

Health Technology Assessment for Universal Health Coverage

A report of the First Regional Conference on Health Technology Assessment
Conference organized by the Middle East North Africa Health Policy Forum



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Introduction

In recent years, the global universal health coverage (UHC) movement has gained momentum, with the UN General Assembly calling on countries to “urgently and significantly scale up efforts to accelerate the transition towards universal access to and availability of affordable and quality healthcare services” in line with the Sustainable Development Goals (SDGs). SDG 3 itself includes a target to “achieve universal health coverage, including financial risk protection, access to quality essential health care services, and access to safe, effective, quality, and affordable essential medicines and vaccines for all.”

Universal health coverage will require fundamental changes in the way health systems work; they must become more effective and efficient, specifically in terms of expanding benefits and managing limited resources through utilization of evidence-based decision-making.

With the ongoing efforts made by governments to move

towards universal health coverage, health care technology, with all its components (innovation, regulation, assessment and management) remains a major challenge. Deciding which health technologies and interventions to invest in, responding to the health needs of populations, ensuring quality and efficacy of used technologies, and achieving fairness and efficiency at the same time, are the ultimate objectives of any policy-maker. This requires a multidisciplinary approach that incorporates the social, economic, organizational and ethical aspects of a health intervention or health technology¹.

The WHO 2015 Global Survey on HTA was undertaken in response to World Health Assembly Resolution WHA67.23 on “*Health intervention and technology assessment in support of universal health coverage*” which called on the WHO Secretariat to assess the status of HTA globally. The report revealed that in the Middle East and North Africa (MENA) region, half the countries have some type of formal process of health care decision-making regarding investments made in the area of health technology. However, only 3% of countries have transparent guidelines, and almost all of them lacked sufficient numbers of qualified human resources, information and knowledge for producing HTA and utilizing findings in decision-making. This indicates a technical and policy gap in MENA countries that will need to be filled if these countries want to achieve Universal Health Coverage.

Recognizing this policy gap --, MENA HPF has initiated a HTA health policy forum in the region that builds on the regional need and on global, regional and national experiences².

1- The World Health Organization (WHO) defines health technologies as the application of organized knowledge and skills in the form of medicines, devices, vaccines, diagnostics or clinical procedures that solve health problems and improve quality of lives.

2- MENA HPF is grateful to WHO EMRO for the valuable technical support and to Roche for providing grant funding in the spirit of the public interest. This conference would not have been possible without their contributions.

Objective of the forum: The ultimate objective is that countries in the region embrace and develop an appropriate HTA policy as part of their progress towards UHC and as a basis for decision-making, to improve the efficiency of their systems and the health outcomes of their population.

Themes

To kick-off the MENA HTA policy network platform, a two day forum was organized in Cairo, Egypt. The objective of the meeting was for international HTA experts, senior policy makers and other relevant stakeholders to share their knowledge and experience in these domains. The aim was to propose a roadmap to institute HTA as a tool to be adopted by MENA policy-makers in order to make rational investments in health technologies in their own settings. The objective of the MENA HTA platform forum is to identify prerequisites, legal frameworks, structures, and resources required to institute HTA within existing national health systems.

The forum covered the following topics:

1. Role of HTA in UHC
2. Prerequisites for successful HTA programs
3. Integrating HTA into public policies
4. Networking and collaboration
5. The way forward

Dr. Adham Ismail (Regional Advisor, Health Technology and Biomedical Devices at WHO EMRO) highlighted the importance of political commitment as a prerequisite for HTA. He emphasized that HTA doesn't only involve assessment of costs, but also technical aspects such as safety and efficacy, as well as legal and ethical issues. HTA should be preceded by health technology regulations and followed by health technology management. Dr. Ismail highlighted the importance of HTA in achieving UHC, and illustrated the role of HTA in selecting the basic benefit package. He also presented the EMR's Regional Network on HTA, which provides members with a forum to pose queries, request consultancies, and exchange news and resources. The network also contains a library of relevant references, technical documents, presentations, and videos.

Dr. Ismail followed by describing the role of HTA in selecting appropriate technologies within the MENA region. His presentation covered HTA selection criteria, and the impact of HTA selection. He introduced the

value-based priority-setting framework for decision-making, which is used to ensure that the full range of benefits is considered. It uses multiple- criteria decision analysis (MCDA) techniques to select appropriate health technologies based on severity and burden of disease, impact on public health and vulnerable populations, urgency of condition, ease of implementation, economic and budget impact analysis, equity/equal opportunity, and the 5 As (Appropriateness, Accessibility, Affordability, Accountability and Availability). He added that HTA reports can influence decision-making at two levels: policy implementation level (pricing and reimbursement), and individual technology decision level (hospital and patient). He also explained the influence of HTA decisions on inclusion/exclusion of clinical interventions, which affect the 3 UHC dimensions. He finally highlighted the impact of using HTA in selection of appropriate technologies (and decision-making) according to stakeholders, usage, market access, reimbursement decisions, pricing, health care expenditures, and others (e.g. development of clinical practice guidelines, innovation, society, etc.).

Dr. Ismail then presented HTA's guiding principles, highlighting that HTA should be an unbiased and transparent exercise, should include all relevant technologies, and that a clear system for setting priorities for HTA should exist and the costs of HTA should be proportionate. He added that HTA should incorporate appropriate methods depending on its goal, should consider a wide range of evidence and outcomes, a full societal perspective should be considered, and HTAs should explicitly characterize uncertainty surrounding estimates. The process should engage all stakeholder groups since HTA findings need to be communicated appropriately to different target groups. Dr. Ismail the point that HTA should also identify areas in which the evidence (on certain interventions) could most usefully be developed in the future. He emphasized that HTA should be timely, market-access decisions should reflect HTA recommendations in a transparent and clearly defined way, and be implemented as intended, and the impact of HTA findings and how they are used needs to be monitored. He also provided examples of HTA decision frameworks from different countries

HTA in the Region

1. 52% perform HTA or HTA-like activities:
Most activities were related to clinical effectiveness

and economic evaluations (67% and 62% respectively); Performed on devices and medicines (79% and 68% respectively); HTA reports were on health care costs and selection of appropriate technologies (60% and 50% respectively).
 2. Remaining 48% (not performing HTA-like activities): Over 50% do not know if there are future plans to develop HTA programs in their national entities; Almost 75% indicated that using HTA in the decision-making process will be their biggest obstacle.
 3. Medicines, vaccines and other health technologies consume approximately 20-60% of the health budget in low and middle income countries.
 4. Over 50% of expenditures on medicines, vaccines and other health technologies is wasted due to one or more reason

Dr. Sophie Werkö, vice-chair of the board of International Network of Agencies for Health Technology Assessment (INAHTA), Sweden, discussed the role of HTA in decision-making. She highlighted the key principles of HTA in terms of structure, methods, processes and usage, and the key principles related to using HTA in decision-making. These included that HTA should be timely, HTA findings need to be communicated appropriately to decision-makers, and that the link between HTA and decision-making processes should be transparent. Dr. Werkö also introduced the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU). SBU's task is to assess, not to make decisions. SBU produces HTA reports that evaluate four perspectives: clinical effectiveness, cost effectiveness, social and ethical considerations. She also drew attention to the EU's POP (Planned and Ongoing Projects) database, which allows HTA agencies to share information with each other on planned, ongoing or recently published projects conducted at the individual agency. The aim of the database is to reduce duplication and facilitate collaboration among HTA agencies.

We believe that knowledge-making should be separated from decision-making.”
 “SBU produces HTA reports that fulfill four perspectives: clinical effectiveness, cost effectiveness, and social and ethical considerations.”

Dr. Werkö then introduced the International Network of Agencies for Health Technology Assessment (INAHTA), which was founded in 1993 by 13 publicly-funded HTA

agencies. It has grown to become a global network of 52 agencies. INAHTA aims to demonstrate the value of HTA agencies as key components of modern health systems to support robust evidence-based decision-making, support best practices and innovation for building and maintaining HTA agencies, and build a strong network to enable continuous exchange of knowledge and learning among its members. She also introduced the INAHTA-WHO Mentorship Program, which was launched in 2014 and aims to connect those looking for mentorship with those able to offer mentorship.

Dr. Mühlbacher (Institute for Health Economics and Health Care Management in Germany) provided an overview of multi-criteria decision-making (MCDA). He illustrated that using structured, explicit approaches to decisions involving multiple criteria can improve the quality of decisions. MCDA has set of techniques that provide clarity on which criteria are relevant, the importance attached to each, and how to use this information via a framework to assess the available options. MCDA can therefore increase the consistency, transparency, and legitimacy of decisions. However, Dr. Mühlbacher warned that MCDA does not provide the “right” answer, does not provide an objective analysis and does not relieve decision-makers of the responsibility for making difficult judgments.

Dr. Alaa Hamed, Senior Operations Officer at the World Bank, looked at the role of HTA in setting priorities for UHC, focusing on population health and fairness, and how these elements are affected by HTA. He stressed that HTA is an essential foundation to secure efficient and equitable allocation of health care. He introduced OPTIMA, which is a new approach for evidence generation and allocative efficiency analysis for use in informing public health investment choices, as well as for academic research. He also spoke of HTA as a framework for evidence-informed priority setting. He concluded that priority setting is a value-laden political process, multiple criteria beyond cost-effectiveness are important, and that priority setting takes time and has other costs.

HTA and UHC:

- UHC is the ultimate expression of fairness;
- HTA is an essential foundation to secure UHC through the efficient and equitable allocation of health care and other resources;
- HTA as a tool for priority setting should not

only involve data/evidence but also values and the population's interests;

- HTA is not only about technology, but also about policies and delivery platforms.

Dr. Ansgar Hebborn, Head of Global HTA at Roche, discussed ways forward in using HTA for UHC, describing HTA as a catalyst for UHC. He mentioned the need for a broad and dynamic consideration of the value of HTA, the importance of stakeholder engagement in HTA, and the need to leverage existing capacity and capabilities from abroad. He also described micro- and macro-level HTA and argued that a stronger focus of limited HTA resources on “macro” aspects of health system architecture may yield higher gains in the mid- to long term

He emphasized that HTA is not a substitute for rational health care system development and reform and that there is no “one-size-fits-all” HTA framework. He also underscored that improving relevance and use of HTA are key to success. This includes the development of the right HTA output and service, as well as mobilizing self-interest to search for efficient and effective health technologies. The latter includes incentives/disincentives, training and guidelines. Dr. Hebborn reiterated that HTA is a “local” public good and that local assessments are necessary and should include cultural values and preferences. He also emphasized the multi-dimensionality of HTA and pointed out that a number of MCDA applications exist. He reflected also on the European collaboration in the field of HTA and the creation of the EU's EUnetHTA and its Core Model for HTA collaboration. He added that this model is adopted.

Country reports

Egypt
 Dr. Aly Hegazy (Head of the Health Insurance Organization in Egypt and Assistant Minister of Health for Health Insurance Affairs) provided an overview of the health care system and Health Insurance Organization (HIO) in Egypt. He noted that only 58% of Egyptians are covered by the current social health insurance (SHI) system and shared the main features of the new comprehensive SHI. He pointed out that one prerequisite for effective implementation of the new SHI law is an integrated health information system.

Dr. Mohamed Maeet (Vice Minister of Finance for Public Treasury Affairs) reiterated the importance of HTA to

achieve UHC. The readiness of the health system in terms of infrastructure and technologies is crucial to enable effective implementation of the new SHI. He spoke about the Egyptian government's efforts to integrate health information systems from the different national programs, linking them all to the national identity card. “Currently the data of 70 million Egyptians has been gathered, verified and unified as a result of integrating different databases”. He added that integration of the different databases will enable the Egyptian government to ensure that different subsidies, social and health programs reach those in real need. Furthermore, a national council for payments has been established to support the digital transformation nationally. “Digital Transformation of the Egyptian Government in Financial Affairs” includes digitalization of salaries and pensions, unifying all government bank accounts by using a single treasury account, and digitization of the public treasury, thus providing a database of all beneficiaries, the creation of the electronic medical file, and identification of those whom the country will financially support.

Dr. Sherine Helmy, the CEO of Pharco Pharmaceutical, presented a case study on the hepatitis C virus (HCV) in Egypt, highlighting how Egypt changed its position from the country with the highest prevalence of the disease to the first country to treat all HCV patients on the waiting lists. He explained that stakeholders joined forces to produce effective, safe, and affordable and nationally produced treatment for HCV cases in Egypt. He provided an overview of the Egyptian initiative of screening of one million citizens for HCV over a year and a half period. He also outlined Pharco's support for national efforts on HCV prevention and control, which include manufacturing effective and affordable treatments, and HCV screening of different population groups.

Dr. Mostafa Hunter - Head of Egypt's Healthcare Governance and Transparency Association (HeGTA)

Assets play a major role in delivering high quality health care services at a lower cost;
 Free of charge does not mean cost-free; wasted assets could be put to better use;
 The representatives of owners of public hospitals are responsible for the utilization of assets to serve beneficiaries at the highest quality and lowest cost;
 Asset integrity management and HTA are interrelated concepts that need to be incorporated immediately within public hospitals.

Dr. Mohsen George, Egypt's Health Insurance Organization

Egypt is committed to attaining UHC by 2030; A new social health insurance system will be defined; Egypt is not waiting for the new insurance system to be implemented, but has started moving towards UHC to bridge the gap; There can be no UHC without priority settings, and no priority settings without HTA; There is therefore, NO UHC without HTA.

Tunisia

Dr. Mouna Jamaluddin shared the Tunisian experience in establishing INASanté, the country's national HTA organization. She stated that priority setting requires an evidence-based process for investment and disinvestment (including analysis of the current benefit package). She described INASanté as public authority that is scientifically independent. It was created in 2012 by ministerial decree and is considered the first national HTA agency in Africa. Highlighting the agency's key achievements, she reported that INASanté is considered a powerful tool for good governance and also an agency for accreditation of both public and private health facilities.

"Must-have" skills for HTA:

- Knowledge of drug and medical devices
- Clinical epidemiology
- Evidence-based medicine, meta-analysis, health economics
- Knowledge of the health system
- Legal, social and ethical aspects
- Perform critical appraisal of literature
- Synthesize the evidence
- Tailor the evidence to the context

Saudi Arabia

Dr. Abdulaziz Al-Saggabi, director of the Drug Policy and Economic Center at the Ministry of National Guard in Saudi Arabia, and the president of International Society For Pharmaco-economics and Outcomes Research (ISPOR)'s Saudi Arabian chapter, discussed the use of HTA in decision-making in Saudi Arabia. He described the Saudi health care system indicators, the Saudi Arabia 2020 transformational program and the Saudi reimbursement drug submission/ HTA guidelines project, and risk-sharing agreements. He

stated that HTA is a process which examines multiple aspects of the value of a new existing technology with the purpose of informing decisions that have to be made about the adoption of that technology while Evidence-Based Medicine (EBM) does not address resource use. HTA tries to incorporate many different sources of evidence. He concluded that the finalization and endorsement of national HTA guidelines will be an important step in establishing a national Saudi HTA Agency.

Why we need HTA?

- To promote best care;
- To depoliticize "rationing" decisions;
- To make the process behind such decisions fairer, more transparent and robust, and evenly applied across the country;
- To ensure best value for money

Kuwait

Dr. Rehab Alwatayan, Director of the primary health care (PHC) sector in Kuwait, presented the Kuwaiti experience in introducing health information systems (HIS) at primary health care centers. She stated that the ministry started using the Primary Care Information System (PCIS) developed by the Department of Information Systems in 2005. Since then, the program has been updated several times. She gave a detailed description of the operation and functions of the system and cited examples, e.g. well-baby care and diabetic patient care clinics

Jordan

Dr. Salah Mawajdeh, former Minister of Health and former Director of FDA, Jordan, discussed HTA at the global level and what institutional frameworks need to be adopted to bring it in at the national level. He argued that HTA should be brought in as soon as possible, saying that once technologies are approved by the regulatory body in a country, then lobbying by different groups begins and pressure mounts on health authorities. The dilemma then is how to take a decision when there is no data. He also addressed what countries can do in the absence of a HTA agency. He proposed reviewing the evidence available globally and considering adaptability to suit the country's context.

United Arab Emirates

Dr. Mohamad Farghaly, Director of Health Insurance Policies in Dubai Health Authority, presented insights from the health insurance experience in Dubai that

was implemented in 2014. He described the two pillars of insurance as access to care and the quality of care. Quality of care involves evidence-based practices. He stated that regulators have initiated the Dubai Standards of Care and developed best practice guidelines which have been distributed to all physicians. They also developed key performance indicators (KPIs) to monitor physicians' progress. He explained how the application of the guidelines has saved a lot of public money. He also introduced the Dubai Standard of Care Payers Club, that provides a forum to communicate guidelines with payers.

Spain

Dr. Merce Obach, from the Pharmacotherapeutic Harmonization Programme, in Catalonia, Spain, presented the Catalan experience in pharmaceutical assessment and reimbursement decisions. The presentation highlighted the Catalan model for pharmaceutical innovation, and the Catalan pharmacotherapeutic harmonization program. Dr. Obach clarified that the Catalan health service developed the program to determine the added clinical value of innovative medicines. She explained that the program functions through the work of a technical committee and deploys multi-criteria decision analysis (MCDA), namely EVIDEM, which is an international and standardized MCDA framework, specifically developed for use in health care decision-making. She reported that this program has become a cornerstone for guaranteeing equity in access to treatments.

Lebanon

Dr. Sizar Akoum proposed that HTA could be a powerful tool for ensuring rational decision-making, investment and adoption of technologies. She said that Lebanon drafted its HTA national strategy with the support of WHO in 2014. She also outlined some of the key challenges to implementing HTA in the country, and noted the important role international networks can play to advance HTA in Lebanon.

To sum up

Dr. Maha El Rabbat concluded the forum with the following remarks

1. This is an opportune time for countries in the MENA region to start HTA, to pave the way for more efficient and effective UHC through evidence-based decision-making;
2. Political commitment is a prerequisite to HTA and UHC;
3. There is no best model for HTA; we need to understand HTA models and each country should select the model that

- best fits its context;
4. No matter how the health system and HTA are organized, there is an explicit need for governance and accountability;
5. Knowledge- and experience-sharing are important given the wealth of experiences available. No country should start from scratch;
6. Analytical approach needs to be adopted to answer questions such as "Where do we stand?" And, "How can we move forward?"
7. HTA is particularly needed in our countries, countries with economies in transition

Key Forum's Recommendations

1. Countries should be committed to the establishment of HTA units along with the necessary processes/rules/regulations to ensure the transformation of purely scientific evidence into rational, implementable decisions.
2. Countries that do not have a formal HTA structure should conduct national orientation workshops for key officials and stakeholders to raise awareness and advocate for adopting HTA.
3. Generally, HTA units should start small in terms of staffing and budget.
4. Each country will be required to conduct a national mapping exercise to identify areas where HTA reports will be needed.
5. The selection of the initial activity for the HTA unit is important. The first report should be carefully chosen.
6. Countries should try to link HTA activities to important ongoing initiatives (benefit packages, UHC, etc.) or programs (MCDA, noncommunicable diseases, etc.).
7. Countries need to identify areas where specific technical support is required (training on the HTA process, literature survey, format and production of reports, etc.) This will help in enhancing the capacities of HTA staff.
8. International donors and many private sector entities are willing to fund development of HTA units.

The Way Forward

The following activities were identified by experts and participants at the forum as milestones to develop HTA programs within existing health systems for countries in the MENA region:

- 1. Rally national HTA support:** A policy brief emanating from the proceedings of this meeting should be developed and disseminated to health ministers, urging them to

support the setup of national HTA programs within their existing health systems. This will represent a substantial advocacy with policy-makers and will rally HTA support at the national level.

2. Conduct national orientation workshops: MENA countries with no formal HTA structure should conduct national orientation workshops for key officials and stakeholders to raise awareness and advocate for adopting HTA. WHO representatives and other international experts should participate in these events to share international experiences and demonstrate potential benefits.

3. Specify size and location of HTA units: HTA units should start small in terms of staffing and budget. They are usually located within health ministries, and their work will be mostly technical (literature search, surveys, etc.). It is therefore essential to transform this purely scientific effort into real, implementable decisions through certain bodies (such as HTA committees). MENA countries should be committed to the establishment of these entities, as well as the necessary processes, rules and regulations.

4. Conduct national HTA mapping surveys: Each MENA country will be required to conduct a national mapping exercise to identify areas upon which HTA reports will be needed as well as in-house talents capable of conducting HTA studies. This will help in expediting the acceptance of the tool as a valid approach that will help in resolving many of the technology-related problems in the country.

5. Choose the initial HTA activity carefully: The first HTA report should be chosen to ensure quick acceptance and full recognition. It is recommended that the primary activity of the newly developed HTA unit should address a high-cost technology of significant public health need to demonstrate potential savings and benefits

6. Link HTA to priority country initiatives or programs: MENA countries should link HTA efforts to ongoing initiatives (such as benefit packages, UHC, health insurance schemes, etc.) or programs (such as maternal and childhood or NCDs) in the country. It is recommended that first HTA product should be related to these initiatives or programs.

7. Seek specific technical support from WHO and HTA agencies and networks: MENA countries need to identify specific HTA areas where technical assistance is required (such as training on HTA process, literature survey, format, and production of HTA reports, etc.). This will help in enhancing capacities of HTA staff in specific areas related to their work. WHO, established HTA agencies, and international HTA networks, such as INAHTA or Health Technology Assessment international (HTAi), can help in providing the needed type of support.

8. Approach international donors on specific HTA

projects: International donors such as Global Fund (GF), Global Alliance for Vaccine Immunization (GAVI), etc., are willing to fund many HTA products related to their areas of interest. It is recommended that MENA countries seek financial assistance from these donors especially at the early stages of the development of their HTA programs

Participants Main Discussion Points

1. The need to have a MENA HTA body that facilitates information sharing as well as support countries developing relevant policies and procedures. This body can advocate policy makers to adopt HTA as a tool for evidence based decision making
2. Countries must enhance their abilities to keep with the pace of change in the technology as it advances very fast.
3. Some challenges for HTA highlighted by participants included the reliance on donation for equipment and medications, use of technology by the health workforce and governance (centralized vs. non centralized decision making). They highlighted that need for special frameworks for HTAs that consider such contexts to support leaders' rational decision making.
4. Confidentiality of the patient data was also raised when automating patients' records in health care system.
5. Some participants also pointed out to the need to have the support from WHO and World Bank to develop HTA Reimbursement system.
6. Participants also requested practical tips to assist countries with pluralistic and fragmented health care system adopting HTA. They questioned if in such countries, HTA should come before health system reform or otherwise

1. The role of the public is crucial through educating them about their health rights and what they need to be asking for. This could be an effective way for advocating for HTA.
2. HTA should not only include interventions directed to patients but any health intervention with public health impact.
3. Institutionalizing HTA was emphasized. The role of academia was also discussed and how can universities support HTA and inform policy makers.
4. Stakeholders who should be involved in HTA were highlighted and Sweden experience was shared.
5. Privatization of hospitals and HTA was also discussed.
6. The importance to build on countries previous experience in health technology was emphasized.

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