KEY ASPECTS REGARDING THE INTRODUCTION OF HEALTH TECHNOLOGY ASSESSMENT IN ROMANIA

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INTRODUCTION

Health Technology Assessment (HTA) is a fashionable subject and in almost all EU countries there is in place some form of HTA; there is also a EuNetHTA network developed at EU level. Starting with the worsening of the financial crisis in several European countries, the HTA subject, related with health policies, appears more and more frequently in the position-papers presented by the policy-makers from Romania.

Nonetheless is HTA something new in Romania? During the documentation for this paper we found an article regarding HTA development in Romania from 2003, published in an international magazine [1]. Ten years ago, there were steps already taken towards a HTA system, published articles etc. which made us think about publishing the results of HTA usage in Romania during the previous years.

Unfortunately, after the first steps taken in 1992-2002 when some form of mentorship was performed in this area [2] and HTA was brought in the attention of the authorities (without any initiation of a Governmental program), HTA remained a subject only for the academic and research purposes, very little being able to be said few words to about the silent evolution of HTA in Romania from 2002-2011. Only the pressure brought by the Memorandum of Understanding between Romanian Government with International Monetary Fund (IMF), World Bank (WB) and European Commission (EC) reactivated in 2011 a subject discussed with a lot of hope 10-15 years ago.

The scope of this article is to briefly present some key principles and aspects which could represent the fundamentals of a quick development of HTA in the following years. The article is not meant to present an evaluation of the HTA steps which have been done so far.

In order to develop a HTA system there is a need for the involvement of key policy making stakeholders who have to express their willingness and demand for the usage of data generated by the HTA system for the decision-making process. Also, there is a need of resources (human, financial, organisational) and for capacity-building of institutions who will offer the ground to develop the HTA. In Romania, the willingness to develop the HTA system is expressed in the health policies (specifically in the Government Program for 2013-2016), but there is still a lot to do in terms of designing the legal framework and the development of required institutions for an HTA system.

In this context, there are four key aspects which could facilitate the introduction and functioning of the HTA in Romania, grouped under the „Four P” (Partnership, Pragmatism, Predictability and Praise), aspects detailed in the context of Romanian health care system. The application of these „Four P” has to be coupled with the health policies in order to integrate the HTA system with the continuous reform of the health services: public financing, basic package, evaluation of quality etc. And to all these aspects there is a need to associate change champions, leaders who believe in HTA and who could become pioneers and development catalysts of HTA in Romania if they get support from the political environment.

Keywords:
HTA - Health Technology Assessment, health policy, health reform, resources allocation.

Health Technology Assessment belongs to health policy, but is connected with research and scientific methods to generate evidences. The term technologies covers not only new drugs, but also methods of diagnostics and treatment, medical devices, medical equipment and materials, surgical or medical procedures, care and support systems and organizational and managerial systems [4].

The first steps regarding HTA were taken in the United States in the ‘70s when a report published by the US Academy of Science presented the broad implications of four health technologies: in-vitro fertilization, choosing the sex of children, retardation of aging and modifying the human behaviour [5]. Later the HTA expanded in Europe, initially in Sweden (Jonsson, Cost-effectiveness of CT scanner) then in Austria, the United Kingdom, Canada, Australia and Asia.
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Although in the first days HTA focused on aspects such as efficacy, safety and cost-effectiveness, the HTA field “has been driven since its early days by policymakers concerns about expenditures (costs)” [6].

The essential conditions required to build a HTA system that is part of the decision-making process could be summarized as follows [7]:

1. The willingness to develop an objective mechanism which supports the policy making process and resources allocation;
2. The need to have available data which is produced by HTA;
3. The demand expressed by decision-makers to get such data;
4. The offer of human and organisational resources that could answer this demand and could produce the data provided by the HTA system.

Have the above presented conditions been fulfilled, in Romania at the beginning of 2013?

1. There is an interest and willingness expressed in the official document of the Romanian Governments from 2011 until now to develop a HTA system and to use it for the evaluation of new drugs to be reimbursed by the public system [8, 9]. Even if the initial scope of the HTA system is limited at drugs assessment, the intentions of authorities are to develop and improve the HTA system and also to apply it to other technologies. The willingness expressed by the policy makers has to be integrated within the existing priorities and rationalisation measures established from a public health perspective (community), meaning to maximize the health care status and to increase the efficiency of resources allocation because frequently the resources allocation is based rather on individual needs than on community needs [10].

2. The data generated by a HTA system is amongst the one missing at this moment at the level of the Romanian health care system. This data could support the provision of answers to some well-known questions of the Romanian decision-makers: which are the services to be covered from the basic package, which new drugs should be reimbursed in the public system, to what degree a medical procedure should be reimbursed, is it worth to introduce a new vaccine in the compulsary vaccination scheme etc.

3. Regarding the demand for such data, our answer is not very obvious: on one hand, there are Governmental voices that explicitly ask for this data, conscious about the fact that the lack of data leads to subjective decisions, while on the other hand there are also whispering voices which consider that the decision making process has to answer the current interests and should be based only on the decision-makers abilities.

4. The capacity to produce and provide such data (the offer) represents the main limitation in HTA development in Romania. In this regard, the Ministry of Health took the first institutional steps developing a HTA Unit within the Ministry of Health, defining its specific roles, hiring and training personnel at the end of 2012 and the beginning of 2013 [11].

In order to respond immediately at the Ministry of Health’s desire to build a HTA system, considering the limited resources (human, financial, logistics etc.), the Romanian model of HTA was given the advice to start using a quick HTA mechanism (based on a scorecard system) until the moment in time when the required capacities are in place to support a full HTA process (recommendation done by NICE International in a consultancy project) [12].

The local development of a HTA system requires also a clear and explicit legal framework to assure the transparency of the process, the involvement of all stakeholders participating in the decision-making or that are concerned by the decisions taken (authorities, patients organisations, professional organisation, health technologies providers etc.) and the integration with specific EU legislation (EU Directive 89/105 in process of revision).

PROPOSALS

The keywords which lay as the foundation of the proposed principles for local adoption, as effective as possible of any HTA model are the following (the „Four P”):

1. Partnership. The development of a performing HTA system can’t be done only by the authorities and payers (both being most interested in cost-containment), other stakeholders of the health system are needed. As soon as the authorities and/or the payers manifest their demand and develop the offer (even partially) for HTA, there is a need from the health technologies providers (and at this moment in Romania the targeted providers are the drugs manufacturers) to mobilize their internal and international resources in order to develop local centres for expertise in HTA (using internal or out-sourcing models), that will become not only institutional partners of the authorities, but also technical partners. Furthermore the involvement of the professionals from patients’ organisations or physicians’ organisations would be very useful, in order to reflect, during the HTA process, not only the essential costs component, but also the needs/preferences of patients and their families, their expectations together with the values and ethical principles which support the decision-making process.
We consider that in Romania, because of a lack of human resources in the area, there is a need of involvement, from the beginning, of as many HTA specialists as possible, so that the HTA system will develop guided by consensus and ready to respond easily to the main expectations of the health care stakeholders.

2. Pragmatism. The experience of pervious changes in the health care system level showed that it’s necessary to create a practical, effective, functional mechanism, adapted to local conditions and users. HTA is functioning in many EU countries, but we consider that none of the examples from other countries is viable for Romanian health care system.

We need to learn from other’s experience, to avoid their mistakes, to always have in mind what we want to achieve using HTA and not to forget the available resources. There is a need of courage in order to locally invent, to avoid saying “it’s not possible” just because it hasn’t been done by others so far, but to have the power to see our limits and interests (at the level of health care system). A good example in this regard is the way HTA works in the United Kingdom (UK) and Scotland, where National Institute for Health and Care Excellence (NICE) and Scottish Medicines Consortium (SMC) have similar roles and functions, while the budgets are very different, but similar results [13].

Regarding the local pragmatism, the example of clawback taxation development and functioning from 2009-2012 reveals what major problems could occur, due to the lack of communication and understanding of the technical aspects, when a complex system with a lot of stakeholders is implemented in practice.

The production and availability of local specific data required by the HTA process (clinical and demographic information, data on efficacy, effectiveness, costs, utilities etc.) has to be the matrix on which the HTA system should be built. The key is represented by the appropriate design of the HTA process, flexible enough so it may evolve at the same time with increases in the amount of data available, experience and expertise.

3. Predictability. Developing of a step by step predictable HTA system will be helpful for everybody: from authorities (which will be able to consolidate their forecasts, strategies and plans based on the information from HTA), to the suppliers of technologies (interested in developing their own market access strategies), the patients (based on their expectations) and the health care professionals (the future users of the respective technologies). Unfortunately, predictability is, at this moment, one of the least present characteristic in the Romanian health care reform.

One of the conditions mandatory for predictability is the transparency which has to be the main characteristic of the entire evaluation process, starting from choosing which technology to be evaluated, to the way the process develops, the results are published and the decisions are taken based on the HTA dossiers [14].

4. Praise. The HTA system development has to be seen in Romania under a mechanism of praise for someone and not of punishment for some others, even if all HTA systems imply making choices. It’s more and more obvious for everyone that the limited resources available at the health care system level impose responsible choices for patients. And the HTA system could help in rewarding those innovations, solutions, technologies and systems etc. which are as effective, safe and efficient as possible.

This way, via the HTA system, some priority criteria could be introduced, in order to reward more the technologies considered much more important from the public health point of view, which could provide an answer to specific needs of some vulnerable populations (children, rare diseases’ perspective etc.) or which target a pre-identified population (personalized health care).

**Conclusions**

Our advice is that we need to make sure we have all “Four P” in practice, in order to realize a functional HTA system in Romania, while also linking these “Four Ps” to the health policy, so that the HTA is integrated with the continuous reform of the other aspects of the health care system: financing, definition of the basic health care package, evaluation of health care quality etc.

That’s why it is necessary to imagine a future for the HTA in Romania based on a realistic strategy that will impose a plan with annual activities to be realized step-by-step and that will keep in touch with the health care system capacity of absorption (regarding the development of human resources expertise and the capacity building).

Meanwhile, the international experience of HTA development in various countries around the world clearly points out the key role which has been played (in almost all countries) by “change champions”; one or several people that engage not only institutionally in promoting HTA, but also personally. Their role cannot supplant the other presented ingredients and is usually strengthened by the political environment which has to adopt and to push these champions [6].

For the moment, these champions are not yet visible in Romania or because they have just started their activities, they can barely be seen. Of course, there are many people with enthusiasm in the HTA realm, and they are expecting to be adopted and promoted by the political environment so may become the pioneers of change in this area.
References:


