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HTA and decision-making processes in Central, Eastern and South Eastern Europe: Results from a survey

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ABSTRACT

Objective: To gain knowledge and insights on health technology assessment (HTA) and decision-making processes in Central, Eastern and South Eastern Europe (CESEE) countries.
Methods: A cross-sectional study was performed. Based on the literature, a questionnaire was developed in a multi-stage process. The questionnaire was arranged according to 5 broad domains: (i) introduction/country settings; (ii) use of HTA in the country; (iii) decision-making process; (iv) implementation of decisions; and (v) HTA and decision-making: future challenges. Potential survey respondents were identified through literature review—with a total of 118 contacts from the 24 CESEE countries. From March to July 2014, the survey was administered via e-mail.
Results: A total of 22 questionnaires were received generating an 18.6% response rate, including 4 responses indicating that their institutions had no involvement in HTA. Most of the CESEE countries have entities under government mandates with advisory functions and different responsibilities for decision-making, but mainly in charge of the reimbursement and pricing of medicines. Other areas where discrepancies across countries were found include criteria for selecting technologies to be assessed, stakeholder involvement, evidence requirements, use of economic evaluation, and timeliness of HTA.
Conclusions: A number of CESEE countries have created formal decision-making processes for which HTA is used. However, there is a high level of heterogeneity related to the degree of development of HTA structures, and the methods and processes followed. Further studies focusing on the countries from which information is scarcer and on the HTA of health technologies other than medicines are warranted.
Classification: Reviews/comparative analyses.

1. Introduction

In most countries the increase in public health spending, coupled with pressing budget restrictions derived from the 2008 economic crisis, are the main challenges for the sustainability of health systems. One of the factors that most influence the increase in health expenditure is the inclu-

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sion of new health technologies [1,2]. There is no doubt that health technologies represent an indispensable element in the provision of quality health care. However, not every innovation represents an improvement, results in better health or is cost-effective. The *World Health Report 2010* [3] identifies the waste in medicines and health technologies as one of the main causes of inefficiency in the delivery of health services. Ensuring the optimal provision of public health services involves prioritizing investment decisions through instruments that give support to political decisions, such as health technology assessment (HTA).

The concept of HTA was originally conceived in 1978 by the Office of Technology Assessment in the US [4], in response to the sharp increase in health spending, the observation of unexplained variability in clinical practice, and uncertainty about the final and global results in the utilization of many health technologies [5]. The purpose of HTA is to determine the value of a health technology by evaluating their benefits and costs compared to existing alternatives for health care, taking into account both clinical and economic evidence, in order to inform pricing and coverage decisions [6]. At present, the most developed European countries have adopted some form of HTA process to assess the value of new health technologies within health services financed by public funds [7]. A large number of publications on the HTA processes followed in industrialized countries [8–13]. Although these processes often have common objectives, their structures are usually different. On the other hand, there is a lack of information on HTA processes conducted in Central, Eastern and South Eastern Europe (CESEE).

In recent years, HTA has gained momentum as a tool for assessing value and gauging value for money in the CESEE region, while its uptake as a formal decision-making mechanism has increased considerably [14]. In these countries, remarkable strides have been made with the introduction and support of HTA. In general, most CESEE countries often have no clear roadmap for HTA implementation [15], and also have a much greater social opportunity cost of adopting inappropriate health technologies and introducing inappropriate decisions on pricing and reimbursement. Critical factors for success in HTA implementation include financial and human resources, the establishment of a systematic and transparent decision-making process as well as relying on a robust HTA implementation methodology.

Thus, the purpose of this survey was to gain knowledge and insights on HTA and decision-making processes in CESEE countries.

2. Materials and methods

A cross-sectional survey of CESEE experts working in positions related to HTA and decision-making processes at institutional level was conducted. The survey was aimed at key informants (key persons representing organizations involved in HTA and/or pricing and reimbursement of medicines) in the selected countries. E-mail contact addresses of potential respondents were compiled from the Pharmaceutical Pricing and Reimbursement Information (PPRI) Network and the websites of public health organizations in target countries.

A survey questionnaire was developed in a multi-stage process. A draft was devised based on previous HTA surveys carried out by the European Network for Health Technology Assessment (EUnetHTA) (2008) [16], the National Institute for Health and Care Excellence (NICE) International and the Inter-American Development Bank (2010) [17], the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) (2012) [18], and the Health Intervention and Technology Assessment Program (HITAP) and NICE International (2013) [19]. The instrument was tested among HTA experts from NICE International and the London School of Economics, and modified according to the feedback received. The questionnaire was arranged according to five broad domains: (i) introduction/country settings; (ii) use of HTA in the country; (iii) decision-making process; (iv) implementation of decisions; and (v) HTA and decision-making: future challenges (Questionnaire available in Supplementary Material online). The instrument had both dichotomous and multiple choice questions, as well as open questions for clarification and explanation of responses.

From March to July 2014, 118 e-mails were sent to potential respondents from the 24 CESEE countries (classified according to the International Monetary Fund, plus Greece and Cyprus; https://www.imf.org/external/pubs/ft/reo/2014/eur/eng/ereo0414.htm), including a cover letter and the questionnaire. An explanation of the survey and an assurance of confidentiality in the treatment of responses was provided. Four survey reminders (March-April 2014) were sent by e-mail to respondents who did not complete the survey within the pre-established deadline, in order to maximise the response rate. To characterise survey data, descriptive statistics and content analysis were employed, where applicable.

In the following sections, results from the survey are presented in a synthesized manner and in more detailed tables. We use "most" or "the majority" to denote instances corresponding to more than 50% of responses given, and "over half" when the number of responses was slightly over 50%.

3. Results

3.1. Response rate and sample characteristics

A total of 118 e-mails were sent to different key institutions such as Ministries of Health and HTA organisations in order to obtain information about the HTA decision making process in the 24 CESEE countries.

At least one informant was contacted per country, ranging from 1 to 11 per country, depending on information availability.

We received 22 questionnaires generating an 18.6% response rate, including four responses indicating that their institutions had no involvement in HTA. No responses were received from Albania, Belarus, Bosnia Herzegovina, Kosovo, Moldova, Romania and Ukraine. Responses from institutions who declared not to perform HTA were excluded from the analysis (Macedonia, Albania, Cyprus, Turkey, Ukraine and Montenegro). Thus, the results are

based on responses from 13 countries, namely Bulgaria, Croatia, Czech Republic, Estonia, Greece, Hungary, Latvia, Lithuania, Poland, Slovakia, Slovenia, Republic of Serbia and Russia. In the cases of Poland, Czech Republic and Estonia we received two answers from different responders. All these cases offered very similar responses and discrepancies were clarified with respondents.

3.2. Structure of HTA systems

The governance and organization of HTA systems are important factors affecting the impact of HTA. In general, pricing and reimbursement decision-making structures are well defined across countries. However, formal HTA processes are only present in some countries, especially for medicines. Overall, there is much heterogeneity in terms of development of such processes. Table S1 shows a transnational overview of the main bodies involved in HTA according to their responsibilities.

3.3. Criteria for topic selection and types of technology assessed

Topics are determined according to the purpose of the assessment body. In general, most assessment topics arise as a result of requests from technology manufacturers. Most cited criteria for selecting technologies include those related to the magnitude of the health problem (frequency of the clinical condition—prevalence, incidence—and/or disease burden—mortality, morbidity and quality of life related to a clinical condition) and political concerns. Meanwhile, most technologies assessed were pharmaceuticals (n = 11), followed by medical devices (n = 7) and medical procedures (n = 5).

3.4. Aspects of HTA

In the decision-making process, manufacturers are required to submit a dossier with clinical and economic information. Normally, the entities responsible for HTA review and validate the industry data, which must be based on literature review of clinical evidence and economic data. Most respondents reported that assessments usually consider efficacy/effectiveness and economic evidence. Expert opinion and group judgment are used in some instances (e.g., Croatia, Russia, Poland). In terms of types of HTA report [20], the majority of respondents reported performing full HTA, while only Bulgaria indicated that they conducted rapid HTA. AOTMiT (Poland), performs mini- (o rapid) HTA, but rarely including economic analysis; only full HTA analysis (clinical effectiveness, and economic effectiveness and budget impact) are provided by submitters and assessed by AOTMiT.

3.5. Economic evaluation

Table 1 provides an overview of the use of economic evaluation across CESEE countries. By and large, the requirement is associated to the reimbursement of new health technologies. In two thirds of countries economic evaluation (EE) is a requirement for decision-making of health technologies. Of note, although EE is formally required in Slovenian regulation, in practice only budget impact analysis (BIA) is employed. It is also interesting to highlight that although Croatia has HTA guidelines —including EE, only BIA is required. In terms of perspectives used, the majority of countries reported taking account of that of the payer. An exception is Russia, where the perspective of the public sector is adopted.

Willingness-to-pay thresholds are used in over half of countries, but they are explicit in just two. Specifically, the Polish threshold is at 3x GDP per capita per QALY/LY gained, whilst the Slovakian one is set at 24/35x average monthly salary per QALY. Implicit thresholds include those used in Latvia (ICER ≤ pharmaceuticals already reimbursed), Czech Republic (3x GDP per QALY) and Estonia (1–3x GDP per QALY).

3.6. HTA guidelines

Over half of respondents replied that there are some sort of HTA guidelines in their countries. Of note, EUnetHTA guidelines are also followed in Slovakia, while Bulgaria and Greece were developing guidelines at the time of the survey. Reported guidelines are mainly methodological and focused on economic evaluation alone. In terms of process, the majority of documents only provide succinct guidance for manufacturers on reimbursement steps and evidence requirements, with only Croatia and Poland having a full HTA process guideline [21,22].

3.7. Link between HTA and decision-making

Over half of respondents reported that they had legislation establishing the use of HTA as mandatory to support decision-making. In addition, although not mandatory, Bulgarian legislation recommends using HTA. Among the countries in which the use of HTA is mandatory, only three (Slovakia, Czech Republic and Estonia) indicated that recommendations arising from assessments are binding to decision-makers (see Table 2 for more details).

3.8. Appraisal/decision-making criteria

Table 3 shows the criteria taken into account for appraisal/decision-making by type of technology. As can be seen, the HTA of medicines is more developed in terms of transparency of criteria compared with medical devices and interventions. Overall, criteria around the benefits, harms and costs of the technology in question are usually considered, whereas criteria related to aspects such as organizational, social or ethical impact are less common.

3.9. Stakeholder involvement

Table 4 illustrates how stakeholders are involved in the decision-making process. HTA systems differ widely in the degree to which stakeholders are allowed to participate in the HTA process. Half of respondents indicated that HTA entities involved stakeholders in their activities or require submissions of evidence from them. Less than half of respondents reported having a decision-making

Table 1
Economic evaluation in the HTA process.

Country[a]	Is an economic evaluation required for the decision-making process?	How often an economic evaluation is explicitly considered in the decision-making process?	Are there explicit 'thresholds' for cost-effectiveness? If not, what other approaches are used to decide whether an intervention is potentially cost-effective?	What is the perspective normally used of the economic evaluation?
BU	Yes	Always	No	Third-party payer
CR	NO. Only BIA	Never	No	No answer
CZ	Yes	ALWAYS	NO(3xGDP per QALY is used as reference)	Third-party payer
EE	Yes	Always	NO. (1–3 GDP per capita is used as reference)	Third-party payer
GR	Not Yet.	Rarely	Not applicable	Not definded yet
HU	Yes	Always	Yes	Third-party payer
LT	No answer	No answer	No answer	No answer
LV	Yes	Always	The ICER for an additionally obtained year of life or progression-free year of life shall not exceed the ICER of pharmaceuticals already included in the Positive list.	Third-party payer
PL	Yes	Always (for reimbursement submissions)	3x GDP per capita for ICUR/QALY or ICER/LYG	National Health Fund (public payer) perspective and joint perspective of payer and patient
RU	Yes	Frequently	No	Public Sector
SI	No	rarely	Yes	Third-party payer
SK	It is mandatory based on the law 363/2011.	Always	Threshold 1 is 24x average monthly salary €/QALY; Threshold 2 is 35x average monthly salary €/QALY	Third-party payer

BU: Bulgaria; CR: Croatia; CZ: Czech Republic; EE: Estonia; GR: Greece; HU: Hungary; LT: Lithuania; LV: Latvia; PL: Poland; RS: Republic of Serbia; RU: Russia; SI: Slovenia; SK: Slovakia; BIA: budget impact analysis; QALY: Quality adjusted life year; ICER: incremental cost effectiveness allocation; ICUR: incremental cost utility ratio.

[a] No respond was obtained from Republic of Serbia.

process open to public scrutiny (including the rationale behind decisions). However, only three countries allow appeal against recommendations/decisions. Poland is the only country reporting that their process is 'partially open', since industry data is confidential on many occasions.

3.10. Conflict of interest management

Except for Serbia, Russia and Slovenia, most respondents reported that their HTA systems have a procedure for managing potential conflicts of interest (CoI). This procedure varies across countries in terms of scope and repercussions. For example, some systems cover all stakeholders along the HTA process (Poland, Estonia) or even exclude stakeholders with CoIs (Czech Republic), while others focus on the assessment/appraisal stage (Latvia).

3.11. Timeliness of HTA

The timing of the HTA process can affect patient access, and a trade-off between ensuring comprehensive evaluation and providing timely information to decision-makers should exist. In line with the levels complexity of HTA systems and requirements across countries, the reported timelines needed to complete the HTA process ranged from 90 days to 365 days (see Table S2 for more details).

3.12. Special contracting and patient access schemes

Data on these arrangements was reported by two thirds of countries. In Slovakia the possibility to apply special contracting and patient access schemes is based on negotiating processes with health insurance funds. In Latvia and Bulgaria, it is possible to apply price-volume agreements and discounts. In Greece, price-volume, risk-sharing agreements or extra discounts can be applied to new products. In Estonia, conditional reimbursement is very common (including outcomes-based and risk-sharing reimbursement). In Poland, Czech Republic, Hungary and Serbia, risk-sharing agreements can also be proposed. It is interesting to highlight the case of Poland, where special measures for expensive medicines exist ('drug/regimen programmes'). If the medicine is not cost-effective, risk-sharing schemes can be proposed. If there is a significant

Table 2
Link between HTAs and decisions.

	BU	CR	CZ	EE	GR	HU	LT	LV	PL	RS	RU	SI	SK
Legislation establishing HTA reports must be considered in the decision-making process as mandatory			√	√	√			√	√			√	√
Legislation establishing HTA reports should be considered to support coverage decisions as recommendation	√			√					√				
There is no specific legislation, but HTA reports have been used to support policy making.		√				√	√				√		
Decisions are not informed by HTA										√			
Decision-maker **always** make decision rely on conclusion of the HTA			√	√[a]									√
Decision-maker **in most of the cases** make decision rely on conclusion of the HTA	√	√				√		√	√			√	
Decision-maker **in some of the cases** make decision rely on conclusion of the HTA					√						√		
Decision-maker **rarely** make decision rely on conclusion of the HTA							√						
Decision-maker make decision without any input from HTA										√			

[a] as full HTA is currently under development, the decision making is done via elements of HTA which are regulated by law. BU: Bulgaria; CR: Croatia; CZ: Czech Republic; EE: Estonia; GR: Greece; HU: Hungary; LT: Lithuania; LV: Latvia; PL: Poland; RS: Republic of Serbia; RU: Russia; SI: Slovenia; SK: Slovakia.

budget impact, sources for additional funds must be proposed.

3.13. Disinvestment decisions based on HTA

Less than half of the countries reported having used HTA to inform disinvestment on health technologies. In Poland, there is a system based on individual request to assess old technologies in specific (off-label) indications.

In Bulgaria, the biannual system for price revision offers the opportunity to delist products, especially of those not marketed for a period of three months. Other respondents provided examples of delisting medicines of unproven effectiveness, such as cinnarizine, orlistat and nicergoline (Czech Republic) and Omacor® (Latvia), or for safety concerns such as rosiglitazone and sibutramine (Croatia).

3.14. Implementation of decisions

Table S3 shows some information related to the implementation of decisions based on HTA. Only two countries (Croatia and Hungary) reported having a national strategy for the implementation of health technologies. Just one third of countries indicated that there were monitoring and evaluation mechanisms for assessing the uptake of recommendations based on HTA. Moreover, CPGs and/or protocols are employed as a mandatory or advisory tool to direct clinicians in half of the countries. CPGs are usually disseminated to users by electronic means (e.g., website, e-mail, e-prescription system). In particular, CPGs are produced and disseminated by clinical societies in Poland and Czech Republic. Lastly, Estonia annexes implementation plans (including specific activities and training) in their guidelines.

4. Discussion

This article contributes to the debate of efficiency in resource allocation by describing the current HTA processes in a group of CESEE countries. Results highlight the heterogeneity in the use of HTA. Some aspects of HTA are in place in these countries. While some jurisdictions only compare the therapeutic value of health technologies, others also take account of the differences in resource use associated to the health technologies. However, in general no comprehensive and transparent system exists in most of them. In some countries there is no defined structure that assumes the assessment function nor legislation supporting HTA. Countries such as Hungary and Poland have more formal HTA systems in place, while other CESEE countries remain in the early stages of developing national bodies. Moreover, and although all technologies should be potential candidates for HTA, survey results show that most technologies assessed are medicines. Furthermore, decision-making is mainly usually based on information provided by the manufacturer, and only few jurisdictions perform their own cost effectiveness models. On the other hand, HTA organizations in the study countries differ widely in the degree to which stakeholders can participate in the process and interact with decision-makers. It is

Table 3
Criteria used for appraisal/decision-making.

	MEDICINES			MEDICAL DEVICES			INTERVENTIONS		
	Explicit criteria	Implicit criteria	No criteria	Explicit criteria	Implicit criteria	No criteria	Explicit criteria	Implicit criteria	No criteria
Efficacy	(SK); (LV); (PL); (CZ); (CR); (RU); (ES); (BU); (SI).			(SK); (PL); (CR); (ES); (HU).	(LV); (CZ).	(SI)	(LV); (PL); (ES); (HU)	(SK); (CZ)	(SI)
Effectiveness	(SK); (CR); (RU); (ES); (HU); (SI)	(LV); (PL); (CZ); (HU); (BU)		(SK); (CR); (ES)	(LV); (PL); (HU)	(CZ); (SI)	(LV); (ES)	(SK); (PL); (HU)	(CZ); (SI)
Safety	(SK); (LV); (PL); (CZ); (CR); (RU); (ES); (HU); (BU); (SI)			(SK); (PL); (CZ); (CR); (ES); (HU)	(LV)	(SI)	(LV); (PL); (ES); (HU)	(SK); (CZ)	(SI)
Quality of Life	(SK); (CR); (RU); (ES); (BU); (SI)	(LV); (PL); (HU)	(CZ)	(SK); (CR); (ES)	(LV); (PL); (HU)	(CZ); (SI)	(LV); (ES); (HU)	(SK); (PL)	(CZ); (SI)
Cost-Effectiveness	(SK); (LV); (PL); (RU); (ES); (HU); (SI)		(CZ); (CR); (BU)	(SK); (PL); (ES)	(HU)	(LV); (CZ); (CR); (SI)	(PL); (ES); (HU)	(SK); (LV)	(CZ); (CR); (SI)
Budget Impact	(SK); (LV); (PL); (CR); (ES); (HU); (BU); (SI)	(CZ)		(SK); (PL); (CR); (ES); (HU)	(CZ); (RU)	(LV); (SI)	(PL); (ES); (HU)	(SK); (LV)	(CZ); (SI)
Ethical, Equity, and Social Issues	(CR); (ES)	(SK); (LV); (PL); (HU)	(CZ); (BU); (SI)	(ES)	(SK); (PL); (HU)	(LV); (CZ); (SI)	(ES); (HU)	(SK); (LV); (PL)	(CZ); (SI)
Organizational Impact	(ES)	(SK); (LV); (PL); (ES); (HU)	(CZ); (BU); (SI)	(ES)	(SK); (PL); (HU)	(LV); (CZ); (SI)	(ES); (HU)	(SK); (LV); (PL)	(CZ); (SI)
Innovation/Industrial Develop-ment/Technology Transfer	(SI);		(SK); (LV); (PL); (CZ); (ES); (HU); (BU)			(SK); (LV); (PL); (CZ); (ES); (HU); (SI)			(SK); (LV); (PL); (CZ); (ES); (HU); (SI)
Geographical Budget Allocations		(HU); (SI)	(SK); (LV); (PL); (CZ); (ES); (BU)	(HU)		(SK); (LV); (PL); (CZ); (ES); (SI)	(HU)		(SK); (LV); (PL); (CZ); (ES); (SI)
Impact on Vulnerable Groups[a]	(ES);	(SK); (LV); (PL); (CZ); (HU); (BU); (SI)			(SK); (CZ); (ES); (HU)	(LV); (SI)	(HU)	(SK); (LV); (ES)	(CZ); (SI)
Burden of Illness	(LV); (PL); (CR); (RU); (ES); (HU); (SI)	(SK); (CZ);	(BU)	(PL); (CR); (ES); (HU)	(SK);	(LV); (CZ); (SI)	(PL); (ES); (HU)	(SK); (LV);	(CZ); (SI)

BU: Bulgaria; CR: Croatia; CZ: Czech Republic; EE: Estonia; GR: Greece; HU: Hungary; LT: Lithuania; LV: Latvia; PL: Poland; RS: Republic of Serbia; RU: Russia; SI: Slovenia; SK: Slovakia.

[a] Vulnerable groups include the elderly, the mentally and physically disabled, at-risk children and youth, ex-combatants, internally displaced people and returning refugees, HIV/AIDS-affected individuals and households, religious and ethnic minorities, in some societies women. (CR y RU): no complete information GR, LI: No answer; (BU)information only for medicines.

Table 4
Stakeholders in the decision-making process.

	BU	CR	CZ	EE	HU	LT	LV	PL	RU	SI	SK
Does the HTA organization involve stakeholders in its activities?	No	No	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No
Does the HTA organization encourage or require submissions of evidence from stakeholders?	Unsure	Yes	Yes	depends on the HTA process	No	Unsure	Yes	Yes	No	No	Yes
Does the HTA organization allow stakeholders to comment on HTA at the draft stage?	No	No	YES	depends on the HTA process	No	Unsure	No	No	No	No	No
Does the HTA organization allow stakeholders to appeal against recommendations/decisions?	No	No	Yes	depends on the HTA process	No	Unsure	Yes	No	Unsure	No	Yes
Is the decision-making process (including the rationale behind technology reimbursement decisions) open to public scrutiny?	Yes	No	Yes	No	No	No	Yes	YES (a)	No	No	Yes

BU: Bulgaria; CR: Croatia; CZ: Czech Republic; EE: Estonia; GR: Greece; HU: Hungary; LT: Lithuania; LV: Latvia; PL: Poland; RS: Republic of Serbia; RU: Russia; SI: Slovenia; SK: Slovakia. (a) HTA process is partially open ('confidential' information may be hidden by applicant, which sometimes constitutes a very important part of the HTA report); No respond was obtained from Greece and Republic of Serbia.

important to note that in some jurisdictions the selection of health technologies to be assessed is driven by manufacturers seeking access, rather than driven by public need.

These results agree with others studies published in the literature [14,23,24].

Major differences of HTA systems from CESEE compared with those from Western Europe relate to politicized decision-making lack of domestic epistemic communities advocating for HTA, scarcity of capacity building in performing HTA, the quality of local data, and as a result of all these, weak structures in HTA decision-making [25,26]. Generally, countries with lower GDP per capita have more limited budgets and human resources for conducting HTA [15]. This limitation leads policymakers and payers to consider foreign HTAs in their decisions. On the other hand, relevant local databases and clinical guidelines are often incomplete or unavailable. This decreases accuracy of HTAs, increases bias in evaluations of medical practice, and makes adaptation of economic models to local reality difficult or almost impossible. Policymakers may even not take account of HTA products if they perceive that their producers lack the necessary skills and knowledge [25]. Overall, there is a need for more transparency in the use of HTA. Improving transparency in the decision process based on HTA needs to be encouraged, taking into account the necessity of balance between transparency and confidentiality. A transparent process would also support the legitimacy of the decisions made [27].

In line with the above, real efforts–including political will and donor commitment–would be needed if advances in the implementation of HTA are to be made. First, a boost in resources for HTA capacity building is required, including financial, technical and training resources. Second, it is important to improve methods and processes, so that HTA products are taken into account for decision-making (e.g., reimbursement, guidelines development) and decisions based on HTA are acceptable for all stakeholders.

Third, collaboration among countries, including harmonization of HTAs and exploring the possibility of transferability of foreign data, is crucial for strengthening and implementing HTA in emerging settings. EUNetHTA is playing an important role in the exchange of information in Europe, but not all the European countries are enrolled in this network. As a result, much information about the HTA regulatory framework missing in the publications of this network has been gathered in this mapping exercise [16]

This mapping survey has several limitations that need to be considered. The response rate was low. For countries with more established HTA activities (e.g, Poland or Slovenia), it was easier to identify experts and get a response from them, compared with those countries with less established HTA activities (e.g. Albania, Moldova). Different ways to ensure an adequate response rate were put into practice, including four reminder e-mails sent to all those that had not responded. This different country response rate could perhaps be explained by the different level of HTA implementation in each country, a lack of interest in the topic, people not feeling qualified to respond the questionnaire or language barriers. Only one person indicated that he/she was not allowed to respond the questionnaire. Another limitation is the possible underrepresentation of HTA processes for health technologies other than medicines. Usually HTA systems are first implemented for the reimbursement and pricing of medicines, and processes for the assessment/appraisal of medical devices or clinical interventions may remain less well known at country level. Moreover, it is possible that decentralized/hospital-based/individual or isolated processes for medical devices and clinical interventions are not well known by respondents.

Some of the countries from which responses were not obtained (e.g., Albania, Bosnia and Herzegovina, Kosovo, Macedonia) do not have a clearly defined HTA process [28]. Most investment decisions in these countries are based on expert opinion and regulatory requirements. The assessment is limited to the review of information provided by industry. On the other hand, the number of HTA experts is also very limited in these countries, which may have influenced on the lack of response [29]. Bosnia and Herzegovina has no systematic HTA process, but there are some positive actions to strengthen it. In April 2011, a new legal act for inclusion and exclusion of new medicines reimbursed was introduced, proposing submission of modelling studies and cost effectiveness, and BIA as part of the decision-making process. The law also includes the establishment of a pharmacoeconomic unit [28].

On the other hand, the mapping also provides information of the HTA process in countries where a lack of public information is notorious. Previous to this mapping exercise, there was no evidence that described in just one document the process of HTA in all CESEE countries to enable us to reflect on the differences or similarities of HTA decision making-processes, implementation and priority-setting.

This HTA mapping survey provides baseline information on the current status of HTA in CESEE countries, from which any stakeholders interested in the advancement of HTA in the region may benefit. There is no a single or common direction; each country has to follow its own route according with their development stage and the characteristics of their health care systems.

5. Conclusions

This study shows that a number of CESEE countries have created formal decision-making processes for which HTA is used. However, there is much heterogeneity related to the degree of development of HTA structures, and the methods and processes followed. These findings can assist both national policymakers and/or international donors in the analysis of needs and the planning of actions to be taken to strengthen regional HTA capacity and systems. Although the response rate was relatively low, most of the countries from which responses were not obtained did not have a clearly defined HTA process. Existing HTA networks can benefit from these findings by using it for advocacy to local policymakers and to provide technical assistance. Further studies are needed focusing on the countries from which information is scarcer and on health technologies other than medicines.

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Authors' contributions

All authors contributed with ideas for discussion, reviewed the manuscript, and approved the final version.

Conflict of interest

The authors report no conflict of interest.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.healthpol.2017.03.010.

References

[1] Organisation for Economic Co-operation and Development. Projecting OECD health and long term care expenditures: what are the main drivers? Organisation for Economic Co-operation and Development Economic Department Working Paper, No 477. Paris: OECD Publishing; 2006. Available at: http://www.oecd.org/tax/public-finance/36085940.pdf. [Accessed 15 March 2015].

[2] Okunade AA, Murthy VNR. Technology as a major driver of health care costs: a cointegration analysis of the Newhouse conjecture. Journal of Health Economics 2002;21:147–59.

[3] World Health Organization. Health systems financing: the path to universal coverage. Geneva: WHO; 2010. Available at: http://www.who.int/whr/2010/en/index.html. [Accessed 15 October 2015].

[4] Office of Technology Assessment. Assessing the efficacy and safety of medical technologies. Washington, DC: US Government Printing Office; 1978.

[5] Banta D, Behney CJ, Andrulis DP. Assessing the efficacy and safety of medical technologies. Washington, DC: Office of Technology Assessment; 1978.

[6] Drummond MF, Schwartz JS, Jönsson B, Luce BR, Neumann PJ, Siebert U, et al. Key principles for the improved conduct of health technology assessments for resource allocation decisions. International Journal of Technology Assessment in Health Care 2008;24:244–58.

[7] Taylor RS, Drummond MF, Salkeld G, Sullivan SD. Inclusion of cost effectiveness in licensing requirements of new drugs: the fourth hurdle. BMJ 2004;329:972–5.

[8] Sorenson C, Drummond M, Kanavos P. Ensuring value for money in health care: the role of health technology assessment in the European Union. Observatory Studies Series No. 11. Geneva: World Health Organization, on behalf of European Observatory for Health Systems and Policies; 2008. Available at: http://www.euro.who.int/...data/assets/pdf_file/0011/98291/E91271.pdf. [Accessed 15 October 2015].

[9] le Polain M, Franken M, Koopmanschap M, Cleemput I. Drug reimbursement systems: international comparison and policy recommendations. In: Health Services Research (HSR). KCE Reports 147C. D/2010/10.273/90. Brussels: Belgian Health Care Knowledge Centre (KCE); 2010.
[10] Wilsdon T, Serota A. A comparative role and impact of health technology assessment. London: Charles River Associates; 2011. Available at: http://www.efpia.eu/uploads/documents/cra-comparative-analysis.pdf. [Accessed 15 October 2015].
[11] Paris V, Belloni A. Value in pharmaceutical pricing. In: OECD Health Working Papers No. 63. Paris: OECD Publishing; 2013. Available at: http://www.oecd-ilibrary.org/docserver/download/5k43jc9v6knx.pdf?expires=1463388855&id=id&accname=guest&checksum=304AA1F638B4DEE62A75AA134A80E611. [Aaccessed 15 October 2015].
[12] Barneih L, Manns B, Harris A, Blom M, Donaldson C, Klarenbach S, et al. A synthesis of drug reimbursement decision-making processes in Organisation for Economic Co-operation and Development countries. Value Health 2014;17(1):98–108.
[13] Kanavos P, Nicod E, Van den Aardweg S, Pomedli S. The impact of health technology assessments: aa international comparison. Euro Observer 2010;12(Winter (4)):1–7. Available at: http://www.euro.who.int/_data/assets/pdf_file/0007/127798/EuroObserver_Vol12_No4_Winter_-2010.pdf. [Aaccessed 15 October 2015].
[14] Gulácsi L, Orlewska E, Péntek M. Health economics and health technology assessment in Central and Eastern Europe: a dose of reality. European Journal of Health Economic 2012;13(5):525–31.
[15] Kaló Z, Gheorghe A, Huic M, Csanádi M, Kristensen FB. HTA implementation roadmap in Central and Eastern European countries. Health Economics 2016;25(Suppl. 1):179–92.
[16] Moharra M, Kubesch N, Estrada MD, Parada T, Cortés M, Espallargues M, et al. EUnetHTA project. Survey report on HTA organisations. Barcelona: Catalan Agency for Health Technology Assessment and Research; 2008. Available at: http://www.eunethta.eu/outputs/survey-report-hta-organisations. [Accessed 9 December 2015].
[17] National Institute for Health and Care Excellence International and the Inter-American Development Bank. HTA survey. London and Washington DC: NICE International and IABD; 2010.
[18] Stephens JM, Handke B, Doshi JA, on behalf of the HTA Principles Working Group. International survey of methods used in health technology assessment (HTA): does practice meet the principles proposed for good research? Journal of Comparative Effectiveness Research 2012;2:29–44.
[19] Health Intervention and Technology Assessment Program and National Institute for Health and Care Excellence International. Situation analysis of HTA introduction at national level. Version 2.0. Nonthaburi and London: HITAP and NICE International; 2013. Available at: https://idsihealth.files.wordpress.com/2014/06/hta-situation-analysis-1_oct_2013.pdf. [Accessed 9 December 2015].
[20] Strategies for the diffusion and dissemination of health technology assessment (HTA) products. http://www.sergas.es/docs/Avalia-t/diffusion-Strategies.pdf. [Accessed 18 July 2015].
[21] Agency for Quality and Accreditation in Health Care, Department for Development. Research and Health Technology Assessment. The Croatian guideline for health technology assessment process and reporting, 1st edition Zagreb: AAZ; 2011.
[22] Agency for Health Technology Assessment and Tariff System. Guidelines for conducting Health Technology Assessment (HTA). Warsaw: AOTMiT; 2009.
[23] Gulacsi L, Rotar A, Niewada M, Lóblovà O, Rencz F, Petrova G, et al. Health technology assessment in Poland, the Czech Republic, Hungary, Romania and Bulgaria. The European Journal of Health Economics 2014;15(Suppl. 1):S13–25.
[24] Ferrario A, Baltezarević D, Novakovic T, Parker M, Samardzic J. Evidence-based decision making in healthcare in Central Eastern Europe. Expert Review of Pharmacoeconomics & Outcomes Research 2014;14(5):611–5.
[25] Olry de Labry Lima A, García-Mochón L, Caro Martínez A, Martín Ruiz E, Espín Balbino J. Mapping capacity to conduct health technology assessment in Central, Eastern and South-Eastern Europe. Croatian Medical Journal 2016;57(1):66–70.
[26] Löblová O. Three worlds of health technology assessment: explaining patterns of diffusion of HTA agencies in Europe. Health Economics, Policy and Law 2016;11(3):253–73.
[27] 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 Review of Pharmacoeconomics & Outcomes Research 2012;12(3):283–7.
[28] Jakovljevic MB. Resource allocation strategies in Southeastern European health policy. European Journal of Health Economics 2013;14(2):153–9.
[29] Dankó D, Petrova G. Health technology assessment in the Balkans: opportunities for a balanced drug assessment system. Biotechnology & Biotechnological Equipment 2014;28(6):1181–9.