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Evidence-based medicine and health technology assessments

Kanıta dayalı tıp ve sağlık teknolojilerinin değerlendirilmesi

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ABSTRACT

Evidence based medicine (EBM) is the transparent and rational use of the best evidence available to make decisions about patient care. Today, health care has become more complicated and expensive, patient demands have increased and EBM is needed to obtain optimal results, to reduce the differences across clinical practices, to provide high quality services and to promote an efficient and cost-effective health care culture. Evidence based medicine practices concern the health policy makers as well as clinicians. As evidence based medicine gained importance in the field of health policy making the concept of "Evidence Based Health Policy" has emerged. This intent of this concept is for health politicians to moderate the purposes, methods and contents of health care offered to the public, to make decisions between alternatives considering up-to-date information and considering the setting, and to identify and announce political goals that benefit the public. Today it serves as an important means of identifying evidence based health policies and assessing health technologies.

In this review, the definition, components, and grounds for evidence based medicine will be discussed, and health technology assessment which is one of the most important instruments of evidence based health policies will be examined.
Keywords: Evidence based medicine; health technology assessment; health policy

ÖZET

Kanıta Dayalı Tıp (KDT) hasta bakımı ile ilgili alınan kararlarda mevcut en iyi kanıtların dikkatli, şeffaf ve akılcı kullanımıdır. Sağlık bakımının daha karmaşık ve daha pahalı olduğu ve hasta beklentilerinin arttığı günümüzde optimal sonuç elde etmek, klinik uygulamalardaki farklılıkları azaltmak, daha kaliteli hizmet verebilmek ve etkin ve maliyet etkin bir sağlık hizmet kültürünü teşvik etmek için KDT'a gereksinim vardır. Kanıta dayalı tıp uygulamalarının sadece klinisyenleri değil aynı zamanda sağlık politikacılarını da yakından ilgilendirmektedir. Kanıta dayalı tıbbın öneminin artması ile birlikta sağlık politikası alanında "Kanıta Dayalı Sağlık Politikası" kavramı ortaya çıkmıştır. Bu kavram, sağlık politikacılarının topluma sunacağı sağlık hizmetinin amaç, yöntem ve içerik olarak düzenlenmesini, alternatifler arasından güncel veriler ışığı altında ortam koşullarının gözeterek karar vermesini ve toplum yararına politik hedefler belirleme ve açıklaması' anlamına gelmektedir. Günümüzde kanıta dayalı sağlık politikalarının belirlenmesinde sağlık teknolojilerinin değerlendirilmesi önemli bir araç olmuştur.

Bu derlemede kanıta dayalı tıbbın tanımı, unsurları ve bu uygulamaya neden ihtiyaç duyulduğundan bahsedilerek, kanıta dayalı sağlık politikalarının en önemli araçlarından biri olan sağlık teknolojilerinin değerlendirilmesi ele alınacaktır.
Anahtar kelimeler: kanıta dayalı tıp; sağlık teknolojilerinin değerlendirilmesi; sağlık politikası

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INTRODUCTION

Our modern days present us with more complex and more expensive healthcare and higher expectations among patients and the best approach to obtaining the optimal result, minimizing discrepancies in clinical practices, offering higher-quality services, and encouraging an efficient and cost-effective culture in healthcare service; and providing a number of people with qualified care is to utilize evidence-based medical practices (1, 2). Sackett et al. defines evidence-based medicine as the use of the best evidence in a careful, open and logical manner while formulating decisions concerning patient care. Evidence-based medical practices are only possible through the integration of the clinical experience of an individual with the best evidence achievable through systematic research (3).

The recent rapid development observed in evidence-based medicine led to the emergence of an evidence-based health policy field in the general area of healthcare policy. Evidence-based healthcare policies require the organization of healthcare services for the public in terms of objectives, methodologies, and content; the formulation of decisions among alternatives in the light of current data and by taking into consideration the applicable conditions; and the designation and announcement of political goals for the society by healthcare politicians. The "Health Technology Assessments" that allows for health technologies to guide healthcare politicians in their decisions in terms of medical, economic, legal, and sociocultural aspects, etc. has become one of the most important tools of evidence-based healthcare policies. The Health Technology Assessment being developed at a rapid pace in North America and Western Europe in the past 20 years is also an area attracting more attention every day in Turkey.

The present review will address the Health Technology Assessment as one of the most important tools of evidence-based healthcare policies with a mention of the definition of evidence-based medicine and the reasons why evidence-based medical practices are necessary.

EVIDENCE-BASED MEDICINE

The origins of evidence-based medical practices in the field of healthcare data back to rather old times; however, its conceptualization into its current meaning coincided with the last 20 years of the 20th Century (5).

Three English scientists, i.e. Sir Ronald Fisher, Sir Austin Bradford Hill, and Archie Cochrane, laid the foundations of evidence-based medicine and contributed to its development. Sir Ronald Fisher is acknowledged to be the father of statistics by reason of his development of the theoretical foundations of modern statistical tests in early 1990s. Sir Austin Bradford Hill is quite a famous biostatistics expert who published on the availability of biostatistical methods for medical research in Lancet Magazine in 1937. In addition, the modern "randomized trial with control group" he organized allowed him to demonstrate the superiority of streptomycin to standard treatment for pulmonary tuberculosis. Archie Cochrane is a general practitioner who conducted a number of epidemiological research studies pertaining to the diseases of the respiratory system with an epic publication on evidence of treatment in perinatal care in the 1970s. Furthermore, he published the book entitled "Effectiveness and Efficiency" providing logical discussions on evidence-based medical training and practices in clinical matters in 1971 (6).

Evidence-based medical practices were put into implementation in clinical problem-solving at McMaster University in Canada and Oxford University in England in the 1990s (7). The term 'Evidence-Based Medicine' was used for the first time by those attending McMaster Medical School in Canada to define a clinical learning method in the 1980s (8). The term 'Evidence-Based Medicine' was used for the first time in an article authored by Guyatt et al. in 1992 (9).

Evidence-based practices add further strength to the bond between knowledge and decision-making and further science and professionalism to the processes of diagnosis, treatment, and patient care. In addition, increased error rates in diagnosis and treatment and growing requests for information and loss of trust in healthcare professionals among patients contribute to the rise in the importance of evidence-based practices (1).

Evidence-based medicine helps healthcare professionals in finding, reaching, and evaluating evidence and guides them in undertaking diagnosis- and treatment-related procedures for patients to offer more benefits (7).

The demand for transparency in decisions formulated in the field of healthcare also directs decision-makers to evidence-based medicine as one of the tools that will allow them to make verifiable, reliable, and explainable decisions (4).

Evidence-based medicine shows us the analysis of research studies that brings us to the result in the presence of conflicting data in scientific literature and points out to the more significant result (10).

Evidence-based medicine requires not conventional knowledge, but the best knowledge available and the combination of the values and preferences held by the individual patient with clinical experience and expertise (11).

Evidence-based medicine incorporates the following elements of importance:

1. Knowledge and Skills of the Clinician

The clinician should demonstrate their experience, skills, and judgment in diagnosing a patient and making decisions concerning the procedures to be undertaken by taking into consideration the identity, conditions, rights, and preferences of the patient.

2. Best Clinical Evidence Available

High-quality and valid clinical research studies pertaining to the matter at hand should be utilized. Such clinical evidence may render an accepted diagnostic test or treatment modality worthless and bring to the agenda new and stronger, more accurate, more effective and more reliable pieces of evidence.

3. Strength of Available Evidence

The clinician applies a critical review on any evidence they have reached through guidance forms developed for this purpose.

4. Patient's Individual Values

Clinical decisions should take into consideration the preferences, interests and concerns, and topical expectations of the patient.

5. Patient's Pertinent Conditions

Clinical decisions should take into consideration the symptoms and findings of the patient's clinical situation (7).

EVIDENCE-BASED HEALTHCARE POLICY

As evidence-based medical practices have occupied their place in discussions concerning healthcare policies, evidence-based healthcare policy has also taken its due item on the current agenda. Healthcare policies feature a variety of application areas including evidence-based medicine, evidence-based healthcare, and evaluation of evidence-based technologies (5). Evidence-based healthcare policy refers to "the organization of healthcare services for the public in terms of objectives, methodologies, and content; the formulation of decisions among alternatives in the light of current knowledge and environmental conditions; and the designation and announcement of political goals for public benefit by healthcare politicians (4).

As experience and expert opinions are easily affected by individual personality traits and political skills, the best approach to political dilemmas is to have recourse to evidence (5).

Evidence should be reached through the use of the most logical and strong findings (4). Therefore, this important process also includes a step to evaluate the systematically obtained results of modern research studies and their integration with the preferences and experience of decision-makers (5).

Today, the emphasis is on the aim to provide high-quality, qualified, and cost-effective healthcare services and this has led to the emergence of a need for tools that will offer guidance in political decision-making processes in healthcare and can be employed in evidence-based practices. The most important one of these tools is the Health Technology Assessment (HTA) (4).

HEALTH TECHNOLOGY ASSESSMENTS (HTA)

Today, rapid developments in technology not only leads to significant changes and developments in many sectors, but also created an important impact on the healthcare sector. As is the case in other sectors, these developments may bring forth a number of benefits or rather high costs to the healthcare sector (12).

Developing technologies and increased healthcare needs have given way to such issues as the financing of healthcare services and increased costs with limited resources (13). Therefore, decision-making mechanisms in healthcare systems should take into consideration medicine, medical materials and devices, analyses and examinations, and medical procedures and therapies used or needed in healthcare in terms of efficacy, efficiency, economy, law, and ethics (14). During this evaluation, HTA becomes one of the most important tools that support the use of evidence, the integration of cost-effectiveness calculations into the process, and decision-making in political terms (4).

HTA is a field of scientific research that aims to shed light on relevant policy- and decision-making mechanisms pertaining to the promotion and utilization of healthcare technologies. Healthcare technologies include medicine, medical devices, diagnostics, procedures, and clinical, public health, and organizational interventions.

HTA is a multidisciplinary area that evaluates the clinical, economic, organizational, social, legal, and ethical effects individual healthcare technologies by considering both its specific healthcare content and currently available alternatives. The scope of and methodologies employed by HTA may be adapted to healthcare needs; however, HTA processes and methodologies should be transparent, meticulous, and systematic in nature.

HTA is a process that is instrumental in enabling decision-making mechanisms in healthcare systems to provide evidence-based and scientific responses to such questions as whether healthcare systems do satisfy the needs; how great a financial burden healthcare services entail; and which methods to use with available technologies (14). HTA plays an important role in terms of its support to decision-making in healthcare systems. In short, HTA is quite an important tool that establishes the balance between countries deriving benefits from technological developments and changes and the current budgetary balance being maintained (12).

European Network for Health Technology Assessment (EUnetHTA) defines HTA as "a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner" and it aims to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value (15).

HTA aims to encourage the use of cost-effective new technologies; to prevent the use of technologies that are not reliable for the healthcare system; and to slow down the commissioning of technologies presenting uncertainties (16). In line with this aim, HTA offers alternative practices to health politicians upon assessing the same from all medical, economic, legal, ethical, and sociocultural aspects (4).

HEALTH TECHNOLOGY ASSESSMENT PROCESS AND PRINCIPLES

A number of health technology assessment processes implemented in Europe follow similar steps. However, there may be distinctive differences among institutions in terms of the commencement of assessments, identification of priorities, authorization of reports, and methods used in further dissemination. Even though report preparation processes demonstrate regional differences, most of the steps therein are of a similar nature (17).

Brusee et al. cascaded the steps necessary for the preparation of an HTA report. Following the authorization established for a report, the first step is to define the political question unless the same has been clearly formulated during the prioritization or authorization process. The second step is to collect background information (a part of which may have already been collected in the prioritization process). During the collection of background data, a decision can be formulated by the researcher as to the areas where they need to deepen their studies (efficacy, ethical concerns, etc.) through contact with the authorizer, if possible. Thus, short research questions will be asked and the methodology summarized (17).

Once the research question has been identified, the result should be assessed in parallel with its efficacy/efficiency, as well as psychological/ ethical/ social, organizational/ professional, and economic aspects. However, it seems reasonable to assess reliability first and foremost among these areas. This is followed by efficacy. If a negative result has been

obtained in previous assessments, follow-up of such assessment may not be required. Considering the process in further detail, if a technology is observed to be suffering from a security gap or overestimated efficacy, it will be more appropriate to refrain from further research studies thereon (17).

Sub-group EUR-ASSESS, on the other hand, proposed a framework specifying the elements to be included in HTA reports. These are policy question; research questions; findings and methodology (including safety, efficacy/effectiveness, psychological, social and ethical considerations, organizational and professional implications, economic issues). It is important to clearly identify data source, research and collection methods, and data synthesis in every field of HTA. If there is an area that has not been addressed, the reason why this area has been disregarded should also be included in the report (e.g. other HTA reports providing sufficient information on the matter) (17).

On the basis of the significant body of experience in HTAs around the world, a number of groups defined good and bad practices and offered recommendations for the smooth implementation of HTAs. The set of fifteen principles proposed by Drummond et al. to implement HTA better or to commence new HTA activities in their resource allocation decisions on the basis of previous studies have been widely accepted by HTA experts around the world. HTA activities relating to or incorporating a specific resource allocation decision represent the most important focal point of this set. It is of critical importance in the context of these HTAs to take into consideration both costs and benefits in terms of economic assessment. The principles are grouped under four headings, i.e. organizational structure of HTA practices, HTA methods, HTA processes, and the use of HTA in decision-making (Table 1) (18).

HEALTH TECHNOLOGY ASSESSMENTS IN TURKEY

Along with the efficient dissemination of healthcare services within the framework of the Health Transformation Project, the accessibility of healthcare services has increased and in consequence, spending in healthcare is on a constantly increasing trend. Around the world and specifically in developed countries, support is provided through HTA to decision-making mechanisms aimed at the accurate calculation of cost-effectiveness for healthcare technologies (medicine, medical devices, etc.) with evidence-based scientific information (14).

Medicine was the first area where Health Technology Assessment or economic assessment methodologies were brought to the agenda in Turkey. In this period, medicinal pricing and refund policies were amended due to the intense pressure applied by IMF for the restriction of public spending; the share of medicine in the total healthcare spending being rather high; and medicinal spending being the most easily forecast spending among other items in healthcare spending(13).

In Turkey, the HTA structure was established less than five years ago along with the official reconstruction of the Ministry of Health on the basis of the decree law dated 11.10.2011 and No. 663 on the Organization and Duties of the Ministry of Health and Affiliated Institutions (19). Thus, Turkey took the first step towards the establishment of an HTA process.

Initially, Ankara Numune Hospital Health Technology Assessment Unit (ANHTA) was established in February 2012. ANHTA offers services as a hospital-based HTA unit aiming to shed light on decisions pertaining to healthcare investments under Ankara Numune Training and Research Hospital (ANH) (20).

Table 1. Principles of HTA

Structure of HTA programs
1. The goal and scope of the HTA should be explicit and relevant to its use
2. HTA should be an unbiased and transparent exercise
3. HTA should ınclude all relevant technologies
4. A clear system for setting priorities for HTA should exist
Methods of HTA
5. HTA should incorporate appropriate methods for assessing costs and benefits
6. HTAs should consider a wide range of evidence and outcomes
7. A full societal perspective should be considered when undertaking HTAs
8. HTAs should explicitly characterize uncertainty surrounding estimates
9. HTAs should consider and address issues of generalizability and transferability
Processes for conducting HTA
10. Those conducting HTAs should actively engage all key stakeholder groups
11. Those undertaking HTAs should actively seek all available data
12. The implementation of HTA findings needs to be monitored
Use of HTA in decision-making
13. HTA should be timely
14. HTA findings need to be communicated appropriately to different decision makers
15. The link between HTA findings and decision-making processes needs to be transparent and clearly defined

The first HTA structure established at the national level is the Health Technology Assessment Department under the General Directorate of Health Research under the Ministry of Health. Even though the law was approved at the end of 2011, the organization could only enter into service in the middle of 2012. In the same year, an HTA unit was established by Turkish Medicines and Medical Devices Agency (TITCK) under the Economic Assessments Department. A unit was established under the Social Security Institution (SSI) as an extension of the General Directorate of General Health Insurance in 2013. (20)

A number of initiatives have been put forth with respect to HTA and Evidence-Based Medicine (EBM) at Non-Governmental Organizations and universities apart from the developments implemented at the Ministry of Health. Conferences and training events were organized in this field. The Evidence-Based Medicine Association of Turkey (KDTD) became the first NGO established in this field with a main focus on HTA and EBM in 2007. In Turkey, KDTD organized the first HTA conference in 2008 (20). A “Eurasian HTA

Initiative" was rolled out in the leadership of KDTD, with the membership of eight members (Albania, Azerbaijan, Bosnia-and-Herzegovina, Kazakhstan, Kyrgyzstan, Macedonia, Montenegro, and Turkey) and the inclusion of Tunisia acting as an observing country. This initiative organizes regular meetings and conducts joint research studies to identify action plans through the exchange of information and experience and addresses common problems (21).

The transition to HTA was possible through the active role assumed by not only KDTD, but also such universities and non-governmental organizations including ISPOR Turkish Chapter, Association of Health Economy and Policies, Hacettepe University, Başkent University, and TUSSIDE (Turkish Institute of Management Sciences).

INTERNATIONAL COOPERATION IN HEALTH TECHNOLOGY ASSESSMENT

Health Technology Assessments International (HTAi)

HTAi is global scientific and professional community for everyone who generates, uses, or encounters HTA. HTAi acts as an impartial forum for all stakeholders including researchers, institutions, policy-makers, the industry and academia, healthcare providers, and patients/consumers to cooperate and share knowledge and experience with each other. HTAi has more than 1200 members in 59 countries (16).

HTAi's mission is to inform decision-makers from a multidisciplinary perspective with respect to scientifically based and effective innovations and to support and encourage the development, communication, and understanding of HTA in the context of the efficient utilization of resources in healthcare services (14).

International Network of Agencies for Health Technology Assessment (INAHTA)

The International Network of Agencies for Health Technology Assessment (INAHTA) was established in 1993 and is a non-profit organization reaching 52 members from 26 countries in 2010. All members are non-profit organizations generating HTAs and affiliated with regional and national governments. Most of INAHTA's activities are coordinated by a secretariat. The members convene annually and take part in various working groups throughout the year. The annual meeting is held along with HTAi Conference. The members of the Board of Directors and other boards are elected for a term of 2 years. INAHTA provides information on on-going activities and HTA reports and publishes summaries on its website regularly (16).

EUnetHTA (European Network for Health Technology Assessment) is the facilitator of choice for high-quality HTA cooperation. HTA institutions consider EUnetHTA as an effective tool for cooperation. The duty of EUnetHTA is to support cooperation among HTA institutions that add value to European, national and regional healthcare systems. SAGEM, KDTD and TUSSIDE from Turkey are participating partners of EUnetHTA (22).

CONCLUSION

Evidence-based practices are methods to reach, assess and act upon scientific knowledge. The main aim is to make the right decision by combining scientific evidence, medical experience, and the patient's wishes (3).

Along with such issues as need for new information, insufficiency of resources, and limited time, the rapid developments in methods to access information and improved public access to information in the field of healthcare stimulated a notion of interest in and need for HTA. Considering the current conditions, HTA has gained further importance for the minimization of errors with respect to patients; reduction of costs of analyses, treatment and diagnosis; and improvement of quality. The institutionalization of evidence-based decision-making processes also contributed to the emergence of HTA as a strong paradigm. Appropriate and right HTA practices make it possible for developing countries to disseminate global knowledge, to support transparent and reliable decision-making processes, and to encourage efficient quality in healthcare (16).

HTA must be for the benefit of patients and encourage innovation. It must pursue an objective that is wider than cost reduction by itself. It should be valid for all care practices and interventions and not only for medicine. If health politicians utilize health technology assessment in their political decision-making processes, this will improve healthcare services further and allow for the making of decisions that will ensure the delivery of better healthcare services (4).

These practices, when designated for the right technologies, are met with a larger number of fields of application every day by reason of their impact in reducing the budgetary burden on institutions and providing for early access to new technologies and cost-effective pricing. In Turkey, any increase in HTA practices can be considered to provide significant contributions to the budget of the Social Security Institution prospectively (12). The development of HTA will become more effective and be supported through active steps to be taken by WHO and other global health organizations.

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