Report on the

First Inter-Country Meeting on Health Technology Assessment (HTA):

A tool for evidence informed decision making in health

Hammamet, Tunisia
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1. INTRODUCTION

Health Technology Assessment (HTA) has become an important tool for informed decision-making by Ministries of Health. It is one of the new approaches in determining cost-effective evaluation of health technologies, in support of the provision of quality health service delivery. The definition of HTA may vary depending on the context of its use, but most definitions are in line with the one stating that “HTA is the systematic evaluation of properties, effects, and/or impacts of health care technology\textsuperscript{1},” which includes a “multidisciplinary process that encompasses information about the medical (clinical), social, economic, organizational and ethical issues related to the use of a health technology (such as drugs or medical devices and procedures) in a systematic, transparent, unbiased, robust manner. It aims to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value\textsuperscript{2}.” So-called “HTA information” or “HTA product” which is commonly used, is then a piece of information generated from an HTA (e.g. clinical effectiveness of a drug in a population or organizational consequences of introducing a device into health care).

Actions by WHO, in collaboration with partners, are necessary to support regional and national initiatives for the advancement of HTA not only in developed but also in developing countries. WHO has considered Health Technology Assessment (HTA) as a way to strengthen evidence based selection and rational use of Health Technologies (HT) and increase efficiency when introducing and using them in health care. In May 2007, the 60th World Health Assembly (WHA) raised concerns about the waste of resources resulting from inappropriate HT investments that do not meet high-priority needs; are incompatible with existing infrastructures; and are irrationally or incorrectly used. The 60\textsuperscript{th} WHA requested the Director-General to provide support to WHO Member States in (1) establishing a mechanism to assess national HT needs and to assure their availability and use; and (2) implementing policies on health technologies, especially for priority diseases, according to different levels of care in developing countries\textsuperscript{3}. Further, the WHO Global Program of Work for 2014-2015, approved by WHA in 2013, states that “another priority of WHO in this area (Health Systems) is the development of tools and guidance to support countries in the prioritization of health technologies through health technology assessment” (…) and that “WHO Headquarters will make recommendations on best practices for supply, reimbursement and pricing policies for health technologies, enhance global observatories with databases and analysis of data on access to health technologies with financial hardship, on barriers to access” (…) and “will develop technical guidelines, formularies, treatment guidelines and protocols, provide a platform for sharing best practices, for the evidence based selection and rational use of essential health technologies and support the development of capacity for health technology assessment.”

\textsuperscript{1} http://www.inahta.org/Glossary/

\textsuperscript{2} http://www.eunethta.eu/about-us/faq#t287n7

\textsuperscript{3} Health technologies Resolution, World Health Assembly WHA60.29 May 2007
In 2012, a briefing paper was presented to the Regional Committee (RC) in which Universal Health Coverage (UHC) was set out as a priority goal for MS in the years to come. To realize this goal, a Regional Committee (RC) resolution requested the Regional Director to support Member States (MS) in building national capacities, including the ability to perform HTA for all HT (medicines, vaccines, biologicals and medical devices). In this regard, the WHO Regional Office for the Eastern Mediterranean (EMRO) has organized a three-day inter-country meeting on HTA for HT-related officials and policy makers from Ministries of Health. The meeting aimed at providing approaches in HT evaluations by applying HTA for making rational decisions on HT investments, especially new and emerging ones in order to make effective use of scarce resources in the public health sector. The meeting was held in Hammamet, Tunisia, from 11 to 13 November 2013. The main objectives of the meeting were to:

a) Introduce HTA concepts, including objectives, organizations, structures and benefits and discuss with HT-related officials and policy makers of Ministries of Health the importance of promoting HTA as a
   - Decision-making tool for better governance;
   - New approach for determining cost-effective evaluation of health technologies, in support of the provision of quality health service delivery;

b) Present the current status of HTA in the EM Region, successful country experiences and lessons learned;

c) Agree on the needs and priorities in EM Region and develop;
   - A roadmap for implementing HTA programmes in the 3 income-based groups\(^4\) of EM Countries.
   - A regional action plan to support MS in their introduction of HTA.

The meeting introduced HTA as an evidence-based decision-making tool for HT-related officials and policy makers in Ministries of Health involved in evaluating HT needs. Regional and Non-Regional Country experiences (e.g. Iran, Tunisia, Thailand, Colombia, and United Kingdom) were used to demonstrate various HTA approaches in place. The meeting provided Member States with the opportunity to develop an HTA programme within their national health systems. The following areas were the main focus of the meeting (full programme can be seen in Annex 1):

- HTA main concepts, products, applications;
- Successful country experiences, including challenges and dimensions in building national HTA programmes;

\(^4\) Group 1: Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and United Arab Emirates. Group 2: Egypt, Islamic Republic of Iran, Iraq, Jordan, Lebanon, Libya, Morocco, occupied Palestinian territory, Syrian Arab Republic and Tunisia. Group 3: Afghanistan, Djibouti, Pakistan, Somalia, South Sudan, Sudan and Yemen.
• Requirements for establishing successful country-specific HTA programmes;
• Use of available experts, resources and reference collaborating centers;
• A roadmap for implementing HTA in the 3 income-based groups of EM countries;
• A regional action plan to support MS in their introduction of HTA and the setup of HTA organization.

The meeting was attended by participants from 18 countries of the Region, staff from relevant programs in WHO Headquarters (WHO/HQ) and the Regional Office for the Americas (AMRO/PAHO); experts from HTA agencies and networks from Asia, Europe, and the Americas; and other stakeholders. The full List of Participants is in Annex 2.

2. OPENING SESSION

Dr Ala Alwan, WHO Regional Director for the Eastern Mediterranean Region, in his opening message (Annex 3), expressed his gratitude to HTA partners and international networks, as well as the HT team and other colleagues at WHO/HQ for their participation in the meeting and for their continuous support. He pointed out that HTA has emerged as one of the tools needed to overcome the financial and technical challenges posed by cutting edge technologies on national authorities. Therefore, networking and sharing experiences and knowledge - with stakeholders of various levels of advancement in the use of HTA - is an important part of capacity-building efforts in the region. Dr Alwan reminded participants of the current economic backdrop and the urge to make rational investments on new HT that are accessible for the majority of the population. He indicated that it will be a true challenge for companies, healthcare providers and policymakers to contain high prices with the growing demand for healthcare from an increasing population, and in a climate of economic and budgetary austerity; however, he indicated that HTA offers a methodology to address these issues and allows for more transparent evidence-based decision-making and for investments in the most appropriate technologies. Finally, Dr Alwan hoped that the meeting will provide clear roadmap for introducing and implementing national HTA programmes into existing health systems. He urged participants and experts to clearly indicate the possibilities and limitations of what EMR can achieve and how.

Dr Samir Ben Yahmed, Director of Programme Management for the Eastern Mediterranean Region, conveyed the Regional Director’s message and reiterated the wise words of the Scottish Philosopher Thomas Carlyle (1795-1881) "He who has health, has hope. He who has hope has everything". This means that health authorities have the responsibility to keep the population healthy and that their main responsibility is to promote and protect health of the entire population. This can be materialized through UHC, the leitmotif for the coming decade, which reflects a balanced approach between quality health services and their costs within a given budget. Regulation, norms and standard setting, and control are government functions that provide the rules of the game.
Private sector may be competing with the public health sector but rules should be applied to both sectors.

Dr Ben Yahmed acknowledged that, after staff costs, expenditure on medical products can be up to 60% of the Ministry of Health (MOH) budget. Yet a high percentage of the population, especially in the developing countries, lacks regular access to safe, quality and effective HT. Therefore, HTA is core to contribute to UHC and many countries can use it to support their decisions on the selection and use of new medicines, vaccines, medical devices and other technologies.

Dr Kees de Joncheere, Director of Essential Medicines and Health Technologies Policies in WHO/HQ, explained the reorganization of his department in Geneva into a comprehensive Programme for all medical products under the title of “Essential Medicines and Health Technologies Policies (EMP) Programme”. He emphasized that HTA is becoming more prominent and relevant to informed decision-making and that a resolution on UHC was endorsed in WHA and therefore, the role of HTA is of key importance as it is not only for assessing treatment and devices but also for health services. He referred to the importance of HTA in reduction of costs and therefore promotion of the UHC global agenda, which is mainly concerned with quality-assured services and preventing catastrophic payments made by patients. He pointed out that in Low- and Middle-Income Countries, patients pay between 20-60% out-of-pocket expenditures for health services. This amount can be lowered by making rational investments on health technologies. Several WHO regional offices have adopted HTA resolutions (PAHO, WPRO, SEARO, and EURO). HTA is not a new area of work, but it was not properly addressed or promoted. It can be seen as a "choice-making" programme. Other tools such as the WHO Model List of Essential Medicines (EML) and pharmaceutical pricing policies can also be used in HTA. They can be seen as HTA approaches for informed decision-making; however, they are not solutions to fix problems encountered in health systems. This meeting is timely to develop a roadmap for HTA implementation in the EM Region.

Dr Marthe Everard, Coordinator Essential Medicines and Health Technologies (EMT) in EMR region, presented the background of the HTA meeting. In 2012, a briefing paper on UHC was presented to Regional Committee (RC)\(^5\). The paper resulted in an RC resolution which requested the Regional Director to support Member States (MS) in building national capacities, including HTA for medical products (medicines, vaccines, diagnostics, and medical devices). This meeting is a response to this request. She pointed out that this meeting was organized together with MS, HTA experts, and HTA networks to discuss approaches in HT evaluation by using HTA for selection, regulation, and procurement. She also referred to HTA as an important tool for supporting core functions of effective health systems. She requested WHO and other stakeholders to support regional and national HTA initiatives in countries with developed, developing or

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emerging economies. Finally, she concluded that this meeting will demonstrate approaches to advance knowledge and effective uptake of HTA in local settings. She presented to the audience the main objectives of the meeting and indicated that the following results are expected:

- Increased awareness of officials and policy makers of HTA and its importance as a tool for evidence-informed decision-making in health;
- Creation of HTA functions within MOHs;
- Initiation of capacity building programmes for staff nominated by MOHs to work on HTA;
- A nationally developed roadmap for implementation of HTA Programme based on the dynamics and socio-economic settings of the country;
- An action plan for EMRO to assist MS in developing their national HTA programmes; and
- At long-term, MOHs to plan for instituting formal HTA bodies/units.

Mr Reiner Banken - Conseiller du PDG - alliances et réseaux, Institut National d’Excellence en Santé et en Services Sociaux (INESSS) - defined and introduced HTA to participants. He explained the importance of HTA and why health systems should use it as an added service to their ongoing activities. He pointed out that HTA should be transparent and scientifically independent and should be able to respond to health systems developments. As a tool for evidence informed decision making in health, Mr Banken pointed out that all political, technical, economic, ethical, social, and legislative dimensions of using any HT should be explored for decision making. HTA is a process of evidence generation and evidence should be collected from various sources, taking into account all surrounding conditions. He concluded that “evidence-informed” is not the same as “evidence-based” as it implies that the resulting evidence should be put into the context (country, health facility, service, products); backed up by research and study findings; and assess risks associated with introduction of new technologies. Finally, he explained that the INESSS network in Canada offers HTA services to hospitals in the province. He mentioned that INESSS is linked to other existing HTA networks in the world for sharing HTA reports and information.

3. HTA CHALLENGES IN THE REGION

The purpose of this session is to receive detailed description of the Regional Situation of HT (including HTA) and of existing national HTA programmes in the EM Region. The Iranian and Tunisian HTA experiences will highlight the challenges encountered, progress made and lessons learnt in implementing national HTA programmes. Discussions at the end of the session identified basic conditions for establishing HTA programmes and ways to avoid or overcome bottlenecks.
3.1 Current Status of HTA in the Eastern Mediterranean Region (EMR)

*Dr Adham Ismail WHO/EMRO*

*Dr Ismail* provided a detailed analysis of the HT situation in the region. He indicated that although no detailed assessment studies were conducted, several studies can be used as proxies to indicate problems related to appropriateness, access, affordability, availability and accountability of HT in MS. He indicated that the major HT challenges can be summarized as follows:

- **Group 3 Member States (Low Income EMR Countries)**
  - Lack of government policies and control (markets are mainly supply-driven).
  - Absence of National Regulatory Authorities (NRAs) that encompass all HT (particularly those in the private sector).
  - Lack of reliable systems for quality assurance and surveillance.
  - Weak HT Management (HTM) plans due to system-wide weaknesses in the form of limited financial resources; lack of production capacity; and absence of human resources.
  - Improper distribution/supply mechanisms leading to high delivery costs and inequitable access.
  - Irrational use (huge challenge especially when in Group 3 MS where 90% of products are imported).

- **Group 2 Member States (Middle Income EMR Countries)**
  - Lack of formal endorsement and/or implementation of written HT policies.
  - Improper management of resources (up to 30% of MOH budget spent on medical products).
  - NRAs are generally weak.
  - Absence of HTA systems.
  - Lack of transparency (leading to unreliable data).
  - Lack of procurement guidelines (especially when they import 60-90% of medical products).

- **Group 1 Member States (High Income EMR Countries)**
  - Concepts such as HTA and HTM are yet to be recognized by national health planners.
  - Issues related to quality and safety (high misuse and medical errors) are major concerns.
  - Mechanisms to manage demand of sophisticated HT (despite bulk procurement) are generally weak.
o Procurement policies, misuse and proper preventive/corrective maintenances are not addressed properly; therefore, leading to low clinical returns on investment made on HT.

_Dr Ismail_ pointed out that the current conditions in EMR MS indicate the need to make evidence based decisions on HT investments and that HTA will be a valid tool to realizing this goal. He claimed that - in contrast to what most officials think - the less the resources in a country, the more the need for HTA for (1) making rational decisions on investments; (2) prioritizing needs on the basis of evidence; and (3) estimating cost vs. efficacy/effectiveness ratios of new and emerging technologies. Finally, he concluded that HTA can be used and introduced in EMR MS based on their capability, capacity and needs. Any MS can access HTA knowledge through international databases, but networking is essential. He pointed out that the biggest challenge is not to find information, but rather to develop the capacity to use information.

### 3.2 HTA Systems in EMR: Tunisia

_Dr Mohamed Ben Ammar, MOH, Tunisia_

_Dr Ben Ammar_ gave a brief overview of the health system in Tunisia and provided statistics on the most important ones. He mentioned that healthcare costs are progressing with a rate of +13% annually and that the contribution of the government is decreasing and the contribution of households is increasing. Despite the increase in government spending, the quality of service provided is not improving that much. He also indicated that health expenditure is covered by various sources of funding, but patients are paying progressively more, although health care is in principle free of charge. His claim was supported by the fact that out-of-pocket payment in Tunisia is currently around 50%. To overcome these challenges, the government has decided in 2012 to establish INASanté (Instance Nationale D’Acrédation en Santé) for the purpose of:

- Certification and Accreditation
- HTA Application
- Development of Guidelines, Norms and Standards
- Evaluation of professional practices
- Health information

He indicated that support is needed from WHO for INASanté to be able to accomplish its goals.

### 3.3 HTA Systems in EMR: The Islamic Republic of Iran

_Dr Alireza Olyaee Manesh, MOHME, Iran_

_Dr Manesh_ kicked off his presentation by giving a brief overview of the health system in Iran at national and provincial levels. He indicated that the recent national health account study conducted in 2008 indicated that household health expenditure on health was around 50% of which 40% on essential medicines and medical devices.
Dr Manesh pointed out that HTA in Iran started in 2007 with the office of the health deputy of MOH as the secretariat. Following changes in the organizational structure of MOH in 2010, the office of the deputy for health was divided into hygiene and curative affairs offices. After this restructuring, HTA was categorized as a department under supervision of Health Technology Assessment, Standardization and Tariffs Office in Deputy of Curative Affairs.

On HTA funding, He explained that initially there was no pre-determined state budget for this new program. First HTA projects were funded by Department of Medical Equipment. Following establishment of formal structure for HTA under supervision of Deputy of Curative Affairs, its budget was considered as an independent source in state budget. Accordingly, HTA projects are funded by the governmental budget. HTA was useful in producing several comparative reports on benefits of new technologies over currently used ones for the purpose of making evidence informed decisions on Iran MOH investments on them. The list includes:

- Pet scan compared to other diagnostic devices for the treatment lung cancer and some other cancers
- HBOT (Hyperbaric Oxygen Therapy) compared to routine treatment for diabetic foot
- HIFU (High Intensity Focused Ultrasound) for prostate cancer compared to cryotherapy and invasive surgical therapy
- CT Scan 64 slice (single and dual) compared to Invasive Angiography
- MRI 3 Tesla compared to 0.5 and 1.5 Tesla
- Cone Beam CT (New Tom 3G) compared to Spiral CT
- Green Light Laser compared to traditional treatment and TURP
- Femtosecond laser compared to current method (mechanical method bladed or grated)
- Optical Mammography compared to X-ray mammography
- Dental CAD CAM system compared to conventional restoration
- Implanon (The Long Acting method for contraception) compared to other family planning methods
- Immune Tolerance Induction method for treatment of Hemophilia children compared to bypassing agents for the management of high-responder hemophilia patients with inhibitors

Dr Manesh presented HTA achievements in Iran in terms of not only formulating HTA structure in MOH but in medical universities of all provinces as well. Moreover, HTA reports have been converted to health system policy notes and were sent to policymakers, HTA stakeholders have been identified, a framework for HTA analysis process has been defined, and most HTA reports have been used (at least partially) by policymakers. He pointed out that HTA future plans is to prioritize topics on basis of a solid
scientific approach, develop and implement hospital-based HTA, and link ongoing HTA efforts with regulations on HT.

3.4 Discussions on HTA challenges in EMR

Moderated by: Dr Marthe Everard, WHO/EMRO

Discussions on challenges associated with HTA implementation in EMR MS revealed the interest of the participants to move this agenda forward in their countries. Somalia raised a question on where to place the HTA unit in a government entity. It was clarified that one umbrella body can host different functions and units for medical products, like medicines, and diagnostics. This may provide better oversight and also to better control borders. Saudi Food and Drug Administration (SFDA) is an example of such setup in the region. Tunisia raised the question on why no countries from the EM Region are members of international WHO collaborating networks (such as INAHTA or HTAi). It was explained that countries should apply to these networks and that one of the aims of this meeting is to stimulate countries to become members and exchange information with these important networks. Yemen requested information on how to start HTA. It was advised to start small with 2-3 people and to build up the system step-by-step in terms of organization, staffing and budget. Capacity building of staff is important to implement HTA. Advocacy is the first step to allow for the methodology to be accepted to evaluate Quality, Safety, and Efficiency and to undertake cost-effective evaluation to measure Effectiveness. At a later stage, other assessments can be added such as legal, social, and macro-economic dimensions. Lebanon remarked that multiparty decision-making will not be easily accepted and that transparency and democracy are needed to implement the HTA roadmap. It was explained that insurance firms are benefitting from HTA as competition will allow for best-buys. It was further remarked that the use of the methodology and the procedures need to be developed for implementation by each country and that no model can fit all countries of the region. Nevertheless, the progressive regional experience can be used to build up a national HTA system. Afghanistan had some queries on the pre-requisites for an HTA programme to be successful in any country. He was informed that conditions for starting a HTA system are: to collaborate with others, to establish links with policy makers, be independent and manage conflict of interest (COI), to have trained staff, to start small and grow further, and to monitor and evaluate HTA work and performance. In the implementation of the HTA programme, Iran experienced that the government intervened in identifying stakeholders. HTA is "intervening" at policy level and not directly at practice level. Iran has public funding for HTA projects but HTA does not have its own budget line in the budget. Therefore, implementation will be more complete when a dedicated budget line is in place. HTA in Iran is undertaken with research institutions. The HTA body is collecting information to make the HTA report. The way that NICE is independent as a government entity (NGO status) is not yet possible in Iran.

Dr Ben Yahmed concluded discussions by pointing out that EMR should start the HTA journey without delay. MOHs should establish HTA bodies with innovative approaches in case their capacities are limited. The Regional Director may send advisory letters to Ministers of Health urging them to start their own HTA programmes. This
advisory may support countries to get the political backing to initiate programmes and working towards independent HTA bodies. He also recommended that studies should be undertaken to provide evidence on the usefulness and cost-effectiveness of a HTA body.

4. **HTA GLOBAL, REGIONAL AND COUNTRY EXPERIENCES**

The purpose of this session is to inform participants about global, regional and country experiences outside EMR. The global WHO initiatives will guide participants on how countries can set up their HTA activities, including HTA outcomes to be applied to social or health insurance schemes for reimbursement, and on where available sources of HTA information can be found. AMRO/PAHO will present their efforts on establishing national HTA agencies/units in the region of the Americas. The experiences of three countries at different income-levels; namely United Kingdom, Colombia and Thailand, will provide additional insight to participants on their challenges, bottlenecks, progress in implementation, achievements and benefits of national HTA programmes in other regions. Discussions at the end of the session should focus on the lessons learnt from global, regional and non-EMR country experiences and how EMR countries can reduce implementation challenges and ways to overcome them when initiating or improving their national HTA programmes.

4.1 **HTA and Decision-Making: The Global Perspective**

*Mrs Adriana Velazquez, WHO/HQ*

*Mrs Velazquez* presented the global perspective of HTA in terms of its use in different countries of the world. She pointed out that in the World Health Assembly (WHA) of 2007; HTA was mentioned for the first time in any WHO Resolution. She emphasized that HTA should be approached by working together in networks and by establishing national HTA entities. Currently, HTA is a priority activity in the Programme of Work and Budget for WHO in the next biennium (2014-2015). In other regional offices, HTA was supported by various RC Resolutions. While illustrating the potential global uses of HTA at various healthcare delivery levels (including macro - meso - micro levels), *Mrs Velazquez* pointed out that HTA tools are already used in several WHO areas of work such as the Model List of Essential Medicines, Model Formulary, etc.

In terms of collaboration with stakeholders and international networks, she explained the different WHO Memorandums of Understanding (MoUs) with various HTA networks, such as INAHTA, HTAi, and EuroScan. These MoUs will help MS in getting technical support from these networks as well as facilitate collaboration in terms of exchange of knowledge and information. WHO has recently produced a document entitled "*Compendium of innovative technologies in developing countries*", which can be used as a source of information on new and emerging useful technologies. Therefore, national HTA entities can rely on such a document when making their decisions on costs, benefits and appropriateness of innovative HT. She pointed out that the document is not to be taken as the ultimate source for such information, but rather a good source of initial information on many inventions.
Mrs Velazquez stressed the need for HTA to become part of any national HT policy and that HTA concepts should be integrated into existing National Health Policy (NHP) such as the ones related to National Essential Medicines Policy. She presented a table depicting the work ongoing in the area of HTA, including documenting what is practiced in countries. She linked HTA to the concept of UHC by explaining that HTA directly affects cost, service and population dimensions of UHC. Finally, Mrs Velazquez invited participants to attend the “Second Global Forum on Medical Devices” which was going to be organized in Geneva from 22nd to 24th of November 2013. She informed participants that a whole session will be dedicated to HTA in the forum.

4.2 HTA incorporation into Health Systems in the Americas

Mr Alexandre Lemgruber, WHO/PAHO

Mr Lemgruber presented HTA as one of the approaches used in AMRO/PAHO MS. A decision-making cycle, which involves HTA, was presented and explained to participants as the basis upon which PAHO countries utilize HTA within their existing national health systems. HTA was eloquently utilized as a tool to overcome many of the health systems challenges such as equity to access health services, quality of care offered and efficiency of services. A RC Resolution on HTA was adopted in the region of the Americas in 2012. The resolution not only stressed the potential benefits of HTA but emphasized its direct link to quality of care and patient safety. A proposal comprising 6 main steps to promote HTA in the Americas was recommended by the resolution, the proposed steps are as follows:

1. Integration of HTA into public policies on health technologies HTA as an integrating force into the cycle regulation-incorporation-rational use.
2. Establishment of an institutional framework for HTA-based decision making explicit links between HTA and decision making, with the definition of transparent process that sets out the relationships and responsibilities of the different stakeholders.
3. Developing a strategy that addresses the different human resources needs in the region.
4. Identifying existing gaps and promoting dissemination of study results among stakeholders and decision-makers.
5. Rational use of health technologies by developing and implementing clinical guidelines and to evaluate the use of health technologies in health services.
6. Promotion of network collaboration by strengthening the HTA Regional Network (RedETSA).

Mr Lemgruber pointed out that explicit links to decision-making is yet to be experienced in MS. He emphasized that HTA reports and decision-making should both be available in the public domain in the sense that study results should be communicated widely. Accordingly, a communication strategy should be in place. Use of HT should be established and formalized and based on clinical guidelines. He explained that HTA will be in support of the UN Resolution on UHC endorsed in December 2012.
Mr Lemgruber demonstrated the potential benefits of having a regional HTA network where collaboration and information exchange can take place. Although RedETSA has started after the RC resolution, 13 members have already joined the network, and soon 14 countries will be members with 25 institutions. AMRO/PAHO is acting as the Secretariat of the network. RedETSA has relations with other institutions, such as the World Bank, Inter-American Development Bank-IDB, and other HTA networks.

Current ongoing efforts in the area of HTA in the Americas involve mapping of the capacities in the region to perform HTA. The mapping investigates (1) different models and organizational frameworks used by MS, (2) HTA institutions currently conducting and/or have the potential to conduct HTA studies, and (3) established HTA links with pricing and regulation. This mapping can also be used to negotiate with the industry and the private sector on the importance of HTA to their investment decisions as well.

Mr Lemgruber concluded his presentation by pointing out that social protection is also benefitting from HTA, especially in the decisions related to equity and health economics. He concluded that HTA should be an integral part of the package to advice countries on their healthcare expenditures. Since its adoption, the RC resolution on HTA generated a series of actions in countries of the region. Various projects are in place such as, the Project "Advance HTA", in collaboration with the London School of Economics and Political Sciences (LSE), and the Project "Regulatory-HTA interactions", funded by USAID. The purpose of these projects is to link HTA regulation and appropriate use with quality, safety and efficacy features of any HTA programme. Monitoring effectiveness and continuous re-assessment are part of a dynamic HTA process, which ensures adequate balance between efficiency and equity.

4.3 High-Income Country Experiences: United Kingdom

Mr Reetan Patel, NICE

Mr Patel started his presentation by giving a historic brief about National Institute for Health and Care Excellence (NICE). He mentioned that during the 1990’s the British NHS was facing a number of challenges including (1) little or no national guidance on the appropriate use of technologies; (2) poor uptake of effective treatments and too great a use of inappropriate or ineffective treatments, which led to a poor uptake of innovative technologies; (3) lack of national clinical guidelines; and (4) variation in practice – so called “NHS postcode lottery”. NICE was established by the UK Government in 1999 to address these challenges, with an evidence-informed, multidisciplinary approach. NICE started off with 10 staff and a budget of £10 Million, with a remit to carry out the appraisal of new and existing HT. The remit of NICE expanded to include the production of clinical guidelines, public health and more recently the development of quality standards and social care guidance. With the expansion of NICE’s remit came more human and financial resource, with NICE’s staff growing to 81 staff and a budget of £17 Million after the first 5 years, and 279 staff and £36 Million budget after the next 5 years. Currently, NICE has a budget of £70 Million and has over 500 staff, working to produce the various types of NICE guidance, products and services.
NICE is a nongovernmental organization (NGO), which enjoys an independent status and is one arm-length from the Department of Health. It is steered by a Board and the budget of NICE reflects that 50% is spent on staff. Over the years, various units were created to deal with different services and products. It has a range of clients, not only the National Health Service (NHS) but also local authorities, health councils and charities.

NICE has a set of 4 core principles which are applied across its wide remit of work. These principles guide them to be robust (underpinned by the best evidence), inclusive (involve genuine consultation with stakeholders), independent (developed by independent, multidisciplinary external committees), and transparent (evidence seen by the committee would be open access and available through the NICE website). WHO highlighted the application of principles as an achievement, in an independent review of NICE in 2003.

NICE decision cycle and single technical appraisals take 7-9 months. There is an appeal process in place for in case the manufacturer is not in agreement with the HTA results. There are three possibilities for appeal: HTA did not follow the process, EU law was broken, or confidential information was published on the web. In principle, the general public can attend meetings. Around 14% of appraisals are not approved (negative advice). Despite these clear principles, the challenges encountered by NICE are mainly in the area of legal issues and court cases. Mr Patel mentioned that it has not always been easy for NICE as they come up against fierce opposition via parts of the British media, they have been taken to court a few times. The lessons about their experiences with the judiciary have taught them that processes need to evolve; good governance structures help to increase the legitimacy of NICE’s work; and the system needs to be responsive and be able to adapt to changing needs/demands. A general lesson include the importance of having government support; without the backing of the UK government, NICE would not have survived the first 5 years.

NICE works closely with range of academic and professional organizations to ensure that the guidance produced is robust and independent. NICE engages with core stakeholders (such as patients, industry, professionals, payers, and providers). This has not always been easy, but it has definitely contributed to the success of NICE over the years. Engaging with the all the key stakeholders and having a consultative approach have helped to ensure NICE ability to get the buy-in from the different groups.

Mr Patel concluded by explaining the role of “NICE International” as a fee-for-service entity created by NICE to assist MS on HTA-related issues. It offers advice/technical support to developing countries but also capacity building, workshops and seminars.

### 4.4 Upper Middle-Income Country Experiences: Colombia

Dr Hector Jaramillo, IETS

Dr Jaramillo opened his presentation with an overview of the Colombian health system which is mainly characterized by a benefit package of health services; however, the offered package was not considered equitable by any standard. It created a large budget deficit and lacked the necessary robustness and transparency. There was no
efficient decision-making process in place. In 2013, a health system reform was initiated, including UHC, and the health system within the country was changed to a tax-based unified system that offers its services to all citizens.

The set-up of a HTA agency in Colombia (IETS) was based on incremental steps with a heuristic approach. IETS aimed at promoting HTA at the national level, and contribute to the development of best healthcare practices by supporting public health policies formulation with evidence based information. IETS decisions and analysis of new HT is balanced between in-house activities and out-sourced external assessment centers. The set-up was politically supported, problem-driven, with strong government commitment and policy formulation. The HTA agency started small due to limited capacity.

IETS is considered an NGO, and the evidence used in HTA reporting is obtained from various information sources. Senior staff was appointed in IETS by public announcements and recruitment decisions were taken on the basis of technical profiles and merits. HTA is promoted as a system to contribute to the development of best healthcare practices and is supported by public health policies. IETS structure and policy implementation were presented as a series of steps in the decision-making process.

Lessons learned, risks and challenges were presented, especially what went wrong and what went well in the first time HTA was developed in Colombia in 2011. Challenges encountered were: competing priorities and projects; public pressure; lack of local capacity; bureaucracy; institutional fragmentation; and insufficient budget. Drivers were identified for future development and the use of HTA, they were mainly to:

- Attain sustainability in the short term and restore trust
- Strengthen key institutions on parallel with the new process
- Clarify the role of marketing authorization of medical procedures
- Build local capacity under time constraints.
- Transfer, adapt, adopt and contextualize methods and methodologies.

4.5 Lower Middle-Income Country Experiences: Thailand

Dr Yot Teerawattananon, HITAP

The Health Intervention and Technology Assessment Program (HITAP), directed by Dr Teerawattananon, is a health technology assessment (HTA) agency under the Ministry of Public Health in Thailand. It was founded in 2007, with the main mission to provide evidence to guide resource-allocation in Thailand. During the past 7 years, the total number of research projects at HITAP accounts for 110 projects, most of which were used to guide coverage decisions in the National Health Security Office and revision of the national pharmaceutical reimbursement list. Unlike other government agencies, HITAP operates as a semi-autonomous research unit. To ensure technical integrity and transparency of research, HITAP observes national HTA methodological guidelines and a set of HTA process guidelines including code of practice on COI management. Thailand started HTA by developing its technical capacity of HITAP, then by developing the HTA process, and later by integrating HTA results into the policy-making process. It was
advised to start small and grow over time, and to engage and train other institutions like research institutes and universities in HTA.

Dr Teerawattananon explained that since its establishment, HITAP has enjoyed great benefit from international collaborations though various means including sharing experience with other HTA agencies in Europe, Australia and North America. Moreover, HITAP has collaborated with more than 10 HTA agencies in the region forming the network namely, HTAsiaLink. The network offers platform for capacity building activities for junior scholars. HITAP is also working closely with NICE International of the UK to help setting up HTA capacity in Low and Middle Income Countries (LMICs). HITAP offers training not only to national stakeholders but to countries as well. They offer work placement for 4-12 weeks, and provide on-the-job training. They use process and method guidelines to respond to policy makers' requests, and they are part of the International Decision Support Initiative (iDSI). Dr Teerawattananon stressed the importance of having a methodology to measure the impact of HTA on policy makers and MOH budget.

At present, HITAP is offering a wide range of technical supports to LMICs so that those countries can overcome challenges of using HTA. The support includes (1) developing technical capacity of individuals on evidence synthesis, health economics and health system research; (2) devising HTA process that matches to social values in particular society; and (3) establishing systems/mechanisms to engage HTA into decision making process.

### 4.6 Discussions on Lessons Learnt from Country Experiences

**Moderated by: Dr Kees de Joncheere, WHO/HQ**

**Jordan** opened discussions on country experiences by remarking that political interference destroys the HTA system. To cope with public pressure it was advised to advocate for the usefulness and limitations of HTA to politicians. It is important to gain legitimacy and reputation from the population. Let the population make the mistakes but do not get involved in political actions and discussions. Price regulation is also helpful.

**Tunisia** raised the issue of transparency procedures and stressed that it should be in place prior to publishing any HTA report. Therefore, the process of HTA should be inclusive in the sense that it should involve as many stakeholders as possible. Publication of reports is at the end of the procedures. The issue of off-label products was raised. This is not against the HTA process. There are many cancer drugs that are off-label and may not be evaluated.

**Iran** pointed out that if HTA is seen as a rigid process; it should be evaluated and adjusted over time. There is room for a robust but flexible approach. It was advised that a draft HTA document should be reviewed by as many HTA entities as possible for their comments. It was further mentioned that conflict and declaration of interest should be in place for each staff member and expert becoming a committee member. COI and declaration checks can be published on-line. Multi stakeholder decision-making can take time for agreeing on a controversial medicine or technology.
A question was raised by Afghanistan whether there is one similar model or concept in place in countries of the Americas. It was explained that the concept, set of functions and key principles of HTA are the same, but the institutional framework are different because there are different health systems in place with different organizational settings. It is important to include national institutions in the process as well as national committees. An inclusive way of working and clear division of labor is advised. In countries of the Americas, the level of independency differs.

Somalia raised a question on how to convince the Governments to have an independent body and at the same time to be funded by the Government and with MOH appointing staff. What can be done to avoid overlap of national Essential Medicines Lists (EMLs) and Standard Treatment Guidelines (STGs)? It was mentioned that this is a big challenge when MOH appoints staff. Therefore, an open or competitive selection process should be followed. The use of a head hunter can be an option to find suitable people. Overlap in existing tools is a big challenge. Therefore, coordination of HTA activities is the key. It was further mentioned that if transparency is not maintained, stories will be made up by others and leaked to the press. NICE provided a clear example. It is essential to have a recognized public process and clear rules of the game in place.

Tunisia raised a question about the cost of an evaluation. Thailand responded that an evaluation may cost between USD 10,000 to USD 1 Million. Cost will not be high when a screening exercise is undertaken as long as the process is contestable.

Iran raised a question on how Colombia could select products without an economic evaluation. Cost-effectiveness is essential for maximizing benefits under financial constraints. What can be done within a given budget by not compromising people’s health and still cutting costs? It is important to use published information and evidence from other countries to gain time and save money. It was explained that HITAP is not only dependable on government funding. It is important to have or build up a strong organization and HTA culture. There is always a time constraint to undertake a comprehensive HTA with a cost-effective analysis. If there is no additional benefit, then there is no need to do an economic evaluation. A trade-off should be made between time, budget and policy-making.

Questions were raised by Lebanon on how to prove adherence to HTA principles and how to overcome the stiff resistance when HTA is introduced. It was made clear that transparency is the key. Lack of trust is the issue that should be overcome. Therefore, HTA agencies should be transparent in hiring staff and in addressing COI. Staff background and qualifications can be published on the web along with their salaries to avoid mistrust of income. Therefore, publishing on the web can be a way of demonstrating openness and clarity. Reputation of the HTA body can also be demonstrated through the publication of international connections or articles. Another possibility to overcome mistrust is to have external audits assessing the HTA process. Declaration of interest is another key principle that has to be taken seriously. To increase credibility is by involving stakeholders in the HTA process and to update the benefit package regularly. Professional bodies can resist and therefore is important to get them on board. Core stakeholders should be fully involved. It was remarked that regional support,
learning from others, sharing information, and meeting members from other networks are all important to build up relevant HTA connections.

Finally, Dr Kees de Joncheere wrapped up the session by concluding that

- Increasing complexity of technologies; growing expectations from professionals and the public; and limited resources calls for priority setting and making choices on what services get offered.
- HTA is an important tool and it can be applied in many different areas such as priority setting on health interventions, public health programmes, reimbursement decisions for medicines, purchase decisions of devices and technologies, clinical guidelines, etc.
- HTA needs to be embedded and integrated in a decision making structure, it cannot work in isolation. HTA needs a transparent process and criteria for topic selection as no entity is capable of looking at all the issues. There needs to be a clear process to move from the HTA report to the final decision.
- HTA agencies need to engage different groups/professionals/academia in its work to create buy-in and commitment. HTA agencies also need to engage regionally and globally with other agencies and groups to avoid duplication and increase their own efficiency. It is equally important to “contextualize” and adapt HTA findings and subsequent decisions to national settings.
- Every country needs to put in place the system in line with their national health system, their resources, and their needs. This can take the form of an agency, of expert groups or committee, or of work being outsourced to academia or other institutions, or a combination of the above.
- Countries should start small but with a clear mandate and try addressing issues where “quick wins” are possible so as to create credibility and buy-in from stakeholders.

5. HTA INTERNATIONAL NETWORKS

The purpose of this session is to inform participants about various existing international HTA networks: HTAi, INAHTA, EuroScan, OSTEBA and others. They will present their ways of working in terms of their structures and services. The session will end with a panel discussion on how these HTA international networks can be consulted and their services requested by EMR countries for the purpose of developing national HTA programmes within their socio-economic settings and existing national health systems.

5.1 Health Technology Assessment International (HTAi)

Dr Inaki Gutierrez, HTAi

Dr Gutierrez gave a presentation on HTAi network. He explained that HTAi is a global scientific and professional society for those who produce, use, or encounter HTA. It currently includes 1,300 members from approximately 60 countries; however, very few of them from Africa and almost no country from EMR is a member of HTAi. The
network includes 16 for-profit and 60 not-for-profit HTA organizations. It embraces all stakeholders, including researchers, agencies, policymakers, industry, academia, health service providers, and patients/consumers. HTAi is considered a neutral forum for collaboration and sharing of information and expertise. Its secretariat is based at the Institute of Health Economics in Canada. Dr Gutierrez mentioned that the main mission of HTAi is to “Support and promote the development, communication, understanding and use of HTA around the world as a scientifically-based means of promoting the introduction of effective innovations and the effective use of resources in health care”.

The portfolio of HTAi activities include annual meetings, policy forums, interest subgroups, regional meetings or platforms, International Journal of Technology Assessment and Health Care (IJTAHC), international collaborations, grants and scholarships, and online resources. Many of these activities are relevant to the developing parts of the world. Dr Gutierrez invited all EMR countries and agencies to be part of HTAi, especially those that (1) want to meet and contact high profile decision makers (clinicians, patients, managers, politicians, etc.) within the HTA and Health Outcomes research arena, (2) consider meeting multiple prospects in one setting a cost effective way of gaining knowledge and experience, and (3) require a fast track to gaining competitive advantage and increased discussion share. He urged all EMR MS to participate in this society and position themselves as thought leaders in the HTA space. Organizations and individuals can become members in HTAi and benefit from HTAi services, including the policy forum (PF) tool. Membership fees are used by HTAi in a completely open manner. All financial details are openly discussed at the annual HTAi business meeting. Dr Gutierrez stressed that HTAi is not a charitable organization and it cannot be hired to do something for an organization. HTAi budget is used in agreement with the whole society. Members come mostly from high-income countries as HTAi started in USA and Europe. Access to annual HTAi meeting is quite expensive, but HTAi offers scholarships and travel grants to attend the meeting for free. For HTAi, it is a challenge to get more people to come to their annual meetings from LMICs.

Finally, Dr Gutierrez browsed HTAi website and illustrated the different services that can be accessed from it. Discussion forums, IJTAHC (which includes a section for debates), articles describing the situation in your country, experiences, and other services are all available freely on the website. HTAi website also gives access to the HTA glossary, which is in different languages (English, French, Spanish, German and in Portuguese and soon it should be in Arabic). “HTAi Portal” is also very useful in providing information on upcoming activities and important meetings.

5.2 The International Network of Agencies for HTA (INAHTA)

Dr Sophie Werko, INAHTA

Dr Werko explained that the International Network of Agencies for Health Technology Assessment (INAHTA) is a not-profit organization which was established in 1993 and now has 57 member agencies from 32 countries. The Network stretches from North and Latin America to Europe, Asia, Africa and Australasia. All members are non-profit making organizations producing HTA and are linked to regional or national
government. Most activities are coordinated by the Secretariat. The membership meets yearly and participates in various working groups meet throughout the year. The Annual Meeting is held in conjunction with the HTAi Conference. The INAHTA board, including the chair of the board, is elected for a period of 2-years.

Dr Werko mentioned that INAHTA's key communication form is internet. The INAHTA website and “Members-only” section include information about ongoing activities; the “Brief Series” (in which member agencies can present overviews of recently published reports); and “HTA Checklists” that provide information on the purpose, methods, and contents of an HTA report. INAHTA also produces a newsletter in three languages on current initiatives and activities among member agencies, new projects within the Network, recent developments and trends in health policy research, publications in the field, and upcoming events.

Dr Werko pointed out that throughout the year members collaborate in working groups on external partnerships, internal communication, impact of HTA, quality assurance, education and training and industry relations. INAHTA membership is open to organizations that (1) assess technology in health care, (2) are non-profit organizations, (3) relate to a regional or national government, (4) are funded at least 50% by public sources, and (5) provide free access to their reports. The common challenges encountered in INAHTA are related to limited staffing and time of its members, geographic distance, languages, cultures, incompatibility of methods, etc.

Dr Werko highlighted that the by-Laws include detailed information on membership criteria and the application and approval process for membership. INAHTA provides different levels of membership fees according to the World Bank Classification. As of June 2011, the annual membership fees are as follows: €2,700, €2,025, €1,350, and €675 for high, upper-middle, lower-middle, and lower income countries respectively. A candidate membership is also possible for agencies that are just starting, have yet to produce HTA reports, or are experiencing financial hardship. Dr Werko also pointed out that it is possible to publish information and HTA reports without being a member. This is part of the open access policy that INAHTA follows. The policy allows for posting reports from non-members, provided they meet the quality standards.

Finally, Dr Werko concluded by referring to the mentorship programme that INAHTA offers to WHO MS. The programme is specialized in building capacities of HTA staff in different skills needed to develop a valid HTA report that can provide valuable and correct information to policy makers.

5.3 The International Information Network on New and Emerging Health Technologies (EuroScan)

Prof Brendon Kearney, EuroScan

Dr Kearney highlighted the mission, vision and activities of the London-based EuroScan network, which is considered the leading HTA network for collecting and sharing information on new and emerging technologies in healthcare in order to support
decision making and the adoption and use of effective, useful and safe health-related technologies. EuroScan is also the principle global forum for sharing and developing methods for the early identification and early assessment of new and emerging technologies and predicting their potential impact on healthcare delivery services. The range of outputs that EuroScan produces include early awareness and alert activities, toolkit for identification and assessment of new and emerging HT, database on new and emerging HT, website, newsletter and publications. At present, there are 18 HTA agencies who are members of EuroScan. The majority of the members are based in Europe but the number of non-European members is growing. EuroScan members and activities are not large (produce 50-60 reports per year); therefore it is important to prioritize what technologies to assess.

EuroScan is managed by an executive committee and a secretariat. The executive committee is made up of representatives from member agencies that, on permanent basis, undertake substantial early awareness and alert activities. The membership criteria are opened to any agency that:

- Develops or has, a programme for early detection of emerging, new or changing HT;
- Possess an ongoing, officially recognized role in relation to regional or national government;
- Is a non-profit organization;
- Has at least 50% funded from public sources;
- Has no link – other than scientific – with commercial companies or R&D centers;
- Is transparent about their funding and financing; and
- Commits to support EuroScan mission.

Industry cannot participate in any HTA activities and therefore cannot influence their HTA work. However, EuroScan has a scientific link with the industry.

Horizon scanning of new technologies is done by HealthPACT in Australia. Scanning is undertaken as part of priority setting, but also scanning of sources. Information from NRAs is difficult to find. Information on EuroScan and HealthPACT is available on their respective websites. Universities are used for database management and for information collection. EuroScan is a young and small organization and collaborates closely with other HTA networks. They work in collaboration with WHO. EuroScan would like to encourage EMR countries to become members and benefit from their array of products and services.

Horizon scanning techniques are applied in most of EU countries, including cost-effectiveness of health technologies, public health interventions, all non-drug
technologies, services and programmes. Almost all HTA agencies almost use horizon scanning in some way (for regulation for instance). But all have their different need. Most have a need for horizon scanning, but problem is that new technologies have not gathered enough data to prove their effectiveness.

5.4 Panel Discussion: What can international network offer to promote HTA in EMR?

Panelists: NICE, HITAP, HTAi, INAHTA, RedETSA and EuroScan

The discussion started with a question from Dr Ismail about what benefits can be expected from regional networks, and the reason for not having a single global HTA network in place. It was remarked that regional networks can assist better with more regional specific information to their members. A network of EM countries will allow for sharing core information and for linking up with other regional and international HTA networks for sharing reports, assessment models and frameworks, tools and organizational modalities. A global or international network is a network of networks.

A question was raised by Tunisia regarding the language used for communicated in the regional network of the Americas (RedETSA). Mr Lemgruber revealed that various languages are used such as, English, Spanish and Portuguese. Inclusion of the Caribbean countries requires English. Language is indeed a barrier but should not stop HTA activities. Heterogeneity exists in every network, with different needs, different capacities, and different levels of country income. It is worth mentioning that in addition to language-related challenges, technical challenges are also faced by every network member. Innovative approaches are found by countries with less developed HTA systems. Dr Werko added that Europe faces similar problems with languages and HTA development. There is a framework that provides step-by-step guidance on setting-up a HTA. The Baltic States found it very useful.

Iran asked about the ways to measure HTA impact and Dr Werko replied that this is a major challenge in many European countries. Information concerning the situation before HTA was implemented is required before measuring the impact of applying HTA. There is a need to know how patients were treated before HTA to be able to determine the comparative advantages of using new treatment modalities recommended by an HTA report. Her advice was to use registries, do surveys and perform pre- and post-assessment studies. The Swedish HTA agency (SBU) has recently produced report on measuring impact and identifying evidence gaps. The report was based on impact questionnaires (can be accessed from INAHTA website) that were sent to healthcare providers to assess and verify their use of HTA. The best impact on measuring HTA will be the changes introduced to clinical practice. Currently, Sweden includes their current health care situation as a chapter in their reports so that the context is clear to others. Dr Teerawattananon added to the ongoing discussion by pointing out that South East Asia also has a regional network which is called “HTAsiaLink”. The context of countries, HTA levels, collaboration with stakeholders, and health systems are not very different from each other. Politicians have an interest to know what other countries are doing. Through a
Dr Kearney emphasized the need of link between global and regional networks; for EuroScan there is maybe only need for one or two of its members to participate in global networks.

Dr Ismail and Prof Ben Ammar asked about the services that can be offered by these networks to EMR MS having no formal HTA functions. Mr Lemgruber mentioned that countries can be members of RedETSA, with or without HTA programmes. The network is based on the solidarity principle among the countries in the region. An example was given of INESSS that does not need RedETSA as a network, but wants to be a member for sharing information with other countries.

Dr Teerawattananon referred to the role of regional networks in building capacities of HTA staff. He gave the example of Myanmar who is currently more involved and wants to know more about cost-effectiveness and use of HTA methods and involve stakeholders/patients. The same with the Philippines which have no health coverage but is interested in using HTA for the evaluation of different vaccines. Both countries are building capacities of their staff in HTA without having formal agencies in their existing health system. He mentioned that countries only need to start with a handful of people who are interested to use HTA. Dr Kearney added that EuroScan can offer or suggest podcasts training courses in horizon scanning to help regions. He added that a podcast training course is scheduled for next year. Mr Patel added that NICE worked with HITAP and made a training blueprint to be used by other countries; however, he emphasized that the support of the government is crucial to organize these training sessions. It was remarked that EMR should continue to meet and the other networks are ready to support with their means. NICE mentioned that they have an agreement with Afghanistan and India to improve quality of services.

Somalia inquired about ways of encouraging countries to be members of these international networks and pay the required fees. Dr Gutierrez advised to use country success stories. In addition, officials should be informed that most HTA reports from other countries can be useful and are free of charge although they have to be adapted. Dr Werko explained that in INAHTA there can be more than one entity from one country as members. For example, Spain has five members, Sweden only one member. Italy has a member that is a hospital (50% publicly funded) and also universities are members. She explained that HTA agencies and provinces have different health systems, as in the case of Spain. Accordingly, there is a possibility of having more than one HTA agency in the country. This information will help any agency in any EMR MS to become a member on its own if needs be. This will also help MS with decentralized health organizations to benefit from the services that can be offered by these networks at their regional, local or healthcare facility levels.

A question was raised whether there is a mentorship programme offered by one of the networks on how to start HTA. It was mentioned that a WHO mentorship programme is almost finalized. It will be presented at the Second Global Forum on Medical Devices in Geneva in November 2013. The EM Region can follow the same way of establishing a
network similar to the one developed by AMRO/PAHO last year. Countries will be stronger when working together.

6. HTA MODELS AND ANALYSIS FRAMEWORKS

The purpose of this session is to demonstrate different HTA models and analysis frameworks in use by some of the existing HTA agencies. This will inform participants about administrative and financial requirements needed for initiating national HTA programmes in terms of structure, status, organization, management, human and financial resources etc. The session will also explain the different approaches and logical frameworks used for HTA assessments of new and emerging technologies, with special attention to low-income countries. The session will also allude to the role HTA can play in the UHC initiative.

6.1 Setting up an HTA programme: The Experience of Taiwan

Dr Churn-Shieh Gau, CDE

Dr Gau highlighted that the need for HTA in Taiwan was realized with the establishment of a National Health Insurance (NHI) program in 1995, which covers over 99% of the population. The total health expenditure was about 6.9% of GDP in Taiwan and the drug claims were about 25% of total medical claims in the NHI program. The NHI program faced some difficulty to introduce new technologies and services under limited resources due to the fact that people were not willing to increase the insurance premium rate. Hence, center for drug evaluation was commended by Ministry of Department of Health to carry out a HTA project in 2007. From that moment, HTA programme in Taiwan became linked to the NHI programme.

HTA in Taiwan started with a team of 14 members having different medical backgrounds. Through trainings, seminars and conferences, concepts of HTA, templates of submission contents, tools and methodologies were delivered to staff as well as corresponding stakeholders. HTA started step-by-step and by learning-by-doing. It received support from HTA agencies from Canada, Australia and UK for developing its own procedures, checklists and submission forms. Pharmaco-economic evaluation studies are undertaken for measuring the budget impact. A regulatory body is reviewing quality, safety, and efficacy of HT in the country whereas the national health system is interested more in cost-effectiveness and cost-benefit issues. The insurance has introduced three categories to list medicines, based on substantial, moderate, and similar therapeutic benefits. This is used for setting the reimbursement price.

HTA in Taiwan has gained trust from stakeholders, including NHI, industries, and expert committees. The need for HTA analysis when new technologies apply for reimbursement was highlighted in the 2013 amendment of NHI act. In order to confront the coming challenges, an independent National Institute of HTA (NIHTA) is currently developed. Assessment reports include cost-effectiveness and economic assessments and are published at the HTA web site of Taiwan. Dr Gau mentioned that an amendment was made to the NHI act in 2013 to introduce HTA in order to broaden the scope of medical
products. A process was introduced for new drug listing and for the application of reimbursement pricing. The Centre is working towards becoming an independent institution.

6.2 Developing National Capacities to Undertake HTA

*Dr Inaki Gutierrez, OSTEBA & HTAi*

*Dr Gutierrez* highlighted that HTA is a knowledge management process that includes knowledge generation and knowledge transfer within a multi-disciplinary team. He noted that the type of knowledge and information that needs to be managed by HTA units can be in the form of (1) Primary or Basic evidence, (2) Information from organizations devoted to produce secondary evidence or digested evidence, (3) Information produced by other HTA units, and (4) Information about context aspects such as epidemiology (morbidity, mortality, prevalence, incidence,…), organization, social, legal, economic, ethics, or cultural. He referred to the European Network for HTA agencies (EUnetHTA) handbook on capacity building and pointed out that this handbook can be clearly used as a reference in developing the knowledge, procedures and attitude of HTA staff. He stressed that for capacity building of staff, countries need to have a plan; type of information that needs to be trained on (primary, secondary, etc.); and skills to be developed (including attitudes). Often HTA agencies have less than 5 professionals of different backgrounds and disciplines. All of them have to be taken into account during the build-up of the training programme. HTA capacity building process can be done using different approaches from bottom-up (academia, professionals), or from top-down (policy makers, managers and medical directors). Accordingly, converging is needed at the micro-meso, meso-macro levels. The customer can be from the public or private sector, provider or purchaser, professionals or managers. Therefore, HTA training models should be based on motives, enablers, and barriers, mostly related to health outcomes; not only on cost considerations. It was remarked that same barriers are encountered by all countries independent of their level of income. It was also mentioned that resistance to change is universal. *Dr Gutierrez* acknowledged that a multidisciplinary team - comprising epidemiologists, biomedical engineers, pharmacists, librarians, economists, ethics specialists, organizations, IT personnel or other specialists - is needed but trained staff is not always available. Therefore, it is important to link to academic institutions for adequate expertise.

6.3 Comparison among different HTA models: Organizational capabilities, funding, processes and impact

*Dr Adham Ismail WHO/EMRO*

*Dr Ismail* highlighted the various issues that should be considered for setting up an HTA unit or functions within existing national health systems. He shared with participants the results of a EUnetHTA comparative study - conducted in 2008 on HTA agencies in 27 countries (21 from Europe) – and pointed out that the study indicated that the main initiative for establishing HTA agencies was governmental (61%). The study also revealed that the main barriers for establishing HTA agencies were in gathering
trained staff (64%), funding (45%) and political will (36%). The study even investigated the potential solutions to each of these barriers and the results indicated that the following actions can be done in order to:

- **Develop the Political Will**
  - Collaboration and Networking
  - Communication with all stakeholders
  - Timely and quality products
  - Demonstration of the need for HTA and its impact.
- **Gather Trained Staff:**
  - Training for staff through official/accredited courses
  - Intensive recruitment efforts
  - Collaboration with universities and hospitals
- **Raise Funds**
  - Attracting different sources of funding
  - Raising awareness about the need for prioritization
  - Public Relations

In another comparative analysis conducted in 2011 by the Charles River Associated (CRA) group of consultants on the role and impact of HTA agencies in 15 selected countries, Dr Ismail demonstrated that HTA agencies vary considerably in terms of their budget, size, length of process, number of produced reports, etc. Therefore, the results of the study indicated that no single model can be applied to all countries and that variation is based on the difference in health systems, organizations, and needs. Finally, Dr Ismail explained that the impact of HTA can be looked at from different angles, such as governance, stakeholders, expenditures, HT usage, and patient safety. All of these can be used as proxies to the importance of HTA in countries.

### 6.4 Innovative Technologies for Low-Resource Settings: Detailed Assessment Methods

*Prof Brendon Kearney, EuroScan*

Dr Kearney presented the Australian experience in dealing with innovative technologies. He explained that Australia achieved 50 years of UHC and 30 years of HTA. The main purpose of HTA was eligibility for long-term reimbursement. Developing countries may not be able to do all HTA assessments. Therefore, it is important to define the PICO (Patient, Intervention, Comparator, Outcomes) criteria to develop well-defined clinical questions for each review. This involves focusing the question on the following four elements:

- patients or problem to be addressed
- intervention or treatment being considered
comparison intervention, if necessary

HTA can study various evidence dimensions and levels of evidence. In Australia, an economic evaluation to demonstrate cost-effectiveness can be seen as "the fourth hurdle" to consider in any HTA assessment (the other three hurdles are quality, safety and efficacy). Dr Kearney explained the cost-effectiveness assessment model as necessary criteria for low-resource settings to use for the purpose of evaluating HT and ensuring that investments are put in the right place. There are variables between countries that should be looked at, such as the incidence and death rate of the disease, and the culture of the technology in a given country. Quality of Adjusted Life Years (QALY) can be used for cost-effective comparisons between different HT. It may be a broad dimension but it relates to GDP of countries. Dr Kearney also mentioned that the assessment framework for new and emerging techniques is best assessed by horizon scanning technique. Formal HTA cannot be used here, only for mature technologies.

6.5 Role of HTA in Universal Health Coverage (UHC): guidance and key issues.

Dr Reiner Banken, INESSS

Dr Banken gave a presentation on the role of HTA in UHC. He indicated that the fact that HTA is linked to evidence-informed decision-making renders it closely linked to UHC dimensions of cost, population coverage and services. There are various institutes, such as the Cochrane Centre, that looks into the impact of HTA on governance and UHC. There are documents available on health systems and policy research undertaken in EMR countries. EMRO is already collaborating with the Cochrane center and more research on its impact on UHC can be jointly investigated. SEARO has undertaken health interventions, procedures and HTA in support of UHC. Reducing waste and inefficiencies of the health system will greatly affect the implementation of UHC in our region. HTA can be used as tool to reduce such waste, which amounts to 20-40% of the procured technologies.

6.6 Discussion on appropriate HTA models and analysis frameworks for EMR Countries

Moderated by Mr Reetan Patel, NICE/UK

Discussion on frameworks and assessment methods that should be employed by EMR MS opened by Dr Ismail describing the journey of a medical product or a HT from regulation (safe and good quality) to assessment (quality, safety and efficacy) to management (sustainability, maintenance, use, etc.). He pointed out that HTA is a tool that can be used to reduce waste, maximize the Return on Investment (ROI) and improve management practices. To do so, HTA framework for analysis should be able to provide valid technical recommendations to policy makers. He pointed out that in the Danish center for HTA (DACEHTA); they use 6 types of HTA reports which differ in characteristics, aim, time frame, and extent as shown in table (1).
**Table 1. Comparison between different HTA reports**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>HTA-broad</th>
<th>HTA-focused</th>
<th>Foreign HTA</th>
<th>Core HTA</th>
<th>mini-HTA</th>
<th>Early Warning HTA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Based on complex problem or disease; Broad and general approach; may include alternative HT.</td>
<td>Based on delineated problem; focus on one technology.</td>
<td>Based on reports related to global or external regional conditions.</td>
<td>Based on problem which is of current interest in a specific country or region.</td>
<td>Based on questions raised within an individual hospital (operation-orientated).</td>
<td>Warns decision makers of future HT early on in their life-cycles</td>
<td></td>
</tr>
<tr>
<td>Aim</td>
<td>Input for political-administrative and clinical decisions</td>
<td>Input for clinical decisions</td>
<td>3-6 months</td>
<td>6 months</td>
<td>1-2 months</td>
<td>2-4 months</td>
</tr>
<tr>
<td>Time Frame</td>
<td>1½ – 2½ years</td>
<td>1 year</td>
<td>Expert assessment</td>
<td>Undecided</td>
<td>No peer review</td>
<td>Expert assessment</td>
</tr>
<tr>
<td>QA</td>
<td>External peer review</td>
<td>External peer review</td>
<td>10-25 pages of summary and comments</td>
<td>50 -100 pages</td>
<td>3-5 pages</td>
<td>4 pages</td>
</tr>
<tr>
<td>Extent of report</td>
<td>200 pages</td>
<td>100 pages</td>
<td>Health Technology Expenditure in Europe</td>
<td>Medical Devices Management in Egypt</td>
<td>Procurement of MRI in public hospitals of Aswan</td>
<td>Cost-benefit analysis of a PET scanners</td>
</tr>
<tr>
<td>Example</td>
<td>Type 2 Diabetes</td>
<td>Reduction of cervical cancer risk by vaccination</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Dr Teerawattananon further elaborated that HTA methods and analysis depend on how HTA functions are designed, target audience, country or region of interest, etc. HTA analysis can be used in some countries (such as Thailand but not UK) to negotiate prices of services.

Prof Ben Ammar referred to the financial linkage between HTA and UHC by referring to the fact that without HTA, MOH Tunisia faced a lot of problems especially in the increase of out-of-pocket expenditure. He added that in Tunisia it is difficult to convince physicians with HTA-related decisions. Dr Gutierrez advised him that when
doing the first HTA report, INASanté should not try to solve all health questions. He stressed the importance of working within the Tunisian framework of decision making, as well as trying not to attack the most difficult topics. HTA is to supplement not to replace physicians.

Dr Manesh referred to Iranian limited HTA capacities in dealing with all requests. He indicated that HTA agency in Iran is only able to assess 30 HT per year and this represents only 10% of the requests they usually receive. Dr Kearney indicated that the same problems are encountered in Australia and his advice was to try to select those that are most important as obviously they cannot cover everything. Dr Gau mentioned that in Taiwan they only apply HTA to technologies related to certain selected diseases and new molecular entities. The panel concluded that there must be a set of criteria for prioritizing topics and this set will depend on many country-specific factors.

Iran posed a query on how to solve the problem of COI and Dr Kearney advised them to sign a declaration of interest (no travel, no gifts) if no charges will be done against that person. Dr Banken stressed the importance of this point and in shielding all deliberations within the HTA team from personal interests. Iran also asked about clinical evidence from manufacturers and their validity in HTA reporting. Mr Patel indicated that NICE usually asks manufacturers to submit such evidence to an independent review or a university to validate them. The independent reviewing body will look into the evidence, review of possible lacks and ask for clarifications.

7. THE WAY FORWARD

The purpose of this session is to split participants into more focused groups with the aim of coming up with concrete recommendations from countries in similar situations on the ways to move HTA forward in EMR. Discussions should lead to clear answers as to where, when, and how to start the activities leading to implementation of national HTA programmes in EMR.

7.1 Introduction to Group Work: Developing a Roadmap for Implementing HTA for 3 income-based group of EMR Countries

Dr Adham Ismail WHO/EMRO

Dr Ismail introduced the group work session of the meeting. He indicated that participants will be divided into 3 groups as follows:

- Group: 1: Countries with Established HTA agencies
  - Tunisia and Iran, presentation
- Group 2: High/Middle income countries with no formal HTA function
  - Egypt, Iraq, Jordan, Lebanon, Libya, Morocco, Oman, Qatar.
- Group3: Low income countries with no formal HTA function
  - Afghanistan, Djibouti, Pakistan, Palestine, Somalia, Yemen.
Dr Ismail explained that the main purpose of the group work is to develop a roadmap for countries to follow in order to implement HTA programmes within their existing national health system. Each group should clearly indicate what WHO and MOH should do in the following to ensure successful implementation of HTA programmes:

- HTA structure and scope of services
- HTA staffing, funding and administrative considerations, including relationship with Government
- Collaboration with other organizations (HTA agencies, international networks, etc.)
- Links with policymakers and stakeholders (universities, research centers, key government officials, Ministries of Finance, etc.)
- Methods to enhance capacities and knowledge of HTA staff.
- Analysis methods and procedures, including reporting and publication of results, as part of the transparency and accountability framework.
- Communication policy and how to respond to a wide range of audience.
- Monitoring & Evaluation mechanisms.

7.2 Group Work Presentations and Discussion

In their presentation, Group 1 indicated that the common challenges associated with countries with established HTA agencies were political instability and credibility. They stressed the importance of getting legislative support by introducing HTA into their laws and regulation to become recognized and respected at all levels. The support of WHO is needed to advice MOHs on the importance of supporting HTA activities by laws and regulations; thereby, making HTA mandatory before making any decision on HT investments. This will help in bringing HTA into practice, linking them to national guidelines, and making them easier to implement.

Group 2 indicated that their common challenges as high and middle income countries are related to linking HTA to regulatory mechanisms, lack of expertise; unavailability of information sources, and pressure from industry. They pointed out that WHO should support the political buy-in of HTA by policy makers, facilitate communication between countries, create a database of all adapted HTA reports that are produced in the region, assist MS in establishing permanent connection links with international networks, and raising awareness of officials and policy makers on the potential benefits of applying HTA.

Group 3 demonstrated the challenges associated with low income countries in establishing HTA functions within their existing national settings. The identified common challenges included lack of national HT policies, lack of support from policy makers, lack of clarity on the difference between HTA and regulation, lack of reliable data sources and information systems, and lack of qualified human resources.

Dr Teerawattananon immediately made a remark that it is not the resources and logistics (office, staff, etc.) that promote HTA in any country, but rather the approach and
the way by which it is introduced is the main challenge in his opinion. It is more important to have the concept and the process right. Dr Kearney also commented on group presentations by advising EMRO to actively promote HTA to health ministers. There is potential in the region and EMRO should move fast and establish a regional HTA network as soon as possible. He advised EMRO to have a HTA coordinator who assists MS in reorganizing all HTA-related/like activities in MOH. There are a lot of possibilities to move on quickly. Dr Jaramillo advised EMRO to advocate well before implementing any HTA programme in any MS. There will be a need for technical capacity building and strengthening. The EMR Network may need assistance and other networks may offer their support. Mr Patel noted that the challenges seem to be similar among countries. Therefore, one of the first steps is to raise awareness at MOH. WHO should use its powerful voice to introduce HTA in the region and to make use of the expertise of other regional networks and invite them to technical meetings. He indicated that the roadmap will formalize the needed actions that were agreed in this meeting. The first step needed is raising awareness at the ministerial level (here WHO can help as a powerful voice) – not only minister of health but also finances and education. He even stressed the importance of bringing INAHTA and HTAi to regional health conferences to convince policy makers on the importance of HTA. Dr Werko was in agreement and offered the use of HTA networks for assistance, including the use of published reports and information. Dr Gau explicitly advised each country to develop its own HTA programme in line with its health system demand. HTA can be set up in different forms and settings to respond to varying demands. Dr Kearney also emphasized the HTA network can take on a backstopping role to assist a country. This can be decided together with WHO. It was announced that how to set up a HTA will be a session in the Second Global Forum on Medical Devices. Dr Ismail mentioned that raising the awareness of policy makers in countries on the importance of HTA can be done in the form of a letter from the EM Regional Director to health ministers of the 23 countries of the region. Technical papers and resolutions to WHA and RC can also be suggested to promote HTA. Political commitment needs to be established, training opportunities should be offered and a regional network should be established.

To initiate the process, Dr Lemgruber advised to set clear objectives for HTA initiatives, be realistic in what can be achieved, follow step-by-step approach to set up a HTA programme and set milestones. The creation of a regional network should start today by agreeing on objectives and expectations of a regional network, by organizing a regional conference for agreeing on the set-up of the regional HTA network, followed by a meeting for the launch of the regional HTA network of which its secretariat will be at EMRO. One of the first activities will be the mapping of the capacity to start HTA programme at country level and the use of HTA in decision-making. A baseline on how decisions are made is important to know. Concrete actions should be planned for the coming 12 months. It was further remarked that assessments of provided health services and packages of health services covered by health insurance schemes should be included in the HTA discussions. Dr Manesh also stressed the importance of having a clear policy approach on the implementation of the recommendations of HTA reports and data analyses. It is advised to work towards the inclusion of HTA policy decisions into national health insurance. COI should be properly addressed in managing health systems.
Prof Ben Ammar suggested that national health insurance should contribute to financing HTA. Therefore, there should be milestones set and strong commitment obtained from the Government. HTA may already be undertaken but not in a systematic manner and with wrong processes. Clear HTA roles should be established and backed up by law and legislation. When establishing a HTA model, the best way will be to start small.

Iran posed a question concerning the best way to undertake HTA either by contracting out HTA work to universities or like Tunisia to have an agency to do the work. Dr Kearney responded that internal and external capacity mix is in place in Australia and that combining both methods is useful. Dr Banken agreed but also mentioned the importance of strengthening the in-house HTA capacities and better organization of HTA decision-making mechanism to achieve good results.

Pakistan indicated that HTA activities are undertaken for medicines and medical devices but not in a systematic and transparent way as it was presented in the meeting. An HTA body may streamline the processes. Health insurance schemes should be part of defining the health care package. HTA can provide the evidence to the decision-making process on how the package is defined. Different ways of working and different health systems will define the structure of HTA.

7.3 Discussion on HTA Regional plan of action to support EMR MS

It was suggested that a high-level Meeting for the health ministers should be organized to promote HTA. Government commitment is important for continuity of HTA programmes at country level. It was remarked that a parallel session with a big event was better as health ministers will not come for one thing. It was also remarked that the implementation of the HTA process, a situation analysis, and capacity building need to be supported by Government commitment as well. A letter to health ministers in the Region on initiation of HTA should be undertaken by EMRO as soon as possible. A strong buy-in by the Government will be triggered by the WHO letter to health ministers. It is also important to inform the WHO country offices to support HTA programmes in countries. Pakistan suggested that it should be communicated in the WHO letter to the health ministers that HTA can be initiated in countries with decentralized health care approach. The outcome of this meeting should be part of the letter as well. National workshops should be organized with international experts to inform all stakeholders.

It was suggested as a first activity in the region that EMRO starts mapping of HTA capacities in the region such that by mid-2014, the possibility of establishing country HTA programmes using available resources should be clearly defined. The first step in that direction is to set-up a small country team to start the mapping exercise of the existing situation, and come up with a clear HTA plan of action, including the component of legislation. The mapping exercise can be a self-assessment exercise, including a SWOT analysis. The participants of this meeting should be the ones responsible for conducting the mapping exercise. In the next HTA regional meeting the results of the mapping exercise should be presented. Legislation should be included in the mapping exercise as well. National workshops on the results of the mapping exercise should be organized too. An external evaluation can be helpful and in support of the outcome of the
self-assessed, mapping exercise. It is important to advocate for political support in setting-up of a national HTA unit, with policies and regulation and the introduction of social insurance scheme.

It was agreed that a regional HTA network is needed. In its first year the objectives should be formulated. A web site will be set up for this network. EMRO will be the Secretariat of the regional HTA network for the first year. In the first year, the needs of capacity building with groups of countries have to be identified but also the commonalities to work together and to learn together.

Qatar remarked that EMRO should link with GCC. It was remarked that a link with essential medicines is important. The selection of essential medicines can be seen as a HTA process with the list itself as the HTA report resulting from the process. In the selection procedures, issues such as quality, safety and efficacy are looked at and an economic evaluation can be added. HTAi annual meeting will be in Washington DC from 15 to 16 June 2014. Two days prior to this meeting, AMRO/PAHO will organize a workshop on UHC and it was agreed that attending this meeting will be important.

Dr Ben Yahmed closed the meeting by remarking that the road to start a HTA programme will be full of bumps and resistance. It was advised to avoid major conflicts with stakeholders by embedding HTA into UHC movement by looking for best-buys and cost-effective interventions in support of quality health service delivery. He requested that other regional networks should share information. It was requested by Dr Ben Yahmed to prepare case studies from successful HTA implementations which can be a guide for countries in the region. EMR MS were encouraged to become members of international networks so that partnerships can be established. It was also mentioned that partnerships within countries can be established with the medicines, vaccines, medical devices regulators. He informed the meeting that the next Regional Committee will be in Tunisia from 19 to 21 October 2014 and that HTA will be on the agenda.

8. RECOMMENDATIONS

8.1 Pre-conditions for successful implementation of HTA programmes

The following issues have to be stressed as pre-conditions for successful implementation of HTA programmes:

- Acceptance of HTA as a new and integrated tool for routine evaluation of health technologies (not a project or one-off exercise).
- Strong commitment and support from the Government to establish national HTA programme in support of Universal Health Coverage
- Establishment of suitable implementation, and monitoring & evaluation mechanisms, and usage of appropriate analysis methods and procedures, including reporting and publication of results, as part of a transparency and accountability framework (better governance).
- Having a clear communication policy on how to respond to a wide audience, on the scope of information that can be publicly disclosed and the ability to respond to important technical questions.

- Having close links with senior policymakers (MOH, MOF, etc.) and involvement of relevant stakeholders (universities, research centers, national regulatory authorities).

- Having sufficient HTA staff capacities and means of improving knowledge, skills and experience needed for HTA activities.

- Collaboration with other entities and organizations (national HTA agencies/units, international and regional networks, etc.).

- Working towards independent status of HTA agencies/units and management procedures, including conflicts of interest.

8.2 Roadmap for developing national HTA programmes within existing health systems

The following set of activities were identified by experts and participants in the meeting as milestones to develop HTA programmes within existing health systems for EMR MS:

1. **Setting up an EM network** - in which the secretariat will be with Health and Medical Devices (HMD) unit in EMRO for the first year will be the first milestone in the roadmap. The network will be comprised of HTA champions in MS and experts from other agencies and international networks (e.g. HTAi, INAHTA, EuroScan, EUnetHTA, OSTEBA, NICE, HITAP, INESSS, IESS, etc.). The network will discuss challenges, share HTA reports, respond to queries, and provide solutions to specific challenges associated with setting up HTA programmes in countries. The launch of the network is scheduled for October 2014.

2. **Briefing Ministers of Health** of the outcome of this meeting within 3 months. The brief should be coupled with an RD Letter addressed to Health Ministers urging them to support the setup of a national HTA programme within their existing health systems. (This recommendation was strongly supported by DPM). This will represent a strong advocacy with policy makers and will start the much needed political buy-in.

3. **Mapping of existing national HTA resources** in each MS – in terms of political buy-in, experts and stakeholders, human and financial capabilities, etc. will help in providing an insight of the ability of MS to overcome many of the barriers associated with the initial development of a national HTA programme. The results of the mapping exercise should be posted on HMD website page with free access to all stakeholders. HMD unit in EMRO will revise and adapt existing AMRO/PAHO mapping tools to be used by EMR MS.

4. **A Second ICP meeting on HTA** processes and programmes that will involve more technical details on HTA framework of analysis, development of reports,
research, linkages between HTA and other WHO programmes, hospital-based HTA, etc. was recommended by all participants and experts to be held in October 2014 and should be coupled with the launch of the EM HTA network.

5. **A series of national meetings**, technically supported by WHO, in needed at the beginning of the process of establishment of national HTA programmes. The meetings should provide specific step-by-step implementation details on the development of an HTA unit/agency within MS. Experiences from Taiwan, Thailand and Colombia is needed and external experts from agencies present in these countries will help MS overcome many of the initial challenges associated with development of HTA programmes at the national level.

6. High-income EMR countries present in the meeting (*Oman and Qatar*) recommended **setting up HTA programmes that are linked to their current regulatory activities** within the country. They opted to follow the model of Taiwan because of the similarity of their health systems- in terms of presence of social health insurance schemes for the entire population.

7. **Collaboration with international HTA agencies and networks** is recommended for all our MS. The presence of these networks in the meeting enabled participants to gain the knowledge about the nature of these networks, the services they offer, the potential benefits for members, and the fees they charge for their memberships. Most participants agreed that joining these networks is a must for exchange of knowledge and experience.

8. Participants were hoping that the new *WHA Resolution on HTA can be followed by an RC Resolution* on the same topic. They expressed their support to any work that is necessary in this respect.
## ANNEX 1: PROGRAMME

**Monday, 11 November 2013**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Speaker(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00 - 8:30</td>
<td>Registration</td>
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<tr>
<td>8:30 - 9:00</td>
<td><strong>Opening Session</strong></td>
<td><em>Message from Dr Ala Alwan, Regional Director, WHO/EMRO</em></td>
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<tr>
<td></td>
<td></td>
<td><em>Dr Samir Ben Yahmed, WHO/EMRO</em></td>
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<tr>
<td>9:00 - 9:30</td>
<td>Introduction and Meeting Objectives</td>
<td><em>Dr Marthe Everard, WHO/EMRO</em></td>
</tr>
<tr>
<td>9:30 - 10:00</td>
<td>Introducing HTA as a tool for evidence-based decision-making in health technologies</td>
<td><em>Mr Reiner Banken, INESSS</em></td>
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<tr>
<td>10:00 - 10:30</td>
<td>Group photo and coffee break</td>
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</tr>
<tr>
<td>10:30 - 11:00</td>
<td><strong>Session 1 – HTA Challenges in EMR</strong></td>
<td><em>Chair: Dr Marthe Everard, WHO/EMRO</em></td>
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<td></td>
<td><em>Dr Adham Ismail, WHO/EMRO</em></td>
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<tr>
<td>11:00 - 11:30</td>
<td>HTA Systems in EMR: Tunisia</td>
<td><em>Dr Mohamed Ben Ammar, MOH, Tunisia</em></td>
</tr>
<tr>
<td>11:30 - 12:00</td>
<td>HTA Systems in EMR: The Islamic Republic of Iran</td>
<td><em>Dr Alireza Olyae Manesh, MOHME, Iran</em></td>
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<tr>
<td>12:00 - 13:00</td>
<td>Discussions on HTA challenges in EMR</td>
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<tr>
<td>13:00 - 14:00</td>
<td>Lunch break</td>
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<tr>
<td>14:00 – 14:30</td>
<td><strong>Session 2 – HTA Global, Regional and Country Experiences</strong></td>
<td><em>Chair: Dr Kees de Joncheere, WHO/HQ</em></td>
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<td></td>
<td></td>
<td><em>Mrs Adriana Velazquez, WHO/HQ</em></td>
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<tr>
<td>14:30 – 15:00</td>
<td>HTA and Decision-Making: <em>The Global Perspective</em></td>
<td><em>Mr Alexandre Lemgruber, WHO/PAHO</em></td>
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<tr>
<td>15:00 – 15:30</td>
<td>HTA incorporation into Health Systems in the Americas</td>
<td><em>Mr Reetan Patel, NICE</em></td>
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<tr>
<td>15:30 – 16:00</td>
<td>High-Income Country Experiences: <em>United Kingdom</em></td>
<td><em>Dr Hector Jaramillo, IETS</em></td>
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<tr>
<td>16:00- 16:30</td>
<td>Coffee break</td>
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<tr>
<td>16:30 – 17:00</td>
<td>Lower Middle-Income Country Experiences: <em>Thailand</em></td>
<td><em>Dr Yot Teerawattananon, HITAP</em></td>
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Tuesday, 12 November 2013

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Chair:</th>
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<tbody>
<tr>
<td>8:30 - 9:00</td>
<td>Health Technology Assessment International (HTAi)</td>
<td>Dr Inaki Gutierrez, OSTEBA &amp; HTAi</td>
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<tr>
<td>9:00 - 9:30</td>
<td>The International Network of Agencies for HTA (INAHTA)</td>
<td>Dr Sophie Werko, INAHTA</td>
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<tr>
<td>9:30 - 10:00</td>
<td>The International Information Network on New and Emerging Health Technologies (EuroScan)</td>
<td>Prof Brendon Kearney, EuroScan</td>
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<tr>
<td>10:00 - 10:30</td>
<td>Coffee break</td>
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<tr>
<td>10:30 - 11:30</td>
<td>Panel Discussion: What can International Networks Offer to Promote HTA in EMR Countries</td>
<td>EUnetHTA, EuroScan, HTAi, INAHTA, NICE, and OSTEBA</td>
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<tr>
<td>11:30 - 12:00</td>
<td>Setting up an HTA programme: The Experience of Taiwan</td>
<td>Dr Churn-Shiouh Gau, CDE</td>
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<tr>
<td>12:00 - 12:30</td>
<td>Developing National Capacities to Undertake HTA</td>
<td>Dr Inaki Gutierrez, OSTEBA &amp; HTAi</td>
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<tr>
<td>12:30 - 13:00</td>
<td>Comparison among different HTA models: Organizational capabilities, funding, processes and impact</td>
<td>Dr Adham Ismail, WHO/EMRO</td>
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<tr>
<td>13:00 - 14:00</td>
<td>Lunch break</td>
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<tr>
<td>14:00 - 14:30</td>
<td>Innovative Technologies for Low-Resource Settings: Detailed Assessment Methods</td>
<td>Prof Brendon Kearney, EuroScan</td>
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<tr>
<td>14:30 - 15:00</td>
<td>Role of HTA in Universal Health Coverage (UHC): guidance and key issues</td>
<td>Dr Reiner Banken, INESSSS</td>
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<tr>
<td>15:00 - 16:00</td>
<td>Discussion on Appropriate HTA Models and Analysis Frameworks for EMR Countries</td>
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<tr>
<td>16:00 - 16:30</td>
<td>Coffee break</td>
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Session 5 – The way forward

16:30 - 16:40  Introduction to Group Work: Developing a Roadmap for Implementing HTA for 3 income-based group of EMR Countries

16:40 - 18:00  Group Work

18:00  Wrap-up and Key Messages of Day 2

Wednesday, 13 November 2013

8:30 – 9:00  Group Work Presentations

9:30 - 10:00  Discussions on Group work and agreement on Roadmap

10:00 - 10:30  Coffee Break

10:30 - 12:00  HTA Regional Plan of Action to Support Countries

12:00  Closing remarks
ANNEX 2: LIST OF PARTICIPANTS

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Dr Asheq Khan Sadaty
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ANNEX 3: MESSAGE FROM THE REGIONAL DIRECTOR

In the Name of God, the Compassionate, the Merciful

Message from

DR ALA ALWAN
REGIONAL DIRECTOR
WHO EASTERN MEDITERRANEAN REGION
to the
FIRST INTERCOUNTRY MEETING ON HEALTH TECHNOLOGY ASSESSMENT (HTA)
HAMMAMET, TUNISIA 11–13 November 2013

Distinguished Participants, Ladies and Gentlemen, Dear Colleagues

I would like to start by welcoming the representatives of health technology assessment agencies and ministries of health to this important meeting, which I hope will make a great contribution to health technology advancement in the Eastern Mediterranean Region. The importance of this area is reflected in your participation here and your commitment to ensuring the safety, quality, efficacy and effectiveness of health technologies circulating in the markets and used by the population. I sincerely regret not being with you today. Unfortunately my original plans to attend had to be changed because of an urgent mission in our region.

Globalization and rapid advances in technology have brought about countless benefits and improved quality of lives. The increasing sophistication of health technologies – which includes medicines, vaccines, diagnostics and devices – and the development of cutting edge technologies pose many financial and technical challenges to national authorities, particularly in developing countries. WHO has long been committed to strengthening capacity in its Member States so that health care delivery becomes more effective. Therefore, networking and sharing of experiences and knowledge with stakeholders of various levels of advancement in the use of health technology assessment is an important part of capacity-building efforts in the Region.
Dear Colleagues,

Before I set out reasons for promoting health technology assessment in the Region, let me remind all of you of the context in which we find ourselves today. The overall economic challenges faced by many national governments have put public spending under pressure. According to WHO, 30% to 50% of the budget of ministries of health is spent on medicines, devices and other health technologies. Yet a high percentage of the population lacks regular access to quality assured health technologies. Low- and middle-income countries of our region import 60% to 90% of health technologies without having established assessment and procurement systems that will aid nationals in making evidence-informed decisions about their investments. In the absence of government policies or capacity to make rational decisions, markets became supply-driven, and this partially explains why some major investments are wasted on inappropriate health technologies. The health sector is clearly vulnerable in this situation, as it constitutes a major element in public health consumption.

Given the current global economic backdrop, increased cooperation among stakeholders must contribute to ensuring the long-term economic sustainability of our health care systems. We should share evidence on how to improve patient outcomes and make efficiency gains, without irrational investment in new health technologies that will not be accessible for the majority of the population.

It will be a true challenge for companies, health care providers and policy-makers to contain high prices with the growing demand for health care from an increasing population, and in a climate of economic and budgetary austerity. Health technology assessment offers a methodology to address these issues. An increasing number of Member States use health technology assessment to support their decisions on the selection and use of new medicines, vaccines, medical devices and other health technologies. This allows for more transparent evidence-based decision-making and for investment in the most appropriate health technologies.
Dear Colleagues,

Last year, the Fifty-ninth Session of WHO Regional Committee for the Eastern Mediterranean emphasized the importance of prioritizing, on the basis of health technology assessment, the use of health technologies. The Regional Committee concluded that Member States need to build their capacities in the area of health technology assessment in order to ensure better access to technologies and to strengthen their health systems. My hope is that Member States will strengthen their capacities in technology assessment and use HTA networks when new expensive technologies – such as diagnostic devices or new vaccines – are introduced. I believe that using the network as a platform for sharing knowledge and experience, is one way of getting more out of limited resources. International health technology assessment networks and collaborative bodies have already developed tools which will be important for effective cooperation. I very much hope that their experience and knowledge can be shared with our Region.

Today marks the start of the discussion with all participating stakeholders on how national health technology assessment programmes should be governed, managed and implemented. The objective of this meeting is to outline for countries a roadmap for introducing and implementing national health technology assessment programmes into existing health systems. You will therefore be key actors in defining both the possibilities and the limitations of what the Region can achieve and how.

Dear Colleagues,

I hope that this meeting will provide a valuable platform for addressing common issues, as well as providing clear guidance on how you would like to use health technology assessment networks as an added value to strengthening national health systems. Finally, I look forward to our future collaboration in the field of health technology assessment – and most of all to the benefits that will arise as a result. I wish you all a fruitful meeting and a pleasant stay in Hammamet.

Thank you.
ANNEX 4: RESOLUTION EM/RC59/R.3 ON HEALTH SYSTEM STRENGTHENING

REGIONAL COMMITTEE FOR THE EASTERN MEDITERRANEAN

Fifty-ninth Session
Agenda item 3

Health systems strengthening in countries of the Eastern Mediterranean Region: challenges, priorities and options for future action

The Regional Committee,

Having considered the technical discussion paper on health systems strengthening in countries of the Eastern Mediterranean Region: challenges, priorities and options for future action;1

Recalling resolutions WHA62.12 on primary health care, including health system strengthening, WHA58.33 on sustainable health financing, universal coverage and social health insurance, WHA64.9 on sustainable health financing structures and universal coverage, EM/RC55/R.2 on commitment to health systems based on primary health care in the Eastern Mediterranean Region and EM/RC57/R.7 on strategic directions to improve health care financing in the Eastern Mediterranean Region; moving towards universal coverage 2011–2015;

Recognizing that significant impact to improve population health can only be realized through well performing national health systems which assure universal access to effective and good quality health care,

Mindful of the expanding role of the private sector in the delivery of health care and the existence of inadequate stewardship and regulatory guidance;

1. **URGES** Member States to:

1.1 Strengthen or establish multisectoral mechanisms with representation from public sector ministries, civil society organizations, the private health sector, community representatives and other stakeholders to prepare a road map for achieving universal health coverage;

1.2 Make national strategic health plans the basis for all health development programmes and activities and ensure their sound implementation and monitoring;

1.3 Review and update public health laws and develop norms and standards in order to ensure equity, quality and safety of care delivered in the public and private sector;

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1 EM/RC59/106/1
1.4 Develop national capacities to strengthen governance, production and deployment of a well balanced health workforce which ensures effective delivery of care;

1.5 Strengthen and integrate the network of primary health care facilities, considering family practice as an effective approach to service provision;

1.6 Strengthen national health information systems by improving reporting of births, deaths and causes of death, by improved monitoring of exposure to risk factors and social determinants of health, morbidity, mortality and performance of the health system and by institutionalising population-based surveys;

1.7 Improve quality, safety, efficiency and rational use of health technologies, including medicines, by strengthening national regulatory authorities;

1.8 Work closely with the Regional Office and country offices in their efforts to strengthen health systems;

2. REQUESTS the Regional Director to:

2.1 Provide Member States with the strategic and technical guidance necessary to establish multisectoral mechanisms in support of universal health coverage;

2.2 Support Member States in building capacity in the area of health systems strengthening, including leadership development, health care financing, human resources development and health system performance assessment;

2.3 Set up mechanisms to share experience among countries in health system strengthening and support sub-regional cooperation;

2.4 Establish networks of health systems experts to support health systems strengthening in the Region;

2.5 Work closely with Member States to support the development, monitoring and evaluation of national health strategies and plans;

2.6 Submit a progress report on health systems performance to the 60th Session of the Regional Committee.