimbursement (which, when entering the reimbursement system, mean long-term high costs for the health insurance budget). It is time for the effective and appropriate use of Health Technology Assessment (HTA) for medical devices to strengthen the healthcare system, not only performing the formal implementation and utilisation of HTA in the public health sector, but a real evaluation of technologies entering the reimbursement process is needed. The implementation of HTA is still an unresolved issue in the Czech Republic. We believe that HTA is one of the crucial challenges that should be presented. It is a way to contribute to healthcare reform to manage society's limited resources more effectively and help solve the problem of finding a new balance in the healthcare system.

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