A Review of Ministry of Health's Experience on Institutionalization of Health Technology Assessment in Turkey

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Abstract- Evidence-based health policies are indispensable for the health systems to achieve their objectives and sustainability. In particular, the importance and necessity of developing evidence-based health policies have increased due to reasons such as aging population, the increase in the innovation of medical technologies and rapidly increasing costs. There are different tools used to generate evidence-based health policies, one of the most powerful of which is the health technology assessment (HTA). The method is gaining importance and its usage becomes widespread in the world. Turkey has also launched some initiatives to institutionalize HTA in 2012. The first important step has taken with the establishment of the Department of Health Technology Assessment under the General Directorate of Health Research (GDHR) of Ministry of Health. However, expectations regarding the institutionalization of the HTA in Turkey have not fully met. In this study, we aim (1) to share our experience on the activities carried out in the institutionalization process of HTA in Ministry of Health of Turkey and (2) to help policy makers to establish more powerful HTA structure by identifying encountered problems and suggested solutions.

Keywords- Institutionalization, Health Technology Assessment, Health Policy, Turkey

1. Introduction

Health systems face tough and complex challenges such as ageing population, growing prevalence of chronic illnesses and intensive use of expensive, fast developing health technologies (WHO, 2010; Kaplan and Porter, 2011). Such factors push rising the cost of healthcare (WHO, 2010). The results in Nghiem and Connelly (2017) work are also quite conspicuous about the healthcare cost; "the main driver for increasing health expenditure is technological progress, which accounts for four percent per year and accelerated faster after each decade in the study period (1975-2004)".

Growing public demand for access to high quality and affordable care causes further increase for the political pressure to lead wise policy choices (WHO,2010) especially on health technologies. There are different tools used to generate evidence-based health policies, one of the most powerful of which is the health technology assessment (HTA). The method is gaining importance and its usage becomes widespread in the world (Busse et al., 2002; McGroger and Brophy, 2005; Drummond, 2009; EU Health Technology Assessment Network, 2014; Banta, 2018).

Health technology assessment is the analysis of the implications of health technology that intended to influence decision-making (EURASSESS, 1997). Its definition by EUnetHTA is as follows; "…a multidisciplinary process that summarizes information about the medical, social and ethical issues related to the use of a health technology in a systematic, transparent, unbiased and robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value. Despite its policy goals, HTA must always be firmly rooted in search and scientific method….." (EUnetHTA, 2007).

The other and older general definition of technology assessment by Office of Technology Assessment (OTA) is ''a comprehensive form of policy research that examines the short and long-term social consequences of the application or use of technology'' (Office of Technology Assessment, 1976). The most prominent part of HTA is to determine, insofar as possible, the benefits and financial costs of a particular technology or group of technologies. The main goal of such studies is to improve "value for money" in health care (EURASSESS, 1997).

Relationships between evidence and decisions are very difficult because there are many other sources that are effective in making decision such as political and institutional factors (Rezi-Kato, 2011; Yuba et al. 2018). However, despite all the challenges, "HTA is a bridge between policy making and science".

In this study, we aim (1) to share our experience on the activities carried out in the institutionalization process of HTA in Ministry of Health of Turkey and (2) to help policy makers to establish more powerful HTA structure by identifying encountered problems and suggested solutions.

2. HTA in Turkey

In Turkey, the Health Transformation Program was launched in 2003. The objectives were "to organize, to provide financing and to deliver the health service in an effective, productive and equal way" (Ministry of Health of Turkey, 2003). Transformation goals are defined in eight themes, however, four components of the program had serious impact on the institutionalization of HTA in Turkey. These components are (Ministry of Health of Turkey, 2003):

1. General health insurance, gathering everybody under a single umbrella,

2. Widespread, easily accessible and friendly health service system,

3. Institutional structure in the management rational medicine and equipment,

4. Access to effective information at decision-making process, health information system.

The program has brought the successful outcomes to Turkey such as more comprehensive health insurance system under one institution, which helped to address inequities in financing, health service access and health outcomes (Atun et al., 2013). In addition, it is possible to say that the reimbursement system has mostly effect on the development of evidence-based decision making on health technologies in Turkey. Due to legislative requirements drug companies had to prepare a report for pharmaceuticals, while submitting dossiers to authority (Social Security Institution, 2007).

Although HTA is a rather new concept, its popularity increased rapidly among the public health sector. During the restructuring of the Ministry of Health, with Article 12 of the Statutory Law No. 663, HTA studies and operations were included in the duties of the General Directorate of Health Research (GDHR). In this context, a

Department of HTA was established in 2012 to perform and operate HTA studies within the GDHR organizational frame (Dilmaç, 2019).

After establishment of the Department of GDHR, Turkish Pharmaceuticals and Medical Devices Agency and Social Security Institution started HTA activities under their own structures (Social Security Institution, 2014; Turkish Medicine and Medical Devices Agency, nd).

Due to a different law (Turkish act 6569 on November 26 of 2017), GDHR enclosed and the Department and its duties transferred to General Directorate of Health Services (GDHS). The Department has been operating as the only official HTA institution at the national level since 2017 under the GDHS.

The initial studies of the Department were to determine how to manage the HTA process and to explain its basic principles. After those studies, the HTA process and its steps were defined as (Department of Health Technology Assessment, 2013):

1. Topic selection,
2. Determination of health policy question and pre-assessment,
3. Determination of research protocols,
4. Formation of the project team,
5. Literature review and collection of available data,
6. Assessment of the data quality and synthesis,
7. Publishing the draft for consultation of experts outside the Department,
8. Publishing the final version of the report,
9. Dissemination, monitoring and updating.

Following the publication of the HTA Regulation and Policy Statement in 2013, the Department started to work on HTA studies (Department of Health Technology Assessment 2013).

2.1. Prioritization of Topics

Process of prioritization of topics starts establishment of the Topic Selection Commission. The Commission comprises different stakeholders such as Social Security Institution, General Directorate of Public Health, General Directorate of Public Hospitals, Turkish Pharmaceuticals and Medical Devices Agency, associations of medical device and drug manufacturers and associations of patient representatives (Department of Health Technology Assessment, 2013). Meanwhile, the Department accepts topic proposals from a

range of stakeholders, including patient groups. While the Commission is working on the topic selection, the following points are taken into consideration in the selection of the topics on which the studies conduct and in the determination of the type of HTA (Department of Health Technology Assessment 2013):

- Importance of the burden of disease relating to the health technology,
- Budget impact of the health technology in the provision of the health service,
- Public attention, including the social and ethical aspects related to the health technology,
- Presence of sufficient data resources about health technology and qualified human resources that can be able to conduct assessment.

All topic proposals duly made are accepted for consideration by the Commission and the decisions of the Commission is published along with the reasons thereof on the website of the General Directorate (Department of Health Technology Assessment, 2013).

2.2. Study Methods of HTA Projects

HTA projects are studied in three ways (Department of Health Technology Assessment, 2019a):

(1) The HTA project can be managed and studied wholly by the Department staff,
(2) Under the coordination of the Department, the project can be studied with academicians and other stakeholders, free of charge,
(3) The project can be studied by individual or corporative consultants in the scope of service procurement under coordination of the Department.

2.3. Examples of HTA Projects

Since its establishment, the Department has carried out HTA projects on different topics. Some examples of these studies are as follows (Department of Health Technology Assessment, 2019a):

- Cessation support program cost-effectiveness analysis of smoking,
- Low density electroshock waves (ESW) therapy in vascular erectile disorder,
- Prophylactic palivizumab use in respiratory syncytial virus infection,
- Role of obesity surgery in obesity treatment,

- Mobil cardiac telemetric monitoring,
- A research on medical oxygen system (PSA system) obtained by on-site production in hospitals and liquid medical oxygen system supplied externally,
- An assessment on chemotherapy drug preparation systems,
- Antivirals used for the chronic hepatitis (B and C) treatment, (Reviewer within EUnetHTA Project),
- Biodegradable stents for the treatment of refractory or recurrent benign esophageal stenosis, (Co-author within EUnetHTA project),
- Role of peritoneal dialysis treatment in renal failure.
- Hyper thermic intraperitoneal chemotherapy (HIPEC),
- Using disposable instrument for circumcision,
- Analysis of indirect costs and role of peritoneal dialysis and hemodialysis treatment in renal failure,
- HTA report on synthetic and biologic disease-modifying antirheumatic drugs (DMARDs) used in the treatment of rheumatoid arthritis,
- HTA report on the rapid molecular diagnostic tests used for identifying the causing agent in the blood sample in sepsis,
- Assessment of effectiveness of trisomies screening tests in pregnancy.

2.4. Clinical Guidelines and Protocols

The Department also works on adaptation or generation of clinical guidelines and protocols with the professionals and the associations. Examples of these projects are listed below (Department of Health Technology Assessment, 2019b):

Clinical Protocols (completed)
• Cataract Surgery • Chronic Heart Disease • Colorectal Cancer • Chronic Obstructive Pulmonary Disease (COPD) • Diabetes Mellitus • Prostate Cancer • Stroke • Total Hip Arthroplasty • Total Knee Arthroplasty
Clinical Protocols (in progress)
• Anemia • Alzheimer • Anxiety • Asthma • Chronic Renal Failure • Dental Implant • Epilepsy • Hypertension • Migraine • Stomach Cancer
Clinical Guidelines (in progress)
• Breast Cancer • Stroke

2.5. Research and Development Projects

The Department also supports research and development projects, such as; Cooperation Network Study with Eskişehir Osmangazi University for the Management of Lung Pathologies Caused by Environmental and Occupational Contact with Mineral Fibres (Department of Health Technology Assessment, 2019c). In addition, the Department works on some other projects such as (SEPD, 2019):

- The Project on Calculation Quality Adjusted Life Years of Turkish Population.
- Adaptation study for the year 2011 version of Health Accounts System of the Organization for Economic Co-operation and Development (OECD),
- Out-of-Pocket and Catastrophic Health Expenditures Study.

2.6. Developing Human Capacity

Building human capacity, establishing a transparent decision-making process, and implementing robust HTA methodology are key success factors for HTA implementation. One of the most important questions of the HTA implementation roadmap is whether capacity building should come first or mandatory HTA requirement in the reimbursement process can induce the necessary background knowledge (Kalo et al., 2013).

In order to increase human capacity at HTA, a master program on health finance and pharmacoeconomic, a joint action of Hacettepe University Faculty of Pharmacy and Washington University Faculty of Pharmacy was conducted. Thirty (30) staff from the Department of HTA of GDHR, Turkish Pharmaceuticals and Medical Devices Agency and Social Security Institution attended the program. In the scope of the program, respected academicians from Harvard University, Liverpool University, Eötvös Lorand University and the London School of Economics and Political Science came to Turkey as lecturers to train attendees (Medimagazin, 2014).

In this context, the Department organized some training programs for capacity building (Department of Health Technology Assessment, 2019d). These are:

- HTA training; general concepts,
- Systematic review, meta-analysis and modeling,
- Multi-criteria decision-making techniques,
- Research techniques,

- Cost measurement and evaluation techniques,
- Project preparation and management,
- Analytical decision making, application examples in health technology evaluation,
- EUnetHTA core model,
- Hospital-based HTA short course.

Also, the Department have organized some national meetings and workshops to create awareness on the HTA field within the country as listed below (Department of Health Technology Assessment, 2019d):

- Health Technology Assessment 1st Annual Meeting 2014,
- Health Technology Assessment 2st Annual Meeting 2016,
- Workshop on the Current Situation Analysis of HTA in Turkey,
- Workshop on the Place of Catastrophic Health Expenditures in Health Politics and Health Expenditures.

3. Essential Problems and Future of the HTA in Turkey

There is still an uncertainty about the new formal HTA structure. HTA activities may be run under different organizations. In such a condition, when the problematic issues about formal HTA in Turkey are concerned, the following implications can occur:

- Legal and administrative insufficiency,
- Divided structure and lack of coordination,
- Possibility of repetitive activities, thereof resource loss,
- Lack of sufficient impact and awareness.

In order to solve these issues and to drive a road map for successful and powerful structure of HTA in the Country, the Department completed a series of activities; on 14-15th July 2016 "Current Situation Analysis Workshop" and "feasibility studies" were performed during the GDHR period (Department of Health Technology Assessment, 2019d). As a result of these studies the National HTA Strategy Document was prepared and published in 2019 (Department of Health Technology Assessment, 2019e)

The main purpose for the creation of the document was to ensure institutionalization by improving concept of HTA and to re-define the internal duties and enable establishment of a new independent institutional structure of HTA in Turkey.

In this document, the HTA activities are recommended mainly be carried out by public staff under an independent structure; however, in order to support the studies, individual or corporative consultancy in the scope of service procurement can also be taken.

The document emphasizes the need to cooperate with universities and the private sector to improve HTA practices. It includes the organization chart of the new institutional structure to guide policy makers.

4. Discussion and Conclusion

The importance of evidence-based decision-making increases day after day. In such an environment, the uncertainty about how the structure of HTA formed will affect the most decision makers in Turkey. For this reason, to establish an independent and robust HTA structure is essential. Primarily, an independent structure of HTA will eliminate the fragmented structure and provide development and continuity of HTA in Turkey. This single structure can be more efficient in using of resources on HTA, like human capacity. "National HTA Strategy Document 2019-2023" has effective strategies for single structure, so these strategies can be used for this purpose.

In addition, the inclusion of this robust HTA tool in the system by the policy makers in Turkey is crucial for producing rational, transparent, effective and evidence-based health policies for sustainability of the national health system.

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