

IMPACT OF HEALTH TECHNOLOGY ASSESSMENT AND EFFECTIVENESS ANALYSIS ON HEALTHCARE SERVICES AND PROCEDURES IN REPUBLIC OF SERBIA

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Summary

Background: Health Technology Assessment (HTA) is “a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. Its’ purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system”

Methods and Objectives: The aim of this study is to identify the place and role of HTA in the decision-making process in healthcare in the Republic of Serbia. To achieve this goal we performed pragmatic, nonsystematic literature review based on analysis of available documents

Results: Since the adoption of the Rulebook on conditions and methods of health technology assessment in 2020, a total of 16 requests were officially submitted, for which the Ministry of Health requested the assessment performed by Institute of public health of Serbia. By the Healthcare law, the aim of the assessment is to have a basis for issuing a license for the use of new technology, but not to reimburse it. The fact of issuing license for use leads the assessment role more to the inspection direction. Furthermore, about a half of those requests were submitted by license holders for medical devices or private practices for the procedures, and the majority of those requests relate to technologies that, according to the literature review, are in the experimental phase of research and/or in the majority of countries that considered reimbursement, they were rejected for regular use due to the lack of evidence of effectiveness and/or or for arguable safety reasons.

Conclusions: Since the function of HTA is exclusively to help the policymakers to use health resources in the most cost-effective way, there is necessity of formulation transitional documents to define the role and place of HTA as well as the assignments of MoH and NHIF related to the final decision of financing the new health technology.

To have an impact of HTA implementation on the healthcare system there is need to face the challenges such as full dedication to HTA, the number of qualified human resources, trainings etc.

Keywords: Health technology assessment, HTA, Medical devices, Procedures, Republic of Serbia

Introduction

Due to increasingly rapid development of technologies, there is no country in the world, even among the richest, that cannot spend the entire national budget on the latest health technologies if they did not apply any limiting mechanisms. Limiting mechanisms must refer to those social values that are generally accepted in the modern world, and certainly in the EU. Those values that are most relevant for health insurance and coverage of a package of basic services include: solidarity, equal access to quality health technology, transparency and rational decision-making. One of the tools viewed as a “bridge between evidence and policy making” [1] or “support for health policy making” [2] is health technology assessment.

Health Technology Assessment (HTA) is “a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. Its’ purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system” [3]

Considering the definition that explains health technology [3] as the application of organized knowledge and skills, in the form of medicines, medical devices, vaccines, procedures and systems developed to solve health problems and improve the quality of life, the main purpose of conducting health technology assessment is to inform health policy makers and decision makers about whether the technology works, for whom, at what cost, and how it compares to the alternatives currently in use [4].

Objective and Methods

The aim of this analysis is to identify the place and role of HTA in the decision-making process in healthcare in the Republic of Serbia. To achieve this goal we performed pragmatic, nonsystematic literature review based on analysis of available documents in Serbian and English (this includes current legislation, reports and publications available on the websites of the Ministry of Health (MoH), the National Health Insurance Fund (NHIF), the Institute for Public Health of Serbia *Dr Milan Jovanović Batut* (IPHS) and others, reports of World Bank (WB) and European Union (EU) projects, external data sources such as publications of the World Health Organization (WHO), European Network for Health Technology Assessment (EUnetHTA), etc.), available statistical data, legislation, and studies.

Results

Institutional setting of HTA

In all health care systems in which HTA is connected with the decision on the inclusion of technology in the package covered by insurance, there are approximately the same stages [5] in the process of making transparent decisions that must also be institutionally separated, precisely in order to ensure conditions for unbiased decision-making decision:

1. Assessment - for evidence-based decision-making, it is necessary to gather evidence on meeting technology quality standards [6]; HTA can be the task of A) HTA institution that hires specialized staff working on the production of overall reports - this type of report is recommended only for certain technologies (prevention, new surgical procedures) because public funds are spent or B) those who submit requests for inclusion in the package covered by insurance and expect income from use of that technology - in that case, the costs of the assessment are borne by the applicants;
2. Quality check/quality control of submissions [7] - applies to HTA institutions that assess the quality of submitted analyzes from point 1B.
3. Appraisal - this phase is carried out by the decision-makers (e.g. MoH, NHIF) considering other factors of importance for the health policy of a country [6]. However, appraisal is often carried out by a separate body or certain commissions (for example, in the Republic of Serbia, it is the Central Commission for Medicines, when it comes to placing the medicine on the List of reimbursed medicines);
4. Decision-making - it is usually up to the Minister of Health, the Director of the HIF, and sometimes, for example, the Minister of Finance.

In the majority of developed countries, decision-making is based on a set of criteria introduced by law, which refer to insurance coverage, i.e. reimbursement [8]. A rational and transparent set of criteria is a fundamental factor that allows judicial oversight of insurance coverage in a given country.

The context in which the HTA is carried out in the Republic of Serbia

According to the current situation, there are two completely separate approaches to new technologies. One approach is represented by the MoH and IPHS, which is regulated by Health Care Law [9] and it is closer to the inspection approach – control and supervision of the implementation of the new procedures and equipment and conditions that performing of such procedures require. The second approach is much closer to the essence of HTA because it concerns the payments, i.e. reimbursement of medicines and is regulated by the Health Insurance Law [10].

In the sense of Health Care Law, the new health technology is the technology that is being introduced for the first time for use in the Republic of Serbia, i.e. on a certain level of health care. Healthcare institution, private practice, manufacturer, or marketing authorization holder submits a request to the MoH for the issuance of a license for the use of a new health technology.

After obtaining a license for use, there are no defined steps as to what to do next. This is a deficiency of both laws. Namely, there is no statement on how a new service (which implies the application of a medical device or procedure) is proposed for registration in the Nomenclature of Health Services (any of the three existing) [9,10]. Nomenclature is under jurisdiction of NHIF [10], although it is adopted by Minister of health. But the Nomenclature serves as a basis for NHIF to adopt the Price list and essentially, it is the frame of basic benefit package in the Republic of Serbia. Lacking the clearly defined steps of both actors (MOH and NHIF) in the process of paying for services that involve the provision of new technologies is the main reason why the HTA, even after more than 15 years different World bank projects and supportive activities by World Health Organization, has not yet taken root in practice, although nominally, there is interest for capacity building of HTA in the country. Additionally, low number of staff with adequate knowledge to perform assessment, together with lack of readiness to perform appraisal by relevant stakeholders and low level of understanding of HTA among policy/decision makers and general public leads to the discontinuity of the process of organizing the functional HTA system.

Since the adoption of the Rulebook on conditions and methods of health technology assessment in 2020 [11], a total of 16 requests were officially submitted, for which the Ministry of Health requested the assessment performed by IPHS. By the law, the aim of the assessment is to have a basis for issuing a license for the use of new technology, but not to reimburse it [9]. The fact of issuing license for use leads the assessment role more to the inspection direction. Furthermore, about a half of those requests were submitted by license holders for medical devices or private practices for the procedures, and the majority of those requests relate to technologies that, according to the literature review, are in the experimental phase of research and/or in the majority of countries that considered reimbursement, they were rejected for regular use due to the lack of evidence of effectiveness and/or for arguable safety reasons.

Conclusions

Having in mind that the function of HTA is exclusively to help the policymakers to use health resources in the most cost-effective way, there is necessity of formulation transitional documents to define the role and place of HTA as well as the assignments of MoH and NHIF related to the final decision of financing the new health technology.

To have an impact of HTA implementation on the healthcare system there is need to face the challenges such as full dedication to HTA, the number of qualified human resources, trainings etc.

References

1. Battista, R. N., & Hodge, M. J. (1999). The evolving paradigm of health technology assessment: reflections for the millennium. *CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne*, 160(10), 1464–1467.
2. Jonsson E, Banta HD (1999). Management of health technologies:an international view. *British Medical Journal*, 319:1293.
3. HTA Glossary, Health Technology Assessment international. Available from: <https://htaglossary.net/health-technology-assessment> [Accessed 25 July 2024].
4. Goodman CS. HTA 101: Introduction to Health Technology Assessment. Bethesda, MD: National Library of Medicine (US); 2014.
5. EUnetHTA Handbook on HTA Capacity Building/Montse Moharra/ Barcelona [Spain]: Catalan Agency for Health Technology Assessment and Research (CAHTA) (2008)
6. Sandman L, Heintz E. Assessment vs. appraisal of ethical aspects of health technology assessment: can the distinction be upheld? *GMS Health Technol Assess*. 2014 Nov 26;10:Doc05. doi: 10.3205/hta000121. PMID: 25493102; PMCID: PMC4260058
7. Chugh Y, Bahuguna P, Sohail A, Rajsekar K, Muraleedharan VR, Prinja S. Development of a Health Technology Assessment Quality Appraisal Checklist (HTA-QAC) for India. *Appl Health Econ Health Policy*. 2023 Jan;21(1):11-22. doi: 10.1007/s40258-022-00766-5. Epub 2022 Oct 19. PMID: 36260276; PMCID: PMC9579659.
8. Mansheim B. J. (1997). What care should be covered?. *Kennedy Institute of Ethics journal*, 7(4), 331–336. <https://doi.org/10.1353/ken.1997.0035>
9. National Assembly RS. Zakon o zdravstvenoj zastiti [Health Care Law]. Official Gazette RS, 25/2019.
10. National Assembly RS. Zakon o zdravstvenom osiguranju [Health Insurance Law]. Official Gazette RS, 25/2019.
11. Minister of Health. Pravilnik o bližim uslovima i načinu vršenja procene zdravstvenih tehnologija. Rulebook on conditions and methods of health technologies assessment. Official Gazette RS, 97/2020-3, 77/2021-73, 89/2021-58, 33/2022-34