Editorial

For reprint orders, please contact: reprints@futuremedicine.com

Journal of **Comparative Effectiveness Research**

European cooperation in health technology assessment implementation: the perspective of Central and Eastern European countries

Bertalan Németh*,[1] & Zoltán Kaló[1,2]

[1]Syreon Research Institute, Budapest, Hungary

[2]Center for Health Technology Assessment, Semmelweis University, Budapest, Hungary

*Author for correspondence: bertalan.nemeth@syreon.eu

> “Internationally, this also means that developed countries cannot ignore unmet medical need in the rest of the world, as consequent health and economic problems originating from these countries may still reach them.”

First draft submitted: 17 April 2020; Accepted for publication: 4 May 2020; Published online: 5 June 2020

Keywords: Central and Eastern European countries • evidence-based decision making • health technology assessment • transferability

As we are writing this Editorial, the Coronavirus Disease 2019 (COVID-19) pandemic is ravaging throughout the world, and despite the measures of many governments, it is overwhelming several healthcare systems and leading to high numbers of fatalities [1]. We believe that this case highlights the importance of putting common interests and public health goals over individual interests, and putting the focus on fair allocation of scarce resources [2]. Internationally, this also means that developed countries cannot ignore unmet medical need in the rest of the world, as consequent health and economic problems originating from these countries may still reach them.

Therefore, it is not an exaggeration to state that international cooperation can indeed save lives [3]. Not only in the context of the current pandemic, not only when we think about how health technology assessment (HTA) should be used to improve the value judgement of the future technologies to tackle COVID-19, but ultimately when we think about our everyday national pricing and reimbursement decisions.

Even during less turbulent times, there is a great pressure on researchers from patients and the general public as well, to eliminate unmet needs by developing new technologies for health conditions without a cure. However, once the added clinical value of new health technologies has been proven, public purchasing of those cannot compromise the sustainability of healthcare systems or patient access to other valuable technologies.

Only carefully designed HTA systems can enforce the healthcare industry to implement value-based pricing based on principles of fairness and justice, as – according to the recent public statement by the European Patient Forum – “*availability and affordability of innovative technologies have never been more important*” [4]. We argue that HTA systems should not be operated only on the national or sub-national level, but on the international, for example European level as well.

Harmonization of HTA across the European Union

The concept of harmonizing HTA in the European Union started many years ago [5], with the ultimate goal of reducing the duplication of efforts, similarly to how the establishment of the European Medicines Agency reduced previous parallel activities of national drug regulatory agencies.

The European Network for Health Technology Assessment (EUnetHTA) has completed the foundation work in four different stages, including an introductory project followed by three joint actions [6]. EUnetHTA delivered harmonized tools, such as databases, procedures and methodological guidelines to reduce the heterogeneity of HTA approaches. Several joint relative effectiveness assessments (REAs) were completed by EUnetHTA for phar-

Future Medicine

maceuticals and other technologies. Finally, specific actions were tested to improve the quality of HTA evidence, namely early dialogues prior to launching new technologies and post-launch observational data collection [7]. As EUnetHTA cannot be continued in another Joint Action, the European Commission made a proposal for a new regulation on Health Technology Assessment in January 2018 [8].

The proposal covered four main areas, including joint clinical assessments for the most innovative health technologies, joint scientific consultation for those companies who seek early guidance from HTA agencies regarding their evidence requirements, horizon scanning to identify the most promising health technologies for patients and health systems at an early stage, and voluntary cooperation in any other areas, such as economic evaluation.

The European Parliament issued a report on the European Commission's proposal for a Regulation on HTA in October 2018. In this report explicit statement was made that "*The outcome of such assessments should not therefore affect the discretion of Member States in relation to subsequent decisions on pricing and reimbursement of health technologies . . . which remain solely a matter of national competence*." [9].

Since then the process for HTA harmonization has been slowed down.

The temptation for 'quick fixes'

The delay in the EU regulation of harmonized HTA has tremendous impact on healthcare systems in Central and Eastern European (CEE) Member states. These countries have poorer health status and more limitations in their healthcare budgets, hence the opportunity cost of inappropriate pricing and reimbursement decisions is greater in in this region compared with Western Europe [10].

Developing a well-constructed HTA system is not a cheap and quick exercise [11]. Unfortunately, several CEE countries could not allocate the necessary human and financial resources to substantiate their coverage decisions with timely and scientifically solid HTA recommendations.

In the absence of sufficient capacities for HTA implementation, some CEE countries have been experimenting with quick fixes, such as relying on recommendations of prestigious Western European HTA institutions without considering the transferability of international cost–effectiveness evidence. This approach is often presented as 'rapid *de-facto* HTA' [12] or 'balanced value assessment' [13]. At first glance, this may appear as a cheap, fast and attractive solution for policymakers. Certain other stakeholder groups can also view this as beneficial, because pharmaceutical prices are generally established while taking into account the purchasing power on the big markets, therefore it is easier to pass the cost–effectiveness criteria and receive a positive recommendation in high-income countries. In practice, this means that more drugs will be accepted locally, but without any local judgement on their value.

However, as has been discussed for decades, the transferability of economic evaluations across jurisdictions is limited, mostly due to the fact that several of the inputs of a well-constructed analysis are country specific [14]. This means, that even when assessing the same health technology in the same indication through adequately conducted analyses, researchers in different countries may reach different conclusions [10]. Therefore, cost–effectiveness evidence in a more affluent early adopter country cannot guarantee the cost–effectiveness in a lower income country, especially if actual prices of high-cost technologies are not known due to confidential discounts.

This method can be interpreted as a loosening of local HTA requirements, with ultimately more therapies needing to be financed from the same limited budget. A recent example from Slovakia has already shown the severe negative effects on the sustainability of healthcare financing after the positive short-term effects on extending the positive drug list [15].

We believe that as full HTA reports are only partially transferable, making decisions based solely on the policy decisions of other countries is ultimately not a scientifically sound methodology, leading to flawed conclusions. Perceived benefits of such systems will only occur in the short-term, and only for a limited number of stakeholders with vested interest in positive reimbursement decisions for expensive health technologies. The negative consequences will inevitably emerge, and the perceived initial benefits in patient access will fade away.

A possible solution: reuse of joint HTA

We acknowledge the costs and human resources associated with the establishment and continuous operation of an HTA body. However, we are afraid that inappropriate policy decisions have a higher price for healthcare systems. Therefore, we advocate for solutions which, while acknowledging the financial limitations, are also in line with the scientific principles of HTA.

Here we wish to make it clear that HTA is not the root cause of drug access limitations. On the contrary, HTA may be one of the most useful tools that healthcare systems possess to mitigate the effects of finite budgets. This is due to the comprehensive, multi-disciplinary, evidence-based approach that is applied in a well-constructed HTA process [16].

The other option for reduced HTA workload at a national level in CEE countries is to de-duplicate the transferable parts of assessment, mainly by conducting joint REA at the European or regional level, or reusing such assessments from other countries, while adhering to the principle of transferability. The transferable international methodologies and reports provide a scientifically solid basis for national appraisal.

An example of such a solution is the HTA Core Model [5,17], in which a joint European REA provides the basis for national appraisals. Local HTA doers therefore can focus their efforts on the nontransferable domains of HTA [18], reducing the amount of resources needed to generate appropriate evidence to support policy decisions of new health technologies. In addition, joint REAs can potentially increase the negotiating power of Europe in the global arena of pharmaceutical research and development [19].

Conclusion

In conclusion, in times of need, the need for making better decisions also increases. HTA can be a useful tool in the hands of decision makers worldwide, especially in difficult health and economic periods. However, resource-constrained CEE countries suffer from delayed or lacking HTA regulation in the European Union. We hope that our scientific community can convince our politicians that international cooperation can save lives even in less turbulent periods.

Even in the case of limited funding being available, adhering to key principles can ensure that HTA is not only being used, but it is being used properly. Appropriate evidence-informed coverage decisions can ultimately improve the allocative efficiency of scarce public resources, hence more health gain can be generated from a given healthcare budget.

Financial & competing interests disclosure

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

No writing assistance was utilized in the production of this manuscript.

References

Papers of special note have been highlighted as: • of interest; •• of considerable interest

1. World Health Organization. Coronavirus disease 2019 (COVID-19): situation report – 85 (2020). www.who.int/docs/default-source/coronaviruse/situation-reports/20200414-sitrep-85-covid-19.pdf?sfvrsn = 7b8629bb_4
2. Emanuel EJ, Persad G, Upshur R *et al.* Fair allocation of scarce medical resources in the time of Covid-19. *N. Engl. J. Med.* DOI: 10.1056/NEJMsb2005114 (Epub ahead of print) (2020).
3. Coronavirus: three things all governments and their science advisers must do now. *Nature* 579, 319–320 (2020).
4. European Patients Forum. An open memo to the health industry (2020). www.eu-patient.eu/COVID-19/epf-covid-statements/open-memo-to-health-industry/
5. Kristensen FB. Development of European HTA: from vision to EUnetHTA. *Michael J.* 9, 147–56 (2012).
6. Migliore A. Towards a regulation of HTA in Europe: the proposal from the European Commission. *Expert Rev. Med. Devices* 16(1), 1–2 (2019).
7. Kristensen FB, Lampe K, Wild C, Cerbo M, Goettsch W, Becla L. The HTA Core Model®—10 years of developing an international framework to share multidimensional value assessment. *Value Health* 20(2), 244–250 (2017).

•• **Overview on the EUnetHTA project, focusing on the health technology assessment (HTA) core model.**

8. European Commission. Proposal for a regulation of the European parliament and of the council on health technology assessment and amending directive 2011/24/EU (2018). https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/com2018_51final_en.pdf
9. European Parliament. Draft Report on the proposal for a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU (2018). www.europarl.europa.eu/sides/getDoc.do?type=COMPARL&reference=PE-622.011&format=PDF&language=EN&secondRef=01

10. 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* 21(4), 442–449 (2012).
11. Löblová O. What has health technology assessment ever done for us? *J. Health Serv. Res. Pol.* 23(2), 134–136 (2018).
- **Article on the importance of HTA.**
12. Lopert R, Ruiz F, Chalkidou K. Applying rapid 'de-facto' HTA in resource-limited settings: experience from Romania. *Health Policy* 112(3), 202–208 (2013).
13. Dankó D. Health technology assessment in middle-income countries: recommendations for a balanced assessment system. *J. Market Access Health Pol.* 2(1), 23181 (2014).
14. Drummond M, Barbieri M, Cook J *et al.* Transferability of economic evaluations across jurisdictions: ISPOR Good Research Practices Task Force report. *Value Health* 12(4), 409–418 (2009).
- **Overview of the transferability issues of economic evaluations.**
15. Tesar T, Obsitnik B, Kaló Z, Kristensen FB. How changes in reimbursement practices influence the financial sustainability of medicine policy: lessons learned from Slovakia. *Front. Pharmacol.* 10, 664 (2019).
- **Demonstrates the negative effects of loosening HTA requirements.**
16. Banta D. What is technology assessment? *Int. J. Tech. Assess. healthcare* 25(S1), 7–9 (2009).
- **Explains the basic concepts of HTA.**
17. Lampe K, Mäkelä M, Garrido MV *et al.* The HTA core model: a novel method for producing and reporting health technology assessments. *Int. J. Tech. Assess. healthcare* 25(S2), 9–20 (2009).
18. Inotai A, Németh B. Navigating Joint HTA, Procurement, and fair pricing: evidence-based insights and practical recommendations – a meeting report from ISPOR Regional Conference in Warsaw. *Expert Rev. Pharmacoecon. Outcomes Res.* 19(4), 379–381 (2019).
19. Kanavos P, Angelis A, Drummond M. An EU-wide approach to HTA: an irrelevant development or an opportunity not to be missed? *Eur. J. Health Econ.* 20(3), 329–332 (2019).