PHD THESIS:

HTA ROADMAP FOR EGYPT

Health Technology Assessment Roadmap and Implementation Action Plan for Egypt

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INTRODUCTION

Background

We deal with regulations on a daily basis, and it has been there for thousands of years. Regulations are rules made and maintained by an authority. The healthcare market is not different. From time to time, new regulations are introduced, or existing ones are altered, based on the prevailing circumstance. Looking back to history, we could find the same trends repeating; new regulations are developed to accommodate the new state of affairs and adapt to changes.

Mithridatium was a semi-mythical remedy with as many as 65 ingredients. It was developed in the 1st century BC. According to Nature (journal), physicians in London officially prescribed mithridate until 1786 (Wikipedia Contributors, 2019). The first supervision on drug manufacturing was in 1540, in England, for the manufacturing of Mithridatium and other medicines (Rägo, 2008). Following that, many countries started to supervise the manufacturing of some medicines, standardizing their methodologies. In 1906, the Food and Drug Administration (FDA) began its regulatory functions in the US. It operated under the name Food and Drug Act until 1930, when it was named as the Food and Drug Administration (Semler, 2019).

Years later, specifically in 1962, the thalidomide disaster influenced the development of medicines regulation far more than any event in history. Thalidomide was a sedative and hypnotic that first went on sale in Western Germany, in 1956. Between 1958 and 1960, it was introduced in 46 different countries worldwide resulting in an estimated 10,000 babies being born with phocomelia and other deformities (Griffin, 2006). Phocomelia is a rare congenital deformity in which the hands or feet are attached close to the trunk, the limbs being grossly underdeveloped or absent (Oxford English Dictionary, 2019). After the thalidomide catastrophe, many countries have evolved systems of drug registration to ensure that individual products approved for sale meet the criteria of safety, quality, and efficacy. A regulatory authority is usually established for administrative control. Medicine registration is often a major element in legislation, to ensure that individual products meet the criteria of efficacy, safety, and quality (Fefer, 2012).

Regulations have been affected by the major changes in health care funding over the years. Health care financing was mostly from out-of-pocket payments, until public health insurance, known as national health insurance, started spreading in many countries. Public health insurance was first
implemented in the late 19th century, becoming the driver for introduction of new tools and regulations. Germany has the world's oldest national social health insurance system, with origins dating back to 1883. In Britain, the National Insurance Act 1911 included national social health insurance for primary care only, not covering specialist or hospital care. Initially, it covered about one-third of the population, who were primarily the employed working-class wage earners. Their dependents, however, were not covered. This system of health insurance prevailed until the creation of the National Health Service (NHS) in 1948. The NHS created a universal service funded out of general taxation, rather than on an insurance basis, providing health services to all legal residents (Mundiharno, 2012).

Governments went a step further by starting the implementation of Universal Health Coverage (UHC). UHC refers to a health care system that provides health care to all citizens (usually more than 90%) of a particular country, without causing financial hardship to the beneficiaries. With the adoption of UHC, the pressure on health care payers to implement sustainable health care financing has been continuously growing (World Health Organization [WHO], 2010). UHC usually includes the full spectrum of essential, quality health services, from health promotion to prevention, treatment, rehabilitation, and palliative care. In 1912, Norway had the first UHC system in the world. As of 2009, 58 countries established functioning universal health care systems (Teerawattananon, 2014). In the recent decade, more and more countries have adopted UHC.

The new health care financing structure puts significant burden on the government but concurrently gives it more power due to the centralization of decision-making. Those changes in health care financing raised new questions beyond the safety, efficacy, and quality of health technologies: the public health priority to cover a particular intervention from public resources; availability of resources to reimburse a technology; and which alternative technologies should be sacrificed? Another question is whether there is sufficient capacity: for example, infrastructure or medical staff who are trained to utilize the new intervention? With the increasing role of public interventions in health care, questions about equity (e.g., equal access, equity in health, equity in health care financing) have also been raised.

Previously, market authorization was the major barrier in the market access, and consequently the return on investment of new health technologies. Nowadays, under national health insurance systems and universal health coverage, new health technologies need to cross a new market access
hurdle to ensure a considerable return on investment, which is reimbursement. Therefore, the health economics research process called Health Technology Assessment (HTA) became an essential and (sometimes obligatory) part of the regulations to attain reimbursement in many countries. Nowadays, a new intervention which is more effective than its predecessor is not enough to grant reimbursement. Two main questions arise. First, we need to ask if the new intervention provides good value for money compared to the current standard of care. The question, “Can the unit price be justified?” is what cost-effectiveness analysis (CEA) answers. Another question that needs to be answered is, even if the new intervention provides a good value for money: “Can we afford it? “In other words, “Do we have enough resources to reimburse the new intervention without compromising the sustainability of health care financing?” This is the question answered by budget impact analysis (BIA). Collectively, CEA and BIA are considered to be the core of HTA.

Health Technology Assessment

According to the World Health Organization (WHO), the main purpose of HTA is to inform policy decision-making. It refers to the systematic evaluation of properties, effects, and/or impacts of health technology (Pan American Health Organization [PAHO], 2018). HTA is defined by the WHO as "the systematic evaluation of properties, effects and/or impacts of health technologies and interventions. It covers both the direct, intended consequences of technologies and interventions and their indirect, unintended consequences" (World Health Organisation [WHO], 2019). It could further be described as a tool that attempts to capture the multifaceted nature of health care interventions or technologies and presents to the stakeholders (those involved in funding, planning, purchasing and investing in health care) a guide for making; the most suitable, clinically effective, affordable, feasible, cost-effective and scientifically sound decision, by maximizing allocative efficiency of resources (Battista, 1999).

HTA refers to the systematic evaluation of the properties and effects of health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informing decision making regarding health technologies. HTA is conducted by interdisciplinary groups that use explicit analytical frameworks drawing on a variety of methods (Facey, 2006). The main purpose of conducting HTA is to inform health care policy-makers to improve the evidence base of policy decisions.
One of the most unique features of HTA is being defined by its purpose and not a specific method; it encompasses different areas on which the introduction of the health technology in question may have an impact. Those areas are grouped into 4 main sections: the technology, the patient, the organization, and the economy. Although they are mentioned separately those elements are connected by common and overlapping factors such as ethics that cannot be separated from any of the 4 sections (Kristensen, 2009).

The cradle of HTA was the Office of Technology Assessment (OTA) which was established by the United States Congress with the Technology Assessment Act of 1972, to provide it with “competent, unbiased information” on the potential impact of technological applications (Burns, 1976). Yet in 1995, the Office of Technology Assessment terminated this act, (O'Keefe, 2011) which was criticized back then by republican representative Amo Houghton, who commented "we are cutting off one of the most important arms of Congress when we cut off unbiased knowledge about science and technology" (Nader, 2010).

HTA began to spread to the rest of the world in the late 1980s, with the formation of the Swedish Council on Technology Assessment in Health Care (SBU), which after five years became an independent body .Two decades afterwards, HTA has spread to nearly all western European countries, then to some of the wealthier countries in Central Europe, Latin America, and Asia. Australia has the Pharmaceutical Benefits Advisory Committee (PBAC), a committee that consists of medical experts who assess the submission of new drugs or technology to be subsidized by the Australian Pharmaceutical Benefits Scheme (PBS). This committee became the first to publish HTA guidelines for pharmaceuticals. As the health care cost rose in 1980, the Canadian government built a body named the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) which was responsible for reviewing the effectiveness of medical devices in 1989. In 1994, Canada released the guideline of the economic evaluation of pharmaceuticals.

The United Kingdom (UK) formed the National Institute of Health Excellence (NICE) in 1999, which aims to guide new technology and treatment of disease. Their existence was alleged to have a massive impact on the globalizing of HTA (O'Donnell, 2009). As reported in (Banta, 2009), the development of HTA was facilitated by the work of the Cochrane Collaboration (CC) and Evidence-Based Medicine (EBM). The first Cochrane Centre was established in the UK in 1992. This community aimed to increase evidence-data production. It was developed and spread to 15
countries. This collaboration facilitated experts to review the literature which covered various health care interventions. Evidence-based medicine is a movement to help health care practitioners consider the evidence from systematic research in their medical practices. This movement aims to improve routine patient care. HTA, CC, and EBM work in harmony. CC attempts to synthesize evidence according to a standard Cochrane methodology and procedure; then according to the EBM concept, health care practitioners translate the evidence into medical practice. HTA is mainly concerned with improving the health system through utilization of different types of evidence to support policy or institutional level decisions.

HTA is the multi-disciplinary process covering several economic, clinical, and social domains used to inform decision-making. According to the International Network of Agencies for HTA, “Health technology assessment is a multi-disciplinary field of policy analysis that examines the medical, economic, social and ethical implications of the incremental value, diffusion and use of a medical technology in health care” (Fattore, 2011). The term “technology” raises the image of a machine or device. However, as used in the context of HTA, the term covers all forms of intervention, including drugs, devices, surgery, diagnostics, psychological interventions, and forms of organization of care which are used to alter the natural history of a disease or to relieve symptoms.

HTA is a comprehensive approach to improve the evidence base of policy decisions related to health technologies. It also acts as a tool for policymakers to make transparent decisions based on a set of defined criteria and thresholds. Moreover, from the perspective of society and patients, fewer resources are sacrificed for inappropriate health care services and technologies. Furthermore, HTA provides health care manufacturers clear criteria for reimbursement, which eventually facilitates fair competition.

Challenges of the Health System in Egypt

Unmet needs
Egypt is a North-African country with population of about 102 million people (1.94% population growth rate) in 2020. According to the World Bank classification, Egypt is one of the lower-middle-income countries (LMIC), ranked 108 out of 187 countries on the UNDP human development index. GDP per capita rose from 1,197 USD in 2005 to 3,100 USD in 2019. Around two-thirds of the population is under 30 years old. The latest Demographic and Health Survey
shows that the total fertility rate has risen from 3.0 in 2008 to 3.5 in 2014 for women between 15 and 49 years (Trading Economics, 2020; World Bank, 2019b; World Population Review, 2020).

Egypt’s health system comprises thousands of health facilities including hospitals, clinics and medical centers, with about 95% of Egyptians living within 5 km of a health facility. However, the utilization of these facilities and opportunities is below expectation (El-Zanaty, 2015).

Egypt has achieved many positive steps toward improving the health status of its population over the last decades. For example, the Egyptian population has become slightly healthier over the past 20 years and the overall life expectancy has increased from 64.5 years to 70.5 years (El-Zanaty, 2018) coming closer to the global average (73 years) but falls far from high income countries (81 years) (World Bank, 2019a). Unfortunately, the benefits of the progress in health status have not accrued equally and these improvements have not been evenly distributed across different geographical regions and different socioeconomic classes. Furthermore, the risk of catastrophic expenditure for surgical care (% of people at risk) in Egypt was around 25% which is still higher than the average for middle income countries (World Bank, 2020c).

Unmet needs represent a major issue in the health care system of Egypt. The concept of unmet needs refers to the difference between health services necessary to treat a particular health problem and services received. Looking from this perspective only, a limited proportion of Egyptians entitled to free or reimbursed public health care services, (mainly through Health Insurance Organization (HIO), and the Ministry of Health (MOH)) have ever visited public health care facilities. Because of the low-quality of services provided in the public sector, beneficiaries tend to utilize private health care providers and pay out of pocket (World Bank, 2015). The main reasons behind the unmet needs for health care are related to the acceptability of health services, followed by availability and accessibility of health services (Ismail, 2013).

Studying the relationship of socio-demographic factors and unmet health care needs indicated that more than half (57%) of those who had unmet health care needs represent the middle-income class. The effect of finances on delayed and unmet needs for medical care in the general population has been well-documented (Ismail, 2013). Inequalities have been evident in diverse dimensions, especially in terms of geographical distribution, gender, income levels, and health outcomes.
Egypt faces challenges in the implementation of sound health systems in the following areas: governance in health, quality and access to health services, human resource imbalances, and financing health care. The health system in Egypt suffers significant systemic inequalities and inefficiencies, which have severely limited the effectiveness of its health system in entirety. Any plans to expand the context of services or increase revenues and enhance the provision of better care to patients have proved difficult. Principally, this is due unaddressed systemic bottlenecks in the management of the health industry, regarding finance especially.

**Out of pocket expenditure**

Out-of-pocket payments (OPP) is the principal scheme of financing health care in Egypt. OPP means that households pay directly to health care providers, as the insurance sector is not strong enough to support the population. The government has not been able to develop a dynamic insurance policy that uplifts the standards of health delivery across Egypt. OPP health care expenditure also means that households are compelled to fully bear the burden of their health care needs, especially those who are not able to pay private health insurance premiums (Farahat, 2018).

The vast majority of Egypt's health spending (72%) come directly from household OPPs (World Bank, 2015), compared to the global average of 18% in 2018 (World Bank, 2018). OPP expenditure is predominant in private health facilities than in governmental ones. OPP expenditure is more prevalent among individuals of high socioeconomic class, with those in the highest income quintile spending significantly more than those in the lowest income quintile. Chronic disease patients face relatively high OPP expenditure. Out of pocket expenditure creates insecurity and acts against equity in the health care systems (Farahat, 2018).

**Realigning Health Care System with Goals of Health Reform Program**

The government of Egypt provides a blueprint for action on health management within primary health care. The Egyptian Health Sector Reform Program (HSRP) provides a framework for enhancing the delivery of health services across Egypt. The objective of HSRP is two folds: to introduce a quality basic platform for primary health care services, support the establishment of decentralized service system and enhance the availability of health services; and establish institutional structural reforms that are based on the elements of providing regulatory functions as defined by the Ministry of Health and Population. Coverage is provided through the National Social Insurance with the goal of expanding access to all and making health care affordable.
The reforms within the health industry in Egypt focus on effective action plan, both at national and state levels, to mitigate any increase in disease prevalence, and to generally ensure a healthy population. The key challenge has been translating goals and policies into effective and concrete actions that address the increasing burden of diseases and examine inequities. There are diverse cooperation, agencies, and institutions in Egypt both in the public and private sectors that are involved in policymaking and implementation, with health management as their focus. The government as the driver interlinks these agencies for an effective health system. The focus is on both short- and long-term solutions to health care problems.

The Health Reform Program incorporates three main elements: service component in the area of Family Health Mode; the role and mandate of Ministry of Health and Population (MOHP); and the establishment of a sustainable universal insurance system in the health sector. An integrated health system model in Egypt may prove essential in realizing these three key goals. Technical support is provided to develop processes and platforms for an integrated health system that is based on interlinking the different levels of health governance across Egypt. The integrated health system as facilitated by technologies facilitates: implementation of District Provider Organization; financial sustainability; defines provision from financing health services; adopts the content of district health coverage plan; offers basic benefits and care packages as primary and secondary levels through public and private partnership and defines HSRP objectives based on the industry trends and changes (El-Zanaty, 2003).

The MOHP’s health care reform objectives have not changes in the last two decades (El-Zanaty, 2003):

- Expanding the social health insurance coverage from 47 percent of the population (in 2003) to universal coverage with the “family” as the basic unit. An affordable and cost-effective package of basic health services based on the priority health needs of the population will be provided.
- Reorganizing services so that they are provided through a holistic family health approach. The provision of the basic package will be based on competition and choice among the different public and private service providers, under a single Public and Health Insurance Fund (PHIF) using incentive-based and other provider payment mechanisms. The MOHP service provision management will be decentralized to the district level (the district
management approach), in the transition period until the MOHP phases out its service delivery function.

- Strengthening management systems and developing a regulatory framework, building institutional relationships to ensure the quality of care and to support the reform of the health sector.
- Developing the domestic pharmaceutical industry and reducing government involvement in the production of pharmaceuticals while strengthening its role as a financier.
- The health sector reform strategies are assisted through the HSRP.

**Significance of the research**

There is an obvious shift in the global attitude towards rationalizing resource utilization, especially after the global recession and the consequent period of declining economic growth. The situation in the Middle East is even worse because of political turbulence related to the Arab spring, and the fall of oil prices. Egypt was not especially immune to the situation; furthermore, it was affected by all the factors at once. Tourism income perished after the Libyan revolution (Ottaway, 2012), whereas the extreme economic constraints in the Gulf region caused a huge number of Egyptians working abroad to return home unemployed. Moreover, second-day multiplication of foreign exchange rates caused a huge disturbance in all industries regardless of their dependency on foreign currency due to the domino effect. Also, Egypt’s internal and external government debt has been doubled over about four years, and Serious inflation almost 30% from the official reports. in one year. The above-mentioned economic factors make what was a very far but achievable dream, of improving the Egyptian health care system, seem an impossible mission today, through the implementation existing health policies.

On the other hand, Egypt like any other country, is facing the same set of forces that drive the growth of health care expenditure. On the demand side, the increasing burden of noncommunicable diseases (i.e., cardiovascular diseases, diabetes mellitus, malignancies) is playing a significant role, whereas, often, the cost of improved diagnostic techniques predispose to larger budget impact. While on the supply side, new treatments that emerge more frequently than ever, and the new trend of highly priced orphan drugs prevail. Given the previously mentioned economic and health industry-specific curb, Egypt desperately needs to employ evidence-based decision-making for its health policies.
There are many stakeholders in Egypt’s the health care scene. Some act as payers, or providers only, while others act on both sides; like the Health Insurance Organization (HIO), or the Ministry of Health and Population (MoHP), and many other national institutes operate their health care facilities. Other key actors are the Ministry of Internal Affairs, which operates health facilities for the police and prison services; the Transport Ministry, which operates hospitals for railway employees; the Ministry of Agriculture; the Ministry of Religious Affairs; and the Ministry of Defense, responsible for health facilities for the Army. Also, the Ministry of Higher Education plays a role as a health care provider in 14 medical schools (Faculties of Medicine) and 36 university hospitals (El-Zanaty, 2003). There are also other service providers like the Curative Care Organizations (CCO), and the General Organization of Teaching Hospitals and Institutes (THO). Provider-payment system is not centralized in Egypt, with the largest share being out of pocket payments, followed by funding from the budget of the Ministry of Health and the Ministry of Finance (Ministry of Health, 2012).

Given the complex and fragmented structure of the Egyptian health care system, as well as the relatively low GDP per capita, differences in social values, etc., it is not efficient to directly adopt decision-making practices from high-income countries - not even other middle-income countries (MICs) - without adjustment to local values and practices. Despite benefiting from the experiences of others, Egypt needs to build up its architecture of HTA. Although the majority of health care expenditure in Egypt is out of pocket, still this segment will most likely get impacted by the outcomes of HTA practice, as drug prices in Egypt are regulated by the Central Administration of Pharmaceutical Affairs (CAPA). CAPA sets the official price for drugs even if the pharmaceutical products are not covered in the basic benefit package, thus affecting every consumer.

This research, therefore, analyzes existing policies on health care financing, including the HTA, from the perspectives of the policy- and decision-makers from the government, and the private sector such as pharmaceuticals, academia and non-governmental organizations. It compares the position of Egypt in terms of OPP, GDP per capita expenditure on health with other countries having similar GDP. It has also brought to light the perceptions, processes and likely impact of HTA on the Egyptian health care system, particularly on future health insurance policies.
Statement of the research problem

In Egypt, we see the impact of the turbulence from political and economic forces on the current health care system. The economic crisis causes a cut down in expenses and volatility of foreign currency exchange rates. Also, the political turmoil causes frequent changes in the health policy leadership, whereas fear from public criticism hinders leaders from taking a lot of fruitful decisions. Furthermore, before the current economic and political situation the Egyptian health care sector was battling with many issues including: the shift from the predominance of communicable diseases to non-communicable diseases, unequal allocation of health care services between urban and rural areas, lack of centralized electronic patient records and health care financing databases.

Egypt has a highly fragmented health care system, with many different public and private providers and financing agents. Health services in Egypt are currently managed, financed, and provided by agencies in all three sectors of the economy - government, non-governmental and private. The government health services in Egypt are organized as an integrated delivery system in which the financing and provider functions are included under the same organizational structure (World Health Organization [WHO], 2006). Only a very limited proportion of Egyptians who were entitled to free or reimbursed public health care services, (mainly through Health Insurance Organization (HIO) and Ministry of Health (MOH)) have ever visited public health care facilities. Because of the low-quality of service provision in the public sector, beneficiaries tend to utilize the private health care providers and pay out of pocket. According to several sources, out of pocket payment may exceed 70% of total health expenditure (World Bank, 2015). The enormous proportion of out-of-pocket payment induces inequity, as only the rich can afford to pay for the high-cost medical services they need, leaving the poor underserved. As much as this seems a disastrous situation, it might not be the worst. Under the current deteriorating economic situation and double-digit inflation rates, demand for free public health care services is expected to increase dramatically. On top of that, the highly promoted new social health insurance planned by the government to reach universal health coverage (UHC) in the short-term, raises expectations of beneficiaries to unprecedented levels, and possibly bringing up new challenges to payers and providers. Over and above, overnight local currency devaluation has increased the cost-of-service provision while the public health care budget has remained almost the same. Conjointly, these factors will inevitably
lead to a complete system failure, if new steps are not taken. Given the current situation, it has never been more important to strengthen evidence-based decision-making in the Egyptian health care sector.

When it comes to evidence-based decision making in health care, one of the important toolkits to justify the allocation of scarce resources is HTA. HTA is a multidisciplinary field that addresses the clinical, economic, organizational, social, legal, and ethical impacts of health technology, considering its specific health care context as well as available alternatives. Health technologies include pharmaceuticals, devices, diagnostics, procedures and other clinical, public health and organizational interventions. The scope and methods of HTA may be adapted to the needs of a particular health system, but HTA processes and methods should be transparent, systematic, and rigorous (Health Technology Assessment International, 2016).

According to (Kaló, 2016) “the purpose of HTA is to support policymakers with the best available information about new and already widely used health technologies to inform resource allocation decisions in a variety of settings”. This also applies in low-income and middle-income countries (Lopert, 2013). Furthermore, the formal implementation of HTA can improve allocative efficiency and have positive spillovers beyond sound reimbursement decisions, such as strengthening the dialogue between relevant stakeholders and focusing the public debate on patient-level outcomes (Gerhardus, 2008).”

**Purpose of the research**

The purpose of this dissertation is to specify the optimum characteristics, and design of the HTA process in Egypt, given the current national health care system situation, alongside elaborating a proposal for a feasible implementation process. In the end, the transferability of the constructed Egyptian HTA roadmap to other Middle Eastern countries with similar cultural and/or economic backgrounds will be briefly assessed.

**Research questions**

Q1- What is the health care financing structure in Egypt?

Q2- How does formal HTA implementation affect the performance of health systems in MICs?

Q3- How do local stakeholders perceive the HTA for decision making in Egypt?
Q4- What is the optimum structure, and process for HTA implementation in Egypt?

Q5- What are the similarities and differences between the HTA implementation roadmap in Egypt and other regions?
OVERVIEW ON RESEARCH METHODS

To implement HTA in a middle-income country in the Middle East, it is not recommended to copy successful systems from other countries due to differences in health care systems and national culture. We started our study by evaluating the current and future direction of health care financing in Egypt, to evaluate where HTA fits today and its potential utilization in future health care reforms. It is also essential to understand the global impact of implementing HTA, and more importantly, whether the effects observed in higher-income countries are transferable to middle-income countries – to understand what should be expected from such implementation in the long run and what not to. As such, the perception of Egyptian decision-makers about the impact of HTA in Egypt was evaluated to similarly assess what effects they strongly expect from HTA implementation, as well as what they might be hesitant would apply locally.

The previous foundation steps were followed by evaluating the current and preferred status of HTA implementation in Egypt, considering various aspects, to generate a roadmap clarifying the general direction for HTA implementation in Egypt. The generated roadmap was then validated by local experts from feasibility and applicability point of view, considering the Egyptian health care financing system, to generate a chronological action plan for HTA implementation in Egypt. Furthermore, the HTA scorecard was applied to MENA region, and the roadmap from Egypt was compared to the MENA region and other regions which have used the same scorecard.

To evaluate the health care financing structure in Egypt (Q1), a systematic literature review including both peer-reviewed articles as well as grey literature was conducted. Sources of grey literature reviewed included but not limited to international organizations reports (WHO, the World Bank (WB), Organization for Economic Cooperation and Development (OECD), Ministry of Health reports, and conference materials.

To understand the implications of formal HTA implementation specifically on the domains of health system efficiency, transparency, and objectivity of decision-making (Q2), a systematic literature review (SLR) was conducted to deduce the benefits of formal HTA implementation in the reimbursement system. Which was then followed by a survey in MIC to validate the findings of the SLR. Qualitative assessment of the perceived implications of formal HTA implementation on resource allocation for pharmaceuticals within the current Egyptian system and middle-income countries in general (Q3) was done through electronically distributed survey distributed among
individuals who are current or previous decision-makers within the government (Ministry of Health, Health Insurance Organization, University Hospitals).

HTA implementation scorecard developed by Kaló, (2016) was used as the foundation for advising the appropriate HTA structure, and implementation process from the point of view of local stakeholders. The scorecard evaluates the current status against the preferred status in 10 years across eight main domains. HTA capacity building evaluating status is a very significant domain crucial to HTA implementation, because if HTA was injected in the legislation of health technology reimbursement and pricing without the availability of experts in the field, it would lead to unfavorable results and probable system failure. Another domain is Legislation on HTA looking at how HTA is embedded in the legal system. One other domain is the scope of HTA implementation, which is concerned with the range of health technologies HTA is used for evaluating. Funding can be dominantly public, or the extreme opposite - mainly privately funded - leaving minimal impact on public resources, or something in between. Other domains are concerned with the use of local data, quality and transparency of HTA implementation. Furthermore, the decision criteria domain specifies what elements are and should be included in the health technology assessment process. Finally, international collaboration domain assesses the role international collaboration in the joint assessment of reports, and in education.

The HTA implementation scorecard was administered to different stakeholders in the Egyptian health care system to assess the current status of HTA implementation in Egypt, and at the same time collect preferences of different stakeholders on the long-term objectives in Egypt (Q4a).

Based on the findings obtained from the initial analysis, a draft action plan was developed to achieve the pre-set goals. The draft action plan was set to achieve the goals, putting into consideration the health care financing structure in Egypt and decision makers perception about the impact of HTA in Egypt, this was achived by conducting a series of interviews with stakeholders from different bodies to validate and assess the feasibility of the roadmap (Q4b). Furthermore, the action plan was broken down into 3 chronological phases. To ensure the quality of the final roadmap, various stakeholders must be involved in the process, naming some; Health Insurance Organization (HIO); Central Administration of Pharmaceutical Affairs (CAPA); Egyptian Drug Authority (EDA); Social Health Insurance (SHI) board; Pharmacoeconomic Unit;
academics; politicians; pharmaceutical companies; hospital managers; physicians; pharmacists; and patients.

Results from the Egyptian survey are compared to findings from other regions based on targeted literature review including studies in Central and Eastern European countries (Kaló, 2016), and Latin America (Rosselli, 2017), as well as from the Middle East (Q5).
RESEARCH

This chapter presents the main findings of the research components conducted, starting with a literature review on the benefits and drawbacks of HTA implementation in health care systems, with special focus on MICs. It is followed by an assessment of the perceived impact of HTA based on a survey conducted in Egypt. Afterward, an overview of health care financing in Egypt from a systematic literature review is presented, with a comparative analysis of health care expenditure of Egypt and other countries with similar economic status. Furthermore, the current status and future preference for HTA implementation in Egypt based on various stakeholders’ opinion is summarized and compared with the direction in the MENA region. Finally, based on the findings from all previous activities, a roadmap and action plan for HTA implementation in Egypt is elaborated and validated by national experts.

Health care financing structure in Egypt

Introduction

It is not possible to propose a realistic feasible action plan for HTA implementation in Egypt without considering the health care financing system first. This section intends to evaluate the current health care system and the expected future structure under the new health care reform in Egypt. The Egyptian health care system is diversified in nature, consisting of a wide range of public and private health care providers, financing agents and financing sources (World Bank, 2019b). An important characteristic of health financing in Egypt is that the flow of funds from sources to financing schemes, to purchasing agents, and to providers, occur without a clear vision about the right pathways. This makes it difficult to effectively coordinate and manage across ministries, sectors (public and private), and entities at all levels of the health system (World Bank, 2015). However, there is very little and scattered information on health care financing in Egypt. Different literature shows diverse information. Therefore, this study aimed to shed light on the pattern of health spending in the Egyptian context and policy implications. In this section, we explored the health care financing structure in Egypt and its comparison to the new system (Q1).

Methodology

A systematic literature review was performed using PRISMA guidelines. For a literature search, three main keywords (Egypt, Health, and Financing) used in Scopus (Peer-reviewed journal) and PubMed. Due to the scarcity of peer-reviewed publications in Egypt about the investigated topic,
grey literature was also visited at the ISPOR databases, and Google. For Google search, the keywords ‘Egypt’, ‘health’, and ‘financing or finance’ were used. Only articles from 2009 to 2019 related to Egypt health care financing were chosen for full-text review. The search was performed on two different dates- 5th and 18th December 2019. The total number of hits from PubMed, Scopus, ISPOR and Google were 76, 236, 23, and 7,700,000 respectively. Out of google search engine hits only the first 100 were screened. The detailed search strategy is presented in Table 1.

A snowball method was used during the full-text review to identify further relevant studies among the references of full-text papers. If a potential study was found, it was added to the full-text review phase. Relevant papers were filtered from the initial search of the different databases and the total number of identified records were 454 articles.

Table 1: Search strategies and number of hits for health care financing in Egypt in different databases

<table>
<thead>
<tr>
<th>Source No.</th>
<th>Search area</th>
<th>Search</th>
<th>Date of search</th>
<th>Number of hits</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PubMed</strong></td>
<td>Combined search</td>
<td>(((Egypt[Title/Abstract]) AND (health[Title/Abstract] OR medica*[Title/Abstract] OR medici*[Title/Abstract]OR pharmaceu*[Title/Abstract])) AND ((finan*[Title/Abstract] OR budget[Title/Abstract] OR expen*[Title/Abstract])) AND (&quot;2009/12/05&quot;[Date - Publication] : &quot;3000&quot;[Date - Publication]))</td>
<td>5/12/2019</td>
<td>76</td>
</tr>
<tr>
<td><strong>SCOPUS</strong></td>
<td>Combined search</td>
<td>(TITLE-ABS-KEY (Egypt) AND TITLE-ABS-KEY (health OR medic* OR pharmac*) AND TITLE-ABS-KEY (financ* OR budget OR expen*)) AND PUBYEAR &gt; 2008</td>
<td>5/12/2019</td>
<td>236</td>
</tr>
<tr>
<td><strong>ISPOR</strong></td>
<td>Scientific presentations database</td>
<td>Egypt AND (health OR medic* OR pharmac*) AND (financ* OR budget OR expen*) *Note: in topics Health Policy &amp; Regulatory OR Health Technology Assessment*</td>
<td>5/12/2019</td>
<td>23</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td>335</td>
</tr>
<tr>
<td><strong>Google</strong></td>
<td>Google search</td>
<td>&quot;Egypt&quot; and Health care and financ* filetype:pdf</td>
<td>8/12/2019</td>
<td>7,700,000 (first 100 were screened)</td>
</tr>
</tbody>
</table>
Screening

An initial screening of publications based on titles and abstracts was performed by two researchers; and disagreements between reviewers were resolved by a principal researcher. The records (titles and abstracts) of the search results were downloaded and imported into the EndNote citation manager (EndNote X9). Due to the overlap of coverage among the databases, the search results were de-duplicated first. Exclusion criteria were built up in a hierarchical order, so that if a record could not be excluded by the first criterion, then it was examined to see if it could be excluded by the second and so forth. The exclusion criteria were the following:

1. No abstract: All articles without abstracts were excluded at this step.
2. Not related specifically to Egypt: Since the literature databases cover health care financing in a lot of countries, studies that are not related to Egypt were excluded at this step.
3. Not related to health care in humans
4. Not related to health care system financing
5. Grey literature excluded due to non-relativeness

Data extraction

After (abstract and title) screening, one reviewer extracted the data from the full-texts and revised by another researcher. Some key themes were extracted and grouped into different categories: General study data (author’s name and year, type of publication, the title of the article, study objective and conclusion), health expenditure in Egypt (total health expenditure as a % of GDP, total health expenditure as a value in billions, governmental/public health expenditure, % of out of pocket payment from total health expenditure, the pharmaceutical expenditure of total health expenditure), private health insurance (% covered by private insurance, types of private insurance schemes available), health insurance payers and their role, the budget of the whole health care system (pharmaceutical budget, medical devices budget, salaries) and data about the providers (freedom of choice of providers from public health care facilities, purchasing of service, purchasing of service description). Data were aggregated to estimate budgets and financing routes.

The articles filtered in different stages and included in the study is shown in Figure 1 below:
Figure 1: Articles filtered and reviewed/PRISMA

Statistical analyses

After extracting the previous data from the full text and excluding non-relevant articles from this step a simple statistic was calculated. For most data extraction categories, descriptive statistics such as median, mean, as well as the minimum and the average values from the latest reported year were recorded. Furthermore, the results in many cases were represented in a box and whisker format showing the whiskers representing the minimum, maximum, as well as the interquartile
range represented in the box boundaries and the median as a line in between, with the mean represented as a cross.

Cost adjustment

Cost data presented per patient were adjusted to population-level using the corresponding population size in the year when the data were reported based on the World Bank population data (World Bank, 2020b). Values that were reported in United States dollars (USD) were converted to Egyptian pounds (EGP) at the year within which the data was reported using the yearly average exchange rate, based on data from the central bank of Egypt (Central Bank of Egypt, 2020). For comparing results from different years, the values were adjusted according to the consumer price index from the world bank for Egypt (World Bank, 2020a). If a year range was used for reporting data, the end value of the range was selected, and in general if more than “>” or less than “<” is written against a number, it was assumed to be the exact value for further calculations like the mean and median calculations.

Results

In this systematic review, studies that describe or assess the health care system financing in Egypt are identified. Of the total of 454 records identified, 335 records were from different databases as following: 236 from Scopus, 76 from PubMed and 23 records from ISPOR database. An additional 119 records were identified from other sources: 100 records from Google search pdf files and 19 records from snowball hits. From the identified records, a total of 380 records were left after duplicates had been removed. Of these 380 records, 290 were excluded. The records met one or more exclusion criterion during title-abstract screening: 7 records had no English abstract, 83 records were not related specifically to Egypt, 31 records were not related to health care in humans, 98 records were not related to health care system financing, 71 grey literatures were non-relative. After title and abstract screening, 90 articles were eligible and reviewed in full text. Of these, 34 studies were excluded at the full text evaluation phase: 4 papers had no data about Egypt, and 25 papers did not contain data about health care system financing. Five papers were excluded due to other reasons. Finally, 56 records were included in the data extraction phase.
Common objectives

Numerous studies have explored and discussed health care system structures and their impact on Universal Health Coverage (UHC) implementation from different perspectives (Abouelmaged, 2019; Colliers International, 2017; El-Zanaty, 2018; Fouda, 2017; George, 2016; Haley, 2012; Hassan, 2012; Ismail, 2018; Radwan, 2019; Saleh, 2014). Other publications were about social justice in health care and compared the current health insurance scheme in Egypt and other countries (Elgazzar, 2009; Government of Egypt, 2013; Mohammadi, 2014; Pande, 2015; Pande, 2017; Rashad, 2015). Many articles and official reports evaluated health care financing in Egypt and the expenditure pattern from governmental and the household (OPP) perspectives (Central Bank of Egypt, 2018; Egyptian Initiative for Personal Rights [EIPR], 2009; Elgazzar, 2010; Giesing, 2019; Nakhimovsky, 2011; Rafeh, 2011; Rashad, 2014; Rashad, 2015; Rizk, 2016; Schneider, 2014; Schofield, 2019). Several articles discussed affordability of drugs and pricing strategies that affected the drug availability some of them highlighting the impact of the 2016 currency devaluation (Abotaleb, 2017; Assefa, 2017; Carapinha, 2017; Diaa, 2011; Elsisi, 2013; Samah, 2015; Wanis, 2015). Few articles highlighted the role of the private health insurance towards UHC implementation and the new opportunities to support the new insurance system (Abbas, 2016; Abouelmaged, 2019; George, 2018; Sustaining Health Outcomes through the Private Sector Project and Health Finance and Governance Project, 2018). One report discussed the region’s health financing landscape, and provided an overview of the private health sector landscape (SHOPS Plus, 2018).

Total health expenditure as a % of GDP

Total Health Expenditure (THE) as a % of Gross Domestic Product (GDP) over the 12 years was ranging from 3.0% (El-Zanaty, 2015) to 7.0% based on 10 articles, with a mean of 5% and median slightly higher 5.5%; whilst the latest average in 2017 was 4% (El-Zanaty, 2015; El-Zanaty, 2018; Radwan, 2019). This shows that THE as % of GDP is almost stagnant if not decreasing over the years, as shown in Figure 2.
THE as a value in billion was calculated and adjusted to year 2019 for 6 articles, the expenditure was ranging from 139 (Saleh, 2014) to 393 billion (Gad, 2016); the mean being 222 billion and with a median of 197 billion (Nakhimovsky, 2011). It shows an increasing trend over a decade as shown in Figure 11. Additionally, the absolute values for expenditure are increased over the years.

Governmental/public health expenditure

Governmental Health Expenditure (GHE) was approximately one-third of the THE. It ranged from 24.8% (Diaa, 2011) to 50% (SHOPS Plus, 2018). The mean was similar to the median (37%), with the latest average in 2016 being 31.2% (Global Burden of Disease Health Financing Collaborator Network, 2020). GHE as a percentage of GDP ranged from 1.8% (Elgazzar, 2009) to 7.3%
(African Development Bank, 2016). Its mean was 3.3% and the median, 2.3%, with the latest average in 2014 being 3.0% (SHOPS Plus, 2018; Sustaining Health Outcomes through the Private Sector Project and Health Finance and Governance Project, 2018). Additionally, Similarly, the mean of GHE as a percentage of governmental expenditure was 6.8%, whilst the median was 5.6% (Colliers International, 2017); a value closer to the minimum of 4.3% (Schneider, 2014). In contrast, the maximum average was extremely higher 24% (Sustaining Health Outcomes through the Private Sector Project and Health Finance and Governance Project, 2018) and most probably differently calculated and was considered an outlier in Figure 8. The latest average in 2017 was 8.7% (El-Zanaty, 2018).

**Figure 4: GHE as % of THE-GDP- Governmental Budget**

GHE as a value in billions increased over years. It ranged from 39 (Egyptian Initiative for Personal Rights [EIPR], 2009) to 111 billion EGP (Pande, 2015), the mean and the median were about 74, and 75 billion EGP respectively, the latest average in 2017 was 111 billion EGP (Pande, 2015). According to the MoF, the government health expenditure in the year 2019-2020 was calculated to be about 73 Billion EGP (Ministry of Finance Egypt, 2019). The fluctuation of the reported values might be partially attributed to the definition of governmental, and public health expenditures. All values are from older studies that does not consider the future status of the new social health insurance system.
Table 2: Governmental Health Expenditure as % of Total Health Expenditure - GDP - Government Budget & Absolute (Adjusted to year 2019)

<table>
<thead>
<tr>
<th></th>
<th>GHE as a % of THE</th>
<th>GHE as a % of GDP</th>
<th>GHE as a % of GE</th>
<th>GHE in Billion EGP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum</td>
<td>24.8%</td>
<td>1.8%</td>
<td>4.3%</td>
<td>38.8</td>
</tr>
<tr>
<td>Mean</td>
<td>36.0%</td>
<td>3.3%</td>
<td>6.8%</td>
<td>73.99</td>
</tr>
<tr>
<td>Median</td>
<td>37.8%</td>
<td>2.3%</td>
<td>5.6%</td>
<td>74.97</td>
</tr>
<tr>
<td>Maximum</td>
<td>50%</td>
<td>7.3%</td>
<td>24%</td>
<td>111.4</td>
</tr>
<tr>
<td>Latest average</td>
<td>31.2%</td>
<td>3%</td>
<td>8.7%</td>
<td>111.4</td>
</tr>
</tbody>
</table>

Out of pocket payment (OPP)

The out of pocket payment as a percentage of total health expenditure was ranging from 41% (Sustaining Health Outcomes through the Private Sector Project and Health Finance and Governance Project, 2018) to 72% (Abbas, 2012). The mean was 63% whereas the median was 60% (Abbas, 2016), with the latest average in 2017 being 56% (Radwan, 2019), as demonstrated in Figure 5.

Figure 5: Out of Pocket Expenditure
The pharmaceutical expenditure percentage of THE ranged from 26.0% (Nakhimovsky, 2011) to 37.0% (Egyptian Initiative for Personal Rights [EIPR], 2009). Its median was 34% (Wanis, 2015), whereas the mean was similar to the latest average in 2011 - 32.5% - (Abbas, 2012; El-Zanaty, 2018), as shown in Figure 6.

The pharmaceutical expenditure after adjustment to the year 2019 mean was 54 billion EGP and the median was 55 billion EGP. The maximum and the latest average in 2009 were the same, 67 billion EGP, whilst the minimum was 40 billion EGP (Nakhimovsky, 2011). The pharmaceutical expenditure percentage of household expenditure was about 43% (Abbas, 2012).

**Health care sectors**

The main health care financing source is OPP which represents more than 60% of THE (Abbas, 2016); then government spending through MoF, which is around 37% of THE. MoF is the main funding source for the Ministry of Health and Population (MoHP), and other different ministries. MoF funds nearly one-third of the total health spending in Egypt (Rashad, 2015). It funds 93% of the MoHP activities, and 72% of the Ministry of Higher Education (MoHE) health care activities. Whereas private agents, including private insurance, syndicate, firms, NGOs, employers (e.g., EgyptAir, The Arab Contractors, etc.), and donors represent the remaining 3%. Listed below are
the major health care sectors in Egypt, categorized into public and private sectors, ending with the new Universal Health Insurance.

**Public Sector**

*Ministry of Health and Population (MoHP)*

The MoHP is the primary government entity which is responsible for providing the preventive and curative services at the primary, secondary, and tertiary levels. Services are subsidized: 80% of them are free and the rest require some user fees (Rashad, 2015; Rizk, 2016). The MoHP was a major and direct funder of parastatal organizations including CCO and THIO (Ismail, 2018; Nakhimovsky, 2011; Rizk, 2016). Aside MoF funding, the MOHP directly collect funds from copayments and user fees. Donors contribute funds via grants and loans for vertical programs - specific programs that focus on certain health condition (El-Zanaty, 2018; Hassan, 2012; Pande, 2015; Rashad, 2015). All uninsured citizens are eligible to use MoHP curative services (Nakhimovsky, 2011), on the other hand they can benefit from the Program for Treatment at the Expense of the State (PTES) as well. PTES expenditure in 2008-2009 was 3 Billion EGP (Nakhimovsky, 2011; Wanis, 2015) which accordingly increased to over 7 billion in year 2019 (Sultan, 2019). User fees collected at Curative Care Organization (CCO) and Teaching Hospitals and Institutes Organization (THIO) are actually retained and used by the MOHP, and therefore do not flow into the national treasury (Ismail, 2018; Nakhimovsky, 2011). MoHP budget was ranging from 3.3% to 4.0% of the annual government budget (Haley, 2010; Saleh, 2014; Wanis, 2015) and reached 15% of health financing in Egypt (Ismail, 2018), which is at the same time equal to 57% of the general government health expenditure (Sustaining Health Outcomes through the Private Sector Project and Health Finance and Governance Project, 2018), 28% of total spending by the MoHP was on medical goods in 2011–2012 (El-Zanaty, 2018).

*Curative Care Organization (CCO)*

CCO provides services for employees of companies with dedicated contracts; it also covers accident cases, private patients, and a limited number of impoverished patients through MOHP grants (El-Zanaty, 2015). CCO has its facilities and relies on different sources of funds such as copayments, general tax, and user fees (El-Zanaty, 2018; Nakhimovsky, 2011; Rashad, 2015). The CCO uses separate funding pools including pools of subsidy from the government for treating the impoverished patients, user fees, Health Insurance Organization (HIO), MOHP, and private companies' contracts (Ministry of Health Egypt, 2010). Different sources report different
breakdowns for the sources of CCO funding but looking at the national health accounts by the USAID, we can see that CCO attributes 46% of its funds from households; 29% from the CCO itself; 4% through contracts with the HIO and the MOHP; and 12% from public firms. In contrast, one paper highlighted that CCO does not receive any subsidy from the government, and hence relies on 100% cost recovery (Rashad, 2015).

**Teaching Hospitals and Institutes (THIO)**

THIO is a separate body under the authority of the Minister of Health, it has its own network of hospitals and specialized institutes. THIO expenditure is estimated at about 1.25% of the THE and 16.5% from MoHP budget (Nakhimovsky, 2011). MOH fund is considered the largest share of its resources 70.8%, followed by revenues coming from providing health care services for a fee to institutes and individuals 29.0%, the donations share is very minor, at about 0.2%. The THIO uses 69% of its funds to finance its hospitals and the remaining 31% for pharmaceuticals (Nakhimovsky, 2011; Rashad, 2015). The THIO budget is collected from MoF fund, MOHP, HIO and private firms through contracts, international donors (through grants), and direct user fees. Half of the THIO’s services are free of charge (Rashad, 2015).

**Health Insurance Organization (HIO)**

The HIO is an independent government organization operating under the supervision of the Minister of Health, that provides compulsory insurance to most of formal sector employees, allowing opting out strategy. Many published articles indicated that HIO coverage exceeds 50% of Egyptians. Between 1994/95 and 2007/08, the percentage of the population insured by the HIO increased from 35% to 55% (Nakhimovsky, 2011). In addition, the HIO expenditures rose three folds within 13 years from 870 million EGP to reach 2.8 billion EGP in 2008 (Ministry of Health Egypt, 2010). This increase was associated with an increase in the number of beneficiaries and a 60% increase in the expenditure per beneficiary (Nakhimovsky, 2011). According to several news sources, the HIO budget witnessed a whopping jump later reaching about 16 billion EGP in 2019 (El Watan News, 2019; Veto Gate, 2018). According to Almasry Alyoum newspaper, it might have increased further to above 20 billion EGP in the fiscal year 2019-2020 (Almasry Al Youm, 2019).

The HIO expenditure represented 8% of the THE, and represented 19% of the governmental budget (Sustaining Health Outcomes through the Private Sector Project and Health Finance and
Governance Project, 2018). The main sources of funds are premiums and employer contributions, beneficiary payments through cost sharing and co-payments in some services accounted for 25% of the service fees, national taxes, payroll taxes; and tobacco ear-marked tax and government subsidization of some population categories; such as students, children under 7 and Female headed household (Egyptian Initiative for Personal Rights [EIPR], 2009; El-Zanaty, 2015; Fouda, 2017; Haley, 2012; Ismail, 2018; Mohammadi, 2014; Rashad, 2015; Shawky, 2010; Sustaining Health Outcomes through the Private Sector Project and Health Finance and Governance Project, 2018).

More than 50% of HIO funding was used to finance HIO hospitals, 19% used for purchasing pharmaceuticals, 4% for other medical goods. The HIO also purchases health care services on behalf of its beneficiaries from non-HIO facilities: MOH hospitals 4.8%, dialysis centers 3.4%, university hospitals 3.1%, and private hospitals 2.0% (Ministry of Health Egypt, 2010).

**Ministry of Higher Education (MoHE)**
The MoHE provides health care services through universities hospitals (Nakhimovsky, 2011). It represented 6.38% of THE (Nakhimovsky, 2011). It is funded through general tax from the MoF (72 %), as well as user fees 27.6%, with donations making up 0.4% of its revenues. The MoHE uses 87 % of its funds to finance their hospitals (includes everything except medication such as infrastructure, medical devices, consumables, staff salaries) and 13% for pharmaceuticals (El-Zanaty, 2018; Nakhimovsky, 2011; Rashad, 2015). The MoHE hospitals budget were reported to be more than 11 billion EGP in 2020 (Youm7, 2020; Youssef, 2020).

**Ministry of Defense MoD & Ministry of Interior MoI**
The Ministry of Defense (MoD) and Ministry of Interior (MoI) provide services for their employees and local civilians, each ministry has its own network of health care facilities (Nakhimovsky, 2011).

**Private Sector**

**Private Medical Insurance**
The percentage of population who are covered by private insurance ranged from 1% (Elgazzar, 2009) to 10% (Abbas, 2016). The mean was 4.3%, whereas the median was 3.0%, with the latest average in 2019 being 5.0% (Abouelmaged, 2019).
**Household out-of-pocket**

OPP is considered the largest source of health care financing. OPP ranged from 41% (Sustaining Health Outcomes through the Private Sector Project and Health Finance and Governance Project, 2018) to 72% (Abbas, 2012). The mean OPP was 63% while the median was 60% (Abbas, 2012), with the latest average in 2017 being 56% (Radwan, 2019), as demonstrated in Figure 9. Private clinics consume the greatest share 38.4%, followed by pharmaceuticals at 33.1%. For hospitalization services, private hospitals receive the chief share 8.2%, followed by MoHP hospitals at 3.5% (Nakhimovsky, 2011).

**Nongovernmental Organizations (NGOs)**

Although Non-governmental Organizations (NGOs) do not contribute significantly to the health care financing budget in Egypt, they play some role in primary health care service provision and raising public awareness (Ministry of Health Egypt, 2010). About one quarter of NGOs funds come from domestic donations and the remaining funds come from external funding sources (Nakhimovsky, 2011).

**Universal Health Insurance**

The UHI is the new entity established to provide UHI services for all Egyptians. The new health insurance system is financed through several sources such as citizen-paid premiums, state budget, government subsidization of the poor, tobacco earmarked tax, copayments (service fees), a contribution of 0.25% of total annual revenues and fees ranging between EGP 1,000 and EGP 15,000 paid by hospitals, medical clinics, treatment centers, pharmacies and pharmaceutical companies to subscribe to the new health insurance system (Colliers International, 2017; Hamza, 2017; Schofield, 2019; Sustaining Health Outcomes through the Private Sector Project and Health Finance and Governance Project, 2018).

The new premiums paid by citizen are as follows: employers would be required to pay a 4% premium of each employee’s salary into the fund (3% for medical insurance + 1% for work injuries and occupational diseases insurance), while employees pay a further 1% premium, which would be deducted from employees’ salary. In addition, breadwinners would pay premiums of an extra 1% for each dependent and 3% for housewives obligatory to cover all family members. The state is responsible for the cost of treatment for those who are unable to fully do so, determined by the Ministry of Social Solidarity according to the Prime Minister decree number 1948 in 2019.
The fees of the Universal Health Insurance for one citizen will range from EGP 1,300 to EGP 4,000, from a mere figure EGP 112 in the current insurance system (Hamza, 2017), and the Egypt’s macroeconomic target to increased spending on health, education and Research and Development - up to at least 10% of GDP (Government of Egypt, 2018).

Provision of the comprehensive basic package will be based on competition and choice among the different public and private service providers, under a single Public and Health Insurance Fund (PHIF) using incentive-based and other provider payment mechanisms (overview of Health system in Egypt).

The health care financing will undergo several changes in the upcoming period. The World Health Organization (WHO) has issued an article titled “Implementing the Universal Health Insurance law of Egypt” which contains diagrams showing the expected changes on health care financing in Egypt. Those are illustrated in Figure 7 & Figure 8.

Figure 7: Current Health Financing System Architecture and Funding Flows

MOHP (Ministry of Health and Population), HIO (Health Insurance Organization), PTES (Program for the Treatment on the Expense of the State), PHC (Primary Health Care), GH (General Hospitals), DH (District Hospitals), SMC (Specialized Medical Centers), GOTHI (General Organization for Teaching Hospitals and Institutes), CCO (Curative Care Organization), OPD (Out-patient department), OOPS (Out of Pocket Payments)
Implication of health care financing structure on the need for HTA system

It can be concluded that the current and planned health financing system provides justification for the implementation of HTA in Egypt and has important implications on its planned structure for several reasons:

- Health care resources are highly limited, which necessitates the efficient allocation of available resources.
- An important policy objective is to reduce OPP expenditure and introduce universal health coverage. As limited incremental resources available for the implementation of universal health coverage due to economic difficulties, it is even more important to use these additional resources in the most cost-effective way.
- The pharmaceutical expenditure from the total health expenditure is relatively high. As in the majority of countries HTA is used to support pharmaceutical policy decisions in the initial implementation phase, it also justify its use to support pharmaceutical pricing and reimbursement decisions before other target areas.
- The fragmented health care financing system necessitates careful central planning of the HTA system with continuous coordination between different HTA units. On the other hand, the UHI is based on reduced fragmentation of health care payers and payer-provider

Source: (Mathauer, 2019)
split, which creates more room for HTA bodies. As such, the new UHI law emphasizes the utilization of health economics for decision making.

Study limitation

Trying to have accurate recent estimates for the budgets and health care spending in Egypt is not an easy task, since the available data is somehow outdated. The latest official data is usually of 2016 or before that. The currency devaluation occurred in Egypt in 2016, so any data reported before 2017 may not be highly relevant presently. However, percentages may still apply. In many cases complementary values might not sum to 100% because the data was extracted from several different sources.

Q1 - What is the health care financing structure in Egypt?

- Egypt has a multiparty health care system, with several different public and private providers and financing sources.
- The governmental part act as one unit encompassing the financing and provider functions under one entity.
- Governmental health expenditure (GHE) as a percent of GDP is about 3%. While according to the parliament obligation in 2019, GHE should not be less than 3% and should gradually increase to match the global levels of THE as a percentage of GDP which is around 10%
- Gigantic out-of-pocket proportion
- Private insurance in Egypt in comparison to countries with a more developed health care system does not currently cover a large proportion of the population, and when it comes to financing, it even has a smaller share.
- The new UHI that will be implemented through six phases ending by 2032 will be trying to tackle the huge out of pocket payments and catastrophic health expenditure issues in several ways, for instance by including all family members in the new insurance scheme and covering the poor from the state budget.
• On completion of the universal health insurance (UHI) system in Egypt, its budget alone should surpass the current total health expenditure increasing THE as a percentage of GDP significantly.

• The current and planned health financing system provides justification for the implementation of HTA in Egypt and has important implications on its planned structure.
Perceived impact of HTA implementation

Introduction
The welfare of patients has always been the core and essence of health care, and accordingly how to choose what is best for patients has always been the ultimate recurring dilemma of those responsible for health care decisions. Advancements in health technologies on one hand and the limited budgets allocated for health care on another, the prevailing era of evidence-based decisions has given rise to the development of health technology assessment.

After the effective utilization of HTA in high-income countries in the European Union, Australia and Canada the anticipation rose regarding what HTA can offer for middle-income countries (MICs), especially securing the financial sustainability needed in UHC. Yet, the impact of formal HTA implementation has not been thoroughly assessed. There is a need to study the evidence on the benefits HTA can offer countries. This is a fundamental step to spread the HTA way of decision-making, bearing in mind that this can be quite challenging due to the absence of formal HTA agencies in most of those countries (Dankó, 2014). Literature on the impact of HTA on decision and policy making in details is quite lacking; an issue which hinders proper HTA appraisal, since the few sources available were not conducted in a formal manner (Raftery, 2013). Thorough appraisal of HTA implications, especially those expected in the long-term, is a very important subject that needs to be addressed (Haily, 2014). Meanwhile, the current focus is more on the short-term policy and administration decisions. This is probably due to the need of extensive resources to conduct a longer term research, however it is achievable through negotiating access to needed resources, and usage of professionally tailored surveys distributed among the correct audience (Haily, 2014).

The aim of the study is to shed light on how HTA adoption impacts the health system, its goals, and to assess the transferability of the benefits and drawbacks expected in MICs from the perspective of local stakeholders (Q2).

Methodology

Literature review
A literature search about the impact of HTA was carried out using Scopus in January 2020. No geographical or economic limitation was posed in the search term. The search terms were
constructed using a combination of domains related to ‘health technology assessment’ and ‘impact’. Proximity operators from Scopus were used to formulate the search term and make it both more comprehensive, and precise at the same time (Table 3). Scopus was chosen because it covers both Embase and MEDLINE databases, in addition to other journals. Search items included the title, abstract, and keywords of the articles.

Table 3: HTA impact search strategy

<table>
<thead>
<tr>
<th>Database</th>
<th>Search Strategy</th>
<th>Date of Search</th>
<th>Hit #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scopus</td>
<td>TITLE-ABS-KEY(&quot;health technology assessment&quot; OR &quot;HTA&quot;) W/15 (benefit* OR consequence* OR impact* OR effect* OR influence*).</td>
<td>18.02.2018 Extended 19.01.2020</td>
<td>1,563</td>
</tr>
</tbody>
</table>

Titles and abstracts of all articles were screened using predefined exclusion criteria; (1) without an abstract; (2) written in languages other than English; (3) not related to impact of HTA implementation; (4) those published before 2013. Title-abstract screening was conducted by two independent reviewers using Endnote and Zotero software’s, and any disagreements were resolved by a senior researcher.

After collecting papers that met the above-mentioned screening criteria, they were reviewed in full text to check their eligibility for data extraction. A standardized data extraction sheet was developed and assessed for fitness for that purpose through a pilot data extraction form that was circulated among reviewers. Afterwards, the extraction sheet was finalized according to the comments and feedback of the reviewers. Screened papers were excluded if: (1) the full-text version was not accessible; (2) duplicated; (3) a book chapter. All extracted data were later double checked by another researcher. The result of this process formed the basis of the qualitative evidence synthesis.

Data extraction process focused on the following research domains: methodology used in data collection (whether the paper reported primary data or based on secondary data such as conclusions of the papers reported elsewhere), the purpose of undertaking HTA (reimbursement, pricing, planning and budgeting, clinical guidelines), impact of HTA including both benefits and drawbacks. Then at a later stage, HTA impacts were categorized according to the broad or
intermediary health system objectives adapted from the World Health Organization (Kutzin, 2008).

The economic status of countries was determined based on the World Bank income categorization (World Bank, 2019b), followed by quality assessment for all papers included in the quantitative analysis. The Standards for Reporting Qualitative Research (SRQR) were used to assess reporting quality of included studies (O’Brien, 2014).

**HTA impact survey in middle-income countries**

To validate the literature review findings and have an in-depth understanding of MICs stakeholders, an online survey was disseminated, using google forms, among selected experts in the health care field from middle-income countries. The survey was broken down into four sections (see Appendix 1): section one was about the respondent demographics; section two was asking about the current status of HTA implementation as well as the current or expected impacts of HTA implementation; section three evaluated expected or perceived impact of HTA implementation on the broad health system goals as well as intermediate objectives of health finance policies (Kutzin, 2008). In the last section, respondents were then asked if they were concordant or not with the findings from the systematic literature review. At the end data usage consent was provided.

To have a reasonable generalizability, the survey was distributed in three countries in three different geographic regions: Egypt, Indonesia, and Ukraine. Different stakeholders were surveyed, representing public, private and academic sectors as well as non-governmental organizations. The ratio of respondents representing different stakeholders was considered during the sample selection.

The survey was first designed by the research team then reviewed by two external experts before dissemination. To avoid selection bias based on English language knowledge, the survey was translated to the Ukrainian language as some respondents were not able to respond to the survey in English. Translation was done by a certified translator, and then reviewed by the research team to make sure the Ukrainian version of the survey is coherent with the original English version.
Results

General SLR results

There were 1,440 papers identified through primary database search after the removal of duplicates. Figure 1 illustrates the literature selection process. After full-text review 113 papers were assessed for eligibility, and 44 were included in the analysis.

The included papers revealed that high-income countries were analyzed 100 times and upper middle-income countries were analyzed 17 times, while low and lower middle-income countries were analyzed only 4 times together (some papers analyzed more than one country). It should be noted that there is a substantial increase in the number of publications across all economic status, indicating rising interest in exploring the impact of HTA. The phenomenon is even more emphasized in middle-income countries in general. Europe and Central Asia region dominated the field by generating the greatest number of assessments (n=82) globally, followed by East Asia and Pacific (n=20) which still exceeds North America’s number of publications (n=9) in the topic, followed by Latin America & Caribbean (n=6).

On the other hand, there are other regions still taking their first steps in the field, such as the Middle East and North Africa (n=2) (Aggarwal, 2014; Yazdizadeh, 2018) South Asia (n=1) (Dang, 2016) and the Sub-Saharan region (Surgey, 2020).
Figure 9: The flow diagram of the Systematic Literature Review
In the 44 publications included in the review, several papers utilized more than one research method, where 16 (37%) publications used literature review in their methodology, three conducted systematic literature reviews, while 9 (20%) collected data through surveys, and 5 (11%) through case studies. Eight (18%) publications used editorial reports专家 commentary in addition to 10 (23%) publications depended on analysis of administrative data, and some included papers did not clarify the methodology used.

Most of the studies (70%) considered HTA to advise reimbursement decisions or to formulate benefit packages, while 45% defined its role in pricing of health technologies. Only few studies considered using HTA for planning and budgeting (20%) or formulating clinical practice guidelines and protocols (23%), or other purposes (18%).

Overall, 75% of included papers discussed only positive impact of HTA on their respective health system; compared to 7% which reported only drawbacks, the remaining 18% reported a mixture of both.

The study by Angelis, (2018) started by a SLR backed up by a survey for primary data collection, which is similar to the method used in our study, yet their study focused mainly on the implementation and outcomes of the conduction of HTA, and did not consider the implication that it may have on their respective health system. It is also included only eight European countries of high income which may influence the transferability of their results to countries of lower economic
status (Angelis, 2018). On the other hand, in a study by Hailey, (2016) did match the aim of our study, in trying to capture the influence/implications of the conduction of HTA on not only economic but also health outcomes of the health system. However, the 19 countries included were of higher economic status (15 high income – 4 upper middle-income countries) in contrast to our study that focused on lower middle-income countries; yet their results depended mainly on secondary data from literature review without any primary data collection. The literature review by Hailey et al recorded 4,767 studies that were identified from the literature search after the removal of duplicates, ending up with 51 included studies. The disparity found in comparing their search outcome to the 1,455 studies we identified from our search, which ended with 44 included studies, is attributed to the difference in the time frames of studies searched for. Hailey’s search covered literature from 2000 till 2014, but was extended to 2015 (15 years), compared to our study which focused on studies published between 2013 and January 2020 (7 years). This represents about half the time horizon, yet the number of included studies was not considerably different (Hailey, 2016).

*Impact of HTA relating to health care system objective*

The broader aim of HTA is improving health systems: two studies (Dang, 2016; Schuller, 2017) support this assumption. Thus, the direct influence of HTA on health systems was assessed. In this study, broad health system goals determined by WHO (Kutzin, 2008) were considered. These include health gain; equity in health; financial protection; equity in finance; and responsiveness. In addition, we adapted three other financing policy objectives & requirements that are instrumental, intermediate objectives to the broad health system goals: transparency and accountability; quality and efficiency in service delivery; fiscal sustainability and administrative efficiency.

The largest impact of HTA was witnessed on intermediate objectives of health finance policies compared with broad health system goals, with 31 (70%) articles reporting impacts related to this category. This is driven by its positive impact on the fiscal sustainability and administrative efficiency, followed by positive impact on the transparency and accountability of the health care system. As regards the direct effect on the broad health system goals it was mainly dominated by the impact of HTA on responsiveness of health systems to the patient needs (48%) and equity in health (45%), while impact on other objectives like direct health gain (27%), and financial
protection (14%) were less evident. The least affected health system objective was equity in finance discussed only in 4 (9%) articles.

HTA contributes to the health gain of the populations through improving patient outcomes (Guthrie, 2015; Hailey, 2016). However, severe restrictions on drug utilisation (Adkins, 2017; Aggarwal, 2014; Angelis, 2018) resulting from HTA barriers may lead to disease progression, which in turn brings a negative impact to the health gain objectives.

Benefits of HTA implementation helps to improve equity in health including better access to drugs which broadens patients’ choices. On the other hand, negative reimbursement decisions might lead to great restrictions when it comes to access. In such context as improving access to orphan drugs, it is suggested that the policymakers consider “accountability for reasonableness” (Culyer, 2012). Moreover, in the comprehensive HTA appraisal, policymakers should take into account equity in the methodological document to improve equity in health (Panteli, 2015).

As HTA strengthens the confidence of payers due to its transparency and accountability, payers in some countries excluded the cost-sharing system for drugs in the positive list (Aggarwal, 2014). This would impact equity in finance. Nevertheless, the increase of drug prices in Japan -with their high co-payment rate- may harm financial equity (Kahveci, 2017). In MICs with high budget restrictions where cost-sharing is applied, HTA is expected to pick the effective treatment and to influence the price negotiation process.

There are several benefits of HTA implementation that supports the improvement of responsiveness, such as broadening of patients’ choices and reducing knowledge gaps. The improvement in responsiveness is directly related to the improvement in knowledge. Accordingly, the HTA team should disseminate clinical guidelines that are easy to use and are acceptable to both patients and physicians (Dillon, 2015). In addition, they should be able to capture the needs of the population. It is preferable that HTA uses real-world data (Godman, 2016).

The dissemination of evidence-based guidelines fills knowledge gaps and improves clinical practice, transparency and communication between medical staff and management, which eventually positively reflects on the efficiency of health care delivery.

As any country faces budget constraints, HTA plays an important role in maintaining the sustainability of health care financing through prioritizing the reimbursement of treatment options.
and exclusion of the ineffective ones. This leads to increase in cost saving, reduction of drug prices, reduction of health expenditure, budget impact minimization, and reduction in length of stay. However, reimbursing high-cost treatment would harm the sustainability of health care financing.
### Table 4: HTA impact summary from the literature

<table>
<thead>
<tr>
<th>Broad health system goals</th>
<th>Health system objectives</th>
<th>Positive impact</th>
<th>Negative impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health gain</td>
<td>HTA increases health benefits of patients along with moderate improvement in clinical efficacy (Chen, 2018; Guthrie, 2015; Hailey, 2016).</td>
<td>ND</td>
<td></td>
</tr>
<tr>
<td>Equity in health</td>
<td>Enables the achievement of greater equity through increasing availability and improving access to innovative health technologies by taming financial barriers such as requiring co-payment at point of access (Aggarwal, 2014; Beletsi, 2018; Callea, 2017; Dabak, 2019; Kanavos, 2019; Nestler-Parr, 2018).</td>
<td>Generates restrictions in accessibility by applying reimbursement for sub-populations or sub-indications (Angelis, 2018).</td>
<td></td>
</tr>
<tr>
<td>Financial protection</td>
<td>Protection of households from catastrophic health spending through different methods such as wavering co-payment of essential drugs (Aggarwal, 2014; Dabak, 2019).</td>
<td>ND</td>
<td></td>
</tr>
<tr>
<td>Equity in finance</td>
<td>Ensuring the accessibility of drugs on the positive list regardless of financial status (Aggarwal, 2014).</td>
<td>ND</td>
<td></td>
</tr>
<tr>
<td>Responsiveness</td>
<td>HTA (including hospital based HTA) accelerates the acceptance of new treatments. This in turn improves patient access to new technologies, providing an array of new choices which cater for diverse patient needs, at the individual and the population levels (Borges, 2018; Gagnon, 2014; Guthrie, 2015; Hailey, 2016; Kanavos, 2019; Kosherbayeva, 2018; Nestler-Parr, 2018; Shafie, 2019).</td>
<td>HTA lacks the ability to incorporate societal values into the decision-making process. HTA tends to slow down decisions due to restrictions generated by the appraisal, which in addition to negative reimbursement decisions hinder patients’ access to health technologies, especially noted in cases of orphan drugs (Adkins, 2017; Aggarwal, 2014; Castro, 2018; Kido, 2019; Van Wilder, 2019; Yazdizadeh, 2018). Negative reimbursement decision led to a strong resistance from clinicians (Schuller, 2017).</td>
<td></td>
</tr>
<tr>
<td>Transparency and accountability</td>
<td>HTA improves transparency and fairness (Aleman, 2017; Angelis, 2018; Borges, 2018; Chen, 2018; Ducournau, 2019; Epstein, 2020; Kao, 2019; Rosén, 2014; Schumacher, 2013; Surdey, 2020; Vostalova, 2017).</td>
<td>Despite the fact that transparency is one of the founding principles of HTA, in real practice it may show the opposite, such as insufficient consultation with experts, manufacturers and patient organizations (Csanádi, 2018).</td>
<td></td>
</tr>
<tr>
<td>Quality and efficiency in service delivery</td>
<td>HTA enables regional decision makers to design more efficient service delivery models by eliminating any uncertainties about clinical effectiveness (Callea, 2019; Kogushi, 2020). Hospital-based HTA improves the quality of medical service through improving clinical practice while integrating patient needs and medical staff capabilities, which ultimately lead to the reduction of patients’ length of stay (Beletsi, 2018; Gagnon, 2014; Kao, 2019; Schuller, 2017).</td>
<td>ND</td>
<td></td>
</tr>
<tr>
<td>Fiscal sustainability &amp; administrative efficiency</td>
<td>HTA induces unit price reduction. It generates cost saving through informing reimbursement and disinvestment decisions, which in the long-term improves technical, and allocative efficiency, as well as strategic pricing. HTA can contribute to budget control to ensure fiscal sustainability (Al-Aqel, 2018; Angelis, 2018; Beletsi, 2018; Borges, 2018; Callea, 2017; Castro, 2018; Dabak, 2019; Dang, 2016; Epstein, 2020; Gagnon, 2014; Guthrie, 2015; Hailey, 2016; Hasegawa, 2020; Kanavos, 2019; Kido, 2019; Leelahavanong, 2019; Mahlich, 2017; Mique-Cases, 2017; Nestler-Parr, 2018; Pearce, 2019; Schuller, 2017; Schumacher, 2013; Surdey, 2020; Tanvejsilp, 2019; Van Wilder, 2019; Vostalova, 2017; Yazdizadeh, 2018). HTA improves pharmaceutical pricing, specially it ensures better value for money of orphan drugs (Kogushi, 2020; Migi, 2018; Nestler-Parr, 2018; Roza, 2019; Vo, 2018). HTA reports help control the demand on novel technologies (Yazdizadeh, 2018). It improves the organizational structure through the establishment of database that documents the administrative processes. (Schumacher, 2013) De-facto HTA could be used to delist ineffective product, set products’ prices, and facilitate price volume agreement/risk sharing scheme. Its implementation results in price cuts and cost shifting. (Lopert, 2013)</td>
<td>Centralized HTA is associated with higher prices for the least expensive product (Callea, 2017). When reviewing already reimbursed technologies HTA may lead to increase in prices based on value for money (Kido, 2018). In Japan HTA resulted in significant increase in drug prices (Mahlich, 2017). De-facto HTA implementation might trigger parallel export as a result of dramatic price cuts (Lopert, 2013).</td>
<td></td>
</tr>
</tbody>
</table>
Aside from the WHO Health system goals mentioned in Table 4, a few more data were found regarding the impact of HTA in the reviewed papers. Some reported that HTA has increases independent research and enhance its quality (Schumacher, 2013), which has led to improvements in guidelines (Guthrie, 2015; Hailey, 2016; Roza, 2019; Vo, 2018). This has further helped in filling the research gap (Guthrie, 2015; Hailey, 2016; Yazdizadeh, 2018) and informing decisions related to inclusion of drugs into the National List of Essential Medicines (Vo, 2018). Additionally, it has increased the private sector share of spending through alternative financing methods and service provision while still identifying additional sources of revenues (Al-Aqeel, 2018).

**HTA impact in middle-income countries**

**Middle Income Countries Literature**

A total of thirteen middle-income countries (according to the WB classification) were discussed 20 times in 16 of the included papers (Aggarwal, 2014; Beletsi, 2018; Borges, 2018; Castro, 2018; Dabak, 2019; Dang, 2016; Hailey, 2016; Kosherbayeva, 2018; Leelahavarong, 2019; Lopert, 2013; Novaes, 2016; Roza, 2019; Shafie, 2019; Vo, 2018; Yazdizadeh, 2018). Most countries reported that HTA enabled the achievement of better decisions.

In Argentina, HTA was reported to generate cost-savings (Dang, 2016). Myanmar’s reported a good experience in using HTA for resource allocation (Dabak, 2019), while Vietnam managed in short time to utilize HTA to maximize the benefits of both old and new technologies to meet public demands (Vo, 2018). In conclusion, most of the studies agreed that HTA could help achieve better health financing decisions (Dang, 2016; Novaes, 2016).

**Lower Middle-Income Countries Survey**

Data were collected from 58 respondents in 3 participant countries (Egypt N=28, Ukraine N=21, Indonesia N=9). Countries were chosen primary to represent middle income countries in different regions and cultures (MENA, Asia, Europe). It was not feasible to include more countries because the whole research was conducted without funding. Participants were asked to choose their affiliation from four options: academia (36%), governmental related (34%), private sector (33%), or non-governmental sector (12%), noting that selection of more than one affiliation was allowed.
HTA progression status in participant countries

Introduction of HTA in lower MICs is still in its early inceptive stages, which was evident when respondents were asked about HTA utilization in their countries. More than half (66%) reported partial HTA implementation in their countries while (29%) reported no HTA implementation. In contrast, (3%) reported full HTA implementation, while (2%) were not aware of HTA implementation status in their country.

Respondents who reported that HTA implementation was progressing in some way in their countries were then asked to choose the main areas where HTA is implemented from four different set options: 1) supporting benefit package/reimbursement decisions, 2) supporting decisions in pharmaceuticals/medical devices, 3) improving clinical practice guidelines/financing protocols, or 4) supporting national, regional or institutional planning/budgeting or others to be mentioned by the respondent.

The majority (75%) reported the use of HTA to inform decisions related to basic benefit packages and/or reimbursement decisions, while half of respondents (50%) reported using HTA to inform health program planning and budgeting. A smaller proportion (20%) reported that HTA is being used for planning and budgeting at national, regional or institutional levels, same proportion (20%) also reported utilizing HTA in improving the clinical practice guidelines and/or their financing protocols. HTA usage to formulate the essential national drug list was only reported by (5%), and finally (3%) reported unawareness of specific defined area for HTA implementation.

![Figure 11: Uses of HTA reported in HTA implementing countries.](image-url)
When respondents were asked about positive HTA implication, most answers revolved around how HTA can improve drug availability and accessibility through the revision of drugs included in the basic benefit package of each country, also improve the performance of the healthcare system through proper allocation of financial resources by improving budgeting and planning decisions, “Support decision making, particularly for national health insurance benefit package”. As for negative implications of HTA, none were mentioned other than questions regarding the cost and time needed to have qualified HTA experts to get it up and running within the health care system. There are indeed many debates, particularly from clinicians because medical aspect is not necessarily hampered by economic or financial issues.

Respondents who reported that HTA was still not implemented or only in the premature phase in their countries were asked to give their opinion about which areas should be prioritized for HTA implementation. They had to choose from five previously set choices and an option to express their own opinion if different from the preset answers.

![Bar chart](image:bar_chart.png)

**Figure 12: Opinion of experts from non-HTA implementing on top priorities for using HTA**

The top chosen priority was reimbursement list/ basic benefit package (44%), followed by formulation of clinical practice guidelines and protocols, and pricing of health products (both 17%) and planning and budgeting of health programs (11%), while 11% opted for other options (HTA would allow better access to more advanced technologies, and improve transparency of medicine reimbursement decisions and procurement decisions allowing more economically feasible health cost allocation process).
The group representing non-HTA implementing countries were then asked about their opinion on how HTA implementation can positively affect the health care system in their country. There was an agreement that HTA implementation would generally have a positive influence, mostly due to rationalizing spending and managing the cost of technologies to be able to equitably distribute health services to improve access. As quote from one of the survey respondents “If done properly (i.e., with account of social solidarity principle), the HTA should secure reimbursement of medicines/medical products and nutrition for vulnerable patient groups, including patients with rare diseases”.

Respondents’ perception towards negative effects of HTA implementation was mild. Most answers were apprehensive not of HTA itself but rather the time required for the HTA program to be implemented and/or integrated in the health care system, which if becomes considerably lengthy, might limit or delay the availability of new products to the public. Others were concerned with the time consumed by the assessment process itself. Others mentioned that if HTA entities were private, they may be manipulated by the pharmaceutical industry.

**Perceived HTA impact on health system objectives**

Respondents were asked about their perception of HTA implementation on the ability of their respective health systems to achieve their goals. Possible answers were positive influence, negative influence, no influence, and not sure/do not know. Respondents reported that HTA implementation would have the most positive influence on transparency and accountability in health care decisions (97%), followed by maximizing health gains of the population (84%), then quality and efficiency in service delivery (81%). These were followed by improving the responsiveness of the health care system to better cater for patients’ needs (72%); a belief that it can help establish fiscal sustainability and administrative efficiency (69%). Equity in finance was the domain perceived be least influenced positively by HTA (64%). It appears that most respondents expect HTA to have a rather positive impact than a negative one as the only a max of 3% thought it would negatively impact the health system goals in 4 domains out of 7.
Table 5: Perceived impact of HTA on health care system goals

<table>
<thead>
<tr>
<th>Domains</th>
<th>Positive influence</th>
<th>Does not influence</th>
<th>I do not know / I am not sure</th>
<th>Negative influence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health gain</td>
<td>84%</td>
<td>3%</td>
<td>12%</td>
<td>0%</td>
</tr>
<tr>
<td>Equity in health</td>
<td>76%</td>
<td>14%</td>
<td>7%</td>
<td>3%</td>
</tr>
<tr>
<td>Financial protection of patients</td>
<td>66%</td>
<td>19%</td>
<td>12%</td>
<td>3%</td>
</tr>
<tr>
<td>Equity in finance</td>
<td>64%</td>
<td>22%</td>
<td>14%</td>
<td>0%</td>
</tr>
<tr>
<td>Responsiveness to patient needs</td>
<td>72%</td>
<td>10%</td>
<td>16%</td>
<td>2%</td>
</tr>
<tr>
<td>Transparency and accountability of health care decisions</td>
<td>97%</td>
<td>2%</td>
<td>2%</td>
<td>0%</td>
</tr>
<tr>
<td>Quality and efficiency in service delivery</td>
<td>81%</td>
<td>10%</td>
<td>9%</td>
<td>0%</td>
</tr>
<tr>
<td>Fiscal sustainability &amp; administrative efficiency</td>
<td>69%</td>
<td>9%</td>
<td>21%</td>
<td>2%</td>
</tr>
</tbody>
</table>

In the final section of the survey, respondents were asked about the expected results regarding implementation of HTA in their respective countries, the results were aggregated in to 15 domains as presented in Table 3. Answers options were either yes, no, or maybe. Majority of respondents believed that HTA would improve the formulation of clinical guidelines (76%), followed by improvement of clinical practice (72%). On the other hand, 67% disagreed that HTA implementation would result in increased prices of selected technologies. Around half of the participants were uncertain towards some domains such as increased patient co-payment, decreased selected health technology prices, and reduction of hospital stay (52%, 48% and 48% respectively).

Table 6: Perceived results of HTA implementation

<table>
<thead>
<tr>
<th>Domain from SLR</th>
<th>Yes</th>
<th>Maybe</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved health outcomes</td>
<td>71%</td>
<td>29%</td>
<td>0%</td>
</tr>
<tr>
<td>Reduced health expenditure</td>
<td>45%</td>
<td>38%</td>
<td>17%</td>
</tr>
<tr>
<td>Cost-savings in selected diseases</td>
<td>67%</td>
<td>31%</td>
<td>2%</td>
</tr>
<tr>
<td>Increased prices of selected health technologies (such as drugs or medical devices)</td>
<td>5%</td>
<td>28%</td>
<td>67%</td>
</tr>
<tr>
<td>Decreased prices of selected health technologies (such as drugs or medical devices)</td>
<td>45%</td>
<td>48%</td>
<td>7%</td>
</tr>
<tr>
<td>Implementation of increased patient co-payment</td>
<td>22%</td>
<td>52%</td>
<td>26%</td>
</tr>
<tr>
<td>Restricted access to drugs due to slower regulatory and reimbursement process</td>
<td>24%</td>
<td>43%</td>
<td>33%</td>
</tr>
<tr>
<td>Restricted access to the expensive (orphan and cancer drug) health technologies due to negative reimbursement decisions</td>
<td>36%</td>
<td>43%</td>
<td>21%</td>
</tr>
<tr>
<td>Improved access to drugs by reducing opportunity cost of inappropriate utilization</td>
<td>71%</td>
<td>22%</td>
<td>7%</td>
</tr>
<tr>
<td></td>
<td>5%</td>
<td>41%</td>
<td>53%</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>-----</td>
<td>-----</td>
<td>-----</td>
</tr>
<tr>
<td>Reduced access to drugs due to parallel exports from countries with lower pharmaceutical prices to countries with higher prices</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reduced knowledge gap among stakeholders</td>
<td>60%</td>
<td>28%</td>
<td>12%</td>
</tr>
<tr>
<td>Improved communication between medical staff and hospital management</td>
<td>62%</td>
<td>31%</td>
<td>7%</td>
</tr>
<tr>
<td>Improved clinical guidelines</td>
<td>76%</td>
<td>21%</td>
<td>3%</td>
</tr>
<tr>
<td>Improved clinical practice</td>
<td>72%</td>
<td>24%</td>
<td>3%</td>
</tr>
<tr>
<td>Reduced length of hospital stays</td>
<td>41%</td>
<td>48%</td>
<td>10%</td>
</tr>
</tbody>
</table>

**Egypt survey findings**

The responses from Egypt were very homogeneous with the responses from other countries, yet Egypt respondents have a slightly more optimistic point of view when it comes to the health system goals.

**Demographics of survey respondents**

In Egypt, 28 persons represented and provided responds to the survey questionnaires. Respondents were asked to choose their association from four options provided: Governmental health-related (57%), Academia (36%), private sector (29%), or non-governmental sector (14%). Selection of more than one choice was allowed.

**HTA Current Structure**

The introduction of HTA in Egypt is still in its early inceptive stages, which became evident when respondents were asked about HTA utilization. Fifty percent (50%) reported partial HTA implementation, while (43%) reported no HTA implementation whatsoever. Only one respondent reported full HTA implementation. When it came to the primary use of HTA, the majority (64%) of respondents considered using HTA to support pharmaceuticals and/or medical devices' pricing decisions. At the same time, 50% considered the use of HTA to inform decisions related to basic benefit packages and/or reimbursement decisions. Only 7 (25%) respondents reported utilizing HTA in improving the clinical practice guidelines and/or their financing protocols followed, by 5 (18%) respondents considering the use of HTA to support planning and budgeting at national, regional or institutional levels.
HTA perceived Impact

HTA impact overview

Positively, HTA can influence pricing of new technologies and generate evidence to support pricing decisions for new pharmaceutical products thereby controlling outrageous prices. Also, HTA will help governmental decision-makers to define best treatment protocols for patients and to evaluate better treatment options for certain diseases. Some respondents indicated that by improving health care services, coupled with effective budget planning it may result in increasing health system effectiveness and coverage, as well as improving quality and efficiency. Furthermore, transparency, explicitness in the process and priority setting may lead to achieving cost efficiency with better clinical benefits. Other respondents also elaborated on improving the health status with quality services without forcing the population into financial hardship would allow more segments of the population with lower income to access quality health care services within reasonable cost, limiting the overpricing of products and allowing the use of the most cost-efficient medication base on clear scientific reasons. At the same time, HTA is perceived to help in decision making, be cost-saving, improve budget efficiency, support quality of health care by effectively assessing supporting evidence on available innovative products with the best quality, decrease system inefficiencies and rationalizing health expenditure.

Regarding respondent’s perception towards negative effects of HTA implementation, most answers were apprehensive not of the HTA itself rather than its time-consuming process. They believed it would take a tremendous effort to hire academic researchers and consultants other than the costs for installing the HTA unit or training of staff that is suitable for the job. Some respondents thought that a lack of qualified HTA experts and its fulfillment on a small scale would lead to weak implementation and bad decisions in some cases. Others were concerned that it would consume more time before the introduction of new medications/interventions. Furthermore, respondents said that HTA is just a tool that is used to reduce prices, and no one would care about its misuse as the market can be manipulated by the domination of huge pharmaceutical companies through HTA agencies. Another respondent also thought that it increases financial burden on people by raising drug prices and/or health care facilities and that stakeholders could use HTA as a source of generating money only.
Perceived HTA impact on respective health systems objectives

Respondents reported that HTA implementation would have the most positive influence on transparency and accountability in health care decisions (96%), followed by maximizing health gains of the population and supporting equity in health (both 89%); after this improving the responsiveness of the health care system to the patient needs (86%); those who believed it can help in establishing quality and efficiency in service delivery (79%); then financial protection of patients (68%). Fiscal sustainability and administrative efficiency followed (61%), with equity in finance being the least positively influenced domain (57%). It appears that almost all respondents expect HTA to have a rather positive impact than a negative impact. Only one respondent thought it would negatively impact the fiscal sustainability & administrative efficiency and none in the other domains.

Table 7: Perceived HTA impact on achieving Health care system goals - Egypt

<table>
<thead>
<tr>
<th>Perceived Impact</th>
<th>Positive influence</th>
<th>Does not influence</th>
<th>I do not know / I am</th>
<th>Negative influence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health gain</td>
<td>89%</td>
<td>4%</td>
<td>7%</td>
<td>0%</td>
</tr>
<tr>
<td>Equity in health</td>
<td>89%</td>
<td>7%</td>
<td>4%</td>
<td>0%</td>
</tr>
<tr>
<td>Financial protection of patients</td>
<td>68%</td>
<td>21%</td>
<td>11%</td>
<td>0%</td>
</tr>
<tr>
<td>Equity in Finance</td>
<td>57%</td>
<td>29%</td>
<td>14%</td>
<td>0%</td>
</tr>
<tr>
<td>Responsiveness to patient needs</td>
<td>86%</td>
<td>7%</td>
<td>7%</td>
<td>0%</td>
</tr>
<tr>
<td>Transparency and accountability of the health care</td>
<td>96%</td>
<td>0%</td>
<td>4%</td>
<td>0%</td>
</tr>
<tr>
<td>decisions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality and efficiency in service delivery</td>
<td>79%</td>
<td>14%</td>
<td>7%</td>
<td>0%</td>
</tr>
<tr>
<td>Fiscal sustainability &amp; administrative efficiency</td>
<td>61%</td>
<td>14%</td>
<td>21%</td>
<td>4%</td>
</tr>
</tbody>
</table>

Transferability of findings from the literature

Based on a previous literature review, frequent HTA implications were assessed by the survey respondents and presented in Table 8. Possible answers were either yes, no, or maybe. The majority of respondents believed that HTA would improve the formulation of clinical guidelines and communication between medical staff and hospital management (both 79%), after that improved access to drugs by reducing the opportunity cost of inappropriate utilization (75%). Improved clinical practice and improved clinical outcomes followed (71%). On the other hand, (54%) disagreed that HTA implementation would result in increased prices of selected health
technologies (such as drugs or medical devices). Around half of the participants were uncertain towards some domains such as an increased patient co-payment, restricted access to drugs due to poor regulatory and slower reimbursement process, reduced access to drugs due to parallel exports from countries with lower pharmaceutical prices to countries with higher prices and reduced health expenditure (57%, 54%, 46% and 46% respectively), which is expected under the limited implementation of HTA scope and experience of the country included in the study.

Table 8: Perceived results of HTA implementation - Egypt

<table>
<thead>
<tr>
<th>Do you think HTA implementation in your country would result in…?</th>
<th>Yes</th>
<th>Maybe</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved health outcomes</td>
<td>71%</td>
<td>29%</td>
<td>0%</td>
</tr>
<tr>
<td>Reduced health expenditure</td>
<td>46%</td>
<td>46%</td>
<td>7%</td>
</tr>
<tr>
<td>Cost-savings in selected diseases</td>
<td>68%</td>
<td>29%</td>
<td>4%</td>
</tr>
<tr>
<td>Increased prices of selected health technologies (such as drugs or medical devices)</td>
<td>11%</td>
<td>36%</td>
<td>54%</td>
</tr>
<tr>
<td>Decreased prices of selected health technologies (such as drugs or medical devices)</td>
<td>32%</td>
<td>68%</td>
<td>0%</td>
</tr>
<tr>
<td>Implementation of increased patient co-payment</td>
<td>29%</td>
<td>57%</td>
<td>14%</td>
</tr>
<tr>
<td>Restricted access to drugs due to slower regulatory and reimbursement process</td>
<td>25%</td>
<td>54%</td>
<td>21%</td>
</tr>
<tr>
<td>Restricted access to the expensive (orphan and cancer drug) health technologies due to negative reimbursement decisions</td>
<td>43%</td>
<td>36%</td>
<td>21%</td>
</tr>
<tr>
<td>Improved access to drugs by reducing opportunity cost of inappropriate utilization</td>
<td>75%</td>
<td>25%</td>
<td>0%</td>
</tr>
<tr>
<td>Reduced access to drugs due to parallel exports from countries with lower pharmaceutical prices to countries with higher prices</td>
<td>11%</td>
<td>46%</td>
<td>43%</td>
</tr>
<tr>
<td>Reduced knowledge gap among stakeholders</td>
<td>54%</td>
<td>36%</td>
<td>11%</td>
</tr>
<tr>
<td>Improved communication between medical staff and hospital management</td>
<td>79%</td>
<td>21%</td>
<td>0%</td>
</tr>
<tr>
<td>Improved clinical guidelines</td>
<td>79%</td>
<td>18%</td>
<td>4%</td>
</tr>
<tr>
<td>Improved clinical practice</td>
<td>71%</td>
<td>25%</td>
<td>4%</td>
</tr>
<tr>
<td>Reduced length of hospital stays</td>
<td>54%</td>
<td>36%</td>
<td>11%</td>
</tr>
</tbody>
</table>
Limitations

However, our study had some limitations including the sample size which was small due to limited available stakeholders in each country with knowledge about the topic especially in Indonesia. Also, the heterogeneity of qualitative data collected from different studies made it harder to aggregate findings. Lastly, literature on the impact of HTA on decision and policy making, in details, is quite scarce, which is an issue that hinders the proper HTA appraisal, since the few sources available were not conducted in a formal manner.

The role of patient organizations in HTA was not considered because patient organizations are in a premature phase in Arab countries (including Egypt), they are mostly established by pharmaceutical companies, and they have limited knowledge about HTA.

Q2 - How does formal HTA implementation affect the performance of health systems in MICs?

- Low and lower middle-income countries were well behind higher income countries in their HTA adoption status and accordingly in their assessment of implications that may accompany HTA implementation.

- Based on international data it was evident that the positive impacts of HTA implementation transcends the negative impacts.

- HTA implementation can introduce a whole myriad of health benefits to health care and health care systems. Although it does have its own shortcomings that are mainly related to benefits (e.g., access to less-effective drugs should be restricted in order to improve allocative efficiency)

- It is clear that HTA can be supportive to control the health care budget in selected areas, however, there is no clear evidence whether it can generate savings at the health care system level especially in underfinanced health care systems of middle-income countries.
Q3 - How do local stakeholders perceive the HTA for decision making in Egypt?

- When considering health system goals, most Egyptian stakeholders expect HTA to have a positive impact rather than a negative one.

- HTA implementation is expected to have the most positive influence on transparency and accountability in health care decisions, followed by maximizing health gains of the population, supporting equity in health, and improving the responsiveness of the health care system to the patient needs.

- HTA implementation is expected to have less influence on fiscal sustainability and administrative efficiency of health care systems and equity in finance.

- HTA is expected to improve access to medicines by reducing the opportunity cost of inappropriate utilization.

- Egyptian stakeholders were uncertain about the impact of HTA on increased patient co-payment, restricted access to drugs due to slower regulatory and reimbursement process.
Current status and future preference for HTA implementation in Egypt

Methodology
A policy survey was conducted in paper form (see appendix 2) on the 11th of July 2018 within a two-day workshop that was held for Egyptian health care decision-makers discussing HTA implementation. A total of 31 local stakeholders including decision-makers, policymakers, public payers and potential HTA users participated in the workshop. The workshop aimed to define the current and the preferred status of HTA in Egypt, in the long run, covering eight areas of HTA roadmap; capacity building, HTA financing, process and organizational structure, the scope of HTA, decision criteria, standardization of methodology, use of local data and international collaboration (Kaló, 2016).

For the dissemination of the HTA roadmap survey online a specifically developed platform was used. It was designed for that purpose specifically. The platform was developed by Syreon Research Institute and the right of utilization of the platform was granted to use it for this research purposes.

Results
31 local stakeholders filled in the survey including 17 decision-makers, policymakers, public payers, potential HTA users from the Ministry of Health. In total, 83.9% indicated employment status in the public sector and 16.1% in the private sector. 48.4 % of respondents had a major training in pharmacy and 22.6% had a major training in medicine and 25.8 % were multidisciplinary (having at least double master degrees in economics, pharmacy or medicine). Most of the respondents fell in the 30 to 50 years age group (74.8%).

HTA capacity building
Project-based HTA workshops or short courses are the most common form of HTA education in Egypt which may not be sufficient to induce hands-on training experience.
Figure 13: Preference for HTA capacity building – (N=31)
Out of the 31 interviewees, 55% were aware of project-based training, while 77% supported the establishment of postgraduate HTA training products in 10 years. About 13% preferred graduate program on HTA.

**HTA funding status**

In total, 87% and 35% of respondents reported no funding for critical appraisal and HTA research, respectively. Almost all respondents (97%) would like to see an increase in funding for critical appraisal. The dominance of public funding was preferred by half (50%) of the respondents compared to 47% for private funding (i.e., submission fees by pharmaceutical companies). Regarding funding for HTA research, the majority of the respondents (94%) preferred to see at least sufficient public funding, while 23% opting for dominant public funding.

**Legislation on HTA**

In response to the question regarding preference on the role of HTA in decision making, eight out of ten respondents (80%) indicated that currently HTA results have no formal role in policy decisions, and 10% reported that only international evidence is considered.
Two-thirds of the respondents (67%) expect that within 10 years, local HTA evidence will be requested in submitted evidence and another one-third (33%) reiterated that it will be mandated in certain domains. Nearly two-thirds of respondents (65%) indicated that there was no public institute for HTA, and 26% reported a committee was appointed, while in the future the majority (83%) opted for some sort of public HTA body.

Regarding the organizational structure, the most preferred option among respondents was establishing a public HTA institute with academic support (47%) or several HTA bodies with a central role.

**Scope of HTA**

Nearly half (48%) of the respondents reported that currently HTA is mainly applied to pharmaceuticals. Most respondents opined that they would increase the utilization of HTA in assessing pharmaceuticals (84%) and extend the scope of HTA to medical devices (87%), prevention program (84%), and surgical interventions (74%). Nearly three-quarters (74%) of the respondents stated that in the future HTA should not only focus on the evaluation of new health technology but also review previous decisions as an essential part of the HTA system.

**Decision criteria**

According to respondents, the current most common decision-making criteria in Egypt is the budget impact (58%) followed by cost-effectiveness (52%). The role of other criteria should also
be increased, such as therapeutic value (from 16% to 84%), health care priority (from 16% to 87%) and unmet medical need (from 13% to 55%). The majority (77%) of the respondents indicated that currently there is no clear threshold for decision making. All respondents are looking for some sort of a threshold in the future. One-fifth (20%) would prefer an implicit threshold, while two-thirds (67%) preferred explicit soft thresholds against 13% preferring to apply hard thresholds as a rule. Almost all (93%) of the respondents indicated that multi-criteria decision analysis (MCDA) should be a preferred method in the future HTA framework.

![Decision criteria chart](image)

**Figure 15: Decision criteria – (N=31)**

**Quality and transparency**

Seven out of ten (70%) respondents indicated that currently no quality elements are applied. In the future, a little more (74%) respondents preferred to having a publicly available critical appraisal checklist, 65% suggested published methodological guidelines for HTA documents and 61% were in favor of the practice of regular follow-up research on previous HTA recommendations.

Similarly, 87% of respondents indicated that currently there is no publication of recommendation and appraisal report. Two-thirds (68%) of the respondents preferred having full transparency by making the HTA body’s recommendations and the related appraisal reports publicly available. Moreover, 83% of answers suggested HTA recommendations and its submissions should be accepted continuously with transparent timelines for issuing recommendations.
Use of local data

While currently, many respondents (73%) indicated that there is no mandate to use local data in HTA, all respondents (100%) preferred relying on local data in the future, 93% would mandate using local data in certain categories with the need for assessing the transferability of international evidence, while the remaining 7% prefer mandating the use of local data but not requiring to assess the transferability of international evidence. All respondents indicated either limited availability or accessibility to local real-world data or that payers’ databases are not accessible for HTA doers. There was a lack of local registries and limited accessibility to payers’ databases. Most of the respondents (73%) were in favor of the ultimate goal of developing the capacity to patient registries or payers’ databases.

Figure 16: Use of local data – (N=31)

International collaboration

Nine out of ten (90%) respondents indicated no involvement in joint work. Most respondents preferred some sorts of international collaboration either by active involvement in joint work initiatives or adaptation of joint HTA documents or appropriate reuse of HTA materials prepared by distinguished international HTA bodies. An overwhelming majority (87%) of participants preferred a high interest in developing and participating in international HTA courses.
Q4 - What is the optimal structure and process for HTA implementation in Egypt?

• Capacity building - More postgraduate HTA programs are recommended based on country-specific needs.

• HTA funding - Public funding should be increased for both HTA research and critical appraisal in addition to increasing the private budget through submission fees to reach balanced funding for critical appraisals.

• Legislation on HTA - Establishment of multiple HTA bodies within a country preferably with central coordination.

• Scope of HTA implementation - Extending the scope of HTA from pharmaceuticals to non-pharmaceuticals is recommended in addition to revising previous policy decisions on top of evaluating new health care technologies.

• Decision criteria - For cost-effectiveness, explicit soft thresholds should be used. Several other criteria than cost-effectiveness and budget impact have to be considered, by applying MCDA.

• Quality and transparency of HTA implementation - Applying multiple methods such as published methodological guidelines and checklists for appraisal are recommended to improve the quality of HTA work. Publication of HTA deliverables and timeliness of HTA processes have to be ensured.

• Use of local data - Developing more patient registries and utilizing local claims data is recommended with the availability of an electronic payer’s database.

• International collaboration - Developing and participating in international HTA courses is highly recommended as well as working on and adapting joint HTA documents on top of work performed by other HTA bodies.
Prospects and plan for HTA implementation in Egypt

Key informant interviews were conducted to validate the findings derived from the preferred HTA status survey in Egypt, with the perspective of feasibility and timeliness, and to provide details about the implementation steps and barriers that might arise while implementing the action plan.

Methodology

One hour telephone/online interviews were conducted with a diverse group of ten key stakeholders representing middle and top tier management of the Egyptian health care system. Interviewee affiliation was multiple. One of the interviewees was from an international organization, while three were from the pharmaceutical industry, and the remaining were from the governmental sector. Furthermore, one of the interviewees worked in an academic institution. Some interviewees were part of the old HIO or the MoHP, whereas others were part of the new UHIA or other newly established bodies like the UMPA, or EDA. Others had overlapping roles from the old system and the new UHC system. The interviewees were selected using a convenience sampling method, utilizing the network of researchers. They were selected based on pre-determined inclusion criteria, having a good understanding of HTA, being influential stakeholders in the Egyptian health care system, and representing different public bodies or the private sector or international organizations. Sex was not a restricted criterion. Open-ended structured questionnaires were used for the interviews; developed based on the eight elements of HTA implementation used by the preferred future policy survey conducted in Egypt (Kaló, 2016).

Each interview started with introducing the research objective, which was followed by a quick brief about the progress of other research steps that preceded this point, then the general structure of the interview was explained, and the eight elements of HTA implementation were listed. The interviewees were asked to comment about the results of the policy survey in all eight elements considering the feasibility of implementation, whether they agree or not and if they would propose any implementation details as well as if they would like to break down the implementation process into phases (short-term 1-2 years, mid-term 3-5 years, or long-term 6-10 years). The interviewees' identity was kept anonymous, and only the aggregated results to be used for research purposes or published.

Results

The results are presented according to the key elements of HTA implementation as stated above.
HTA capacity building

Most of the respondents agreed with the HTA roadmap survey results and recommended more postgraduate HTA programs based on country-specific needs. Half of them opined that technical training (hands-on) should focus not only on theoretical knowledge. Three out of ten pointed out that institutional-based capacity building could be the most appropriate approach. Simultaneously, two of them highlighted that health economics should also be embedded in undergraduate training. One respondent stressed that we need to develop capacities in different specialties and not only health economists with that same background. Three interviewees highlighted that either capacity building is not a priority at the current phase or that we already have enough capacity.

Some interviewees proposed timelines for the development of capacities. In the short term, it is recommended to develop technical skills for those who already attended previous postgraduate training that was focused on theoretical training on technical skills, for example, modeling could be achieved through 3 months to one-year targeted courses and specialized diplomas. There was a common belief that in 3-5 years, there should be another master program in health economics besides Cairo University and make it more technically oriented. Furthermore, in 6-10 years, Egypt should implement Ph.D. program(s) in HTA and/or health economics. It was also highlighted that in 3-5 years, health economics should be injected in undergraduate training more actively, and in general, within five years, Egypt might have the required basic capacities with adequate skills in health economics.

HTA funding

All interviewees agreed with private funding through submission fees and highlighted that Egypt's HTA funding would never be dominantly public funding. They mostly agreed that research works should be powered by manufacturers, while the appraisal should be made with public funding. Only one interviewee did not comment on HTA funding. Although agreeing to private funding through submission fees, two interviewees emphasized that caution must be taken to avoid bias toward the manufacturer that may arise from the power of submission fees. They suggested that the submission fees should be very reasonable, covering only the cost (non-profit).
Legislation on HTA

Most of the interviewees (7 out of 10) were in favor of having a central HTA agency compared to multiple HTA agencies. It was mentioned that there is an expectation for some overlap in the function, and there must be central coordination; otherwise, the scene will be biased. Among those who proposed either a central or multiple HTA agency, the majority preferred the Unified Medical Procurement Authority (UMPA) to house an HTA agency. Only one interviewee proposed the HTA agency to be an independent body. Also, the Egyptian Drug Authority (EDA) was among the frequently mentioned bodies to house an HTA office. For those who proposed multiple HTA bodies they listed the following, in addition to the previously mentioned bodies:

- Universal Health Insurance Authority (UHIA)
- Health Insurance Organization (HIO)
- General Health care Authority (General Health care Authority)
- Supreme Council of University Hospitals
- Armed Forces Medical Service Department

One interviewee emphasized that HTA must be obligatory and not only when requested. Moreover, it should be used for pricing instead of external price referencing.

Scope of HTA implementation

There was an agreement that it is not feasible to start with all technologies; it must be gradual. One interviewee mentioned that non-pharmaceuticals might be a good start, but it will be more challenging because fewer HTA personnel are experts in medical devices, and fewer data would be available. There was a broad consensus among the interviewees (7 out of 10) that we should start assessing innovative high budgets impact pharmaceuticals and gradually widen the scope afterward in the first two years. One interviewee recommended starting with non-pharmaceutical like equipment's expensive low consumption.

In the medium-term (3-5 years), interviewees suggested widening the scope while a few others (n=3) suggested incorporating the revision of previous decisions. It was also suggested to expand to health programs and medical devices, as well as diagnostics and new interventional therapies. Others proposed using HTA for tenders through the utilization of Multi-Criteria Decision Analysis.
(MCDA) especially for out of patent pharmaceuticals. On top of that, it was proposed that HTA should be linked to the pricing certificate phase.

In the long run, it was recommended to go with the full scope of HTA or go with full HTA implementation covering all technologies, including services. The majority recommend considering the revision of previous decisions from 6-10 years, while even some mentioned that it would need more than ten years for implementing revisions of older decisions.

Decision criteria

Interviewees' opinion was split between implementing an explicit or an implicit threshold. One interviewee mentioned that there will be an impediment in implementing an explicit threshold and two sounded the alarm that manufacturers would be pricing their products based on the threshold. Four interviewees suggested using multiple thresholds. One proposed using multiple thresholds based on disease area or severity. Another one proposed different threshold for the public and another one for reimbursement. Two interviewees proposed using a hard threshold while four proposed better using a soft threshold of which two proposed negotiation or Managed Entry Agreements (MEAs).

Most of the interviewees (n=7) emphasized the importance of MCDA; even one said that it is more realistic to start with MCDA. It was mentioned that MCDA is a must for tenders, especially for off-patent pharmaceutical. One of them also focused on the price weight in the MCDA, saying that we should put a reasonable weight on the price. Continuing with MCDA criteria Cost-effectiveness Analysis (CEA) and Budget Impact Analysis (BIA) were labeled as essential as MCDA criteria. It was even mentioned that CEA should be the main criteria, but other criteria must be included—no alternatives, first in class, unmet need, history of manufacturer and health care priority.

Quality and transparency of HTA implementation.

All interviewees agreed with implementing both guidelines and timelines for the HTA process. However, two of them questioned the pragmatism of the implementation of the timelines. Another three expect implementing such guidelines is not feasible in the short term and needs about 3-5 years for full implementation. One interviewee mentioned that within 1-2 years, we could have deliverables and timelines for the process, and within 3-5 years, we can have published guidelines for economic evaluations.
Use of local data

Most interviewees acknowledged the importance of local data uses in HTA, but many raised existing hurdles focusing on the legal accessibility hurdles. One interviewee said, "The problem is not with the data availability as much the possibility to utilize". For that, all data must be stated in a legal framework: the information circulation law should provide advice on what data is allowed to be exchanged and the fees. Data can be extracted as summary statistics, not raw data, to decrease sensitivity. Regarding the data availability, although the quality of available data might not be optimal today, General Health care Authority and UHA both will have useful data because of the currently undergoing automation. It is anticipated that the data would be readily utilized in 3-5 years.

International collaboration

All interviewees supported an international collaboration in general and not reinventing the wheel. They would like to avoid duplication of efforts. One interviewee said that this could be a pivotal point to start all formal HTA implementation, but the political will is questionable. Several bodies were proposed for collaboration, including NICE from the UK, HAS from France, Southeast Asia, South Korea, Taiwan, and Italy. Others proposed European partnerships, especially Eastern Europe, and Tunis because they have experience in formal HTA implementation. In general, they proposed countries with similar economic status and health systems but have a better health state. One interviewee focused on formal collaboration with HTA bodies in the region for training to share experience and especially in providing hands-on training.
### HTA implementation in Egypt action plan

#### Table 9: HTA implementation in Egypt action plan

<table>
<thead>
<tr>
<th></th>
<th>Actions in 1-2 years</th>
<th>3-5 years</th>
<th>6-10 years</th>
</tr>
</thead>
</table>
| **Capacity building**| Postgraduate diploma in HTA focused on country specific needs and technical skills (what will be actually done in routine practice) | 1) Another master program more technical oriented  
2) Undergraduate training in health economics development                                                                 | 1) Train the trainers program  
2) PhD program                                                                                                             |
| **HTA funding**      | 1) Research works should be powered by manufacturers  
2) Set initial submission fees for appraisal                                        | 1) Redefine submission fees based on HTA department cost calculation.                                                |                                                                                                                     |
| **Legislation on HTA**| 1) HTA is obligatory for pricing and reimbursement of selected technologies.  
2) Empower the central HTA unit in EDA for the purpose of OOP pricing and providing guidance and data to UPA, HIO and UHIA.  
3) Establish a supplementary HTA unit in HIO for assessing the budget impact  
4) Establish a supplementary HTA unit at UPA for developing MEAs with manufacturers                                           | 1) Establish a supplementary HTA until within the Universal Health Insurance Authority (UHIA) for the purpose of assessing the budget impact in the organization  
2) Central coordination of HTA activities between the different HTA bodies to avoid duplication of work.                  | Merge the team from the HTA unit from the HIO to the new UHIA                                                             |
<table>
<thead>
<tr>
<th>Scope of HTA implementation</th>
<th>Start assessing innovative pharmaceuticals with high budget impact to support reimbursement decisions.</th>
<th>1) Expand the scope of HTA to cover health programs, medical devices, diagnostics, and interventional therapies for the purpose of reimbursement. 2) Expand the use of HTA for the purpose of OOP pricing</th>
<th>1) full scope of HTA or go with full HTA implementation covering all technologies, including services. 2) revision of previous decisions for reimbursement and OOP pricing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decision criteria</td>
<td>1) Publishing explicit multiple thresholds for OOP pricing and reimbursement by taking into account the severity of disease 2) Implement systematic scientific MCDA in tenders for OOP and medical devices in different organizations 3) Pilot MEAs</td>
<td>The use of systematic, scientific MCDA is obligatory for all tenders.</td>
<td>State MEAs as obligatory for reimbursement</td>
</tr>
<tr>
<td>Quality &amp; transparency</td>
<td>1) Publishing guidelines for the HTA process. 2) Publishing timelines for the HTA process</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use of local data</td>
<td>Several costing studies for different disease areas</td>
<td>Readily use of local data (primarily cost and occasionally real-world evidence) in HTA.</td>
<td>1) National public data bank for HTA input parameters 2) Information circulation law should provide advice on what data is allowed to be exchanged and at what fees</td>
</tr>
<tr>
<td>International collaboration</td>
<td>International partnership in training programs</td>
<td>Partial adaptation of the work of international HTA bodies or organizations</td>
<td>Establishing an international HTA network for collaboration on transferable HTA component with countries with similar economic status and health care structure</td>
</tr>
</tbody>
</table>

*EDA – Egyptian Drug Authority; UPA – Unified Procurement Authority; HIO – Health Insurance Organisation; UHIA - Universal Health Insurance Authority; OOP – Out-of-pocket; MEA – managed entry agreement; MCDA – multicriteria decision analysis*
HTA Implementation in MENA Region

The economic status of countries in the Middle East and North Africa (MENA) is heterogeneous, as the region includes some of the highest income countries globally alongside several low- and middle-income countries (Yorulmaz, 2016). Nonetheless, several commonalities are shared culturally and specifically in health care systems, including the fragmentation of health care provision, financing and efforts to implement universal health coverage. Budget constraints are on the health policy agenda in almost all countries due to several reasons among which: political instability, refugee crisis upscaled economic problems of several low- and middle-income countries. In the recent era of lower oil prices, even high-income Gulf countries are also forced to rethink their public policies, including health policies toward a more cost-conscious direction (Fitch Solutions, 2016).

Whether the objective is to rationalize health care expenditure or increase return on investment, the term health technology assessment (HTA) started to gain attention in countries of the region. Although HTA has been increasingly considered to support health policy decisions in the MENA region, some of the core HTA components, the specific economic evidence is not heavily and formally utilized in pricing and reimbursement decisions of health technologies (World Health Organization [WHO], 2015). While HTA implementation strategies and experiences from other countries can provide guidance, HTA roadmaps are not still fully transferable (Kaló, 2016).

Thus, the implementation of health technology assessment (HTA) is still in the early stage with some heterogeneity in the Middle East and North Africa (MENA). This study aimed to assess the current and future status of HTA implementation in the MENA region focusing on regional commonalities and to recommend middle to long-term objectives considering these commonalities.

Methodology

The study used two different participatory methods, which were:

(i) ISPOR conference: Preparatory discussion in the first ISPOR conference held in Dubai in September 2018 including the satellite meetings held at the MENA policy forum. The preparatory work included several meetings and teleconferences among HTA experts representing different ISPOR teams and MENA organizations. These discussions were so
rich in potentially generalizable conclusions, which resulted in a consensus among experts to summarize the current and future status of HTA implementation in the MENA region in a health policy paper.

(ii) Policy survey: In order to widen the perspective, a policy survey was conducted among 51 conference participants by applying an HTA implementation scorecard that had been designed to support the formulation of HTA roadmaps in developing countries (Kaló, 2016). Current status and future preferences for HTA implementation were explored in eight areas: capacity building; HTA financing; process and organizational structure; the scope of HTA; decision criteria, standardization of methodology; use of local data; and international collaboration.

An online anonymous survey form was distributed to registrants of the ISPOR Dubai conference a few days before the event in September 2018. The link of the survey was emailed to participants from the MENA region and other HTA experts not registered at the conference. A paper-based version of the same survey was distributed during the onsite registration for those conference participants, who had not previously filled in the online survey. The paper-based version of the survey is listed in Appendix 3. Survey response was considered valid if not more than four answers were missing or invalid (e.g., providing multiple answers for a single-choice question, or not answering a question).

Preliminary survey results were presented during the ISPOR Dubai 2018 conference in a policy panel with senior HTA experts from Egypt, Jordan, Kuwait, Lebanon, and Tunisia. The discussion was led by two international HTA professionals from outside the region. Comments of panelists were transcribed and included in the research.

Results
Participants from 11 countries contributed with valid responses to the survey (}
Table 10). More than two-thirds of respondents were from Saudi Arabia, Egypt, Jordan, and Lebanon. Less than four respondents represented Kuwait, United Arab Emirates, Tunisia, Oman, Iran, Yemen, and Qatar.
Table 10: Demographic characteristics of the survey respondents

<table>
<thead>
<tr>
<th>Main employment</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Public sector</td>
<td>28 (54.9%)</td>
</tr>
<tr>
<td>Private sector</td>
<td>23 (45.1%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Major training</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Economics</td>
<td>4 (7.8%)</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>25 (49.0%)</td>
</tr>
<tr>
<td>Medicine</td>
<td>8 (15.7%)</td>
</tr>
<tr>
<td>Other health care (e.g., nursing, dietetics)</td>
<td>6 (11.8%)</td>
</tr>
<tr>
<td>Multidisciplinary (at least two master’s degrees from the above list)</td>
<td>5 (9.8%)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (5.9%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Below 30</td>
<td>9 (17.6%)</td>
</tr>
<tr>
<td>Between 30 and 50</td>
<td>32 (62.7%)</td>
</tr>
<tr>
<td>Above 50</td>
<td>10 (19.6%)</td>
</tr>
</tbody>
</table>

After the exclusion of 39 non-valid responses, 51 responses were aggregated. More than half (55%) of respondents were from the public and academic sector, while 45% were from the private sector - pharmaceutical or medical device manufacturers. About half of the respondents (49%) had primary education in pharmaceutical sciences (Table 11).

Table 11: Aggregated results of valid responses from HTA implementation survey

<table>
<thead>
<tr>
<th>1. HTA Capacity Building</th>
<th>Current</th>
<th>Preferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No training</td>
<td>14 (29.2%)</td>
<td>2 (4.0%)</td>
</tr>
<tr>
<td>Project-based training and short courses</td>
<td>18 (35.4%)</td>
<td>2 (4.0%)</td>
</tr>
<tr>
<td>Permanent graduate program with short courses</td>
<td>5 (10.4%)</td>
<td>8 (16.0%)</td>
</tr>
<tr>
<td>Permanent graduate and postgraduate program with short courses</td>
<td>13 (25.0%)</td>
<td>39 (76.0%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. HTA Funding</th>
<th>Current</th>
<th>Preferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Financing critical appraisal of technology assessment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No funding for critical appraisal of technology assessment reports or submissions</td>
<td>41 (78.0%)</td>
<td>4 (7.8%)</td>
</tr>
<tr>
<td>Dominantly private funding (e.g., submission fees) by manufacturers for the critical appraisal of technology assessment reports or submissions</td>
<td>8 (14.0%)</td>
<td>12 (21.6%)</td>
</tr>
<tr>
<td>Dominantly public funding for critical appraisal of technology assessment reports or submissions</td>
<td>4 (8.0%)</td>
<td>37 (70.6%)</td>
</tr>
<tr>
<td>b) Financing health technology assessment (i.e., HTA research)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No public funding for technology assessment; private funding is not needed or expected</td>
<td>27 (52.0%)</td>
<td>5 (9.8%)</td>
</tr>
<tr>
<td>No or marginal public funding for research in HTA; private funding is expected</td>
<td>19 (38.0%)</td>
<td>7 (11.8%)</td>
</tr>
<tr>
<td>Sufficient public funding for research in HTA; private funding is also expected</td>
<td>2 (4.0%)</td>
<td>20 (39.2%)</td>
</tr>
<tr>
<td>HTA research is dominantly funded from public resources</td>
<td>5 (6.0%)</td>
<td>21 (39.2%)</td>
</tr>
</tbody>
</table>
### 3. Legislation on HTA

#### a) Legislation on the role of the HTA process and recommendations in the decision-making process

<table>
<thead>
<tr>
<th>Current</th>
<th>Preferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>No formal role of HTA in decision-making</td>
<td>27 (55.3%)</td>
</tr>
<tr>
<td>Dominantly international HTA evidence is taken into account in decision-making</td>
<td>17 (36.2%)</td>
</tr>
<tr>
<td>International and additionally local HTA evidence is taken into account in decision-making</td>
<td>4 (8.5%)</td>
</tr>
<tr>
<td>Local HTA evidence is mandatory in decision-making</td>
<td>1 (0.0%)</td>
</tr>
</tbody>
</table>

#### b) Legislation on organizational structure for HTA appraisal

<table>
<thead>
<tr>
<th>Current</th>
<th>Preferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is no public committee or institute for the appraisal process</td>
<td>31 (58.8%)</td>
</tr>
<tr>
<td>A committee is appointed for the appraisal process</td>
<td>12 (21.6%)</td>
</tr>
<tr>
<td>The committee is appointed for the appraisal process with the support of academic centers and independent expert groups</td>
<td>2 (2.0%)</td>
</tr>
<tr>
<td>A public HTA institute or agency is established to conduct a formal appraisal of HTA reports or submissions</td>
<td>2 (3.9%)</td>
</tr>
<tr>
<td>Public HTA institute or agency is established to conduct a formal appraisal of HTA reports or submissions with the support of academic centers and independent expert groups</td>
<td>3 (5.9%)</td>
</tr>
<tr>
<td>Several public HTA bodies are established without central coordination of their activities</td>
<td>4 (7.8%)</td>
</tr>
<tr>
<td>Several public HTA bodies are established with central coordination of their activities</td>
<td>0 (0.0%)</td>
</tr>
</tbody>
</table>

### 4. Scope of HTA Implementation

#### a) Scope of technologies (multiple choice)

<table>
<thead>
<tr>
<th>Current</th>
<th>Preferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>HTA is not applied to any health technologies</td>
<td>26 (51.0%)</td>
</tr>
<tr>
<td>Pharmaceutical products</td>
<td>24 (49.0%)</td>
</tr>
<tr>
<td>Medical devices</td>
<td>7 (14.3%)</td>
</tr>
<tr>
<td>Prevention programs and technologies</td>
<td>2 (4.1%)</td>
</tr>
<tr>
<td>Surgical interventions</td>
<td>1 (2.0%)</td>
</tr>
<tr>
<td>Other scope of technologies (separated by commas)</td>
<td>1 (2.0%)</td>
</tr>
</tbody>
</table>

#### b) Depth of HTA use in pricing and/or reimbursement decision of health technologies

<table>
<thead>
<tr>
<th>Current</th>
<th>Preferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>HTA is not applied to any health technologies</td>
<td>33 (60.8%)</td>
</tr>
<tr>
<td>Only new technologies with significant budget impact</td>
<td>15 (29.4%)</td>
</tr>
<tr>
<td>Only new technologies</td>
<td>2 (3.9%)</td>
</tr>
<tr>
<td>New technologies + revision of previous pricing and reimbursement decisions</td>
<td>3 (5.9%)</td>
</tr>
</tbody>
</table>

### 5. Decision criteria

#### a) Decision categories (multiple choice)

<table>
<thead>
<tr>
<th>Current</th>
<th>Preferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>None of the below categories are applied</td>
<td>17 (33.3%)</td>
</tr>
<tr>
<td>Unmet medical need</td>
<td>12 (19.6%)</td>
</tr>
<tr>
<td>Health care priority</td>
<td>9 (15.7%)</td>
</tr>
<tr>
<td>Assessment of therapeutic value</td>
<td>19 (35.3%)</td>
</tr>
<tr>
<td>Cost-effectiveness</td>
<td>21 (39.2%)</td>
</tr>
<tr>
<td>Budget impact</td>
<td>18 (33.3%)</td>
</tr>
<tr>
<td>Other decision categories</td>
<td>0 (0.0%)</td>
</tr>
</tbody>
</table>
### b) Decision thresholds

<table>
<thead>
<tr>
<th>Description</th>
<th>Current</th>
<th>Preferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thresholds are not applied</td>
<td>36 (70.0%)</td>
<td>3 (5.9%)</td>
</tr>
<tr>
<td>Implicit thresholds are preferred</td>
<td>11 (22.0%)</td>
<td>8 (15.7%)</td>
</tr>
<tr>
<td>Explicit soft thresholds are applied in decisions</td>
<td>4 (6.0%)</td>
<td>27 (51.0%)</td>
</tr>
<tr>
<td>Explicit hard thresholds are applied in decisions</td>
<td>1 (2.0%)</td>
<td>15 (27.5%)</td>
</tr>
</tbody>
</table>

### c) Multi-criteria decision analysis

<table>
<thead>
<tr>
<th>Description</th>
<th>Current</th>
<th>Preferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>No explicit multi criteria decision framework is applied</td>
<td>48 (98.0%)</td>
<td>8 (14.3%)</td>
</tr>
<tr>
<td>Explicit multi criteria decision framework is applied</td>
<td>1 (2.0%)</td>
<td>44 (85.7%)</td>
</tr>
</tbody>
</table>

### 6. Quality and transparency of HTA implementation

#### a) Quality elements of HTA implementation (multiple choice)

<table>
<thead>
<tr>
<th>Description</th>
<th>Current</th>
<th>Preferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>None of the below quality elements are applied</td>
<td>38 (77.6%)</td>
<td>4 (6.1%)</td>
</tr>
<tr>
<td>Published methodological guidelines for HTA/economic evaluation</td>
<td>4 (8.2%)</td>
<td>24 (53.1%)</td>
</tr>
<tr>
<td>Regular follow-up research on HTA recommendations</td>
<td>3 (6.1%)</td>
<td>23 (44.9%)</td>
</tr>
<tr>
<td>A checklist to conduct a formal appraisal of HTA reports or submissions exists but not available for public</td>
<td>6 (10.2%)</td>
<td>19 (36.7%)</td>
</tr>
<tr>
<td>A published checklist is applied to conduct a formal appraisal of HTA reports or submissions</td>
<td>0 (0.0%)</td>
<td>34 (67.3%)</td>
</tr>
</tbody>
</table>

#### b) Transparency of HTA in policy decisions

<table>
<thead>
<tr>
<th>Description</th>
<th>Current</th>
<th>Preferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technology assessment reports, critical appraisal and HTA recommendation are not published</td>
<td>41 (81.6%)</td>
<td>3 (6.0%)</td>
</tr>
<tr>
<td>HTA recommendation is published without details of technology assessment reports and critical appraisal</td>
<td>6 (10.2%)</td>
<td>6 (12.0%)</td>
</tr>
<tr>
<td>Transparent technology assessment reports, critical appraisals and HTA recommendations</td>
<td>4 (8.2%)</td>
<td>44 (82.0%)</td>
</tr>
</tbody>
</table>

#### c) Timeliness

<table>
<thead>
<tr>
<th>Description</th>
<th>Current</th>
<th>Preferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>HTA submission and issuing recommendation have no transparent timelines</td>
<td>42 (85.4%)</td>
<td>6 (12.0%)</td>
</tr>
<tr>
<td>HTA submissions are accepted/conducted following a transparent calendar, but issuing recommendation has no transparent timelines</td>
<td>6 (12.5%)</td>
<td>5 (10.0%)</td>
</tr>
<tr>
<td>HTA submissions are accepted continuously and issuing recommendation has transparent timelines</td>
<td>1 (2.1%)</td>
<td>42 (78.0%)</td>
</tr>
</tbody>
</table>

### 7. Use of local data

#### a) Requirement of using local data in technology assessment

<table>
<thead>
<tr>
<th>Description</th>
<th>Current</th>
<th>Preferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>No mandate to use local data</td>
<td>43 (84.0%)</td>
<td>4 (8.3%)</td>
</tr>
<tr>
<td>The mandate of using local data in certain categories without the need for assessing the transferability of international evidence</td>
<td>4(8.0%)</td>
<td>7 (14.6%)</td>
</tr>
<tr>
<td>The mandate of using local data in certain categories with the need for assessing the transferability of international evidence</td>
<td>4 (8.0%)</td>
<td>39 (77.1%)</td>
</tr>
</tbody>
</table>

#### b) Access and availability of local data

<table>
<thead>
<tr>
<th>Description</th>
<th>Current</th>
<th>Preferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limited availability or accessibility to local real-world data</td>
<td>43 (82.4%)</td>
<td>5 (9.8%)</td>
</tr>
<tr>
<td>Up-to-date patient registries are available in certain disease areas, but payers’ databases are not accessible for HTA doers</td>
<td>7 (13.7%)</td>
<td>4 (7.8%)</td>
</tr>
<tr>
<td>Payers’ databases are accessible for HTA doers, patient registries are not available or accessible in the majority of disease areas</td>
<td>2 (2.0%)</td>
<td>6 (11.8%)</td>
</tr>
<tr>
<td>Up-to-date patient registries are available in certain disease areas and payers’ databases are accessible for HTA doers</td>
<td>1 (2.0%)</td>
<td>39 (70.6%)</td>
</tr>
</tbody>
</table>
### 8. International collaboration

#### a) International collaboration, joint work on HTA (joint assessment reports) and national/regional adaptation (reuse) (multiple choice)

<table>
<thead>
<tr>
<th>Option</th>
<th>Current (%)</th>
<th>Preferred (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No involvement in joint work; and no reuse of joint work or national/regional HTA documents from other countries</td>
<td>36 (75.0%)</td>
<td>2 (4.3%)</td>
</tr>
<tr>
<td>Active involvement in joint work (e.g., EUnet HTA Rapid REA, full Core HTA)</td>
<td>6 (8.3%)</td>
<td>20 (43.5%)</td>
</tr>
<tr>
<td>National/regional adaptation (reuse) of joint HTA documents</td>
<td>9 (18.8%)</td>
<td>27 (56.5%)</td>
</tr>
<tr>
<td>National/regional adaptation (reuse) of national/regional work performed by other HTA bodies in other countries</td>
<td>1 (2.1%)</td>
<td>36 (71.7%)</td>
</tr>
</tbody>
</table>

#### b) International HTA courses for continuous education on HTA

<table>
<thead>
<tr>
<th>Option</th>
<th>Current (%)</th>
<th>Preferred (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limited interest in (1) developing / implementing of and (2) participating at international HTA courses</td>
<td>31 (60.0%)</td>
<td>6 (11.8%)</td>
</tr>
<tr>
<td>Interest only in regular participation at international HTA courses</td>
<td>12 (22.0%)</td>
<td>2 (3.9%)</td>
</tr>
<tr>
<td>High interest in (1) developing / implementing of and (2) participating at international HTA courses</td>
<td>9 (18.0%)</td>
<td>46 (84.3%)</td>
</tr>
</tbody>
</table>
Capacity Building

Three-fourths of the respondents (76%) stressed conducting permanent graduate and postgraduate programs with short courses, which is available currently as perceived by only 25% of the respondents. Similarly, a permanent graduate program with short courses was preferred by 16% which was less available at present (10.4%).

HTA implementation necessitates highly skilled professionals in a multidisciplinary field and capacity building of human resources as a critical element of HTA roadmaps. Nearly two thirds (65%) of respondents indicated limited current options existed for HTA training. Indeed, project-based HTA workshops or short courses – usually sponsored by pharmaceutical companies - are still the most common form of HTA education in the MENA region, which may not be sufficient to induce hands-on training experience. On the other hand, capacity building should not focus only on “HTA doers” with advanced technical skills, because without decision-makers’ understanding and commitment, HTA implementation cannot be accelerated. As a good example, INEAS, the Tunisian HTA body invested in both training of its staff and eminent representatives of different stakeholder groups, including policymakers and clinicians. Training of potential “HTA users” improves general understanding of what can and what should not be expected from HTA implementation, how to frame and scope HTA in countries with limited HTA resources and increase the impact of HTA deliverables in decision-making.

The following are selected examples of interviewees’ quotes during the interviews:

“Undergraduate courses are not optimal for in-depth HTA training, especially for the methodology of economic modeling. However, they are important options to raise awareness, positive attitude, basic knowledge, and understanding of the potential contribution of health care professionals to the HTA process.” “Medical and pharmaceutical education is strong and well established in the MENA region. Furthermore, many health care managers in the region hold MBA degrees, still, these courses have limited HTA related components currently.” “Some universities in Egypt, Jordan, or Lebanon have already launched HTA related subjects to the curriculum of pharmacy or economic undergraduate training.”

“Another way to build capacity is holding intensive training programs within specific organizations, such as the HTA department of the Ministry of Health or even large-scale hospitals.
The capacity building program for hospital pharmacists at King Hussein Cancer Center in Jordan was established based on a needs assessment to tackle the scarcity of HTA analysts. “The Jordanian experience shows that a structured HTA capacity-building program can be developed and implemented even in countries with limited resources.”

In the future, 76% of survey respondents would prefer having permanent postgraduate HTA training (supported by other training tools) in their own countries. Sending students to acquire postgraduate training abroad (e.g., in Europe or North America) is a common practice in several MENA countries to induce the capacity-building process. However, it is not a sustainable long-term solution to overcome limited human resources due to the high cost of living and training abroad and the possibility of talented postgraduates pursuing career opportunities in more developed countries, and never return to their region. This approach may be reasonable to train those future trainers, who can help to establish and lead local academic programs (Kaló, 2013).

If HTA is mandated in local pharmaceutical pricing and reimbursement decisions with a bottleneck on local training opportunities, experienced HTA professionals from the public sector may move to the pharmaceutical industry. The brain drain can be reduced by increased output from local postgraduate courses, which should be accessible at fairly low cost for young talents.

Such postgraduate HTA training has recently started in Egypt, where the first postgraduate diploma in health economics with core HTA components was established in 2012 at the graduate school of the Arab Academy of Science and Technology, followed by a Master program provided in collaboration with the public health department at Faculty of Medicine and Faculty of Political Sciences and Economics at Cairo University in 2014. In 2017, the Faculty of Pharmacy at Monastir in Tunisia launched a post-graduate program in pharmacoconomics, market access and HTA by inviting lecturers from INEAS and the international HTA community (Fasseeh, 2020). A Market Access of Health Products master program at the Lebanese University in Beirut was launched in 2014 with courses on Pharmacoconomics, Pricing and reimbursement of pharmaceuticals and Introduction to HTA (Fasseeh, 2020).

HTA Funding

The success of HTA implementation partially depends on how many financial resources are invested in both HTA phases. The assessment phase focuses on rigorous review and synthesis of
scientific evidence, which is followed by the appraisal phase, the contextualization of assessment results (Kristensen, 2019).

In the policy survey, half (52%) of respondents indicated no public funding for HTA assessment currently whilst 38% reported mainly private funding. Pharmaceutical manufacturers may have an interest in referring to HTA evidence from those countries, where market access to their products is already granted. Some companies have already invested in HTA research in the region, hence, limited sporadic private funding is available in selected MENA countries (Fasseeh, 2020).

In the future, the majority of respondents prefer less dependence on private investment to HTA, hence 39% expect sufficiently and another 39% dominant public funding for HTA research. Reasonable public investment into HTA research is desirable even in less affluent MENA countries, as public funding does not only ensure the sustainability of HTA and reduce conflict of interest but also indicates the political will and the conviction of governmental officials to HTA implementation and its use for decision making in health care. In addition, public funding is necessary to review the appropriateness of previous HTA decisions or conduct multiple technology assessments in which several technologies of different manufacturers are evaluated in priority disease areas.

On the other hand, several middle-income countries, including those in Central and Eastern Europe decided that private industry should be responsible for generating and funding HTA evidence in submission dossiers, and public bodies should mainly be responsible for critically appraising the submitted evidence (Kaló, 2016). In countries with severe resource constraints, the Scottish Medical Consortium (SMC) is often referenced in policy discussions, as the HTA organization in Scotland is quite efficient comparing its work output to its fairly small size and low budget (Kaló, 2016).

Similarly, in the survey, 78% of respondents reported highly limited funding for the appraisal process. In those countries, where there is no dedicated agency to review HTA evidence submitted by pharmaceutical manufacturers, critical appraisal is expected by non-paid HTA committee members. If an HTA agency is established with highly trained employees, more budget is needed for the critical appraisal process. In the future, 22% of survey respondents expect private funding (e.g., submission fees by pharmaceutical manufacturers), and 71% expect public funding (e.g., budget from general government revenues) for the critical appraisal.
Legislation on HTA

Capacity building and securing funding are essential for HTA implementation, but without embedding HTA in the legislation, in other words, making HTA an obligatory step for either pricing or reimbursement of new technologies, the efforts would go in vain. More than half (55%) of respondents indicated that HTA did not have a formal role in their countries, whilst 36% reported that mainly international HTA evidence was considered in policy decisions. Indeed, some experts believe that in resource-constrained countries policymakers may improve evidence of their decisions by relying on HTA recommendations from other countries (Dankó, 2014; Lopert, 2013). Still, 87% of respondents disagreed with this approach by highlighting the need for local HTA evidence in the future.

If the HTA process considers local evidence, a committee may not be sufficient for the appraisal of HTA dossiers. Six out of ten (59%) of respondents reported that HTA was not institutionalized in their countries, 24% reported that only an HTA committee was responsible for providing HTA input into policy decisions in their countries.

For the future, 80% of respondents prefer either a single HTA agency or multiple agencies. The centralization or decentralization of the HTA body is highly dependent on the country size, fragmentation of health care financing, HTA capacities, and readiness of health care systems. Academic support of HTA agencies is more appropriate in those countries, where postgraduate HTA training is available.

Institutionalization of HTA has already been initiated in selected MENA countries. In Saudi Arabia, mandatory HTA for high-cost drugs was initiated through the High-Cost Medication Committee under the Saudi Health Council, supported by a forthcoming HTA center under the Ministry of Health, which has already been budgeted with ongoing implementation. HTA programs have also been initiated at the Drug Policy & Economics Center under the Ministry of National Guard Health Affairs as part of the 2020 National Transformation Program. In Egypt, a pharmacoeconomics unit was officially established in 2011 under the Central Administration of Pharmaceutical Affairs within the Ministry of Health, but HTA is not obligatory for pricing or reimbursement. However, the recent universal health insurance law from 2018 mandates the representation of health economists in the governing boards of the new Universal Health Insurance Authority and the health care provider bodies. In Tunisia, the central HTA body (INEAS)
represents a national authority under the auspices of the Ministry of Health to assess the added benefit and cost-effectiveness of health technologies and provide rigorous evidence-based recommendations to decision-makers on pharmaceuticals and other technologies’ uptake and use. In 2016 the Lebanese Ministry of Public Health (MoHP) drew a Health Strategic Plan for the medium term with a focus on health technology assessment systems and procedures. Jordan started hospital-level HTA at King Hussein Cancer Center (KHCC). The Center for Drug Policy and Technology Assessment at KHCC is responsible for conducting HTAs, their assessments are appraised by the Pharmacy and Therapeutic (P&T) Committee and HTA results are currently utilized to support formulary listing decisions (Fasseeh, 2020).

Scope of HTA

Half of the respondents (51%) stated that HTA was not applied to any health technologies in their countries at present, whereas 49% reported that HTA was utilized to support decisions related to pharmaceuticals, and few reported the current use of HTA for other health technologies. In the future, the majority of respondents prefer extending the scope of HTA to different technologies, including pharmaceuticals (92%), medical devices (78%), prevention programs (66%) and surgical interventions (64%). 63% of respondents believe that in the long-run HTA should not be restricted only to new interventions but should be extended to the revision of previous HTA recommendations because once a technology goes into the benefits package, it is hard to remove it without HTA evidence.

Capacity at the early stages may not be sufficient to support a wide range of services or decision domain, so prioritization is needed. It is important to start embedding HTA in the legislation, even if it does not cover a wide scope of services or decisions (Fasseeh, 2020). First, HTA can be used to advise new pharmaceuticals with high expected budget impact, like what has been done in some MENA countries. In Tunisia, INEAS currently focuses on technologies with high cost or an important impact on the Tunisian health system. At King Hussein Cancer Center (KHCC) in Jordan, HTA has targeted expensive pharmaceuticals. Also, Saudi Arabia has started to use HTA evidence at the national High-Cost Drugs Committee. Once sufficient HTA capacities are available and different stakeholders are aligned about the HTA process, the scope of HTA can be extended to cover all new pharmaceuticals, partly because it is easier to synthesize clinical evidence for pharmaceutical therapies due to the mandatory registration trials. In the next phase, HTA evidence
can be mandated for medical devices, other health technologies and revision of previous HTA recommendations can also be considered.

WHO is playing an important role in framing and scoping of HTA as a pertinent question. The Regional Office for the Eastern Mediterranean has initiated technical missions in several MENA countries to assist Ministries of Health in improving the process for evidence-based health policy decision making.

Decision criteria

Health technology assessment has multiple domains, and individual countries may not necessarily consider all domains in their policy process. Thirty-three percent of respondents indicated that their own country did not consider any decision categories. The most common decision criteria are cost-effectiveness (39%), therapeutic value (35%), and budget impact (33%). In the future, participants prefer considering more categories for decision making including health care priority (76%), therapeutic value (78%), cost-effectiveness (82%), budget impact (84%) and unmet medical need (63%).

Justification of policy decisions based on HTA results can be improved, if decision rule in selected domains of HTA is determined. Decision thresholds are generally applied for the cost-effectiveness criterion. The major differences across countries are 1) whether the threshold is published (i.e., explicit) or not, 2) whether the hard threshold is used as a rule (e.g., if a technology is not cost-effective, it cannot be reimbursed) or the soft threshold is applied as a tool to negotiate about price reductions (e.g., not cost-effective technologies still can be reimbursed with managed entry agreements) and 3) how the threshold is established. Incremental cost-effectiveness ratios may be compared to the economic status of countries, which was initially applied in the WHOM-CHOICE project (Hutubessy, 2003). Although the WHO does not recommend this practice anymore (Garner, 2018), GDP per capita is still the most frequently applied cost-effectiveness threshold (Cameron, 2018). 70% of respondents reported no thresholds in their countries. In the future most respondents would like to have some sort of a threshold, 51% of them prefer selecting an explicit soft threshold.

Multicriteria decision analysis (MCDA) is increasingly used in health care globally to improve the consistency and transparency of policy decisions (Thokala, 2016). Although MCDA has been
applied only in pilot studies in the MENA region (Abdullah, 2019; Fouad, 2017), in the future the majority of respondents (86%) consider the broader utilization of this methodology.

Quality and transparency

The quality of HTA can be improved by multiple approaches. Three-quarters (78%) of respondents were not aware of using any tools for quality improvement in their countries. In the future, however, respondents would prefer having published methodological guidelines (53%), follow-up on HTA recommendations (45%), an internal checklist for the critical appraisal of submitted HTA reports (37%), or even a published critical appraisal checklist to allow HTA doers to conduct self-appraisal of their dossiers before submission (67%).

Leaders of ISPOR Egypt Chapter and the Pharmacoconomics Unit of the Ministry of Health published recommendations for reporting pharmacoeconomic evaluations in Egypt (Elsisi, 2013). In Tunisia, INEAS published HTA submission guidance (clinical part) for pharmaceutical companies (Instance Nationale de l'Evaluation et de l'Accréditation en Santé [INEAS], 2019). In Lebanon, the Ministry of Health, the National Social Security Funds in collaboration with the Lebanese University developed the first Lebanese pharmacoeconomic guidelines.

Transparency of HTA documents is an integral component of justifiable policy decisions. 82% of respondents indicated that these documents were not in the public domain in their countries, however, they prefer publication of technology assessment reports, critical appraisals and HTA recommendations. Tunisia is a good example of HTA transparency, as HTA projects and reports are published on the INEAS website.

Timeliness of HTA is a key element to improve the predictability of evidence-based policy decisions. Eighty-five percent of respondents indicated limited transparency of HTA timelines, however, for the future 78% of respondents advocate that HTA submissions should be accepted continuously and issuing recommendations should have transparent timelines.

Use of local data

Transferring good quality international evidence – typically about the relative effectiveness of technologies - could be beneficial and save resources for local HTAs (Kleijnen, 2014). However, making decisions based on international HTA recommendations without considering limitations
of transferability (especially related to treatment costs) makes more harm than good. Certain elements of HTA reports are transferable, but the adjustment to local data is necessary (Kaló, 2012).

A great majority (84%) of respondents reported that use of local data in the HTA process was not mandated in their countries, while in the future the majority (77%) preferred having the mandate of using local data in certain categories with the need for assessing the transferability of international evidence.

Survey results highlighted the limitations of local data for conducting HTA in MENA countries due to limited availability of patient registries and restricted access to payers’ databases. Although the deficiency of high-quality local data is another barrier in the region currently, efforts to collect and use local data may teach HTA doers how to improve its quality, especially in countries with significant investment in the information technology infrastructure of health care financing and provision. In the future, 82% of respondents would invest in patient registries and make payers’ databases available for HTA doers.

**International collaboration**

The respondents viewed that duplication of efforts in HTA research should be avoided, hence international collaboration among HTA bodies can be highly beneficial. As opposed to the current situation where many of the respondents (75%) reported no involvement in joint international work, almost all (96%) opted for some sort of international collaboration either by active involvement in joint work initiatives or reuse of HTA materials prepared by distinguished international HTA bodies. Efforts of the European Union to facilitate HTA collaboration provides useful experience on how to develop methodology and network for joint HTA work (Kristensen, 2009). On the other hand, joint HTA assessment can also be done for specific technologies in developing countries with a more modest investment (Pichon-Riviere, 2015).

International collaboration may also contribute to the process of capacity building, hence 84% of respondents would prefer developing and/or participating in international HTA courses. In Tunisia, INEAS joined the International Network of Agencies in Health Technology Assessment (INAHTA) in 2015 to facilitate international collaboration.
Similarities and differences between Egypt and other regions in HTA implementation roadmap

Comparing to other countries or regions who implemented the same score card (Romania, Ukraine, MENA, Latin America, Turkey, CEE), we can see consensus on some major elements of HTA implementation, as well as some heterogeneity for some other aspects. Findings in Romania demonstrated that a more efficient HTA system should result from continuous need to enhance the educational and methodological basis of recent operations. Findings also indicated that the evidence gathered locally should be given higher priority in policy decision (Rais, 2018). Romania's roadmap establishes long-term purposes centered on a multi-stakeholder discussion. Ukraine is still in the beginning stages of HTA implementation, with a unique requirement to increase the number of experts involved. On the other hand, more than half (61%) respondents mentioned that currently HTA has no formal role in Ukraine by 2016. All Ukrainian experts support HTA implementations for pharmaceuticals and most of them preferred cost-effectiveness and the health care priority should apply for decision making. Majority of Ukrainian experts (81%) preferred public funding for HTA appraisal in the future. Majority respondents mentioned that local data is not available currently and they preferred use of local data by creating national registry in future. Nearly all respondents preferred publicly available critical appraisal checklist and transparent timeline for HTA submissions and evaluations. On the other hand, significant developments concerning the quality and transparency of the HTA method in Ukraine have lately been enacted: Drafted regulations for planning HTA entries were drawn up and shared with the public; Suggestions on the HTA documents issued by manufacturers were shared publicly (Csanádi, 2018).

At present, HTA execution in MENA countries is still in the initial phase, with specific heterogeneity. The quality of the HTA job must be enhanced by implementing several procedures. Issuing of HTA deliverables and time-frames of HTA operations have to be guaranteed (Fasseeh, 2020). HTA analysis and the accurate review of HTA applications require expanded public funding since execution of HTA is most developed with consistent funding supply. In detail, the survey outcomes revealed limited options for HTA training, as those available were provided as short courses with industry sponsorships. The respondents preferred to see permanent graduate or postgraduate programs in the future.
Western Europe, North America, and Middle-income countries are all progressively using HTA to help health care policy choices (Rosselli, 2017). Latin American countries are upgrading their HTA systems according to their requirements. The nations of Latin America are taking steps in implementing HTA and boosting its inclusion in the decision-making process. However, the survey outcome revealed about half of the respondents were not aware of permanent HTA training. Almost all participants, prefer graduate and postgraduate programs in the future. More than half of the respondents reported that currently, HTA has no formal role during decision making process. On the other hand, almost all respondents prefer to see formal HTA process and use of local data in the future. Most of the participants would prefer to apply HTA for pharmaceuticals, medical devices and prevention programs. Half of the respondent indicated that currently, cost-effectiveness criterion applies for decision making. Almost all respondents prefer to increase role of this criterion together with budget impact and therapeutic value in the future. All respondent suggested to use explicit threshold during decision making process with more than half preferring hard explicit threshold while others prefer soft explicit threshold. Two thirds of respondents were aware of published methodological guidelines for economic evaluations while some respondents mentioned that HTA reports, and appraisals are not publicly available. They supported that this should change to a preferred easy access of HTA reports and appraisal from public web pages. Most of the respondents indicated that use of local data is not currently necessary, but they prefer to use local data in the future. Almost all respondents believe that joining international bodies for collaborative purposes will be helpful for both decision making and capacity building (Fasseeh, 2020).

The similarities of expectations and differences of current practice is obviously clear based on the survey outcomes from our study and previous studies in different regions. Turkey’s successfully implementation of the Universal Health Coverage has not extensively used HTA. Similarly, Ukraine, MENA and Latin American countries are in the beginning of the HTA implementations, Romania has started to improve evidence-based transparency in health policy decisions since 2014. On the other hand, Turkey has been applying economic evaluations for many years but institutionalization of HTA and systematic evaluation methods was not developed as expected (Kahveci, 2017). Differently, Romania has been using international HTA evaluation reports for decision making. Similar with other countries, respondents expect to see graduate and post graduate programs on the future. About half of the respondents support public funding for HTA
appraisal similarly but higher support in Ukraine (81%). Differently, respondents in Romania prefer to balance public and private funding for HTA appraisals. Most of the respondents have same expectation for the role of HTA on decision making. Respondents mentioned that currently, HTA has no formal role and majority of them prefer to apply HTA for decision on the future in Turkey, Ukraine, Romania, MENA and Latin America Region. Budget impact become first criterion and cost-effectiveness is second for all countries mentioned. Respondents support the use of other criteria such as unmet medical need and therapeutic value. Transparency in published methodologic guidelines and checklist for appraisal were expected in Turkey and other countries. The use of local data is currently possible only in Turkey but respondents expect to see accessible real-world data for HTA submissions in the future. On similar line of local data usage, respondents from Turkey, Ukraine, Romania, MENA and Latin America region and countries prefer to use local data in the future (Csanádi, 2018; Fasseeh, 2020; Rais, 2018; Rosselli, 2017).

Several middle-income countries including those in Central and Eastern Europe decided that health technology manufacturers should be responsible for generating and funding HTA evidence in submission dossiers while public bodies be made responsible for critically appraising of the submitted evidence. In countries with severe resource constraints, the Scottish Medical Consortium (SMC) is often referenced in policy discussions, as the HTA organization in Scotland is quite efficient compared to its reasonably small size and low budget (Kaló, 2016). Private funding through submission fees for critical appraisal would be additional financial support to public funding. HTA capacity at the early phases may not be sufficient to support a wide range of services or decision domains, so prioritization is needed. It is crucial to start embedding HTA in the legislation, even if it does not cover a broad scope of services or decisions. First, HTA can be used to advise new pharmaceuticals with high expected budget impact, similar to what has been done in some MENA countries (Fasseeh, 2020).

Comparing Egypt specifically to the Middle East North Africa (MENA) region we can deduce that both are quite similar in the preferred structure of HTA in almost all aspects except for few elements among which is the funding. Egypt tends to go more with private funding rather than public funding compared to the MENA region for both HTA research and appraisal. Furthermore, Egypt tends to put less emphasis on budget impact in the future compared to other countries in the region. Additionally, Egypt is seeking higher confidentiality when it comes to publishing HTA
appraisal results, as Egypt prefers more HTA recommendation to be published without details of technology assessment reports and critical appraisal as opposed by other countries in the MENA region preferring transparency and public sharing of technology assessment reports, critical appraisals and HTA recommendations.
Table 12: Comparison Egypt and Middle East HTA Roadmap

<table>
<thead>
<tr>
<th>Region/Country</th>
<th>Egypt</th>
<th>Middle East</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HTA Capacity Building</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No training</td>
<td>0 (0.0%)</td>
<td>2 (4.0%)</td>
</tr>
<tr>
<td>Project based training and short courses</td>
<td>3 (9.7%)</td>
<td>2 (4.0%)</td>
</tr>
<tr>
<td>Permanent graduate program with short courses</td>
<td>4 (12.9%)</td>
<td>8 (16.0%)</td>
</tr>
<tr>
<td>Permanent graduate and postgraduate program with short courses</td>
<td>24 (77.4%)</td>
<td>39 (76.0%)</td>
</tr>
<tr>
<td><strong>HTA Funding</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Financing critical appraisal of technology assessment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No funding for critical appraisal of technology assessment reports or submissions</td>
<td>1 (3.3%)</td>
<td>4 (7.8%)</td>
</tr>
<tr>
<td>Dominantly private funding (e.g. submission fees) by manufacturers for the critical</td>
<td>14 (46.7%)</td>
<td>12 (21.6%)</td>
</tr>
<tr>
<td>Dominantly public funding for critical appraisal of technology assessment reports or</td>
<td>15 (50.0%)</td>
<td>37 (70.6%)</td>
</tr>
<tr>
<td><strong>Financing health technology assessment (i.e. HTA research)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No public funding for technology assessment; private funding is not needed or</td>
<td>0 (0.0%)</td>
<td>5 (9.8%)</td>
</tr>
<tr>
<td>No or marginal public funding for research in HTA; private funding is expected</td>
<td>2 (6.5%)</td>
<td>7 (11.8%)</td>
</tr>
<tr>
<td>Sufficient public funding for research in HTA; private funding is also expected</td>
<td>22 (71.0%)</td>
<td>20 (39.2%)</td>
</tr>
<tr>
<td>HTA research is dominantly funded from public resources</td>
<td>7 (22.6%)</td>
<td>21 (39.2%)</td>
</tr>
<tr>
<td><strong>Legislation on HTA</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Legislation on the role of HTA process and recommendations in decision-making</td>
<td>0 (0.0%)</td>
<td>4 (8.7%)</td>
</tr>
<tr>
<td>Dominantly international HTA evidence is taken into account in decision-making</td>
<td>0 (0.0%)</td>
<td>2 (4.3%)</td>
</tr>
<tr>
<td>International and additionally local HTA evidence is taken into account in decision-</td>
<td>20 (66.7%)</td>
<td>22 (47.8%)</td>
</tr>
<tr>
<td>Local HTA evidence is mandatory in decision-making</td>
<td>10 (33.3%)</td>
<td>19 (39.1%)</td>
</tr>
<tr>
<td><strong>Legislation on organizational structure for HTA appraisal</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>There is no public committee or institute for the appraisal process</td>
<td>0 (0.0%)</td>
<td>5 (9.8%)</td>
</tr>
<tr>
<td>Committee is appointed for the appraisal process</td>
<td>0 (0.0%)</td>
<td>2 (3.9%)</td>
</tr>
<tr>
<td>Committee is appointed for the appraisal process with support of academic centers and independent expert groups</td>
<td>5 (16.7%)</td>
<td>3 (5.9%)</td>
</tr>
<tr>
<td>A public HTA institute or agency is established to conduct formal appraisal of HTA</td>
<td>4 (13.3%)</td>
<td>3 (5.9%)</td>
</tr>
<tr>
<td>Public HTA institute or agency is established to conduct formal appraisal of HTA</td>
<td>14 (46.7%)</td>
<td>22 (43.1%)</td>
</tr>
<tr>
<td>Several public HTA bodies are established without central coordination of their activities</td>
<td>0 (0.0%)</td>
<td>1 (2.0%)</td>
</tr>
<tr>
<td>Several public HTA bodies are established with central coordination of their activities</td>
<td>7 (23.3%)</td>
<td>17 (29.4%)</td>
</tr>
<tr>
<td><strong>Scope of HTA Implementation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Scope of technologies</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HTA is not applied to any health technologies</td>
<td>0 (0.0%)</td>
<td>4 (4.0%)</td>
</tr>
<tr>
<td>Pharmaceutical products</td>
<td>26 (83.9%)</td>
<td>37 (92.0%)</td>
</tr>
<tr>
<td>Medical devices</td>
<td>27 (87.1%)</td>
<td>37 (78.0%)</td>
</tr>
<tr>
<td>Prevention programs and technologies</td>
<td>26 (83.9%)</td>
<td>34 (66.0%)</td>
</tr>
<tr>
<td>Surgical interventions</td>
<td>23 (74.2%)</td>
<td>34 (64.0%)</td>
</tr>
<tr>
<td>Other scope of technologies (separated by commas)</td>
<td>0 (0.0%)</td>
<td>4 (8.0%)</td>
</tr>
<tr>
<td>Depth of HTA use in pricing and/or reimbursement decision of health</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>HTA is not applied to any health technologies</td>
<td>0 (0.0%)</td>
<td>6 (11.8%)</td>
</tr>
<tr>
<td>Only new technologies with significant budget impact</td>
<td>2 (6.5%)</td>
<td>9 (15.7%)</td>
</tr>
<tr>
<td>Only new technologies</td>
<td>6 (19.4%)</td>
<td>5 (9.8%)</td>
</tr>
<tr>
<td>New technologies + revision of previous pricing and reimbursement decisions</td>
<td>23 (74.2%)</td>
<td>34 (62.7%)</td>
</tr>
</tbody>
</table>

| Decision criteria |
|---------------------------------|---|---|
| Decision categories             |
| None of the below categories are applied | 0 (0.0%) | 3 (2.0%) |
| Unmet medical need              | 17 (54.8%) | 33 (62.7%) |
| Health care priority            | 27 (87.1%) | 40 (76.5%) |
| Assessment of therapeutic value | 26 (83.9%) | 40 (78.4%) |
| Cost-effectiveness              | 22 (71.0%) | 39 (82.4%) |
| Budget impact                   | 17 (54.8%) | 42 (84.3%) |
| Other decision categories       | 1 (3.2%) | 1 (2.0%) |

| Decision thresholds |
|---------------------|---|---|
| Thresholds are not applied | 0 (0.0%) | 3 (5.9%) |
| Implicit thresholds are preferred | 6 (20.0%) | 8 (15.7%) |
| Explicit soft thresholds are applied in decisions | 20 (66.7%) | 27 (51.0%) |
| Explicit hard thresholds are applied in decisions | 4 (13.3%) | 15 (27.5%) |

| Multi-criteria decision analysis |
|----------------------------------|---|---|
| No explicit multi criteria decision framework is applied | 2 (7.4%) | 8 (14.3%) |
| Explicit multi criteria decision framework is applied | 25 (92.6%) | 44 (85.7%) |

| Quality and transparency of HTA implementation |
|-----------------------------------------------|---|---|
| Quality elements of HTA implementation        |
| None of the below quality elements are applied | 0 (0.0%) | 4 (6.1%) |
| Published methodological guidelines for HTA/economic evaluation | 20 (64.5%) | 24 (53.1%) |
| Regular follow-up research on HTA recommendations | 19 (61.3%) | 23 (44.9%) |
| Checklist to conduct formal appraisal of HTA reports or submissions exists but not available for public | 8 (25.8%) | 19 (36.7%) |
| Published checklist is applied to conduct formal appraisal of HTA reports or submissions | 23 (74.2%) | 34 (67.3%) |

| Transparency of HTA in policy decisions |
|----------------------------------------|---|---|
| Technology assessment reports, critical appraisal and HTA recommendation are not published | 0 (0.0%) | 3 (6.0%) |
| HTA recommendation is published without details of technology assessment reports and critical appraisal | 10 (32.3%) | 6 (12.0%) |
| Transparent technology assessment reports, critical appraisals and HTA recommendations | 21 (67.7%) | 44 (82.0%) |

<p>| Timeliness |
|------------|---|---|
| HTA submission and issuing recommendation have no transparent timelines | 1 (3.4%) | 6 (12.0%) |
| HTA submissions are accepted/conducted following a transparent calendar, but issuing recommendation has no transparent timelines | 4 (13.8%) | 5 (10.0%) |
| HTA submissions are accepted continuously and issuing recommendation has transparent timelines | 24 (82.8%) | 42 (78.0%) |</p>
<table>
<thead>
<tr>
<th>Use of local data</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Requirement of using local data in technology assessment</strong></td>
<td></td>
</tr>
<tr>
<td>No mandate to use local data</td>
<td>0 (0.0%) 4 (8.3%)</td>
</tr>
<tr>
<td>Mandate of using local data in certain categories without need for assessing the transferability of international evidence</td>
<td>2 (6.7%) 7 (14.6%)</td>
</tr>
<tr>
<td>Mandate of using local data in certain categories with need for assessing the transferability of international evidence</td>
<td>28 (93.3%) 39 (77.1%)</td>
</tr>
<tr>
<td><strong>Access and availability of local data</strong></td>
<td></td>
</tr>
<tr>
<td>Limited availability or accessibility to local real world data</td>
<td>0 (0.0%) 5 (9.8%)</td>
</tr>
<tr>
<td>Up-to-date patient registries are available in certain disease areas, but payers’ databases are not accessible for HTA doers</td>
<td>2 (6.7%) 4 (7.8%)</td>
</tr>
<tr>
<td>Payers’ databases are accessible for HTA doers, patient registries are not available or accessible in the majority of disease areas</td>
<td>6 (20.0%) 6 (11.8%)</td>
</tr>
<tr>
<td>Up-to-date patient registries are available in certain disease areas and payers’ databases are accessible for HTA doers</td>
<td>22 (73.3%) 39 (70.6%)</td>
</tr>
<tr>
<td><strong>International collaboration</strong></td>
<td></td>
</tr>
<tr>
<td>International collaboration, joint work on HTA (joint assessment reports) and national/regional adaptation (reuse)</td>
<td></td>
</tr>
<tr>
<td>No involvement into joint work; and no reuse of joint work or national/regional HTA documents from other countries</td>
<td>0 (0.0%) 2 (4.3%)</td>
</tr>
<tr>
<td>Active involvement in joint work (e.g. EUnetHTA Rapid REA, full Core HTA)</td>
<td>15 (50.0%) 20 (43.5%)</td>
</tr>
<tr>
<td>National/regional adaptation (reuse) of joint HTA documents</td>
<td>15 (50.0%) 27 (56.5%)</td>
</tr>
<tr>
<td>National/regional adaptation (reuse) of national/regional work performed by other HTA bodies in other countries</td>
<td>15 (50.0%) 36 (71.7%)</td>
</tr>
<tr>
<td><strong>International HTA courses for continuous education on HTA</strong></td>
<td></td>
</tr>
<tr>
<td>Limited interest in (1) developing / implementing of and (2) participating at international HTA courses</td>
<td>0 (0.0%) 6 (11.8%)</td>
</tr>
<tr>
<td>Interest only in regular participation at international HTA courses</td>
<td>4 (12.9%) 2 (3.9%)</td>
</tr>
<tr>
<td>High interest in (1) developing / implementing of and (2) participating at international HTA courses</td>
<td>27 (87.1%) 46 (84.3%)</td>
</tr>
</tbody>
</table>
Q5 - What are the similarities and differences between the HTA implementation roadmap in Egypt and other regions?

- Comparing Egypt specifically to countries in the Middle East North Africa (MENA) region we can find that both are quite similar in the preferred structure of HTA in almost all aspects except for few of the elements.

- Egypt tends to go more with private funding rather than public funding compared to the MENA region for both HTA research and HTA appraisal (i.e., submission fees by pharmaceutical companies).

- Furthermore, Egypt tends to put less emphasis on budget impact in the future compared to the region.

- Also, Egypt is seeking higher confidentiality when it comes to publishing HTA appraisal results, as Egypt prefers more HTA recommendation to be published without details of technology assessment reports and critical appraisal as opposed to the MENA region tending toward transparent technology assessment reports, critical appraisals and HTA recommendations.
DISCUSSION & CONCLUSION

With the implementation of the health care reform in Egypt expanding coverage, the new health care financing structure has increased the government’s burden and at the same time its power, due to the centralization of decision making. The issues of access, safety, efficacy, quality, and equity on health care services have become a growing concern. The introduction of newer health technology in the health care sector highlights other issues such as the lack of medical human capital, availability of resources including infrastructure, access to reliable information for informed decision making and appropriate policy development, fulfilling the unmet needs, and ensuring equity in accessing new technologies. Egypt is facing systemic inequalities and inefficiencies that have severely limited the effectiveness of its health system. Increasing OPP expenditure particularly for utilizing private health facilities is a major problem. The vast majority of Egypt's health spending comes directly from household OPP (World Bank, 2015). The old model of care is being criticized as non-affordable and less cost-effective. However, in the absence of an assessment of the new health technology and the related policies its implementation outcomes are unclear. Moreover, systematic evidence is necessary for informed decision-making and policy development. This study, therefore, posed seven key research questions.

1. How does formal HTA implementation affect the performance of health systems in MICs?
2. Is the current structure of health care expenditure in Egypt proportional to countries with similar economic status?
3. How the current health care expenditure scheme in Egypt supports equity in finance compared to other countries?
4. What is the health care financing structure in Egypt?
5. How do local stakeholders perceive the HTA for decision making in Egypt?
6. What is the optimum structure, and process for HTA implementation in Egypt?
7. What are the similarities and differences between the HTA implementation roadmap in Egypt and other regions?

Systematic literature review (Q 1,4), comparative analyses of an international database on health expenditure (Q2) discussion in the conference through semi-structured interviews (Q5), stakeholder interviews using HTA implementation scorecard (Q6) and survey and targeted grey
literature review (Q7) were undertaken to answer the above research questions and prepare the future roadmap on HTA implementation.

**Health care financing structure in Egypt**

The findings of the systematic review provide an overview of the structure and dynamics of health care financing in Egypt. Only a few peer-reviewed papers were found discussing the health care financing in Egypt, and so most of the data came from grey literature, indicating the topic is under published.

Although values of the same estimate were heterogeneous between different studies, this review gave an outline of the health care financing indicators, structure, funding mechanisms and budgets for different payers in the health care system. Despite an increase in the total health expenditure as an absolute number, THE as a percentage of GDP is decreasing, and when the absolute numbers were adjusted to inflation, the real expenditure in Billion EGP seems to be stagnant in the last couple of years. Governmental health expenditure (GHE) as a percent of GDP ranged from 1.8% (Elgazzar, 2009) to 7% (Sustaining Health Outcomes through the Private Sector Project and Health Finance and Governance Project, 2018) with the two most recent references reporting 3% (El-Zanaty, 2018; World Bank, 2015). While according to the parliament obligation in 2019, GHE should not be less than 3% and should gradually increase to match the global levels of THE as a percentage of GDP which is around 10% (Egyptian Parliament, 2019).

Egypt is a large country geographically and population-wise with a multiparty health care system and several different public and private providers and financing sources. The government acts as one unit encompassing the financing and provider functions under one entity (El-Zanaty, 2015). Correspondingly, the governmental insurance landscape has the same characteristics, which affect the quality of services provided by HIO. Egyptians who have a higher ability to pay, usually utilize private sector facilities and pay out of pocket. Moreover, the major issue in the Egyptian health care financing system is the gigantic out-of-pocket proportion which puts families at a huge financial risk of catastrophic expenditure and a decrease in the performance of the health care system.

Therefore, it was a pressing need for the Egyptian government to seek universal health insurance (UHI) to ensure the availability of health care services to the whole population regardless of their
income level. As a response, the government issued law number 2 for 2018 (Government of Egypt, 2018) that stated the establishment of the new health insurance system in line with sustainable development goal number three (United Nations, 2019) and the sustainable development strategy for Egypt (Central Agency For Public Mobilization And Statistics [CAPMAS], 2016).

The efficiency of health care financing can be improved by increasing the proportion of public funding and reducing fragmentation of financing through implementing the Universal Health Insurance. The new UHI will be trying to tackle the huge out of pocket payments and catastrophic health expenditure issues in several ways, for instance by including all family members in the new insurance scheme and covering the poor from the state budget. However, due to the lack of resources it is difficult to sufficiently finance a comprehensive health care coverage for all Egyptians in one stage, thus the new insurance system will be implemented through six phases by the end of 2032.

On completion of the universal health insurance (UHI) system in Egypt, its budget alone should surpass the current total health expenditure increasing THE as a percentage of GDP significantly. The UHI is based on the unification of the payers and payer-provider split. Furthermore, providers will no more be dominantly public providers instead all providers can enroll under the umbrella of the new system.

Private insurance in Egypt in comparison to countries with a more developed health care system does not currently cover a large proportion of the population, and when it comes to financing, it even has a smaller share. Private health insurance (PHI) can have a new role after implementing UHI, in the form of providing complimentary (CHI) and supplementary health insurance (SHI) in addition to the public health insurance scheme (Abouelmaged, 2019).

Because of the high purchasing power parity of the Egyptian pound, health care services in general are not expensive compared to other countries. However, pharmaceuticals do not strictly adhere to this formula and their prices are closer to global and regional averages compared to other health care services, which results in pharmaceutical expenditure composing a significant part of the health care budget in Egypt compared to other countries, as it presents 32% of THE and 43% of household expenditures (Abbas, 2012; Kaló, 2015).
Overall, even the current health financing system provides justification for the implementation of HTA in Egypt, but in the planned future system there is even greater need for HTA. The health care financing system has important implications on the planned structure of HTA. As such, HTA is expected to play a major role in achieving the Egyptian health care reform objectives. On one hand, the new reform paves way for HTA implementation since the new universal health insurance system is based on reduced fragmentation of public health care payers. On the other hand, the wider range of coverage, in terms of population and services, puts a huge burden on the government. Even if the total health care budget will increase, HTA will be very useful in priority setting for allocation of the scarce health care resources.

Perceived impact of HTA implementation

Health technology assessment adoption’s impact of on health systems, and their goals; as well as assessing the transferability and consequent benefits and drawbacks in MICs from the perception of local stakeholders were assessed through the utilization of secondary data derived from the systematic literature review, as well as primary data generated from dissemination of the survey among local stakeholders.

Our findings revealed that middle-income countries were well behind higher income countries in their HTA adoption status and accordingly in their assessment of implications that may accompany HTA implementation, which might be attributed to lower HTA implementation rates in those countries. Nevertheless, recently there has been a clear rise in HTA activity which is evident in the increased number of publications noticed in the available literature. Still Europe and Central Asia region dominate the global publication arena by generating the greatest number of articles on assessment of HTA implementation impact. However, only a fewer paper is based on analysis of administrative data in comparison to other methods (23%).

It was quite evident in the results of both the literature review and accompanied survey that the positive impacts of HTA implementation transcends the negative impacts. The majority of papers included (almost 75%) in the literature review only discussed positive impact of HTA on their respective health system, while in contrast only 7% reported only drawbacks.

Most papers found in the literature mainly focused on HTA impact on intermediate objectives, and broad health system goals which is influenced by its favorable impact on the fiscal sustainability
& administrative efficiency; in contrast the impact on direct health gain and financial protection was less referred to. According to the survey respondents, the most favorable influence of HTA implementation was on transparency and accountability of health care decisions, followed by maximizing health gains of the population and improving responsiveness of the health care system to better cater patients’ needs. At the same time more than two thirds of respondents believed it can help establish fiscal sustainability and administrative efficiency, and the least observed effect was equity in finance (64%).

In general, it appears that most respondents expect HTA to have a positive impact rather than a negative one; only 3% thought it would have a negative impact on health system goals if ever in 4 domains out of 7. While survey respondents appeared to have very high expectations of HTA implementation, still the introduction of HTA in MICs is still in its incipient stage, and all the three middle-income countries included in our survey do not qualify as a full blown HTA implementation, as their focus was limited to utilizing HTA to inform decisions related to basic benefit packages and/or reimbursement decisions.

Based on the scientific literature, it is clear that HTA can be supportive to control the health care budget in selected areas, however, there is no clear evidence whether it can generate savings at the health care system level. Consequently, it cannot be answered whether those countries who are advanced in HTA implementation could reduce health care expenditure or could have better budget control compared with those countries who were lagging in HTA. Even if a future study can provide the answer based on the experiences in HICs, it is uncertain whether such evidence is transferable to MICs, whose health care systems are relatively underfinanced compared with more affluent countries. Interestingly less survey respondents from MICs also expected that HTA could contribute to financial goals of health care systems in comparison with other benefits. Overall, there is no guarantee that HTA implementation generates cost-savings in relatively underfinanced health care systems of MICs.

HTA is gradually spreading in middle income countries, yet this process should be modulated by continuous assessment of HTA impact during this process to guide it specifically according to their specific conditions rather than using data of other more developed countries. The responses from Egypt are very homogeneous with the responses from other countries yet Egyptian respondents have a slightly more optimistic point of view when it comes to the health system goals.
HTA implementation can introduce a whole myriad of health benefits to health care and health care systems, although it has its own shortcomings that are mainly related to benefits. For example, you need to restrict access to non-effective drugs in order to improve allocative efficiency. There should be a shift in the focus of future HTA policy research to modulating elements of HTA to maximize benefits and reduce risks/drawbacks rather than trying to classify the impact of HTA implementation as positive or negative.

It should be acknowledged that the sample of participants was not representative, which limits the generalizability of conclusions, but this was mostly due to limited research funds and human resources. Furthermore, it is seldom to find stakeholders from different entities with knowledge in HTA who can fully understand and adequately respond to questions. Yet, to our best efforts we tried to include multiple stakeholders representing different entities.

Current status and future preference for HTA implementation in Egypt

There is obvious progress in HTA implementation in Egypt in many aspects, yet ambitions are higher. Currently, Egypt has developed in capacity building from sporadic short courses on health economics to a postgraduate and master degree in health economics, however, more postgraduate and PhD programs are recommended based on country-specific needs. It has also conducted several cost-effectiveness and budget impact analyses in response to requests by the public sector entities. Several criteria such as unmet medical needs and health care priority should be considered to improve HTA implementation as well as applying explicit willingness to pay thresholds. Currently, PEU uses European HTA reports, therefore more emphasis should be given on utilization of local data and the available payer’s database.

Much more efforts should be made to secure HTA funding since there is currently limited funding for critical appraisal of HTA, as well as HTA research by the public sector. It is recommended to increase both public and private funding of HTA activities. Another problem is the existence of a gap between HTA research and actual reimbursement decision making, on top of legal references for HTA in recently published law. The decision-makers need to actively work on materializing HTA implementation. Published methodological guidelines and checklists for appraisal are recommended to overcome the low-quality data issue. Similarly, as in many other countries, HTA in Egypt focuses mainly on pharmaceuticals, especially the new technologies with high budget impact. More efforts are needed to include other technologies in the scope of HTA implementation.
as well as revising previous policy decisions in addition to evaluating all new health care technologies. Egypt should participate in international HTA courses as well as working on and adapting joint HTA documents in addition to work performed by other HTA bodies.

Table 13: HTA Roadmap Summary

<table>
<thead>
<tr>
<th>Capacity building</th>
<th>More postgraduate HTA programs are recommended based on country-specific needs.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HTA funding</td>
<td>Public funding should be increased for both HTA research and critical appraisal in addition to increasing the private budget through submission fees to reach balanced funding for critical appraisals.</td>
</tr>
</tbody>
</table>
| Legislation on HTA| An additional role of local HTA evidence in decision making is needed. There are two main options for the institutionalization of HTA:  
  - A central HTA agency with the support of academic networks  
  - Establishment of multiple HTA bodies within a country preferably with central coordination. |
| Scope of HTA implementation | Extending the scope of HTA from pharmaceuticals to non-pharmaceuticals is recommended in addition to revising previous policy decisions on top of evaluating new health care technologies. |
| Decision criteria | For cost-effectiveness, explicit soft thresholds should be used. Several other criteria than cost-effectiveness and budget impact have to be considered, by applying MCDA. |
| Quality and transparency of HTA implementation | Applying multiple methods such as published methodological guidelines and checklists for appraisal are recommended to improve the quality of HTA work. Publication of HTA deliverables and timeliness of HTA processes have to be ensured. |
| Use of local data | Developing more patient registries and utilizing local claims data is recommended with the availability of an electronic payer’s database. |
| International collaboration | Developing and participating in international HTA courses is highly recommended as well as working on and adapting joint HTA documents on top of work performed by other HTA bodies. |
There are several barriers to HTA implementation considering the current Egyptian situation. Notwithstanding, at the same time, we can see initiatives and some steps are taken, which is indicated by different stakeholders regarding the potentiality of HTA in enhancing the health care system in Egypt. This is hauled by the relatively more developed capacity-building programs. Aside from the rarity of peer-reviewed papers discussing the topic of HTA in Egypt from any aspect, most of the literature reviewed either peer-reviewed or grey literature concurred about the potential benefits of full HTA implementation in Egypt. No publications were found during the literature search discussing systematically a plan for implementing HTA in Egypt.

Our results indicate a need to strengthen the educational and methodological basis of current HTA activities in Egypt which should lead to a more effective HTA system. Findings also point out that the locally collected evidence should get higher priority in policy decisions. Our roadmap should set up long-term objectives based on a multi-stakeholder dialogue.

Comparing Egypt specifically to the Middle East and North Africa (MENA) region, we can find that both are quite similar in the preferred structure of HTA in almost all aspects except for few of the elements among which is the funding. Egypt tends to go more with private funding rather than public funding compared to the MENA region for both HTA research and HTA appraisal. Furthermore, Egypt tends to put less emphasis on budget impact in the future compared to the region. Also, Egypt is seeking higher confidentiality in publishing HTA appraisal results, as Egypt prefers more HTA recommendation to be published without details of technology assessment reports and critical appraisal as opposed to the MENA region, which tends toward transparent technology assessment reports, critical appraisals and HTA recommendations.

Similarly, to the previous section, it should also be acknowledged for the HTA scorecard survey that the sample of participants was not representative, which limits the generalizability of conclusions, but this was mostly due to limited research funds and human resources.

**Prospects and plan for HTA implementation in Egypt**

This section provides summary on how the Egyptian health authorities and other stakeholders perceive HTA roadmap suggested earlier and what could be the optimum structure and process for HTA implementation in Egypt, and finally, proposed action plan as an evolving process.
The findings were informed by phone interviews with a diverse spectrum of stakeholders representing the Egyptian health care system. Their perspectives were focused on the eight elements of HTA implementation in Egypt along with the preferred future policy on HTA. In terms of HTA capacity building, they preferred more post-graduate/Masters HTA programs in the long term and technical skills trainings in the short-term. Regarding HTA funding, all interviewees agreed with private funding through submission fees and highlighted that Egypt's HTA funding would never be dominantly public funding. Few interviewees cautioned potentially manufacturer bias and suggested that the submission fees should be very reasonable. Most of the interviewees were in favor of having a central HTA agency rather than multiple HTA agencies but with a strong coordination mechanism. The majority preferred the Unified Medical Procurement Authority (UMPA) to house an HTA agency. While few other interviewees proposed UHIA, HIO, GHA, supreme council of university hospitals and armed forces medical service department as potential HTA bodies.

Although having only one central HTA agency might seem like the optimal situation especially under the new health care reform since health care financing will be streamlined in Egypt, several public payers will remain (e.g., the Army). Every governmental institute - including Ministry of Health and major public payers and institutes (such as the largest public cancer hospital) - would like to have their own HTA unit to increase their influence. So central coordination of HTA to avoid duplication of efforts might be a realistic target, but it is difficult to have restriction on the number of HTA units.

Similarly, the interviewees suggested gradual development of HTA and that there is a need to start assessing innovative high budgets impact pharmaceuticals and to gradually widen the scope afterward in the first two years. According to them, in the long run, the full scope of HTA could be implemented covering all technologies. The interviewees were diversified in whether decision criteria should be explicit or implicit. Most of them were in favor of multiple soft thresholds. Most of the interviewees emphasized the importance of MCDA with clear criteria for cost-effectiveness analysis (CEA) and budget impact analysis (BIA). They even mentioned that CEA should be the main criteria, but other criteria must be included such as availability of therapeutic alternatives / unmet need, first in class innovation and health care priority. Moreover, all interviewees agreed with implementing both guidelines and timelines for the HTA process. Concerning the use of local
data, most interviewees acknowledged the importance of local data uses in HTA, but many raised existing impediment focusing on the legal accessibility. The interviewees also stressed the need of having international collaboration avoiding duplication and with strong political will particularly with countries having similar economic status and health systems having better health of people.

**Egypt current HTA status**

The first workshop about HTA in Egypt kicked off in 2010. The year 2011 witnessed some significant movement towards establishing HTA in Egypt. The Egyptian chapter of the International Society of Pharmacoeconomics and Outcomes Research (ISPOR) was established, and it has been instrumental in moving the momentum. In the same year, a ministerial decree was signed on the establishment of the Pharmacoeconomics unit (PEU) at the central administration of Pharmaceutical Affairs (CAPA) which is part of the Ministry of Health (MoH). In 2013, recommendations for reporting pharmacoeconomic evaluations in Egypt were published (Elsisi, 2013) as the first step in the development of the national guidelines for the economic evaluation of pharmaceuticals.

The PEU receives requests for cost-based analyses from various public-sector entities such as the Tender/Procurement Department, Health Insurance Organization, Drug Shortage Department, CAPA Pricing Committee and Technical Office. In the past year, PEU has conducted around 18 economic evaluations, including cost-effectiveness and budget impact analyses, and close to 30 evaluations since its inception. The PEU heavily relies on European HTA reports (e.g., NICE) and published clinical data to adapt it to local realities. The Egyptian Drug Authority (EDA) agrees that several processes still have to be accomplished and installed to have HTA streamlined. The EDA recognizes the need for collaboration with the manufacturers and admits that there is a general lack of cost of illness studies and there is a desire for the establishment of a more credible local QALYs system. Still, the Egyptian public payers are the most active in the region in terms of usage of economic evaluation (IMShealth, 2017).

In 2012, the first postgraduate education program in health economics was established at the Arab Academy of Science Technology and Maritime. Before that, only some sporadic courses about Health economics were held intermittently. Since 2014, a 2-year master program in Health Economics has been running in Cairo University as a joint program between the Faculty of
Medicine (Public Health Department), and the Economics Department of the Faculty of Economics and Political science (Cairo University, 2014; Samir, 2018). Moreover, some undergraduate courses were established specifically in Faculties of Pharmacy in public (Elmahdawy, 2016) as well as private universities.

In a presentation at the Regional Forum of the ISPOR African Network the president of the Egyptian ISPOR chapter who was also working in the Central Administration for Pharmaceutical Affairs at that time emphasized the lack of funding and resources for HTA implementation as well as the low quality of data and lack of an explicit willingness to pay threshold in Egypt (Elmahdawy, 2016). Another issue Egypt is confronted with is the gap that exists between HTA research and actual reimbursement decision making (Wild, 2017).

The law of universal health care coverage was published in 2018, which contains a clause for the establishment of the HTA unit within the payer body (Ismaeil, 2018). In 2019 law for unified procurement was published which contain another clause for the establishment of a full department for HTA (Elsisi, 2019).

The introduction of both laws created a need to build up the capacity to fill in required positions within both authorities. In the last quarter of 2019 and for the first time in Egypt, a professional diploma was created to help build capacity in both authorities (Hosny, 2019). Other authorities participated in capacity building programs e.g., Egyptian Drug Authority, Health Insurance Organization and the Army.

As work on this dissertation was completed over a long period of time, some of the action plan elements from the 1-2 years period was already implemented. Table 14 below summarizes the progress till date -July 2021.

Table 14: Current state of HTA Implementation in Egypt (July 2021)

<table>
<thead>
<tr>
<th>Action point</th>
<th>Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>More postgraduate programs (diplomas or similar) focused on technical skills</td>
<td>Fully implemented</td>
</tr>
<tr>
<td>HTA is obligatory for pricing, and reimbursement for selected technologies</td>
<td>Not implemented yet</td>
</tr>
<tr>
<td>Empower the central HTA unit in EDA - pricing, &amp; recommendations</td>
<td>Partially implemented</td>
</tr>
</tbody>
</table>
### Summary conclusions

Based on the research findings the following summary conclusions can be made with regards to the roadmap and implementation of HTA in Egypt:

i. Systematic literature review, interviews, and the online survey suggested positive perception on the likely impact of HTA implementation such as support the pricing decisions of pharmaceuticals and/or medical devices, support benefit package/reimbursement decisions, improve clinical practice guidelines, financing protocols and support in planning and budgeting at various levels, among others. However, improvement in the regulatory process is necessary.

ii. The total health expenditure (THE) in Egypt is low compared to other lower-middle-income countries having similar economic status and the THE as a percentage of GDP is decreasing which is expected to change with the gradual implementation of the UHI. Egypt needs a massive reduction of out-of-pocket (OPP) expenditure to be halved to about 30% by 2032 which is again in line with the implementation of the new UHI. As the preferred single-payer (or at least the less fragmented) health care financing model for Egypt will result in high negotiation power for the UHI governance, efficient resource allocation to maximize return on public investment can be supported with a carefully designed, properly resourced and centrally coordinated HTA system.
iii. Building capacity for the implementation of HTA is crucial. The role of the academic postgraduate program, short-term training and national exposure to international courses and collaboration is highly important for the successful implementation of HTA in the future. There is a need to strengthen the educational and methodological basis of current HTA activities in Egypt.

iv. A clear HTA roadmap with action plan outcomes and timelines and adequate HTA funding is nevertheless important. Similarly, a strong central HTA body, use of explicit MCDA framework, ensuring publication of HTA deliverables and timeliness of HTA processes, strengthening local evidence and data, international collaboration avoiding duplication, enhancing local political will, and adoption of best international and regional practices are considered vital for the success of the HTA implementation in Egypt. Unified Medical Procurement Authority (UMPA) is recommended by all the stakeholders.

v. Most Egyptian stakeholders are in favor of determining multiple and soft thresholds as decision rules in HTA. Most of them preferred aggregating different HTA domains in MCDA with clear criteria for cost-effectiveness analysis (CEA) and budget impact analysis (BIA).
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SUMMARY

With the implementation of the health care reform in Egypt, the government will have high negotiation power due to the extended beneficiary coverage and expanding the benefits package, which can eventually help to improve the efficiency of resource allocation and maximize health outcomes. Health technology assessment (HTA) is an important tool to increase the evidence base of resource allocation decisions. Given the complex and fragmented structure of the Egyptian health care system, as well as the relatively low GDP per capita, differences in social values, it is not recommended to directly adopt decision-making practices from high-income countries - not even other middle-income countries (MICs) - without adjustment to local values and traditions. Despite benefiting from the experiences of others, Egypt needs to build up its own HTA architecture. Currently, HTA implementation is taking its first steps in Egypt with some visible achievements. The purpose of this study is to explore long-term objectives in HTA implementation in Egypt and propose specific actions over the next ten years. Evaluation of current and preferred status of HTA highlighted the most important gaps to set objectives for the HTA roadmap. Local experts validated the roadmap for feasibility and applicability, developing a chronological set of actions for HTA implementation in Egypt.

National experts agreed that several actions are vital for HTA implementation in Egypt, including coordination between HTA bodies and strengthening local evidence generation. They also recommended using innovative tools like "multicriteria decision analysis (MCDA)" for procurement of health technologies and "managed entry agreements" for reimbursement of high-cost medicines. To implement these actions, investment in technical capacity building is indispensable. Most of the experts favored using multiple and soft cost-effectiveness thresholds for the value judgement of health technologies. Experts recommended that HTA should initially be used to assess innovative pharmaceuticals then expand the scope to cover other health technologies in the longer term.
ÖSSZEFÖGGLALÓ

Az egészségügyi reform előrehaladtával a biztosítottak számának növelése és a biztosítói csomag kiterjesztése miatt az egyiptomi kormányzatnak nagyobb tárgyalóereje lesz a jövőben, amely végső soron elősegíti a forrásallokáció hatékonyságának javulását és a lakosság egészségi állapot indikátorainak a maximalizálását. Az egészségügyi technológiaértékelés (Health technology assessment - HTA) egy fontos eszköz a forrásallokációs döntések tudományos megalapozottságának javítására. Mivel az egyiptomi egészségügyi rendszer komplex és fragmentált, az ország egy főre jutó nemzeti jövedelme relatív alacsony, a társadalmi értékek sajátosak, ezért nem javasolt, hogy a magas jövedelmű - sőt a közepes jövedelmű - országok egészségügyi döntéshozatali gyakorlatát közvetlenül átültessék anélkül, hogy azt a helyi társadalmi értékekhez és hagyományokhoz igazítsák. Bár más országok tapasztalatait érdemes tanulmányozni, de Egyiptomnak a saját HTA struktúráját kell kiépítenie. Az egyiptomi HTA rendszer implementációja jelenleg gyerekipőben jár, de már láthatóak az első eredmények.

A tanulmány az egyiptomi HTA rendszer hosszútávú céljainak, valamint a célok megvalósításához szükséges speciális lépések meghatározására törekedett. A HTA rendszer jelenlegi és preferált jövőbeni státuszának a felmérésével rávilágított a legfontosabb hiányosságokra, valamint kijelölte HTA akcióterv irányait. Helyi szakértők segítségével validálta a terv megvalósíthatóságát és alkalmazhatóságát, valamint meghatároza a szükséges lépések időrendjét.

A tanulmányba bevont szakértők között egyetértés mutatkozott abban, hogy jelentős lépések szükségesek a HTA rendszer fejlesztéséhez, többek között ki kell alakítani a HTA irodák közti koordinációt, valamint fokozni kell a helyi tudományos bizonyíték előállítását. A szakértők javasolták az innovatív döntéstámogatói módszereket, mint pl. a többkritériumos döntéselemzés és a feltételes befogadás alkalmazását a nagyértékű gyógyszerek ártamogatási folyamatában. A feladatok végrehajtásához nélkülözhetetlen a technikai kapacitások bővítése. A legtöbb szakértői többszörös és puha költség-hatékonysági küszöbérték bevezetése mellett érvelt az egészségügyi technológiák értékének a meghatározásához. Emellett azt is javasolták, hogy a HTA rendszer kezdetben az innovatív gyógyszerek egészségpolitikai döntésire fókuszáljon, majd hosszabb távon terjedjen tovább az összes más technológiára.
Appendix 1

Health Technology Assessment (HTA) Implementation Implications

The main aim of an HTA is to inform health policy decision making. It is defined by the WHO as "the systematic evaluation of properties, effects and/or impacts of health technologies and interventions. It covers both the direct, intended consequences of technologies and interventions and their indirect, unintended consequences." (WHO, 2019). Yet, despite the rapid pace of HTA development, there is inadequate information about the impact of HTA.

This survey is designed to explore and assess the perception of different stakeholders from middle-income countries about the implications of Health Technology Assessment (HTA) implementation.

Answers to this survey are anonymous, they would be presented only in the aggregated format in scientific publications and presentations on the implications of HTA.

Please provide answers by checking boxes or radio buttons.
Please provide an answer to every required question.
For "multiple choice" questions, please select all relevant options, or choose "other" to indicate additional options.

* Required

1. What is your affiliation? (if you have multiple affiliations choose all relevant) *

  Check all that apply.

  - Governmental health related
  - Academia
  - Private (ex. Health technology manufacturers, health care providers, etc.)
  - Non governmental organization (NGO)
2. Which country do you represent by filling the survey? *

*Mark only one oval.*

3. Does your country currently use Health Technology Assessment (HTA) in decision making? *

*Mark only one oval.*

- [ ] Full HTA implementation  
  Skip to question 4
- [ ] Partial HTA implementation  
  Skip to question 4
- [ ] No  
  Skip to question 7
- [ ] I do not know  
  Skip to question 7

Countries implementing HTA
4. What is HTA used for in your country? *

Check all that apply.

☐ To support benefit package / reimbursement decisions
☐ To support pricing decisions of pharmaceuticals and/or medical devices
☐ To improve clinical practice guidelines and/or financing protocols
☐ To support planning and budgeting at national, regional or institutional level
Other: ________________________________

5. How do you think current HTA implementation is affecting the health care system in your country? In other words, in your opinion what are the main POSITIVE implications of HTA currently? *

____________________________________
____________________________________
____________________________________

6. How do you think current HTA implementation is affecting the health care system in your country? In other words, in your opinion what are the main NEGATIVE implications of HTA currently? *

____________________________________
____________________________________
____________________________________

Skip to question 10

Countries not implementing HTA
7. What should be the most prioritized place to use HTA in your country? *

*Mark only one oval.*

- [ ] Reimbursement list / benefit package
- [ ] Pricing of health products
- [ ] Clinical practice, guidelines, and protocols
- [ ] Planning and budgeting
- [ ] Other: ________________________________

8. How do you think HTA implementation in the abovementioned area would affect the health care system in your country? In your opinion what could be the main POSITIVE implications of HTA currently? *

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

9. How do you think HTA implementation in the abovementioned area would affect the health care system in your country? In your opinion what could be the main NEGATIVE implications of HTA currently? *

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Perceived Implications of HTA implementation
10. How do you think official HTA implementation would influence the following health system goals? *

*Mark only one oval per row.*

<table>
<thead>
<tr>
<th></th>
<th>Postively influence</th>
<th>Does not influence</th>
<th>Negatively influence</th>
<th>I do not know / I am not sure</th>
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</thead>
<tbody>
<tr>
<td>Health gain</td>
<td></td>
<td></td>
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<tr>
<td>Equity in health</td>
<td></td>
<td></td>
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<tr>
<td>Financial protection of patients</td>
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<tr>
<td>Equity in Finance</td>
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<td>Responsiveness to patient needs</td>
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<td>Transparency and accountability of the health care decisions</td>
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<tr>
<td>Quality and efficiency in service delivery</td>
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<tr>
<td>Fiscal sustainability &amp; administrative efficiency</td>
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</tbody>
</table>
11. Do you think HTA implementation in your country would result in...? *

*Mark only one oval per row.

<table>
<thead>
<tr>
<th>Response</th>
<th>Yes</th>
<th>Maybe</th>
<th>No</th>
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<tbody>
<tr>
<td>Improved health outcomes</td>
<td></td>
<td></td>
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<tr>
<td>Reduced health expenditure</td>
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<td></td>
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<tr>
<td>Cost-savings in selected diseases</td>
<td></td>
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<td></td>
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<tr>
<td>Increased prices of selected health technologies (such as drugs or medical devices)</td>
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<tr>
<td>Decreased prices of selected health technologies (such as drugs or medical devices)</td>
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<tr>
<td>Implementation of increased patient copayment</td>
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<tr>
<td>Restricted access to drugs due to slower regulatory and reimbursement process</td>
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<tr>
<td>Restricted access to the expensive (orphan and cancer drug) health technologies due to negative reimbursement decisions</td>
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<tr>
<td>Improved access to drugs by reducing opportunity cost of inappropriate utilization</td>
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<tr>
<td>Reduced access to drugs due to parallel exports from countries with lower pharmaceutical prices to countries with higher prices</td>
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<tr>
<td>Reduced knowledge gap among stakeholders</td>
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<tr>
<td>Improved communication between medical staff and hospital management</td>
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<td>Improved clinical guidelines</td>
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<tr>
<td>Improved clinical practice</td>
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<tr>
<td>Reduced length of hospital stay</td>
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</table>
Consent

12. Hereby, I accept that my anonymous answers can be aggregated and used in preparing scientific publications and presentations. *

*Mark only one oval.*

☐ Yes
☐ No

Thanks for your time & help

13. If you would like to receive a copy of the paper when it is published, please leave your email. (optional)

____________________________________

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Google Forms
Appendix 2

HTA implementation scorecard

Comparison of current status and future directions

A scorecard was designed to assess the current status of HTA implementation and to set up long-term objectives. Our scorecard must be viewed as an initial step in a multi-stakeholder dialogue on identifying best practices, common problems and proposing further directions in the region.

Please provide answers by checking boxes or radio buttons for your own country. For “single choice” questions please select only 1 option for current status and 1 option for preferred status in 10 years. Please provide answer for all questions. For “multiple choice” questions please select all relevant options related to your country, or the first option when none of the listed options are relevant to your country. In most cases you may also select “other” to indicate additional options.

The anonymity of respondents is guaranteed. Aggregated results will be presented first at the ISPOR Dubai 2018 conference, then in a peer-reviewed scientific journal.

Should you need further information about the terminology in the survey, please check the below paper:


Consent

Hereby, I accept that my anonym answers can be aggregated and presented in educational events.

Hereby, I accept that my anonym answers can be aggregated and used in scientific presentations and publications.
HTA implementation scorecard

Please provide answers about your own background

(individual survey results are kept strictly confidential)

Country
Please indicate your country:

..........................................................................................................................................

Main employment
Public sector
- Decision-maker, policymaker, public payer, Ministry of Health (potential HTA user)
- HTA agency
- Academic sector
- Public health care provider (e.g. clinician)
- Other (please explain): .................................................................

Private sector
- Health care industry (e.g. pharmaceutical or medical device company)
- Private health care provider (e.g. clinician)
- Pharmaceutical trade sector (e.g. wholesaler, pharmacy)
- Private insurance
- Consultancy
- Journalist
- Other (please explain): .................................................................

Major training (single choice)
- Economics
- Pharmacy
- Medicine
- Other health care (e.g. nursing, dietetics)
- Multidisciplinary (at least two master’s degrees from the above list)
- Other (please explain): ................................................... 

**Age**
- Below 30
- Between 30-50
- Above 50
1. HTA capacity building

**Education (single choice)**

- No training
- Project based training and short courses
- Permanent graduate program with short courses
- Permanent graduate and postgraduate program with short courses

2. HTA funding

**Financing critical appraisal of technology assessment (single choice)**

- No funding for critical appraisal of technology assessment reports or submissions
- Dominantly private funding (e.g. submission fees) by manufacturers for the critical appraisal of technology assessment reports or submissions
- Dominantly public funding for critical appraisal of technology assessment reports or submissions

**Financing health technology assessment (i.e. HTA research) (single choice)**

- No public funding for technology assessment; private funding is not needed or expected
- No or marginal public funding for research in HTA; private funding is expected
- Sufficient public funding for research in HTA; private funding is also expected
- HTA research is dominantly funded from public resources

3. Legislation on HTA

**Legislation on the role of HTA process and recommendations in decision-making process (single choice)**

- No formal role of HTA in decision-making
- Dominantly international HTA evidence is taken into account in decision-making
- International and additionally local HTA evidence is taken into account in decision-making
- Local HTA evidence is mandatory in decision making

**Legislation on organizational structure for HTA appraisal (single choice)**
- There is no public committee or institute for the appraisal process
- Committee is appointed for the appraisal process
- Committee is appointed for the appraisal process with support of academic centers and independent expert groups
- A public HTA institute or agency is established to conduct formal appraisal of HTA reports or submissions
- Public HTA institute or agency is established to conduct formal appraisal of HTA reports or submissions with support of academic centers and independent expert groups
- Several public HTA bodies are established without central coordination of their activities
- Several public HTA bodies are established with central coordination of their activities

### 4. Scope of HTA implementation

#### Scope of technologies (*multiple choice*)
- HTA is not applied to any health technologies
- Pharmaceutical products
- Medical devices
- Prevention programs and technologies
- Surgical interventions
- Other (please specify): ...........................................

#### Depth of HTA use in pricing and/or reimbursement decision of health technologies (*single choice*)
- HTA is not applied to any health technologies
- Only new technologies with significant budget impact
- Only new technologies
- New technologies + revision of previous pricing and reimbursement decisions
5. Decision criteria

**Decision categories (multiple choice)**
- None of the below categories are applied
- Unmet medical need
- Health care priority
- Assessment of therapeutic value
- Cost-effectiveness
- Budget impact
- Other (please specify): ...........................................

**Decision thresholds (single choice)**
- Thresholds are not applied
- Implicit thresholds are preferred
- Explicit soft thresholds are applied in decisions
- Explicit hard thresholds are applied in decisions

**Multi criteria decision analysis (single choice)**
- Explicit multi criteria decision framework is applied

6. Quality and transparency of HTA implementation

**Quality elements of HTA implementation (multiple choice)**
- None of the below quality elements are applied
- Published methodological guidelines for HTA/economic evaluation
- Regular follow-up research on HTA recommendations
- Checklist to conduct formal appraisal of HTA reports or submissions exists but not available for public
- Published checklist is applied to conduct formal appraisal of HTA reports or submissions
Transparency of HTA in policy decisions (*single choice*)

- Technology assessment reports, critical appraisal and HTA recommendation are **not published**
- HTA recommendation is published without details of technology assessment reports and critical appraisal
- Transparent technology assessment reports, critical appraisals and HTA recommendations

**Timeliness** (*single choice*)

- HTA submission and issuing recommendation have no transparent timelines
- HTA submissions are accepted/conducted following a transparent calendar, but issuing recommendation has no transparent timelines
- HTA submissions are accepted continuously and issuing recommendation has transparent timelines

**7. Use of local data**

**Requirement of using local data in technology assessment** (*single choice*)

- No mandate to use local data
- Mandate of using local data in certain categories **without** need for assessing the transferability of international evidence
- Mandate of using local data in certain categories **with** need for assessing the transferability of international evidence

**Access and availability of local data** (*single choice*)

- Limited availability or accessibility to local real world data
- Up-to-date patient registries are available in certain disease areas, but payers’ databases are not accessible for HTA doers
- Payers’ databases are accessible for HTA doers, patient registries are not available or accessible in the majority of disease areas
- Up-to-date patient registries are available in certain disease areas and payers’ databases are accessible for HTA doers
8. International collaboration

International collaboration, joint work on HTA (joint assessment reports) and national/regional adaptation (reuse) (*multiple choice*)

- No involvement into joint work; and no reuse of joint work or national/regional HTA documents from other countries
- Active involvement in joint work (e.g. EUnetHTA Rapid REA, full Core HTA)
- National/regional adaptation (reuse) of joint HTA documents
- National/regional adaptation (reuse) of national/regional work performed by other HTA bodies in other countries

International HTA courses for continuous education on HTA (*single choice*)

- Limited interest in (1) developing / implementing of and (2) participating at international HTA courses
- Interest only in regular participation at international HTA courses
- High interest in (1) developing / implementing of and (2) participating at international HTA courses
Appendix 3

HTA implementation scorecard

Comparison of current status and future directions

A scorecard was designed to assess the current status of HTA implementation in the region of Middle East and North Africa (MENA) and to set up long-term objectives. Our scorecard must be viewed as an initial step in a multi-stakeholder dialogue on identifying best practices, common problems and proposing further directions in the MENA region.

Please provide answers by checking boxes or radio buttons for your own country. For “single choice” questions please select only 1 option for current status and 1 option for preferred status in 10 years. Please provide answer for all questions. For “multiple choice” questions please select all relevant options related to your country, or the first option when none of the listed options are relevant to your country. In most cases you may also select “other” to indicate additional options.

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**Consent**

*Hereby, I accept that my anonym answers can be aggregated and presented in educational events.*

*Hereby, I accept that my anonym answers can be aggregated and used in scientific presentations and publications.*

[yes/no]
HTA implementation scorecard

Please provide answers about your own background

(individual survey results are kept strictly confidential)

**Country**

Please indicate your country:

………………………………………………………………………………

**Main employment**

**Public sector**

- Decision-maker, policymaker, public payer, Ministry of Health (potential HTA user)
- HTA agency
- Academic sector
- Public health care provider (e.g. clinician)
- Other (please explain): ………………………………………

**Private sector**

- Health care industry (e.g. pharmaceutical or medical device company)
- Private health care provider (e.g. clinician)
- Pharmaceutical trade sector (e.g. wholesaler, pharmacy)
- Private insurance
- Consultancy
- Journalist
- Other (please explain): ………………………………………

**Major training (single choice)**

- Economics
- Pharmacy
- Medicine
- Other health care (e.g. nursing, dietetics)
- Multidisciplinary (at least two master’s degrees from the above list)
- Other (please explain): .............................................

**Age**
- Below 30
- Between 30-50
- Above 50
1. **HTA capacity building**

**Education (single choice)**

- No training
- Project based training and short courses
- Permanent graduate program with short courses
- Permanent graduate and postgraduate program with short courses

2. **HTA funding**

**Financing critical appraisal of technology assessment (single choice)**

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- No or marginal public funding for research in HTA; private funding is expected
- Sufficient public funding for research in HTA; private funding is also expected
- HTA research is dominantly funded from public resources

3. **Legislation on HTA**

**Legislation on the role of HTA process and recommendations in decision-making process (single choice)**

- No formal role of HTA in decision-making
- Dominantly international HTA evidence is taken into account in decision-making
- International and additionally local HTA evidence is taken into account in decision-making
- Local HTA evidence is mandatory in decision making

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- Several public HTA bodies are established without central coordination of their activities
- Several public HTA bodies are established with central coordination of their activities

| 4. Scope of HTA implementation |
|---------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|
| **Scope of technologies** (multiple choice) | current status | preferred status in 10 years |
| - HTA is not applied to any health technologies | | |
| - Pharmaceutical products | | |
| - Medical devices | | |
| - Prevention programs and technologies | | |
| - Surgical interventions | | |
| - Other (please specify): ......................... | | |

<table>
<thead>
<tr>
<th><strong>Depth of HTA use in pricing and/or reimbursement decision of health technologies</strong> (single choice)</th>
<th>current status</th>
<th>preferred status in 10 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>- HTA is not applied to any health technologies</td>
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<tr>
<td>- Only new technologies with significant budget impact</td>
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<tr>
<td>- Only new technologies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- New technologies + revision of previous pricing and reimbursement decisions</td>
<td></td>
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</tbody>
</table>
5. Decision criteria

Decision categories (*multiple choice*)
- None of the below categories are applied
- Unmet medical need
- Health care priority
- Assessment of therapeutic value
- Cost-effectiveness
- Budget impact
- Other (please specify): ..............................................

Decision thresholds (*single choice*)
- Thresholds are not applied
- Implicit thresholds are preferred
- Explicit soft thresholds are applied in decisions
- Explicit hard thresholds are applied in decisions

Multi criteria decision analysis (*single choice*)
- Explicit multi criteria decision framework is applied

6. Quality and transparency of HTA implementation

Quality elements of HTA implementation (*multiple choice*)
- None of the below quality elements are applied
- Published methodological guidelines for HTA/economic evaluation
- Regular follow-up research on HTA recommendations
- Checklist to conduct formal appraisal of HTA reports or submissions exists but **not available** for public
- Published checklist is applied to conduct formal appraisal of HTA reports or submissions
Transparency of HTA in policy decisions (*single choice*)

- Technology assessment reports, critical appraisal and HTA recommendation are **not published**
- HTA recommendation is published without details of technology assessment reports and critical appraisal
- Transparent technology assessment reports, critical appraisals and HTA recommendations

Timeliness (*single choice*)

- HTA submission and issuing recommendation have no transparent timelines
- HTA submissions are accepted/conducted following a transparent calendar, but issuing recommendation has no transparent timelines
- HTA submissions are accepted continuously and issuing recommendation has transparent timelines

7. Use of local data

**Requirement of using local data in technology assessment (*single choice*)**

- No mandate to use local data
- Mandate of using local data in certain categories **without** need for assessing the transferability of international evidence
- Mandate of using local data in certain categories **with** need for assessing the transferability of international evidence

**Access and availability of local data (*single choice*)**

- Limited availability or accessibility to local real world data
- Up-to-date patient registries are available in certain disease areas, but payers’ databases are not accessible for HTA doers
- Payers’ databases are accessible for HTA doers, patient registries are not available or accessible in the majority of disease areas
- Up-to-date patient registries are available in certain disease areas and payers’ databases are accessible for HTA doers
### 8. International collaboration

**International collaboration, joint work on HTA (joint assessment reports) and national/regional adaptation (reuse) (multiple choice)**

- No involvement into joint work; and no reuse of joint work or national/regional HTA documents from other countries
- Active involvement in joint work (e.g. EUnetHTA Rapid REA, full Core HTA)
- National/regional adaptation (reuse) of joint HTA documents
- National/regional adaptation (reuse) of national/regional work performed by other HTA bodies in other countries

**International HTA courses for continuous education on HTA (single choice)**

- Limited interest in (1) developing / implementing of and (2) participating at international HTA courses
- Interest only in regular participation at international HTA courses
- High interest in (1) developing / implementing of and (2) participating at international HTA courses