

Turkish Health Policy and Health Technology Assessment

Introduction

Countries around the world are faced with increasingly difficult challenges when it comes to managing their health systems. How can a nation meet unlimited demand for healthcare services when it has limited resources to do so? Health policy makers are constantly faced with the iron triangle of access, quality, and cost. There is no current model for providing top quality healthcare to everyone at low cost and so, each nation must find the best possible balance according to its own resources and needs. Finding this balance requires systematic approaches to identifying needs, setting priorities, implementing strategies and measuring the results. One tool that has been gaining popularity throughout the world is Health Technology Assessment (HTA). Although there are several definitions of health technology assessment, the World Health Organization's definitions are commonly used (World Health Organization, 2015):

Health Technology is “the application of organized knowledge and skills in the form of medicines, medical devices, vaccines, procedures and systems developed to solve a health problem and improve quality of life.”

“**Health technology assessment (HTA)** refers to the systematic evaluation of properties, effects, and/or impacts of health technology. It is a multidisciplinary process to evaluate the social, economic, organizational and ethical issues of a health intervention or health technology. The main purpose of conducting an assessment is to inform a policy decision making.”

The history of HTA in health policy began almost 40 years ago. The first public HTA agency, the U.S. Office of Technology Assessment (OTA) was established in 1976. The OTA informed the U.S. Congress on matters of new science and technology so that they could develop policies. The focus during these early days was on developing methods for evaluating efficacy, safety, and cost-effectiveness. This generated a demand for evidence-based assessments of technology that was met with the enthusiastic production of literature. The literature, in turn, generated a demand for clear methodologies and criteria. The systematic literature review discipline that is used today by the Cochrane Group and the Centre for Reviews and Dissemination are based on the OTA's work. The foundation that the OTA built still

underlies HTA work around the world as is illustrated by the recent publication “Office of Technology Assessment: History, implementation, and participatory critique” in which the author states “OTA was a blueprint for institutionalizing politically accountable technology assessment” (Sadowski, 2015).

It took another ten years before HTA made its way to Europe with the establishment of the Swedish Council on Technology Assessment in Health Care (SBU) in 1987. As the oldest HTA agency in Europe, SBU has developed best practices in the areas of methodology, dissemination and impact evaluation. In 2007, the European Union (EU) presidency issued a report titled *Health Care across Europe: Striving for Added Value* which stated “We can improve the health-care quality standards across the different health systems in the EU through the following: evidence-based medicine, health technology assessments, cost-benefits-analyses” (Presidency of the European Union, 2007). In that same year, an international study referred to as the Cox Report was supported by the European Commission which included the statements quoted below:

- HTA can play a valuable role in health-care decision-making but the process must be transparent, timely, relevant, in-depth and usable.
- Assessments need to use robust methods and be supplemented by other important criteria.
- By maximizing the potential of HTA, decision-makers will be better able to implement decisions that capture the benefits of new technologies, overcome uncertainties and recognize the value of innovation, all within the constraints of overall health system resources (Sorenson, 2008).

Twenty years later, HTA is being used at varying degrees in Latin America, the United States, Canada, Australia, New Zealand, Asia and Central Europe. International communities like the Health Technology Assessment International (HTAi), the International Network of Agencies for Health Technology Assessment (INAHTA) and The European Network for HTA (EUnetHTA) are helping new countries get started while helping more mature HTA agencies further develop methodologies and promote HTA use internationally.

The World Health Organization (WHO) started supporting HTA with a 2008 Policy Brief titled *Health Technology Assessment: An introduction to objectives, role of evidence, and structure in Europe* and the adoption of The Tallinn Charter: Health Systems for Health and Wealth, which supported the use of HTA as a tool for managing health system resources (World Health Organization, 2008). The Tallinn Charter stated “fostering health policy and systems research and making ethical and effective use of innovations in medical technology and pharmaceuticals are relevant for all countries; health technology assessment should be used to support more informed decision-making” (World Health Organization, 2008). Most recently, in May of 2014, WHO approved resolution WHA7.23 *Health Intervention and Technology Assessment in Support of Universal Health Coverage* at the 67th World Health Assembly. The resolution urges Member States to consider a number of steps outlined below regarding the use of HTA:

- (1) to consider establishing national systems of health intervention and technology assessment, encouraging the systematic utilization of independent health intervention and technology assessment in support of universal health coverage to inform policy decisions, including priority-setting, selection, procurement supply system management and use of health interventions and/or technologies, as well as the formulation of sustainable financing benefit packages, medicines, benefits management including pharmaceutical formularies, clinical practice guidelines and protocols for public health programmes;
- (2) to strengthen the link between health technology assessment and regulation and management, as appropriate;
- (3) to consider, in addition to the use of established and widely agreed methods, developing, as appropriate, national methodological and process guidelines and monitoring systems for health intervention and technology assessment in order to ensure the transparency, quality and policy relevance of related assessments and research;
- (4) to further consolidate and promote health intervention and technology assessment within national frameworks, such as those for health system research, health professional education, health system strengthening and universal health coverage;
- (5) to consider strengthening national capacity for regional and international networking, developing national know-how, avoiding duplication of efforts and achieving better use of resources;
- (6) to consider also collaborating with other Member States' health organizations, academic institutions, professional associations and other key stakeholders in the country or region in order to collect and share information and lessons learnt so as to formulate and implement national strategic plans concerning capacity-building for and introduction of health intervention and technology assessment, and summarizing best practices in transparent, evidence-informed health policy and decision-making;
- (7) to identify gaps with regard to promoting and implementing evidence-based health policy, as well as improving related information systems and research capacity, and considering seeking technical support and exchanging information and sharing experiences with other Member States, regional networks and international entities, including WHO;
- (8) to develop and improve the collection of data on health intervention and technology assessment, training relevant professionals, as appropriate, so as to improve assessment capacity (World Health Organization, 2014)

The World Bank has also supported the spread of HTA globally with workshops dedicated to priority setting and HTA like one held in India in October of 2014 (The World Bank, 2014).

HTA in Turkey

Turkey's first introduction to HTA was in 2009 during the third World Bank Health Transition Project when the Ministry of Health invited England's National Institute for Health and Clinical Excellence (NICE) to consult on the development of a short clinical guideline on Caesarean Section deliveries (NICE). The initiative was designed to be a pilot project to illustrate NICE's approach to guideline development using HTA methodology. In 2010, NICE also provided four days of HTA training to 35 officials from the Ministry of Health (MoH), the Ministry of Labor's Social Security Institute (SSI), the Ministry of Finance, and the Ministry of Development that year. In 2012, NICE was invited again to conduct three focus groups with the World Bank to assess the role of family physicians in the Turkish healthcare system.

In January of 2013, the Ministry of Health was reorganized to meet the objectives outlined in the Health Transition Project. Within the scope of this reorganization, the MoH passed a Directive on Health Technology Assessment which defined a national HTA process to be carried out within the MoH. The Directive established an HTA department within the MoH's Health Research General Directorate. Part 1 of the Directive defines HTA, health technology, efficacy, clinical effectiveness, rapid /short/full reporting, and adaptive studies. Part 2 of the Directive establishes a Topic Selection Commission, defines its members and describes how topics are to be submitted for consideration, how they are to be evaluated, and how decisions are to be made within the Commission. Part 4 describes the HTA process including pre-assessment, the types of HTA that may be conducted, the format and functions of the project teams, how literature reviews are conducted, and how monitoring and updating shall be performed (Ministry of Health, 2011).

As part of the same MoH reorganization, the Turkish Pharmaceutical and Medical Device Council was established to conduct all licensing activities. Within that commission, the Economic Assessment Department set up a small HTA unit.

Also in 2013, the Ministry of Labor's Social Security Institute (SSI) established an HTA department within the General Health Insurance General Directorate. This department's charter includes the following duties:

- e) Conduct, monitor and collaborate on national and international projects regarding HTA
- f) Develop evidence-based clinical pathways and guidelines by collaborating with other relevant organizations
- g) Support the development of policies on health economics and financing by preparing recommendations reports
- h) Conduct and support national conferences, congresses, symposiums and training on HTA methodology and implementation

- i) Prepare cost effectiveness analysis and recommendations regarding new health technologies upon the request of relevant organizations (SSI).

In 2013, the MoH published a policy declaration regarding HTA:

"Health Technology Assessment" is the evaluation and interpretation of various aspects of technologies used in healthcare services. Although this assessment primarily targets to guide policy making, in reality it aims to inform all of the parties related to the health technology in question. By definition, health technology includes Drugs, Medical devices, Medical treatment techniques, Surgical techniques, Healthcare service systems, and likewise.

Health technology assessment is started initially by the evaluation of clinical effectiveness and patient safety. Secondly, the aspects of economic and organizational actions together with social and ethical aspects are evaluated by a final report. Scientific evidence is used in all evaluation stages. In addition, patients, health professionals and health technology producers contribute to the interpretation. Transparency is one of the main principles in this process.

The main policy of the Department for health technology assessment process is;

- To encourage the use of new or ignored clinically effective health technologies in a reasonable and equal manner, and
- To prevent waste in healthcare services by decreasing the use of health technologies which are clinically ineffective or financially unsustainable despite its effectiveness.

In the health technology assessment process, we declare that the HTA Department is faithful to the basic values of MoH of Turkey as follows: Human Focused, Universality, Fairness, Participation, Solidarity, Respectability, Professional ethics, Transparency, Accountability, Sustainability, Evidence-based, Quality & Efficiency , Innovation (Ministry of Health, 2013)

The Topic Selection Commission was established and held its first meeting in July of 2013 to officially kick off HTA work within the MoH. Members include officials from the MoH, the Turkish Public Health Institute, the Turkish Pharmaceutical and Medical Device Council's HTA team leader, the Turkish Public Hospital Council, the Social Security Institute's HTA Division Head, the Ministry of Science, Technology and Industry, non-governmental organizations representing patients or industry as well as pharmaceutical and medical device company representatives. The first meeting was an orientation and training session. The second meeting was held in September of 2013 and considered the first submitted topic suggestions. A total of 11 topics were considered. Two were excluded from consideration for the year 2013 because work had already begun on those topics (Smoking Cessation and Gastric Surgery for Obesity). Two others were approved for the year 2014 (Hyperthermia Treatment for Cancer and Chronic Obstructive Pulmonary Disorder). The other seven were rejected. Disposable medical equipment was

rejected for being non-specific. Neurostimulators for autistic patients was rejected due to a lack of literature on the subject. Development and manufacturing of disposable circumcision materials was rejected as low-priority. A burden of disease study for Idiopathic Pulmonary Fibrosys was rejected as low-priority because the MoH had previously issued an evidence-based guideline on the subject. The measurement of the side effects of streptococcus pneumonia infections and Neisseria meningitis and the manufacturing of Hepatitis B recombinants were rejected for being outside the scope of HTA (Ministry of Health, 2013).

The third Topic Selection Meeting was held in March of 2014. Seven topics were considered. Chronic Hepatitis B medications and Peritoneal Dialysis for Chronic Renal Failure were accepted for 2014. Medication for general anxiety disorders (pregabalin) was put on the waitlist for 2014 in the event that the other four projects can be completed on time and on budget and remaining resources are sufficient for a fifth project. Renal denervation, antibiotic coated surgical sutures, antibiotic and external ventricular drainage shunts, and Rheumatoid Arthritis (general) were rejected as lower priorities according to the principles outlined in the Directive and Policy Declaration (Ministry of Health, 2014).

As of May of 2015, a total of five reports have been published in Turkey:

- *A Value Analysis of the Top 100 Drugs Used in Public Interventions between 2008 and 2013* (Turkish Pharmaceutical and Medical Device Council, 2014).
- *The Role of Obesity Surgery in Treatment for Obesity in Turkey* (Ministry of Health, 2014)
- *Low Intensity Shock Wave Therapy for Vascular Erectile Dysfunction* (Karadayı B. , 2013)
- *Smoking Cessation Support Program Cost Effectiveness Analysis* (Kılıç, 2013)
- *Prophylactic use of Palivizumab for Respiratory Syncytial Virus Infections* (Karadayı B. , 2013)

A review of these reports reveals a number of challenges that researchers are facing when conducting HTA work. First, that the reports that have been published do not match with the topics that had been approved by the Topic Selection Committee (obesity surgery and smoking cessation had already begun before the first meeting). This implies that resources can be allocated to HTA topics through a secondary channel that is not transparent. Second, reported that they found it difficult to make any certain conclusions or recommendations regarding the economic analysis because of poor or non-existent data (Karadayı B. , 2013), (Karadayı B. , 2013) (Kılıç, 2013).

The SSI's HTA department has not produced any HTA reports to date, but in 2014, the Pharmaceutical Reimbursement Policy department of the SSI completed two initiatives related to HTA's role in approving drugs for licensing decisions made by the MoH and reimbursement decisions made by the SSI. The projects involved revising the process for drug applications and review to include HTA principles as well as capacity building training for the staff of decision making bodies within the MoH, the SSI, Treasury

Department, Turkish Pharmaceutical and Medical Devices Commission, the Ministry of Economics, and the Ministry of Development.

Although not included within the scope of this study, it is of note that the Turkish Evidence Based Medicine Association and Ankara University have been actively involved in HTA promotion and use at the hospital level. Hospital HTA use was excluded because it does not influence national health policy, but it is an important field of HTA and can be of particular benefit as the new Private-Public-Partnership hospital projects move from construction to purchasing of medical equipment.

The Ministry of Health's HTA department (SAGEM) is a member of EUnetHTA along with TÜBİTAK TÜSSİDE (The National Science And Technology Council's Management Sciences Institute) and the KDTD (The Turkish Evidence Based Medicine Association).

Key Success Factors for HTA Programs

Upon reviewing the literature regarding the various HTA models programs around the world, hundreds of researchers referred to Drummond's key principles for the improved conduct of health technology assessments for resource allocation decisions as outlined in Figure 1 (Drummond, 2008).

- Principle 1: The Goal and Scope of the HTA Should Be Explicit and Relevant to Its Use
- Principle 2: HTA Should Be an Unbiased and Transparent Exercise
- Principle 3: HTA Should Include All Relevant Technologies
- Principle 4: A Clear System for Setting Priorities for HTA Should Exist
- Principle 5: HTA Should Incorporate Appropriate Methods for Assessing Costs and Benefits
- Principle 6: HTAs Should Consider a Wide Range of Evidence and Outcomes
- Principle 7: A Full Societal Perspective Should Be Considered When Undertaking HTAs
- Principle 8: HTAs Should Explicitly Characterize Uncertainty Surrounding Estimates
- Principle 9: HTAs Should Consider and Address Issues of Generalizability and Transferability
- Principle 10: Those Conducting HTAs Should Actively Engage All Key Stakeholder Groups
- Principle 11: Those Undertaking HTAs Should Actively Seek All Available Data
- Principle 12: The Implementation of HTA Findings Needs to Be Monitored

Figure 1: Principles for the improved conduct of HTA (Drummond, 2008)

In April of 2014, 178 of the 224 attendees of the Health Technology Assessment First Annual Meeting in Antalya participated in a survey conducted by the Turkish National Science and Technology Council's Management Sciences Institute (TUBITAK-TUSSIDE). The survey was based on a pre-tested Turkish

translation of Drummond's 12 principles. The participants represented all of the stakeholders defined by the conference organizers and included the MoH, universities, non-governmental organizations, manufacturers, public and private hospitals, SSI, as well as officials from the Finance Ministry, Economics Ministry, Science-Industry-Technology Ministry, Development Ministry and the Treasury. The participants were asked to describe their organization's HTA activities and their level of awareness regarding HTA activity in Turkey and available international HTA resources. 56% reported medium or high levels of awareness while 44% reported little or no awareness. Only 25% of participants were able to name a HTA report published in Turkey. They were then asked to rate how well they believe Turkey complies with each of Drummond's 12 principles on a 4 point Likert scale (0=Disagree, 1=Somewhat Disagree, 2=Somewhat Agree, 3=Agree). The highest average score was 2.28 for the 11th principle. The lowest average score was for the 1st principle. The study concluded that awareness among stakeholders and a common framework for HTA in Turkey is lacking (Ozturk, 2014).

During the 2014 Health Technology Assessment First Annual Meeting in Antalya, a workshop was conducted with the same individuals that participated in the Drummond survey. During the workshop, participants were organized into 18 small groups and asked to describe the current HTA environment in Turkey (strengths, weaknesses, opportunities and threats) and develop recommendations for improvement. The final recommendations that came out of the workshop are listed below:

1. The creation of an independent, unbiased, scientific, and transparent HTA agency outside of the MoH and the SSI.
2. The development of a common set of definitions, policies and procedures for triggering, conducting, appraising, and monitoring the impact of HTA.
3. A national multidisciplinary strategy to develop data sets to support HTA.
4. The promotion of HTA among Turkish health policy makers and providers.
5. The development of HTA capacity through better human resources management and health economics training opportunities.
6. The development of a QALY value index for Turkey.
7. The approval of a national budget for HTA research.

In 2008, before any HTA departments had been established in Turkey, Kahveci and Meade analyzed the strengths, weaknesses, opportunities and threats (SWOT) in the development of HTA in Turkey by interviewing stakeholders in the Turkish healthcare system. The results of that qualitative study are summarized in Figure 2. Between 2008 and 2013, there has been some improvement in the areas of awareness, political stability and an acceptance that continuing with the current policy development system will mean a continuing rise in healthcare expenditures that are not sustainable. A recently implemented national strategy to increase drug and biomedical technology manufacturing in Turkey and the recent approval of legislation in 2014 to establish a national health sciences institute under the MoH

are expected to put new pressures on the licensing and reimbursement policies to approve locally manufactured products instead of imported products. HTA will give policy develops the tools they need to objectively assess the value of these new products against existing technologies.

| Strengths | Weaknesses |
|---|--|
| Individuals skilled and trained in HTA related fields International contact: World Bank and European Union relations Recent reforms in health care; investments for information network and databank Good examples of evidence-based decision making | Poor multidisciplinary approach, poor communication between stakeholders Traditional “expert-based” decision making Poor availability of data Poor quality of data Poor priority setting process Lack of general awareness of HTA Lack of interest by universities Lack of trained human resources Poor information technology |
| Opportunities | Threats |
| Demand for transparency in decision making Demand for evidence and demand for credibility by decision makers Interest of mass media in healthcare reforms Overwhelming demand for new technologies requires evaluation Current healthcare reforms: restructuring of health care, general health insurance Opportunity to engage politicians interest | Funding Political instability “New and expensive” is good belief Not a priority in current reforms Recent big national investments could challenge resources Possible resistance for use by decision makers |

Figure 2: SWOT Analysis for HTA in Turkey (Kahveci R. , 2008)

Conclusion

In conclusion, Turkey is a relatively newcomer to the field of HTA. Despite the challenges that persist, the level of awareness regarding the strengths and weaknesses of the current system and the increasing international interaction between Turkish stakeholders and the international HTA community through EUnetHTA are contributing to the continued development and promotion of HTA in Turkey. As a decade of intense health system reform winds down, the new health system focus will be on sustainability and effectiveness. There is an opportunity for HTA to make a meaningful contribution to the discussions that will be forthcoming when policy makers are forced to make difficult decisions regarding alternative health technologies and health care delivery systems.

References

- Drummond, M. (2008). Key principles for the improved conduct of health technology assessments for resource allocation decisions. *International Journal of Technology Assessment in Health Care*, 244-258.
- Kahveci, R. (2008). Analysis of strengths, weaknesses, opportunities, and threats in the development of a health technology assessment program in Turkey. *International Journal of Technology Assessment in Health Care*, 235-240.
- Karadayı, B. (2013). İmpotenste düşük yoğunluklu elektro şok dalga terapisinin etkinlik ve güvenliği. *Health Technology Assessment First Annual Meeting*. Antalya: Ministry of Health.
- Karadayı, B. (2013). Palivizumab Tekli Teknoloji Değerlendirmesi. *Health Technology Assessment First Annual Meeting*. Antalya: Ministry of Health.
- Kılıç, M. (2013). Sigara Bırakma Destek Programının Maliyet Etkinlik Analizi. *Health Technology Assessment First Annual Meeting*. Antalya: Ministry of Health.
- Ministry of Health. (2011). *Directive on Health Technology Assessment*. Accessed on May 2015 at Health Technology Assessment Department: http://hta.gov.tr/pdf/STD_HTA_Yonerge.pdf
- Ministry of Health. (2013). *Health Technology Assessment Department*. Accessed on May 2015 at <http://www.hta.gov.tr/pdf/2013%2009%2030%20Komisyonu%20toplant%C4%B1%20utana%C4%9F%C4%B1.pdf>
- Ministry of Health. (2013). *Policy Declaration*. Accessed on May 2015 at Health Technology Assessment Department: Health Technology Assessment Department
- Ministry of Health. (2014). *Health Technology Assessment Department*. Accessed on May 2015 at <http://www.hta.gov.tr/pdf/Konu%20%C3%96nerisi.pdf>
- Ministry of Health. (2014). *The Role of Obesity Surgery in Treatment for Obesity in Turkey*. Ankara: Ministry of Health.
- NICE. (no date). *Developing a clinical guideline in Turkey*. Accessed on May 2015 at NICE: <http://www.nice.org.uk/about/what-we-do/nice-international/nice-international-projects/developing-a-clinical-guideline-in-turkey>
- Ozturk, K. (2014). *The First Health Technologies Assessment Meeting Report*. Antalya: TUBITAK TUSSIDE.
- Ozturk, K. (2014). *TUSSIDE Health Technology Assessment 1st Annual Meeting Survey Analysis Report*. Kocaeli: TUBITAK TUSSIDE.
- Presidency of the European Union. (2007). *Health Care Across Europe: Striving For Added Value*. Berlin: Presidency of the European Union.
- Sadowski, J. (2015). Office of Technology Assessment: History, implementation, and participatory critique. *Technology in Society*, 9-20.

Sorenson, C. (2008). *Ensuring value for money in health care: the role of health technology assessment in the European Union*. Copenhagen: WHO Regional Office for Europe (Observatory Studies Series No. 1).

SSI. (no date). *General Health Insurance General Directorate*. Accessed on May 2015 at General Health Insurance General Directorate:
http://www.sgk.gov.tr/wps/portal/tr/kurumsal/merkez_teskilati/ana_hizmet_birimleri/gss_genel_mudurlugu/hakimizda!/ut/p/b1/hZLbcqpAEEW_xQ8wDMNNHgXGYRS5zCC3FwtF5SpGDQhffoxOHnLqVJJ-667VXdV7by7hIi45p11xSu9Fe07r9z6Rt5jHWNX4OQAbagDCB8QxTYInlvIE4q_AjAHwBKAYAObx

The World Bank. (2014). *Better Decisions for Better Health*. Accessed on May 2015 at The World Bank:
<http://www.worldbank.org/en/news/feature/2014/10/16/better-decisions-for-better-health-making-each-rupee-go-longer-way>

Turkish Pharmaceutical and Medical Device Council. (2014). *A Value Analysis of the top 100 drugs used in public interventions between 2008-2013*. Ankara: Ministry of Health.

World Health Organization. (2008). *The Tallinn Charter: Health Systems for Health and Wealth*. WHO European Ministerial Conference on Health Systems. Tallinn: WHO.

World Health Organization. (2014). Resolution WHA67.23 Health intervention and technology assessment in support of universal health coverage. *67th World Health Assembly*. Geneva: WHO.

World Health Organization. (2015). *Medical Devices*. Accessed on May 2015 at World Health Organization.