MAPPING THE INTRODUCTION OF HEALTH TECHNOLOGY ASSESSMENT IN ROMANIA

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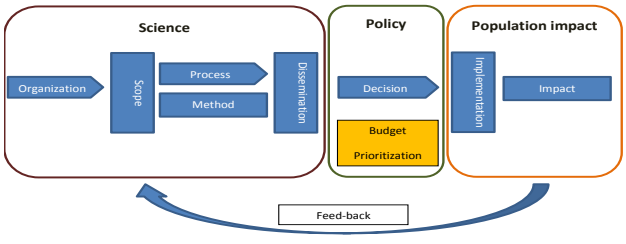
Abstract: *Background: Health technology assessment (HTA) is the multidisciplinary evaluation of "value for money" of health care interventions. Although the need to develop HTA through evidence based decision making in Romania was identified as early as 1992, an HTA unit was establish only in 2012. Objective: map the introduction HTA in Romania. Methods: This study represents a policy review based on 3 different stages. Results: We have arrange in chronological order the main HTA related events, fill in these gaps via in-depth, semi-structured interviews and aligned all the findings and map the process of HTA implementation in Romania. Conclusions: We can identify more than five different attempts of introducing a fully functional system that will meet the standards of international guidelines. Political decision proves to be the key element in failure of numerous implementation attempts and also the determinant factor of the current HTA status in Romania.*

INTRODUCTION

According to Health Technology Assessment International, "Heath Technology Assessment (HTA) is a field of scientific research to inform policy and clinical decision making on the introduction and use of health technologies. Health technologies include pharmaceuticals, devices, diagnostics, procedures and other clinical, public health and organizational interventions."

From a functional perspective, HTA involves 3 different activity levels: (a) a scientific level where through organizational procedures a new technology is evaluated in accordance with a pre-defined process and in line with a specific methodology. The results of this process are then disseminated to each actor involved in (b) policy sector that have to take the "go/no-go" decision based on the analysis provided by the scientific level and in the same time by prioritization models in line with their budget limitation and general strategy. Further on the decision will be implemented and disseminated in the (c) target population. Ideally, the results of the decision will be measured and will offer a direct feed-back for the scientific level in order to adjust and improve the process and the evaluation methodology (see figure no. 1).

Figure no. 1. Functionality of HTA system



Although the need to develop HTA through evidence based decision making in Romania was identified as early as 1992, an HTA unit was established only in 2012. Identifying factors that contributed to repetitive failure of HTA introduction may represent a learned lesson for future health policy initiatives.

MATERIALS AND METHODS

A desk research completed by face to face interviews have been undertaken to map the introduction of health technology assessment in Romania and fill in the gaps that were not properly documented. In the first part of our research we reviewed all the academic literature, legislative regulation, official reports and statements and identified the segments in time that were not fully or completely covered by relevant information. We then filled in these gaps via in-depth, semi-structured expert/elite interviews. Review of grey literature served as primary sources to complement interview data and allow for triangulation. The third stages consisted of aligning all the findings and maping the process of HTA implementation in Romania.

Stage 1: Literature review

An electronic search was performed in several databases, namely PubMed, Web of Science, Scopus and Google Scholar, using a broad search term, i.e.: "health technology assessment" AND "Romania" as well as the Romanian translation "evaluarea tehnologiilor medicale" AND "Romania". The search result was screened based on title and abstract. The full text report was screened when ambiguous information was found in the abstract. An article was included in the review if: 1) it presented data on the HTA policy, 2) it was published in English or Romanian. Grey literature was further identified based on the review of the references' lists. To better understand the environment and key influencers of HTA development in Romania we scan for information World Bank Data base to map loans and reports on Romanian Health Care financing and end evaluation of health care service from 1991 until 2017. The initial electronic search was performed in November 2016 and replicated in April 2017. At this stage, we identified a list of gaps in information and came up with a list of

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stakeholders that could bring more information for specific periods of time and for specific subjects.

Stage 2: In-depth interviews with key representatives from public sector, academia and pharmaceutical industry

We developed an opened question toll to collect the relevant data related to the development of HTA in Romania. In-depth interview were conducted with a number of 11 stakeholders to certify and to fill in the gaps identified in stage 1. The questionnaires were sent before the interview to all the subjects in order to have time to get all the relevant information during the face to face interview. All the subjects where anonymized to protect them and they were also assured of the confidentiality of the information. The questions from the interview were categorized in 4 main areas: their understanding of HTA and how this concept works; their personal interaction with the field of HTA; main influencers and context of current HTA system in Romania and future developments of this concept.

Stage 3: review and alignment of the information collected from literature review and interviews

The authors of this article debated each finding and agreed based on principles of independence, expertise, objectivity and evidence based information on the final draft. Further on, the draft was reviewed and adjusted by third and fourth authors of the study.

RESULTS AND DISCUSSIONS

Actors, interests and concerns in developing HTA in Romania

Although the term itself has been used in current practice starting with 2014, various similar ideas circulated and had the same meaning: organization; health economics ("organizare", "economie sanitară") and covered more or less the same principles that now governs HTA.

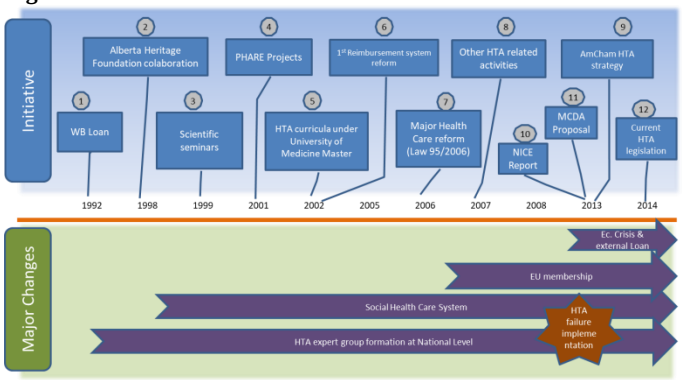
First finding is related to the actors with their interests and concerns that have influenced the HTA in Romania as it can be seen in table no. 1.

Table no. 1. Main actors in the Romanian HTA field, their interests and concerns

Key stakeholder	Interest	Main concern
Policy-makers	Broad concerns, but tending toward the value for money perspective	Lack of technical elements; public pressure for specific problems
Payers	Resources allocation and predictability of budget	Over-riding concern for expenditures and their control
Clinical physicians	Mostly interested in quality, little attention to expenditures or other public policy issues. Fast and unlimited access to new treatment alternatives	Administrative burden and refractory to any clinical guidance restrictions with impact on freedom of choice
Industry	Fast and non-conditional reimbursement for all approved medicines	Over-riding concern for profits, however, competition forces increasing attention to efficacy and cost-effectiveness.
Academia (Public Health, Epidemiology etc) through epistemic group	Interest in the poor state of research and how to improve it, including attention to systematic reviews and dissemination of information; disseminate information and knowledge; partnership with other institutions	Lack of awareness from decision maker;
International organization (World Bank, European Commission etc)	Unity of decision making process; appropriate health care expenditure in line with local needs	Unclear local priorities; lack of process management
General public	Access to personal care of acceptable quality	Information asymmetry

Based on the above methodology we have managed to depict a coherent evolution model of HTA in Romania. The information resulted from interview, desk research, legislative documents and public source of information were compiled and arranged in a manner that can offer a clear and coherent image of each milestone, from World Bank loans, epistemic group formation, various initiatives failures, surrogate measures that for a period of time took the place of HTA developments and result of main reforms in the medicine policy.

Figure no. 2. Overview of HTA evolution in Romania



1. World Bank projects

First report dates back in 1991 and was signed between Romania represented by the Ministry of Health and the International Bank for Reconstruction and Development (IBRD) and had as main objective Health Care System Rehabilitation Project. In terms of HTA (as of health care reform) IBRD loan was mainly focused on the preparation and the start of implementation of a new national health strategy, including studies of health policies and the development of reform proposals and carrying out of a two-year pilot decentralization program in four districts, with the provision for such districts of technical assistance in the preparation and implementation of their action plans for the delivery of health care. The loans of World Bank continued in various forms for more than 28 years and are still continuing. A World Bank report says that the WB interventions must be matched with political and social context of that period in order to be more easily implemented in practice. Health care reforms, including HTA must be in line with other reforms implemented in other sectors (taxation, financing, banking etc).(1)

2. 1st mentoring program of Public Health chair of University of Medicine and Pharmacy Carol Davila

In 1998 a mentoring relationship was started between Alberta Heritage Foundation for Medical Research, Edmonton and Department of Public Health and Management, University of Medicine and Pharmacy "Carol Davila" Bucharest.(2) The program had included providing of HTA materials, involvement in local seminars, assisting contact with HTA and funding organizations, and in-house preparation of professional from Romania to further expand and develop local HTA. In June 1999 and November 2000, there were held 2 seminars in Bucharest on Evidence Based Medicine and HTA. At the same time, it was translated into Romanian language Sackett's book "How to teach, how to practice Evidence Based Medicine", Timisoara 1999 – Marius Marginean, "Medicina Bazata pe Dovezi".(3) The nucleus of experts reunited under the epistemic group of Public Health Chair in University of Medicine and Pharmacy "Carol Davila" continued to drive the expansion of HTA in Romania with publication of a "Glossary of Terms"

generally used in HTA. Among the most important deliverables of the mentoring program, was the introduction of HTA in Public Health Master Program held at University of Medicine and Pharmacy Carol Davila.

3. 2nd Mentoring Program

Another successful story from mentoring perspective was the formalization of HTA development program between National Health Insurance House and German Federal Association of the Regional Health Insurance Funds (2000–2002). From policy perspective, this memorandum to develop HTA was agreed between main stakeholders including Ministry of Health at that time. From the interviews it resulted that mentoring programs were a useful exercise mainly from the academic perspective and did not have a strong component policy implementation. One explanation may be that HTA was a "difficult to understand concept" and as a consequence, the advantages using such a system were hard to be understood in the Romanian context. Another explanation for the lack of results of mentoring program was the general limitation of translating health care practices from one place to another. "One size fits all" is not a suitable standard because of the wide systemic and cultural differences between health care systems.

4. PHARE projects

Between 1999 and 2003 a series of PHARE projects were implemented in Romania and some of them had the objective of promoting evidence based decision making in health care, including medicine evaluation through comprehensive technology assessment. Some of the sub-projects were run at county level involving local stakeholders by disseminating principles of Evidence Based Medicine ("RO-IB-99-CO-02 Development of Institutional Capacity of National and District Health Insurance Houses"). None of the PHARE projects, from the records analyzed so far, had any detailed objective of developing HTA in Romania.(4)

5. Health economic curricula introduced in Public Health Master Program

In 2001 Health Economic module was introduced in Public Health Master Program under Chair of Public Health, University of Medicine and Pharmacy "Carol Davila". The program trained graduates to have basic knowledge of Health Economics, meta-analysis, systematic review and evidence based decision making. Through this program it was ensured a consistent pull of professionals in the field of Health Economics that could respond to basic needs in relation with the establishment of HTA department / unit.

6. First reshuffle of reimbursement list without any economic criteria used

In 2003 through Government Decision no. 516/2003 a major reshuffle of reimbursement list was made at the recommendation of World Health Organization Report. No reference regarding evaluation criteria for medicines is mentioned. The government decision included a number of 248 INN on the list with patient copayment and 214 medicines without copayment. In 2005, the Center for Planning and Development was established under the National Health Insurance House coordination with the objective to use Evidence Based Medicine and HTA to inform decisions maker regarding best alternatives of financing in a resource limited environment. At that time, Prof. Enăchescu was nominated as adviser to NHIH President. He took advantage of the mentoring experience with Alberta Foundation and reaches out to Carmen Moga (Romanian Public Health doctor working for Alberta Heritage Foundation) for advice in developing evaluation capacity for the future center. At that time, no financial provisions were in place to develop the above center and as such.

7. 2006 health care reform

In 2006 Law 95/2006 matched national health care legislation with the "acquis communitaire" due to the fact that in January 2007 Romania joined the EU. Unfortunately, no reference to HTA was mentioned in this law. Further on, only in 2011 when the European Commission approved the Directive 2011/24/EU on the application of patients' rights in cross-border health care had to be transposed into the Romanian Law that HTA activities started to develop.

8. Other activities related to HTA

At the beginning of 2006 the World Bank initiated a project with the main objective of supporting the institutional establishment of a Romanian HTA Commission including an HTA Office as its central substructure. As a result of this World Bank project, the Minister of Health in Romania at that time would have been supporting the function of a National HTA Commission. As part of this project an EBM-HTA Unit was developed in 2006 within the National School of Public Health and Health Services Management (NSPHHSM) in Bucharest. In 2008 another major general reshuffle of reimbursement was started based on Ministry of Health Order number 318/2008 (5) and before that 169/2008 (6) through these internal regulation, Ministry of Public Health delegates the establishment of the selection criteria for the positive list to the Transparency Commission but at the same time indicating five basic criteria: efficacy; safety; improvement of patient compliance to treatment and treatment cost evaluation. The unit functioned for 1 year (2006-2007). During this time, a series of training related to Qualitative Research Methods and Systematic Review and Meta-analysis courses took place.

In 2008 a major reimbursement list update was put in practice (Government Decision no.720/2008) that is in place today (10 years later).

In 2011 the Memorandum of Understanding with IMF, EC and World Bank underlined the introduction of HTA in the decision making process. This initial agreement was further developed in June 2012 by "Letter of Intent, Memorandum of Economic and Financial Policies, and Technical Memorandum of Understanding between Romanian Government and International Monetary Fund. In this letter MoH promised to put in practice among other reform measures a special HTA unit that would have the role to control expenditures and ensure gains of health care budget on the short term. This should be done under the assistance of National Institute for Health and Clinical Excellence (NICE International). The introduction of new drugs or indications in the list of compensated drugs will be made only through an interim health technology assessment. The NICE report (7) was made public in December 2012 and contained some good proposals, but also some questionable solutions. The report was followed by an article (8) that highlighted the proposal to match GDP per capital in the local setting with drug prices until a solid HTA could be established of a so called "de facto HTA". The report further suggested that this method could support future analysis of list and net prices, and other policy measures in order to limit the impact of such high medicines prices.(9)

In 2012, MoH developed an internal HTA structure were only 2 people were hired. They were part of a group of 15 persons who took part in an extensive training provided under the same IMF contract by CRED Foundation together with expert from Switzerland and UK.(10)

MoH published in June 2013 the Order No. 724/2013 that was the first version of new HTA-like criteria that would enter into force starting with 2013. The order detailed the criteria and the HTA methodology for inclusion or rejection of new molecules/indications on the Reimbursement List and made

the provision that reimbursement list would be updated twice every year.(11) The criteria took into consideration a score card of maximum 10 points were 2 points were given based on positive decision from UK HTA bodies and France HTA; 2 points from the number of countries that already granted reimbursement for the specific product in EU and 2 points each for Relative Efficacy, Relative Safety, and Patient Reported Outcomes. Reimbursement was granted if a minimum of 6 points were accumulated. Budget impact was used only to provide the necessary substantiation for the payer and did not have any implication on further negotiation with Marketing Authorization Holder. Until December 2013 HTA Unit from MoH evaluated 167 reimbursement files and approved for non-conditional reimbursement 82% of them.(12) Although the necessary steps have been taken to update the reimbursement list, changes at the political level, involving MoH resulted in keeping reimbursement list update a matter of the future. In February 2014 the new Minister of Health amended the proposal to update reimbursement list based on the fact the reimbursing such a high number of medicines without any financial agreements between Marketing Authorization Holder and payer would be a huge burden of the Health Care System. It was estimated that the general amount of money needed to include in non-conditional reimbursement was around 266 mil EUR (17% increase of the medicine budget).(12) In line with the new government decision HTA process was moved from MoH to National Medicine Agency by Government decision no. 734/2010 with Apr. 2014 amendments (13) in April 2014.

9. AmCham and pharmaceutical industry position

Form pharmaceutical industry point of view HTA was becoming a mandatory instrument that was needed to be put in practice. Many interactions between industry association's leaders (ARPIM (14), LAWG (15), AMCHAM (16), FIC (17)) and decision makers have taken place. A technical document that synthesized a pragmatic proposal of industry was published by AmCham in March 2012. The report defines 3 general objectives: (1) development of institutional capacity; (2) HTA guide-line development and (3) preparedness of Health Care system in order to implement HTA decisions and recommendations. Although the report was based on solid proposal that had the potential to introduce a mature HTA system in Romania the lack of "political support" was the main cause of postponing the introduction of once again of an HTA system.

10. Current status of HTA system in Romania

After the failure of February 2014 attempt to reshuffle the reimbursement list by introducing a high number of medicines, MoH come-up with a new order in July 2014 (861/2014). On this amended Ministry of Health Order, National Medicine Agency evaluated and published between 2014 and 2018 more than 250 HTA reports.(18) Beside the evaluation of the new medicines proposed for reimbursement, this MoH order specifies the possibility of "de-listing" (taken out of the reimbursement list) or reducing the percentage of reimbursement of specific medicines. This new approach of decreasing the pressure on medicines budget was one of the recommendation of NICE report a total of 16 INN were de-listed and 21 INN were included in a lower reimbursement category (20% of the reference price).(19) The method of evaluation for new INN was based on score card that took into consideration 3 criteria: (1) HTA reports from UK, France and Germany. Each of the 3 reports is awarded a number of maximum 15 points (if the reports are published with restrictions vs. Summary of Product Characteristics or have a lower than 3 SMR – Service Medicale Rendu, then a maximum of 7 points are rewarded); (2) maximum of 25 points for more than 14 countries that have already granted reimbursement for the specific INN/indications at the level of European Union; (3) Cost of Therapy vs. Reimbursed comparator in Romania - 30 points if a new drug generates more than 5% savings in comparison with the alternative therapy, or 15 points if a new drug has a neutral budgetary impact in comparison with the comparator (±5%). The thresholds for reimbursement were established between 60 and 80 for conditional reimbursement (conditioned by a signed agreement between MAH and NHIH), above 80 points for non-conditional reimbursement. All the medicines that received less than 60 where rejected.

Compared with the previous version of the score card, where 82% of the medicines received non-conditional reimbursement, this methodology allowed non-conditional reimbursement for only 15% and 30% received decision on conditional reimbursement.(19) One particular criteria that was different for this MoH order was the different method of evaluation for orphan medicines (if a medicines had orphan drug designation for European Medicine Agency, the only criteria that needed to be included in reimbursement list was to be reimbursed in more the 14 countries in EU). The results of this new methodology were received with scepticism by pharmaceutical industry and by experts in this filed.(20) For the medicines that received conditional reimbursement a methodology that will regulate cost-volume and cost-volume-result agreement was published in March 2015.(21) Although the negotiation methodology and the agreements between NHIH and the industry were made to increase patient access to new, more expensive treatment alternatives, only a limited number of 26 INN were introduced.(22)

CONCLUSIONS

The effort of implementing a fully functional HTA system in Romania was not an easy task. We can identify more than five different attempts of introducing a fully functional system that will meet the standards of international guidelines. In the interviews taken to make this research, a lot of frustration and regret were emerging from scientific community (research and academia); in the same time decision makers who had expressed high hopes for a solution that would address the current concerns (e.g. budget predictability, constant access to new medicines, etc) did not go unnoticed. Both our interviews and the literature take note of the "numerous attempts to introduce" HTA in Romania. Interestingly, this phenomenon is also reported for other countries in the region. For example, Gulacsi (2012) observes that "the idea of implementing HTA-based reimbursement practices has emerged from time to time in other countries in Central and Eastern Europe, such as Bulgaria, Croatia, Romania, Slovak Republic and Serbia". Even when HTA is finally introduced by law in Romania, in a relatively short time frame of four years, there are "several iterations of national HTA guidelines" (WB 2017) promulgated by the Ministry of Health.

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