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Report on the

**Second intercountry
meeting on health
technology assessment:
guidelines on the
establishment of
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Cairo, Egypt
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1. INTRODUCTION

Health technology assessment is a multidisciplinary decision-making process that uses information about the medical (clinical), social, economic, organizational and ethical issues related to the use of a health technology (medicines, vaccines, biologicals, medical devices, clinical interventions, etc.) in a systematic, transparent, unbiased, and robust manner. It aims to support the formulation of safe and effective health policies that are patient focused and seek to achieve best value of money and improved patients' health outcomes. As one of the new approaches in which cost-effective and cost-benefit evaluations are included to make purchase decisions in a given budget for health technologies, it has become an important tool for informed decision-making by ministries of health. Health technology assessment contributes to reducing waste and inefficiencies resulting from inappropriate investments in health technology; it also contributes to the provision of quality health service delivery. This tool is not only for developed countries but also for developing countries working towards universal health coverage.

In 2013, the World Health Organization (WHO) Regional Office for the Eastern Mediterranean conducted the first intercountry meeting on health technology assessment in Hammamet, Tunisia. This raised awareness among Member States on the usefulness of the tool in providing evidence for rational, informed decisions on investment in health technologies.

In this regard, the WHO Regional Office organized a second intercountry meeting on implementing health technology assessment programmes within existing national health systems. The meeting provided guidelines for Member States to initiate the development of national action plans that aim at instituting these programmes within existing health systems structures. The meeting took place in Cairo, Egypt during 1–4 December 2014.

The main objectives were to:

- provide Member States with insights for overcoming the barriers associated with the initial development of a national health technology assessment programme;
- enhance national technical capacities on analytical methods (research and development, investigation, gathering scientific data, etc.) to provide policy-makers with evidence on health technologies and their appropriateness, cost-effectiveness, and returns;
- inform Member States on the results of the mapping exercise aimed at identifying national resources (political buy-in, experts and stakeholders, human and financial capabilities, etc.) in each Member State;
- introduce the regional health technology assessment network (a direct recommendation of the first intercountry meeting on health technology assessment held in Tunisia in 2013) and its roles and functions.

In addition, WHO will assist Member States in developing national programmes by providing technical advice on appropriate structures, staffing, funding and products.

The outcome of the meeting provided a framework for developing national health technology assessment programmes within existing national health systems. Country

experiences from Canada, France, Islamic Republic of Iran, Republic of Korea, Malaysia, Spain, Sweden, Thailand and the United Kingdom helped in demonstrating the various implementation modalities and options that can be employed by different countries. The meeting focused on several areas including main concepts, products and applications; successful country experiences, including challenges and dimensions in building national assessment programmes; guiding principles for establishing successful country-specific programmes in terms of scope, methodology, process and impact; national action plans that aim at instituting health technology assessment programmes within existing health systems structures; and a roadmap for implementing programmes in terms of actions required by Member States and technical support needed from WHO (see Annex 1 for full programme).

Participants in the meeting were two officials from the ministry of health of each country, one of whom was responsible for health technology and one policy-maker responsible for taking medical, strategic and financial decisions on investment in new and emerging health technologies. The meeting was also attended by staff from relevant programmes in WHO Headquarters, experts from health technology assessment agencies and networks in Asia, Europe and North America, and other stakeholders. The full list of participants is given in Annex 2.

The meeting was opened by Dr Jaouad Mahjour, Director of Programme Management for the Eastern Mediterranean Region, who delivered a message from Dr Ala Alwan, WHO Regional Director for the Eastern Mediterranean. Dr Alwan pointed out that policy-makers were constantly faced with making decisions related to choice of appropriate technologies in health. These decisions should not be guided by intuition or by commercial interests but rather by a rational, evidence-based approach. Therefore networking and sharing experiences and knowledge with stakeholders at various levels of advancement in the use of health technology assessment were important for capacity-building efforts in the Region. Most countries in the Region lacked a well-developed health technology assessment structure or function within their existing national health systems. It was therefore the aim of WHO in the Region to see that such capacity was developed in all countries, whatever their level of income or development.

Three important actions had been undertaken since the first intercountry meeting on health technology assessment in November 2013. The first was adoption by the World Health Assembly of resolution WHA67.23 on clinical interventions and health technology assessment. In the resolution, Member States were urged to consider establishing national health technology assessment systems, thereby encouraging its systematic utilization. The second important action was performing a mapping survey on regional health technology assessment resources. This had aimed at mapping existing regional and national resources, including entities with no formal structure for assessment but with possible resources that could be used to establish such a structure in the near future. The final important action was establishment of a regional health technology assessment network aimed at discussing challenges, sharing reports, responding to queries and providing solutions to specific challenges associated with setting up programmes in countries.

It was expected that the meeting would provide a clear roadmap for introducing national programmes and implementing them into existing health systems, and that the possibilities and limitations of what can be achieved in the Region and how this can be realized would be evident. The importance of health technology assessment was reaffirmed, not only in providing evidence for informed decision-making on investments made in health technologies but also for Member States to achieve universal health coverage, the leitmotif for the coming decade.

Dr Marthe Everard, Coordinator, Essential Medicines and Technologies, explained the current situation of countries in the Region in terms of income and emergency status as well as the chronology of activities and events that led to the current meeting. Recommendations made during the first meeting in Tunisia encompassed the establishment of a regional health technology assessment network, Member States' political buy-in, and the mapping of existing regional resources. Most of the recommendations were implemented, and this second meeting is dedicated to presenting approaches, advance knowledge and effective uptake of health technology in local settings.

The main objectives of the meeting and expected outcomes were to:

- provide Member States with insights to overcome barriers associated with initial development of a national health technology assessment programme;
- enhance national technical capacities on analytical methods (research and development, investigation, gathering scientific data, etc.);
- inform Member States on the results of the health technology assessment mapping exercise aimed at identifying national resources in each Member State; and
- introduce the regional health technology assessment network and its roles and function.

2. BACKGROUND

Dr Adham Ismail, Regional Adviser, Health and Biomedical Devices, presented the findings of a recent survey on mapping health technology assessment resources in the Region. Rationalizing health technology expenditures is of great importance, especially given that these account for 20%–50% of the recurrent annual budget of any low- or middle-income country. More than half of the expenditures on health technologies are wasted due to mismanagement. Therefore, there is a dire need to manage these resources in the most effective and efficient way to maximize the cost–benefit ratio. The survey in 2013 sought to obtain basic information on the familiarity of Member States with health technology assessment, whether there were any units performing assessments and evaluating health technology within the ministries of health, and the presence of national reports on new health technology. Only 9 out of 22 Member States contributed to this survey and although most of the countries were familiar with the tool, none of them had units dedicated to that purpose and therefore ministry of health publications on health technology are very limited.

In 2014, a second survey (based on the recommendations of the first intercountry meeting in Tunisia in November 2013) was conducted with the aim of mapping regional resources. This targeted academic institutions; national organizations, institutions or entities;

ministry of health focal points for health technology; health technology assessment entities; etc. In all, 51 responses were received from 15 Member States: 43% from academia, 36% from regulatory authorities, 25% from health technology assessment champions and stakeholders, 23% from health care providers, 2% from manufacturers, and 2% from reimbursement agencies. Almost 80% of respondents operated at the national level. Almost 52% of respondents performed health technology assessment or similar activities on new and emerging technologies. Most of these activities were related to clinical effectiveness and economic evaluations (67% and 62% respectively) and on medical devices and medicines (79% and 68% respectively).

The reports were mainly related to health care costs and selection of appropriate technologies (60% and 50% respectively). The main target audiences for these reports were government, other national authorities and health care providers (54%, 46% and 38% respectively). Most of the respondents who did not perform any type of assessment-related activities did not know if there were plans to start such activities in the near future (55%). Introducing health technology assessment into the decision-making process, access to reliable information, financial resources and political buy-in (75%, 70%, 65% and 60% respectively) were cited as major obstacles to initiating such an activity in the local settings. It was clear that health technology assessment would be introduced in the Eastern Mediterranean Region only by:

- accepting it as a new and integrated evaluation tool for informing decision-making (a permanent tool, not a project or a one-off);
- having strong political and financial commitment from governments;
- establishing national units and working towards the independence of their management procedures, including conflicts of interest;
- considering health technology assessment as part of a transparency and accountability framework;
- developing a clear communication policy on the scope of information that can be publicly disclosed and the ability to respond to important technical questions;
- engaging relevant stakeholders (universities, research centres, well-established national regulatory authorities, etc.);
- enhancing staff knowledge, skills and experience;
- collaborating with other entities and organizations (national, regional and international agencies/units/networks).

Resolution WHA67.23 on health intervention and technology assessment in support of universal health coverage was highlighted to present the global perspective and to explain what Member States and the Secretariat had committed to in the last World Health Assembly. The resolution recognized the importance of health technology assessment in achieving universal health coverage and called upon Member States to establish systems within their national local settings and to link to the regulation and management of health technology. The resolution also called on WHO to include health technology assessment in their work and support Member States in achieving these recommendations. Thus, the next steps should be to: undertake a global mapping survey of current capacity and perceived needs for health technology assessment in Member States; focus on important issues such as advocacy and

promotion of priority-setting best practices, sharing of experiences, and capacity-building of nationals; promote collaboration among agencies and nongovernmental organizations; and increase awareness and understanding of what health technology assessment is and what it is not.

To demonstrate the importance of health technology assessment to current global initiatives (such as universal health coverage), Dr Majid Davari, from the Islamic Republic of Iran and Dr Yot Teerawattananon, from Thailand, demonstrated the experiences of these countries in using this tool in developing the universal health coverage benefit package. They stressed that scarcity of resources and priority-setting were inevitable, and that there is no way to extend all possible services to everyone without prioritization. In this context health technology assessment can be used to support priority-setting in universal health coverage and make it sustainable.

Currently, health technology assessment is used in the Islamic Republic of Iran for a number of projects including reducing out-of-pocket payments in public hospitals by 10% for inpatient services; improving access to specialists and quality of outpatient specialist visits in public clinics; and providing financial protection for high-cost services and specific diseases (e.g. haemophilia and renal disease). In all of these projects assessment can enhance the development of clinical guidelines, improve the management of new health technologies, help Member States use their resources more efficiently, and improve the efficiency of the health care delivery system. This will lead to improving the capacity of Member States to achieve universal health coverage.

3. PREREQUISITES FOR A SUCCESSFUL HEALTH TECHNOLOGY ASSESSMENT PROGRAMME

3.1 Ingredients of a successful health technology assessment programme

Dr Iñaki Gutiérrez-Ibarluzea, Health Technology Assessment International, Spain

The key elements that should be present for the success of any health technology assessment programme in any national health system are: health system knowledge, health needs assessment, customer identification, and stakeholders' knowledge and involvement. All of these factors, along with employing skilled professionals, when put together produce timely, high quality information that is tailored to the requirements of each client. This is exactly the aim of health technology assessment: to put timely and accurate information (in the form of primary or basic evidence, secondary or digested evidence, information produced by other assessment units, and context-specific evidence) in front of decision-makers. In fact, these elements are not only related to the success of any assessment process but also to the success of any knowledge-generation and dissemination process. Member States are therefore advised to:

- know their health system and its needs
- identify solutions to these needs
- identify the main stakeholders and their importance
- identify target audience or customers

- study customers' characteristics and how their needs can be met
- establish liaisons
- look for international collaboration
- look out for high quality products,
- ensure active participation in the decision-making process
- involve all relevant stakeholders
- have multidisciplinary teams
- ensure financial sources
- cooperate at national level
- secure legal support.

3.2 Good governance of a health technology assessment programme: strategies and concepts

Dr Sophie Werkö, Swedish Council on Health Technology Assessment, Sweden

Recommendations for efficient governance of any health technology assessment programme were presented by Dr Sophie Werkö, who identified four components: setup, relationships with the ministry (laws/decrees/standard operating procedures), transparency, and accountability (how government should use the reports). She explained how these components are applied in the Swedish Council on Health Technology Assessment (SBU) and how they led to its success and credibility. These measures not only affect the governance of SBU but also the topics to be studied. Priority is given to topics which: are of great importance to life and health; affect many people (i.e. common health problems); have far-reaching economic consequences; are of great ethical or social importance; are of great importance to health care; are controversial or high-profile; and exhibit great variations in clinical practice.

Factors of good governance also include clear commitment from government, independent financial resources, and monitoring of the implementation of health technology assessment recommendations.

3.3 Human and financial resources required to establish a health technology assessment programme

Dr Yot Teerawattananon, Health Intervention and Technology Assessment Program, Thailand

Member States are recommended to start with a small and committed group of young researchers – it is not always necessary to start with well-qualified health technology assessment or health economics champions. Although post-graduate training is important, on-the-job training has played a vital role during the development of the agency in Thailand. The recommended size of a good team is 2–10 staff per study. This team should be multidisciplinary in nature and should encompass different backgrounds to ensure that their product is of a high quality. All reports produced by the team should be publicly available and published in academic journals whenever possible. As an example, the Health Intervention and Technology Assessment Program (HiTAP) agency in Thailand started with seven staff (five full time and two part time) in 2006 and in almost eight years this had risen to 57 (42

full time and 15 part time) because of the success of the agency. In terms of financing, models of different agencies in Europe showed how the concepts of cost-recovery and financing options are looked at and balanced within the criteria of independence; flexibility; continuity, stability and financial sustainability; and the local legal framework and feasibility.

3.4 Discussion on the prerequisites of a successful health technology assessment programme

Moderated by Dr Sameen Siddiqi, WHO Regional Office for the Eastern Mediterranean

The discussion started with questions on the frequency of research done by the SBU in Sweden, the costs associated with these studies and the monitoring of reports. The SBU do not perform research themselves, their reports are merely syntheses of high quality reports published in recognized forums. Most of the costs associated with health technology assessment studies are covered via the regular annual budget (€ million) funded by the government. The typical cost of a report varies depending on the type and number of staff working on it; it is extremely difficult to estimate exactly for each report.

Participants were briefed on the medicines situation in Egypt and the need for health technology assessment to solve various problems associated with medical products. However, assessments do not always provide a complete answer for many of the problems associated with technologies in the country (for instance, mechanisms used for cost-sharing insurance coverage for non-recommended products). This results in policy-makers losing interest in health technology assessment. There was some debate on this point. Even if it cannot answer all questions it does not mean that it is not useful, and participants were advised to highlight successful assessment recommendations with decision-makers. Then again, if the policy question posed at the start was realistic and rational, health technology assessment would be able to provide a complete answer. The capacity of the unit to provide alternatives for decision-makers was emphasized: this will make their work more visible and more appealing to governments. Examples from the work of HiTAP in Thailand included the cost-effectiveness of screening compared with the provision of human papilloma virus (HPV) vaccines.

The nature and purpose of health technology assessment studies (fixed prices, commercialization of products, reimbursement) was discussed. These tools can be applied for many purposes and can be used to answer any technology-related questions. The most important point to start with in any health ministry should be the appointment of a focal point who employs dedicated staff. The assessment group needs to work closely with the decision-makers in the ministry. This setup has been successful for the initiation of health technology assessment programmes in Myanmar and Viet Nam; clear examples, success stories and concrete figures on the benefits and outputs of a successful process were identified. As an example, in a case from Italy it was discovered that in some parts of the country the expenditure on certain diseases was not linked to their prevalence. With the introduction of health technology assessment, the situation improved and expenditures were distributed accordingly.

The question of whether assessment units should be in contact with the research and development departments of manufacturers was discussed. Examples from the United Kingdom's National Institute for Clinical Excellence (NICE) can confirm that this is possible. Showing the impact of health technology assessment on the budget and presenting the experiences in other countries would be a good starting point for developing successful programmes. In Scotland, for instance, they introduced a pharmacist in each hospital; this resulted in extremely high costs but the benefits in terms of rational use and quality of care were far greater than the amount spent on the salaries of these pharmacists.

Participants also deliberated on whether health technology assessment should be providing options for decision-makers (as in the case with economic analysis) or recommending a particular technical decision for policy-makers to take. Here, it is important to differentiate between the assessment and the appraisal phases. While the assessment phase will lead to a technical decision on the technology, the appraisal phase can provide options (other than technical) to communicate to policy-makers and decision-makers. Decision-making may be considered an ad hoc process that can be driven by a number of factors – it took NICE many years to convince policy-makers of the benefits of health technology assessment. The fact that most reports are for medicines, and are especially tailored for high-income countries was highlighted. There is a need to conduct assessments in low- and middle-income countries as well. The speed with which decisions are taken (especially in low- and middle-income countries) and the linkages to other government entities are issues that have to be taken into account. The process and the prioritization of needs will create conflict in any country because some services and populations will be left out and Member States need to be prepared for this. This is a further indication of the importance of separating the assessment and the appraisal phases.

Involving healthcare providers was also stressed because of their importance and their proximity to decision-makers in many countries. There is a need to submit evidence via health technology assessments, not to just leave politicians to take decisions based on intuition. Each Member State should decide where the units should be located so that they will have good policy penetration without being affected by policy-makers' opinions or intuition.

4. POSSIBLE STRUCTURES AND ORGANIZATION OF HEALTH TECHNOLOGY ASSESSMENT SYSTEMS

4.1 Organizational differences in health technology assessment frameworks across countries

Dr Adham Ismail, WHO

The structure of any health technology assessment system relies greatly on the objectives and guiding principles describing its role. These principles fall into 4 broad categories, listed here.

- Scope and prioritization
 - Health technology assessment should be an unbiased and transparent exercise.

- It should include all relevant technologies.
- A clear system should exist for setting priorities, and the costs should be proportionate.
- Methods
 - Health technology assessments should incorporate appropriate methods depending on its goal.
 - They should consider a wide range of evidence and outcomes.
 - A full societal perspective should be considered when undertaking assessments.
 - They should explicitly characterize uncertainty surrounding estimates.
- Process
 - Those conducting health technology assessments should actively engage all key stakeholder groups.
 - The findings need to be communicated appropriately to decision-makers.
 - Evaluations should allow new data to be considered.
 - The assessments should identify areas where the evidence base on an intervention could most usefully be developed in the future.
- Impact
 - Health technology assessment should be timely.
 - Pricing reimbursement and market access decisions should reflect the assessment in a transparent, clearly defined way and be implemented as intended.
 - The impact of the findings and how they are used needs to be monitored.

Taking these into consideration, the influence of assessment in the decision-making process of any system can generally be measured at two main levels. The first level is the policy implementation level, in which the health technology assessment system is established as a policy decision of government. The objectives of the system, its legal status and relationships with the national health system, with other public sector bodies, and with other stakeholders such as industry and patient groups are influencing factors at this level. The second level is the individual technology decision level, i.e. the processes by which individual technologies are dealt with in the system. How decisions are made, and how they are implemented are major concerns at this level.

The main goals for the participants were to set out the role and position of health technology assessment in the health system (according to the guiding principles) and to set up the framework that would support decisions at policy and individual health technology levels.

The framework in various countries was studied (Australia, Brazil, Germany, Italy and the Netherlands), and the changes that each country made based on the characteristics of each health system were noted. It is clear that there is no unique decision framework that can be applied to all Member States and that different frameworks exist in different countries. Member States should develop their own policy decision framework based on the health system existing in their country.

4.2 Health technology assessment in the United Kingdom: National Institute for Clinical Excellence

Dr Derek Cutler, National Institute for Clinical Excellence, United Kingdom

The National Institute for Clinical Excellence (NICE) was established by the United Kingdom government in 1999 to address a number of challenges using an evidence-informed, multidisciplinary approach. Originally it had 10 staff and a budget of £10 million, with a remit to carry out the appraisal of new and existing health technology. The remit expanded to include the production of clinical guidelines, public health, and more recently, the development of quality standards and social care guidance. With this expansion came more human and financial resources, growing to 81 staff and a budget of £17 million after the first five years, and 279 staff and a £36 million budget after the next five. Currently, NICE has a budget of £70 million and has over 500 staff working to produce the various types of guidance, products and services.

It is a nongovernmental organization steered by a board. It enjoys independent status but it is close to the Department of Health. Over the years, various units have been created to deal with different services and products. It has a range of clients, not only the National Health Service but also local authorities, health councils and charities.

A set of four core principles are applied across its wide remit of work. These guide NICE 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 is open access and available through the NICE website).

The decision cycle and single technical appraisals take 7–9 months. There is an appeal process in place for cases where the manufacturer is not in agreement with the results of a health technology assessment: challenges encountered by NICE are mainly in the area of legal issues and court cases. A general lesson that should be learned from NICE's long experience is the importance of having government support: without the backing of the United Kingdom government, NICE would not have survived the first 5 years.

Working closely with a range of academic and professional organizations helps NICE to ensure that the guidance produced is robust and independent. Engaging with core stakeholders (such as patients, industry, professionals, payers, and providers) has not always been easy, but it has definitely contributed to its success. Engaging with all the key stakeholders and having a consultative approach have helped to ensure the ability of NICE to gain the support of different groups.

NICE International is a fee-for-service entity created by NICE to assist Member States on health technology assessment-related issues. It offers advice/technical support to developing countries and also capacity-building, workshops and seminars.

4.3 Health technology assessment in the Islamic Republic of Iran: the Iranian health technology assessment unit

Dr Majid Davari, Health Technology Assessment, Islamic Republic of Iran

According to the 2008 national health account study, household expenditure on health was around 50%, 40% of which was spent on essential medicines and medical devices. In 2007 health technology assessment was launched, with the office of the health deputy of the Ministry of Health and Medical Education as the secretariat. Following changes in the organizational structure of the health ministry in 2010, the Office of the Deputy for Health was divided into hygiene and curative affairs and health technology assessment was categorized as a department under the supervision of the Health Technology Assessment, Standardization and Tariffs Office with the Deputy for Curative Affairs.

The first projects were funded by the Department of Medical Equipment. Following the establishment of a formal structure for health technology assessment, its budget was considered an independent item in the state budget. Accordingly, projects are funded from the government budget. The programme has been useful in producing several comparative reports on the comparative benefits of new technologies for making evidence-informed decisions on Ministry of Health and Medical Education investments in technologies.

The agency is usually concerned with four types of studies: stakeholder analysis and role, cost-effectiveness threshold values, population-based preference weights, and analysis of factors influencing time preferences and discount rates for costs and health outcomes. The strong commitment of policy-makers to the use of health technology assessment principles and knowledge production in the decision-making process, along with the availability of expert personnel and scientific institutions in the country, means that the agency is able to provide a better service.

However, there are currently some limitations: poor understanding of the role of health technology assessment among clinicians and some health policy-makers, a shortage of academic experts for undertaking quality assessments as needed, and the lack of any established relationship between stakeholders. Future steps planned to strengthen the process in the Islamic Republic of Iran include:

- developing the local pattern of prioritization for health technology assessment (based on burden of disease, health outcome, budget impact, etc.);
- developing an equity framework for health technology assessment (this should provide a level of trade-off between efficiency and equity);
- investigating the impact of assessment on the national health system and health care delivery;
- establishing an effective relationship among all stakeholders;
- developing an acceptable pattern for linking health technology assessment to policy and governance.

4.4 Health technology assessment in Malaysia: the Malaysian Health Technology Assessment Section

Dr Rugayah Bakri, Malaysian Health Technology Assessment Section, Malaysia

Dr Bakri gave an overview of the Malaysian health system and epidemiological indicators of the health situation. The health technology assessment unit is located within the Ministry of Health. The unit was established in 1995 under the Medical Devices Division in response to the policy of ensuring that safe, effective and cost-effective health technologies are being used in Ministry of Health facilities. In 2001, the unit was upgraded to a section, the Malaysian Health Technology Assessment Section (MaHTAS), and the development of evidence-based clinical practice guidelines was put under their review. This helped in reducing variations in clinical practice and in improving quality of care. From 2004 to 2014, MaHTAS was designated as a collaborating centre for “evidence-based health-care practice” for the WHO South-East Asia Region.

Currently, MaHTAS employs 26 staff (head of the section, 18 technical reviewers, 3 information specialists, and 4 administrative staff). It has produced (as of 2013) 58 detailed reports, 260 rapid assessment reports, 80 clinical practice guidelines and 58 information briefs. These products have been used by specialists to update their clinical practices and to assist in policy-making.

The main challenges currently facing MaHTAS are in the areas of human resources (training of staff, finding skilled/trained staff, creating multidisciplinary teams, and most importantly retaining skilled staff), financial resources (for implementing clinical practice guidelines, evaluation research, international participation in relevant scientific meetings), information resources (finding scientific databases and joining recognized international agencies), harmonization with other national health technology-related agencies, awareness on the requirements of health technology assessment processes (especially by local industries), and utilization of assessments/clinical practice guidelines and recommendations. It is envisaged that in the near future MaHTAS can expand its scope to include “horizon scanning” activities, to play a bigger role in policy-making and decision-making related to health technologies (pricing decisions, fee schedule, reimbursement, essential health technologies, benefit package, workplan for coverage of healthcare services and technologies, etc.), and to upgrade to an institute/centre.

4.5 Health technology assessment in Thailand: Health Intervention and Technology Assessment Program

Dr Inthira Yamabhai, Health Intervention and Technology Assessment Program, Thailand

The Health Intervention and Technology Assessment Program (HiTAP) is an agency under the Ministry of Public Health in Thailand. It was founded in 2007 to provide evidence to guide resource-allocations in Thailand. During the past seven years a total of 110 research projects at have been carried out, 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, this unit observes national health technology assessment methodological guidelines and a set of process guidelines, including a code of practice on conflict of interest management. Thailand started by developing the technical capacity of the programme, then developing the process, and later integrating results into the policy-making process. It was advised to start small and grow over time and to engage and train other institutions such as research institutes and universities in health technology assessment.

Since its establishment, the unit has enjoyed great benefit from international collaboration, including sharing experiences with other agencies in Europe, Australia and North America. It has collaborated with more than 10 agencies in the region to form the HTAsiaLink network. This network offers a platform for capacity-building activities for junior scholars. The unit also works closely with NICE International to help in setting up health technology assessment capacity in low- and middle-income countries. Training is offered 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 are part of the International Decision Support Initiative. Dr Yamabhai stressed the importance of having a methodology to measure the impact of health technology assessment on policy-makers and the Ministry of Health budget.

At present, HiTAP is focusing on two major projects: the development of a national plan for universal health coverage and the revision/updating of the national list of essential medicines. Both projects are top priority for the country and health technology assessment has a strong role in the discussion to prioritize the interventions and medicines to be covered. It has been employed for informing coverage decisions in Thailand, and in this regard political will and commitment are essential. The approach is systematic, participatory and transparent. Projects expected to start in the near future include assessment for disinvestment, assessment for health promotion, and monitoring and evaluating the impact of health technology assessment.

4.6 Discussion on lessons learned from country experiences

Moderated by Dr Marthe Everard, WHO

Participants discussed the role of NICE, whether it was considered a standardization organization, and whether its recommendations were mandatory or not. Although NICE is funded by the Department of Health in the United Kingdom, they only provide guidance – most of their products are produced by academic institutions and research centres. Guidance on clinical interventions is not mandatory, however, any public entity needs to explain their reasons for not following NICE guidance. In the case of technology appraisals, a negative recommendation by NICE means that the particular drug or device in question will not be available for reimbursement on the National Health Service. On the other hand, if the NICE recommendation is positive, the technology is expected to be available and reimbursed within three months, and there is a legal clause in support of positive recommendations.

In a discussion on the duration of the assessment process, it was recognized that there are some bottlenecks in the implementation of the processes, for example the lack of

knowledge of health and economic evaluations, and addressing these could help in promoting health technology assessment in Member States. On average, it takes about 48 weeks for a report to be completed. Some studies showing the impact of health technology assessment on several health areas were shared during the meeting.

There was much discussion on whether seeking information and conducting health technology assessment studies (as in the case of Thailand) by manufacturers can be trusted. However, HiTAP ensures the fairness and subjectivity of these studies with strict guidelines that manufacturers must follow, especially on methodology and process. These guidelines are distributed to all manufacturers and disseminated to all stakeholders, and the results of the studies are shared with all stakeholders. The studies executed by the industry in Thailand were not always in favour of the technology. In fact, unfavourable reports have had a greater impact on clinical practice and acceptance of benefit packages since they are produced by the industry and not by the Ministry of Health.

It was explained that clinical practice guidelines are not binding but they are used to establish protocols, which are mandatory. In Malaysia, clinical practice guidelines cover all diagnosis and rehabilitation services.

Participants were interested in whether any of the countries presenting information on their health technology assessment agencies had carried out any research on the cost of conducting an assessment in relation to its benefits and also in the monitoring and evaluation process of the unit/agency and who was responsible for these, given the independent nature of the agencies. Establishing an agency in the Basque region of Spain cost the government almost €1 million. However, conducting health technology assessment for one project saved the government almost €4.5 million and therefore the return was almost 4.5 times the initial investment. Similarly, in the United Kingdom the NICE budget is less than 0.5% of what the Ministry of Health spends; but the overall gain of having NICE far exceeds that.

It was noted that, in fact, most Member States are already performing one or more types of health technology assessment activity (selection of medicines, public reimbursement, certificate of need, etc.) and all that is now needed is to put all these activities together under one umbrella with some sort of organization, framework and recognition by government.

5. THE HEALTH TECHNOLOGY ASSESSMENT PROCESS

5.1 Key principles for conducting the health technology assessment process

*Dr Reiner Banken, Institut national d'excellence en santé et en services sociaux,
Canada*

The purpose of health technology assessment is to solve problems by mobilizing the types of evidence required and the concerned actors to support political, organizational or clinical decision-making. It relies on the examination of contextual, colloquial and scientific evidence as well as on interactions with stakeholders for making recommendations. Defining health technology assessment as a knowledge mobilization process might lead to consideration of the different orders of knowledge; the social, political and ethical

dimensions; and the interactions with stakeholders as essential contexts to all those concerned with the issues involved in the evaluation question. The use of health technology assessment in health systems is still evolving and institutional requirements (rules and regulations, organizations, legal frameworks, etc.) are important and should enable it to evolve further. Mature systems include a wide range of health technologies and interventions to be assessed, strong stakeholder involvement and knowledge mobilization activities. Development occurs within a political arena, and therefore the objectives and processes have to be clear from the start. The guiding axiom is “start small, have a clear audience and scope, and address important questions”.

Countries are advised to develop scientific capacity for knowledge synthesis in collaboration with universities, the Cochrane Collaboration, and other health systems research initiatives; use country- or region-specific policy windows; join regional communities involved in health technology assessment; build up the capacity of nationals using the support of existing networks such as the International Network of Agencies for Health Technology Assessment (INAHTA) and Health Technology Assessment International (HTAi); and promote health technology assessment with policy-makers and funding agencies (under the necessary conditions of rigor, independence and transparency).

5.2 Identification of technologies to be assessed and setting priorities for health technology assessment

Dr Iñaki Gutiérrez-Ibarluzea, Health Technology Assessment International Spain

The first task that a health technology assessment unit/agency undertakes is the selection of technologies to be assessed from the vast number of new and emerging technologies available on the market. The choice depends on a number of factors, including but not limited to: the nature of the health system, customers and their priorities, availability of information, and current staff skills. A process of “horizon scanning” is needed. Sources that can be used to identify the technologies to be assessed include: primary sources (information is obtained directly from sources closest to the technology); secondary sources (information is obtained from sources that have used primary sources but may have edited or filtered the information); tertiary sources (information is obtained from sources that have prioritized the information themselves and perhaps carried out an assessment).

The EuroScan International Network offers support in identifying technologies and sources of information; it is the leading global collaborative network collecting and sharing information on innovative technologies in healthcare to support decision-making and the adoption and use of effective, useful and safe health-related technologies. EuroScan is also the principal global forum for the sharing and development of methods for the early identification and early assessment of new and emerging health-related technologies, and predicting their potential impact on health services and existing technologies.

Following the EuroScan information on new and emerging technologies, each health technology assessment unit/agency should conduct a filtering process to ensure that only those technologies which are appropriate to the customer are considered. Filtering should take into account the interests of the stakeholders and the time horizon, and will be health

system-dependent. Once irrelevant technologies have been filtered out, those remaining can be prioritized according to the resources available. It is recommended that a set of pre-defined prioritization criteria based on stakeholder/customer requirements is constructed. Technologies must satisfy one or more of these threshold criteria before being accepted for further consideration. The prioritization criteria should include effectiveness, safety, cost-effectiveness, organizational issues, preferences of patients and clinicians, frequency of use of the technology, and ethical/legal/social aspects.

An example was given from Spain: the initial list of domains and prioritization criteria was drawn up by the technical group (comprising three methodology experts) in consensus with the working group (made up of 11 health technology assessment experts from different agencies/units). The preliminary list included a total of 15 criteria grouped in four domains: population/end-users; technology; safety/adverse effects; and costs, organization and other implications. Members of a panel of experts (policy-makers, clinicians and system end-users) scored and weighed the proposed prioritization criteria. Five of the 15 prioritization criteria initially proposed were classified as clearly important (score > 6). Finally, a questionnaire on the selected criteria was passed to the experts for scoring and prioritization. This example clearly demonstrates the importance of systematic planning in identifying technologies to be assessed by the health technology assessment process.

5.3 Pre-analysis phase: collecting background information

Dr Andres Freiberg, National Institute for Clinical Excellence, United Kingdom

To obtain background information on assessed technologies, NICE uses trained researchers (information specialists) working within independent academic groups. They collect and assess evidence, either from scratch (using independent academic or technical advisory groups) or by reviewing evidence submitted by manufacturers and submit it to NICE. Therefore, NICE is a “client” acting as a deliberative decision-maker. A committee then appraises the evidence received and issues guidance on the selected technology. To unify submissions and the background search process, NICE guides how evidence should be searched, submitted, processed and interpreted. The guidance includes a step-by-step approach that should be followed by the information specialists to produce background information on a certain technology. The approach includes techniques such as good-quality systematic reviews (and their references), good-quality randomized controlled trials, cohort/case-control studies, observational studies, case series/reports, and experts’ opinions. The search process should be thorough, transparent, and reproducible.

5.4 Stakeholders, health technology assessment products and project processes

Dr Sophie Werkö, Swedish Council on Health Technology Assessment, Sweden

Stakeholders can be divided into: payers, providers, patients and their families, healthy citizens, and industry. Each of these groups has to be involved in the health technology assessment process. For example, patient groups should be involved in the following instances:

- in project planning – always consider and document which groups of patients are affected and which patient/user-organizations have an interest in the topic;
- at the start of a new project – ask for views of the concerned patient organizations on the research questions;
- when there is a need for a reference group of patients who will follow the project during the whole process;
- before the finalization of the project to discuss possible implications of the findings and how the results can be implemented in health care;
- when reports are being distributed to relevant patient organizations;
- on the health technology assessment board to present patients' views and interests.

A number of different types of reports are generated and disseminated by SBU in Sweden. The SBU products are usually divided into full health technology assessment reports (taking approximately three years; a project group collaborates with external experts to prepare the report; the scientific advisory committee and the SBU Board approve the report) and SBU alerts (the work is carried out by a small group of experts in the field and by staff; the SBU Board and the Alert Advisory Board approve the SBU assessment of the current state of knowledge). The assessment process itself is usually divided into four stages: (1) identification of reviewers and experts, (2) SBU comments on the product, (3) internal and external scrutiny of the product, and (4) final approval and publication.

The agency is now providing two new services to Swedish citizens and experts, “the enquiry service”, which allows anyone to pose questions for SBU, which is committed to providing fast responses, and the “scientific uncertainties service”, which provides information on knowledge gaps and future research agendas for research centres and institutions.

Another project that SBU is conducting on behalf of the Swedish government is the “prioritization project”. This is aimed at looking into the possibilities of providing the health care sector with information about technologies that may be considered for disinvestment such as those that are ineffective, are associated with risks or discomfort for the patient, are very costly, lead to inequalities in the delivery of health care, or for which there is poor evidence of their effectiveness.

5.5 Conducting a successful health technology assessment process

Dr Rugayah Bakri, Malaysian Health Technology Assessment Section, Malaysia

There are two overlapping processes in MaHTAS, one on health technology assessment for new and emerging technologies and another on the production of clinical practice guidelines. MaHTAS produces three types of documents.

- Information briefs: These require a very rapid information response (within two weeks); they are applied when urgent information is needed and a decision needs to be made within a short span of time. They involve systematic literature searches.
- Technology review reports: These also require a fairly rapid assessment process (2–4 months); they deal with an existing problem for which a decision will be made with or

without evidence. A systematic literature search along with a restricted systematic review (based on best available evidence) are used. The reports are externally reviewed (if necessary).

- Health technology assessment reports: These are traditional assessments (8–18 months); they are comprehensive in nature (clinical, social, organizational, ethical, economic, etc); involve a systematic literature search, scientific research and/or technology assessment reports conducted by other organizations; and usually incorporate Malaysian data. Technologies to be assessed are usually determined by dedicated council members.

Clinical practice guidelines reports are usually evidence-based and look into implementation strategies. They can be used as quick reference, training modules, training of core trainers, or even patient information leaflets. They are usually published in journals (such as the Malaysian family physician journal). The clinical practice guidelines and health technology assessment reports are disseminated as printed copies (ISBN-indexed publications, information briefs, or quick reference) or soft copies (through the Ministry of Health, Academy of Medicine, professional society websites or links to international agencies/organizations such as HTAi, Guidelines International Network, and INAHTA). Excerpts from selected clinical practice guidelines, health technology assessment, and technology review reports, as well as MaHTAS news may be highlighted in a newsletter, publications in peer-reviewed journal, social media networks (such as Facebook), messages (such as SMS), or mobile applications (such as the android and iOS application called “myMaHTAs” which can be downloaded free from app store.).

5.6 Elaborations of recommendations of the health technology assessment process: strategies for dissemination and implementation of results

*Dr Jeonghoon Ahn, National Evidence-based Healthcare Collaborating Agency,
Republic of Korea*

Participants were briefed on the work of the National Evidence-based Healthcare Collaborating Agency (NECA) in the Republic of Korea. There is a serious need for health technology assessment in the country for several reasons including the rapid adoption of new health technologies and the escalating fees for service, the trend towards increasing healthcare expenditure, the rapid growth of the elderly population, and increasing out-of-pocket expenditure on health (about 62% in 2010). The agency works mainly in three areas related to health technology assessment research (largely based on topic suggestions from the general public; study period is one year or longer; output is generally a full report on safety, effectiveness, and economic evaluation of the assessed technology), new health technology assessment (based on requests from applicants to assess any new procedures or diagnostic methods to be used in the country; study period is usually 6 months or less and the process produces partial reports on safety and effectiveness of the assessed technology), and other research (including that requested by the government, usually manuals used in health technology assessment education, public health, policy analysis, etc.).

Several methods are used to disseminate NECA products. They include the release of the health technology assessment report and media kit in the form of home pages, social media and media kits for mass-media. Reports are also sent to the ministry, congress, public institutions,

professional societies, medical libraries, etc. The round table conference is an excellent way of disseminating/implementing assessment results, especially when conflicts of interest need to be considered. The conference tries to reach a consensus which can be released to the public. Additional dissemination strategies include annual courses and manuals.

Dr Ahn explained how health technology assessment research was conducted and how results were disseminated for three examples: nicotine e-cigarettes in 2009, the effectiveness of glucosamine on osteoarthritis in 2010, and a budget impact analysis on changing reimbursement criteria for osteoporosis treatments in 2010.

Since it is part of administrative process in the Medical Act, all the new reports from NECA go to the (ministerial) Committee of New Health Technology Assessment. The decisions of this committee are released as a Ministry of Health and Welfare public notice, and legal implementation is guaranteed. Even though there is an appeal process, many unsatisfied applicants go to the Congress to try to modify the law (political threats).

5.7 Panel discussion on work process of health technology assessment

There was some discussion on whether health technology assessment can be applied in a broader sense and for areas other than health technologies. It was agreed that it can be applied in various areas of health, not only on medical products although more needs to be done in the way of marketing and advocacy, especially since it can be applied to clinical interventions and treatment modalities. In some cases country visits by health technology assessment experts may be useful.

Similarly, participants discussed whether the tools for prioritization of technologies can be applied in most countries or would need to be adapted; they also expressed some concern on the length of the reports, especially those produced by SBU, and whether this affected the ability of policy-makers to make quick decisions on technologies. There was consensus on the importance of speed in producing reports, but this should not be at the expense of quality. Although SBU do take a considerable time to produce a good report, if a quick report is needed, they can provide a mini report for quick decisions, but this will not be publicly disclosed and only contains clinical evidence.

The inclusion of clinical engineers was discussed, and it was agreed that they should be part of a health technology assessment team, particularly if the assessment project needs them. This is already the case in NECA in the Republic of Korea.

Starting a health technology assessment programme in a country is a step-by-step process. Initially, it should involve capacity-building of nationals; networking with other agencies will also provide momentum to the implementation process. In fact, lack of information is not the problem in conducting assessments and initiating a programme, it is the adaptation to local settings where each country will need support. Adapting an existing structure and building on it was also considered a good starting strategy.

Participants then discussed the application of health technology assessment to existing technologies as well as new ones. Most established processes are for new technologies; however, it can be applied on existing technologies: the glucosamine study conducted by NECA is an example of this. All types of technology (devices, drugs, surgical procedures, etc.) are eligible to be included in a study: health technology assessment is a tool that can be applied anywhere in the health system and health technology can be considered to be “any knowledge and practice” that can be applied to the medical field. The use of health technology assessment in disinvestment studies is growing and its application on evaluating the cost-effectiveness of existing technologies may become more prominent in the future. Assessments can also be used in adding/removing medicines from the national essential medicines list: currently in Palestine they are using cost-effectiveness and safety measure as criteria for inclusion or exclusion from the essential list: the outcomes from this meeting may be the seed for the programme in the country. There was a suggestion that for future meetings the agenda should be structured more around individual country experiences, with experts advising countries on how to move forward and overcome challenges.

Other topics discussed included the limitations of the health technology assessment programme and how focal points would be appointed in each Member State. Although there are a number of limitations in the health technology assessment process, it is still the only way to secure a rational collective decision on investment in technologies. The lack of quality studies that can help agencies reach a rational decision is a major limitation. However, countries can use certain tools (such as sensitivity analysis, etc.) to minimize the effect of these limitations. On the question of focal points, all participants in the meeting are considered the focal points for initiating programmes in their countries. More focal points could be added to the regional network that is to be launched on the final day of this meeting.

Queries were raised about two further topics: establishing a programme in partnership with one of the existing agencies and whether reaching a consensus between NECA and stakeholders was mandatory or not. In the case of SBU, services are not actually limited to the Swedish government; all their findings and reports are, however, in Swedish (though available online) and this may be a barrier. For NECA, it was confirmed that consensus has to be reached before policy-makers in the Republic of Korea come to any decision.

6. OUTCOMES OF THE HEALTH TECHNOLOGY ASSESSMENT PROCESS

6.1 Effect of health technology assessment on policy-making and clinical practice

Dr Sophie Werkö, Swedish Council on Health Technology Assessment, Sweden

The Swedish health technology assessment agency (SBU) was founded in 1987 with no legislative power to implement change, no decisions concerning approval or reimbursement of drugs, and no supervisory function. Accordingly, SBU relies only on its ability to convince decision-makers and professionals to change their practices if they believe the agency is correct and trustworthy.

In 2010, Statistics Sweden conducted a survey on a random sample of 1833 health professionals (63% response rate) to examine public opinion of SBU and its work. In general,

great confidence was shown in SBU compared with other organizations (professional societies, industry etc.); information from SBU was the single most reliable source, and about 80% of respondents said they had made practical use of SBU results. Despite the positive opinion of SBU by the Swedish population, this is not a measure of the impact of SBU or whether the agency is making any difference in health technology investments in the country.

In a study conducted in 2014 on how health technology assessment influenced clinical practice and policy-making in Sweden, the impact of certain SBU reports were as detailed below.

- National or regional policy decisions: Only 4 out of 26 published SBU reports were used in policy decisions.
- National or professional guidelines: Only 10 out of 26 published SBU-reports were used in national guidelines, 7 implemented by the National Board and 3 by professional organizations. All guidelines extensively referred to the SBU reports.
- Confidence/trust among health professionals: Results showed high confidence in SBU (as previously indicated in the 2010 Statistics Sweden study).
- Patients: Results matched the 2010 study.
- Research or knowledge gaps: SBU has started to build up a database for “scientific knowledge gaps”, similar to the Database of Uncertainties about the Effects of Treatments (DUETs) in the United Kingdom. Research areas identified by SBU as priorities were used by the Swedish Research Council, several other research councils, and universities.
- Clinical practice: Out of 26 published SBU reports, eight resulted in a change in the clinical practice in Sweden: two of these had a high impact on the clinical practices for mild head injury and dyspepsia/gastro-oesophageal reflux. The remaining six reports had a moderate impact on triage methods at emergency departments; obstructive sleep apnoea syndrome; methods of early prenatal diagnosis; methods for promoting physical activity; treatment of insomnia; and antibiotic prophylaxis for surgical procedures.

6.2 Health technology assessment and social health insurance: impact on pricing, reimbursement and market access

Dr Adham Ismail, WHO Regional Office for the Eastern Mediterranean

The expected impact of a health technology assessment process depends on its role and objectives: the greater its role and the better the legal backup, the greater the effect. For instance, NICE produces mandatory government guidelines, therefore it is expected to have a significant impact on the use of health technology. Additionally, assessment might have a role in pricing and reimbursement decisions. In general, the existing literature divides the impact of HTA according to:

- Stakeholders: health technology assessment has an impact on:
 - patients (allocation of resources, speed of access to health technologies and availability of good value products);
 - payers (efficiency of the health system and direct costs incurred);
 - physicians (best clinical practices and clinical guidelines);

- industry (returns on investments and predictability of future gains).
- Usage: Health technology assessment reports can have either a positive or a negative effect at different phases of product development (research and development, experimental technology, market access and obsolescence/replacement).
- Market access: health technology assessment affects the speed with which decisions are made and when patients will have access to essential health technology. The processes are time consuming because of the steps that must be followed and the complexity of its multidisciplinary nature. Processes may take longer if health technology assessment bodies with limited resources have to deal with an increasing number of applications. The average duration of the review process varies from one agency to another.
- Reimbursement decisions: One of the most common uses of health technology assessment is to support pricing and reimbursement decisions. A favourable report should result in a greater proportion of reimbursement decisions and a better price. In a study conducted in 2010 on coverage decisions for 59 anti-cancer drugs in the United States of America and the United Kingdom, while all drugs were approved by the American Food and Drug Administration and NICE made positive recommendations for only 39% of the drugs licensed in the United Kingdom, greater restrictions on pricing and reimbursement were imposed in the United Kingdom. Therefore, innovative and cost-effective technologies were better rewarded in the assessment-based system.
- Pricing: Results of a study conducted in 2010 on price changes following health technology assessment decisions in selected countries, indicated that:
 - in Canada health technology assessment recommendations were usually associated with upward price volatility for several quarters after publication of recommendations;
 - in England/Scotland the trend effect was an immediate increase in price following recommendation, moderating after 6–9 months;
 - in France there was no visible effect on price of either positive or negative recommendations;
 - in Sweden there was some volatility in both directions following health technology assessment recommendations.
- Healthcare expenditures: Actual benefits involve a comparison of expenditure with and without assessment. To illustrate, the Ministry of Health in Barbados performed a review of its national drug formulary using health technology assessment. The country reduced medicine expenditure by US\$ 6 million in the first 6 months (April–September 2011) following the adoption of changes, without compromising the quality of care.

The impact of health technology assessment and its potential benefits were also emphasized: the scarcer the resources, the greater the need to make rational decisions on investments made in health technology, to prioritize health technology needs on the basis of evidence, and to estimate cost–efficacy/effectiveness ratios of new and emerging technologies. The impact on pricing and reimbursement or market access relies especially on the decision-making framework in the Member State itself, and can definitely lead, in some cases, to better governance of already meagre resources.

6.3 Health technology assessment for pharmaceuticals, devices and other technologies: impact and applications

*Dr Reiner Banken, Institut national d'excellence en santé et en services sociaux
Canada*

The health technology assessment agency in Quebec, Canada, Institut national d'excellence en santé et en services sociaux (INESSS), provides health technology assessment reports. These include the following.

- Health technology assessment of drugs and devices for listing purposes: (new active substances, generics, formulations, etc.) The reports are mandatory for drugs and on-demand for devices. They are used by the Patented Medicine Prices Review Board for drugs but only to guide decision-makers for devices.
- Health technology assessment of laboratory tests for listing purposes: Until 2012, all tests submitted for entry were accepted with minimal evidentiary requirements. Starting in June 2012, an expert committee on appropriateness recommended putting in place a permanent assessment mechanism (similar to health technology assessment) for biomedical tests. The assessment framework involved both clinical (utility and validity) and non-clinical (economic, organizational, ethical, professional, legal and social) dimensions. In 2013, the committee recommended 42 laboratory tests for inclusion (minimum 30 per year). The mandate was given to INESSS to develop and implement this mechanism.
- Full health technology assessment reports (related to health and social care interventions): Health Canada gives market authorization for the whole country but drug listing is usually done at the provincial level. If INESSS considers the therapeutic value of a medication has been established, it sends its recommendation to the Minister after assessing the reasonableness of the price, the cost-effectiveness ratio of the medication, the impact that adding the medication to the list will have on the health of the general public and on the other components of the health and social services system, and the advisability of including the medication on the list, given the purpose of the basic prescription drug insurance plan. The process is deliberative in nature and involves clinicians, pharmacists, ethicists, economists, and citizens. Reports are made public on the day of their decision.
- Optimal use guides: The case of proton-pump inhibitors was used as an example to illustrate the use of health technology assessment to guide optimal use of a technology. Quebec is the only province in Canada reimbursing all proton-pump inhibitors available on the market. This amounts to Can\$ 197 million (nearly 7% of the public plan), of which nearly 64% was attributed to innovator drugs. The evidence showed that the clinical benefits of using these drugs were not statistically significant, except for some particular clinical circumstances (drug interactions, pregnant women and children). There were no data demonstrating the superiority of any proton-pump inhibitor, nor were there any data on efficacy or safety. Accordingly, assessment studies indicated that full reimbursement for these drugs was no longer valid and suggested a preferential reimbursement for four proton-pump inhibitors with the price fixed at that of the lowest cost-effective generic. This resulted in savings of over Can\$ 34 million and reductions in the price of the drugs.

In Canada health technology assessment is also used for other purposes such as clinical practice guidelines, production of rapid reports, etc. Essentially, the use of assessment should be tailored to the needs of the decision-makers, and the closer the assessment is linked to the decision-making processes, the greater the contribution to evidence-informed decision-making.

6.4 Hospital-based health technology assessment: concept and impact

Mr Bjorn Fahlgren, Assistance Publique – Hôpitaux de Paris, France

The application of health technology assessment at the hospital level rather than at the national level is important in countries where the health system is mainly run by the private sector (such as Lebanon). There may be a number of reasons that a Member State would want to use hospital-based health technology assessment, for instance, when no national agency exists and some large hospitals would like to take evidence-based decisions in regard to their investments in equipment and other technologies. Even where a national agency does exist, not all technologies are evaluated at the national level (as in the case of some medical devices); therefore, hospital-based assessment can perform these appraisals. Even if the technology has been evaluated at national level, some conclusions and recommendations from the assessments are quite global and hospitals may not find them suited to the local context and their specific needs. New and expensive technologies arrive mainly at university hospitals, which have immediate pressure from manufacturers, physicians and patients to adopt them. Additionally, hospitals may have an interest (medical, economic, organizational) in accelerating the process of assessment and reimbursement at the national level (e.g. for medical procedures).

The four distinct hospital-based health technology assessment models that can be adopted by Member States are:

- **Ambassador model:** Clinicians (opinion leaders) play the role of ambassadors of the health technology assessment message. They may not take part in assessments but play a key role in dissemination of results within hospitals.
- **Mini health technology assessment:** Single professionals participate in the assessment process collecting data at organizational level to inform decision-makers at a higher level. This is used at the local level and it eases the implementation of technology to a fair degree.
- **Internal committee:** Multidisciplinary groups representing different perspectives are responsible for reviewing evidence to issue useful recommendations hospital-wide. Documents are produced by professionals who rarely work full time on health technology assessment. This model – found in the United States of America and Canada – is based on financial assessment, and can be used for purchasing decisions or cost control.
- **Health technology assessment unit:** This is a formal organizational structure with specialized personnel working on a full-time basis inside the unit. This model represents the highest degree of structure for hospital health technology assessment. It usually leads to broad assessment of technologies and can be used for all types of questions (clinical practice and decision-making). The recommendations are followed and the process can allow the efficient allocation of resources.

After a brief introduction on the nature and structure of hospital-based health technology assessment, Mr Fahlgren described the experience of Assistance Publique – Hôpitaux de Paris (AP-HP), comprising 39 hospitals, 90 000 employees including 22 000 doctors, and serving more than 7 million patients, and the Comité d’Evaluation et de Diffusion des Innovations Technologiques (CEDIT), a hospital-based HTA agency founded in 1982 to advise the Director-General of AP-HP to support strategic decisions regarding health technologies; assessment on technical, clinical, economic, organizational, legal and ethical aspects; and horizon scanning. The goal of CEDIT is to verify:

- technical aspects, such as confirming that a technology is doing what it was designed for, or to help the implementation of equipment or a device;
- medical/clinical aspects, such as providing knowledge about the intrinsic benefit/risk balance of a technology or therapeutic progress (or relative effectiveness) in regard to alternatives;
- economic aspects, such as helping the decision-makers with optimal allocation of resources (mainly economic evaluations but also budget impact analysis);
- social acceptability aspects, such as the investigation of the adoption and dissemination of technologies based on local context;
- any other aspect (organizational, ethical, legal, or psychological).

Requests for assessment for innovations monitored by horizon scanning emanate from practitioners and decision-makers. Analysis, aggregation and synthesis of all data available on the technology under investigation start upon receipt of the request. The analysis includes primary and secondary sources, AP-HP-specific data (from medical information systems, research projects), and expert opinions. The appraisal options are then submitted by CEDIT to AP-HP decision-makers in a health technology assessment report. Historically, reports and recommendations from CEDIT were binding; nowadays they are not binding but are often followed.

Hospital-based health technology assessment is on the rise in Europe and efforts are starting or ongoing in several countries, for instance Denmark, Germany, Italy, Spain and Sweden. The first European project on hospital-based health technology assessment (AdHopHTA) is ongoing, with the involvement of the European network of agencies (EUnetHTA) and other networks. Outside Europe, INAHTA is now taking many hospital-based agencies as members, HTAi has established an interest sub-group on hospital-based health technology assessment, and countries such as Japan and Kazakhstan are developing an interest in implementing hospital-based assessment.

6.5 Discussion on hospital-based health technology assessment

Moderated by Dr Adham Ismail, WHO

Discussion on the outcomes of the health technology assessment process started with observations on the importance of using windows of opportunity to establish it at lower levels (such as hospitals) and then moving them to the national level at a later stage. In Quebec province in Canada, health technology assessment is performed by universities; there are 15 units (one in every university dealing with patient safety and healthcare delivery). Italy has

established units in exactly the opposite way. The country started health technology assessment at the national level and then started establishing smaller units to perform specific research or micro-costing studies. The importance of involving hospitals in any assessment study (even those conducted at the national level) was emphasized. Difficulties are often encountered in convincing clinicians and medical staff when communicating health technology assessment recommendations, however, making the report as scientific and solid as possible will minimize these difficulties and reduce their frequency.

Participants expressed an interest in the AP-HP reports. These are published on an open-source domain and are available free on the AP-HP website in French. Currently, AP-HP has no tools to measure the impact of these reports although they would like to do so, they are short of resources. In Quebec a study conducted in McGill University measured the impact of health technology assessment on the decisions made at the university hospital level. Findings indicated that for every \$1 spent on the process, they managed to save \$10 (from disinvestments on technologies negatively assessed), a good return on investment. In fact, HTA can be applied in any type of hospital, public as well as university hospitals, but this is a decision that has to be taken by the officials. Some participants queried whether Carte-santaire influenced HTA decisions in France; actually the converse is true, health technology assessment reports influence Carte-santaire.

6.6 Group exercise: using health technology assessment for universal health coverage benefit package development

As part of the guidance on the process of prioritization and decision-making, participants were divided into groups to carry out an exercise using materials prepared by HiTAP and NICE. The purpose of the exercise was to illustrate how actual decisions are made using available data and how health technology assessment can be used to rationalize and prioritize clinical interventions in any health ministry. Discussion and reasoning were used by the members of each group to decide on the interventions to be funded and the factors that led the group to these decisions. During the feedback, it became clear that the results of the deliberations were different in each group, and this showed that health technology assessment is not a static procedure but rather a dynamic process which can be looked at differently depending on the national health systems, demography, available resources, etc.

7. INTEGRATING HEALTH TECHNOLOGY ASSESSMENT INTO PUBLIC POLICIES

7.1 Integration of health technology assessment into public policies: introduction

Dr Adriana Velazquez, WHO

Any national health plan includes a section on health systems, in which health technology assessment should be embedded with other activities. Depending on the coverage and resources of the health system, a country can define the strength and role of health technology assessment in the decision-making and public health processes. In other words, the scope of work of the unit in any Member State can be classified according to the nature of

the national health system. In fragile states health technology assessment is used to define basic packages, emergency kits, and disaster planning. In low-income countries with low coverage (primary health care interventions) health technology assessment is used to determine the essential medicines package, essential interventions mainly for the Millennium Development Goals, the vaccination package, and guidelines on prevention and a few treatment interventions: assessment merely defines which technology to add and to whom. In middle- and high-income countries with medium coverage health technology assessment is used to determine packages of interventions on prevention and promotion, along with some on treatment and rehabilitation. It is also used to define interventions for noncommunicative diseases and vertical programmes for specific sectors of the population. Where there is a strong health system (integrated care, people-centred, universal health coverage), health technology assessment is used to cover many issues related to prevention, diagnosis, treatment, rehabilitation, palliative care, and home care medical products (medicines, devices, vaccines and diagnostics). It targets all sectors of the population including children, adolescents, mothers, and the ageing population. In addition, it defines innovative technologies and research agendas.

The integration of health technology assessment into current health systems has been included in the text of resolution WHA67.23, and WHO is currently involved in several projects aimed at integrating HTA concepts and principles into relevant strategies and areas of work. These projects include the WHO Model List of Essential Medicines (EML), the Package of Essential Noncommunicable Disease Interventions (PEN) for primary health care, “best buys” for noncommunicable diseases, WHO-CHOICE (CHOosing Interventions that are Cost Effective), the Global Health Technologies database (GHT), the OneHealth Tool (designed to inform national strategic health planning in low- and middle-income countries), and the Guidelines Review Committee, as well as more than 50 WHO guidelines.

7.2 Health technology assessment for adding value to innovation: from research to use in health systems

*Dr Reiner Banken, Institut national d'excellence en santé et en services sociaux,
Canada*

The definition of innovation as it is adopted by INESSS in Canada, and inspired by the Global Forum for Health Research, is “innovation encompasses the entire process from the generation of new ideas to their transformation into useful services, products, methods, management practices and policies in health and social services”. Any invention becomes an innovation when it is adopted by the health system.

All stakeholders share common objectives in the sense that industry needs profits, health systems need to be sustainable, patients want the best care regardless of cost, and economic development wants to favour home-grown innovation. Evaluation, health technology assessment as well as other types, is essential for translating the promise of innovation into reality. In December 2012, an INESSS advisory committee on health technology assessment and innovative technologies, the Canadian Emergency departments Team Initiative (CÉTI), was developed to advise on innovative technologies. Its objective is to promote a common understanding of the challenges of introducing innovative technologies

into the health system and to identify possible solutions to ensure consistency in doing so for the benefit of users. The committee comprises representatives from patient and user groups, the health technology industry, research and assessment communities, the economic development community, and managers of the health and social services network (local, regional and national levels). The current focus of CÉTI is to optimize the generation of knowledge in real-world settings for innovative technologies with the greatest potential for positive impacts on patients and the health system.

7.3 Promoting production of evidence and dissemination of information

Dr Majid Davari, Health Technology Assessment, Islamic Republic of Iran

Promoting the production of evidence and sharing reports has become part of the current Iranian health system. A wide range of comparative reports has been produced using health technology assessment on the benefits of new technologies over currently used ones for making evidence-informed investment decisions. The list of reports includes:

- PET scan compared to other diagnostic devices for the treatment of lung cancer and some other cancers,
- hyperbaric oxygen therapy compared to routine treatment for diabetic foot,
- 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 (long-acting contraception) compared to other family planning methods,
- immune tolerance induction method for treatment of children with haemophilia compared with bypassing agents for the management of high-responder haemophilia patients with inhibitors.

To publicize the information, the reports are uploaded on the health technology assessment department website, and every 6–10 reports are published in a separate book.

Assessment decisions are linked to policy-making. Transforming the health technology portfolio (a description of the technology, what it does, the prevalence of the disease it deals with and its market) to policy profiles (a list of policies concerned with a specific technology) is supported by the “designing-decision support system”. This is a step-by-step approach that integrates appraisals into public policies. The designing-decision support system starts with considering six domains: technology, health problem, beneficiaries, market, health system and budget. The following indicators are assessed in every domain:

- technology: effectiveness, consistency and validity of evidence for effectiveness, safety, and cost of production, installation and provision;

- health problem: severity of disease and cost of illness;
- beneficiary: size of affected population, poverty, geographic distribution;
- market: product quality, importer, producer, potential for off-label use, potential for misuse;
- health system: public health priority and availability of required human resources;
- budget: available resources, expected lifetime costs, etc.

The second step in the designing-decision support system is to define the different types of policy that need to be present for each of the identified technologies. They are generally classified into seven main sectors: technology and market, provisional, funding and reimbursement, regulation and pricing, investigational, educational, and innovation policies. The completed technology portfolio is delivered to an expert panel for scoring, analysis and ranking. The policies are then prioritized and sent on to public health officials for integration within the national health policies.

7.4 Discussion on how to formalize health technology assessment in the Eastern Mediterranean Region

Moderated by Dr Marthe Everard, WHO

A number of important topics were raised during this discussion. Because regulation, assessment and management of health technology are independent functions, even in a system that has weak regulations and poor management of health technology, it is still possible to establish an effective health technology assessment programme. The independence of the assessment unit is essential to prevent bias; even when it is located within the Ministry of Health and funded from the national budget, the methodology should be designed to be independent, transparent, robust and unbiased. Participants debated whether health technology assessment could affect (increase or decrease) funding of some activities. It would definitely help officials looking at clinical interventions and taking decisions on their cost-effectiveness and can help in increasing or decreasing funding for some interventions but there have been examples where it was not able to do so. For instance, in low- and middle-income countries where funding is provided by global donors (who want to promote specific interventions at the global level), health technology assessment fails to make an impact on the decision-making process.

Some countries felt that they would need support in convincing nationals of the importance of health technology assessment. In such cases, the entry point should be that it is one of the tools that can save resources for the health ministry; WHO and international agencies and networks are ready to support any Member State in that direction. The benefits that can influence policy-makers include shielding them when making difficult decisions, improving the health of populations, helping them make the best use of their budget, and assisting them in standing up to pressure from specific groups. Sharing a report and explaining how it affected decisions and impacted the budget in another country would also be a useful strategy.

Concern was raised about the difficulties faced in some countries in gathering national data (burden of disease, cost of interventions at secondary and tertiary levels, etc.) which can be relied on when making decisions. There are, nevertheless, ways to overcome lack of data.

For instance, Member States can tackle the problem from the quality aspect. Uncertainties in data should not stop them from performing health technology assessment; they should use whatever data are available and, rather than not starting at all, health technology assessment should be started even if the available data are of low-quality.

8. NETWORKING AND COLLABORATION

8.1 Implementation of health technology assessment in low- and middle-income countries: challenges, opportunities and networking

Dr Jeonghoon Ahn, HTAsiaLink

Implementing HTA is a challenge in many low- and middle-income countries. This is why Asian countries decided to develop a network, HTAsiaLink, that would accelerate sharing of information resources and develop an efficient methodology for health technology assessment in the continent. This network, which was established in 2011, operates on an informal and voluntary basis with no requirements for membership fees and no compulsory engagement in particular networking activities. The main objectives are to strengthen individual and institutional capacity in health technology assessment research and the integration of evidence into policy decisions; avoid duplication; facilitate learning and achievements; reduce the use of resources; enhance efficiency at organization level through collaborative activities across the network; and fulfil the need for transferring and sharing health technology assessment-related lessons across countries and organizations in Asia and beyond.

Membership can be institutional (public institutions approved by the Board), individual (any individuals who subscribe to the newsletter), or associate (any institution outside Asia approved by the Board – currently NICE International (United Kingdom), HealthPact (Australia), and ASERNIP-S (Australia) are associate members. Current HTAsiaLink members include agencies from China, Chinese Taipei, Japan, Malaysia, the Philippines, the Republic of Korea, Singapore and Thailand. Each member country has many challenges and threats relating to its political situation, misunderstandings among decision-makers (perhaps related to ambiguity in legal function), etc. Support is needed from the health ministry and from the network to overcome these challenges. Nevertheless, there are opportunities which come from the strong team spirit and networking capacity, a young workforce, experiences of international predecessors, and the similarities in culture observed among members. All sorts of networking and collaboration are provided through HTAsiaLink (collaborative projects, annual conferences, communication, and quick surveys among members) that enhance these opportunities and help Member States overcome the challenges.

8.2 International Network of Agencies for Health Technology Assessment strategies and mentorship programme

Dr Sophie Werkö, International Network of Agencies for Health Technology Assessment

The International Network of Agencies for Health Technology Assessment (INAHTA) was established in 1993; it currently has 57 member agencies from 32 countries. The network stretches from America to Europe, Asia, Africa and Australasia. All members are non-profit organizations producing health technology assessments and are linked to regional or national

governments. Most activities are coordinated by the secretariat. The membership meets yearly and participates in various working groups which 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 two years.

The aims of this network are to bring agency leadership and expertise to the science and practice of health technology assessment in the international health community, demonstrate the value of agencies as key components of modern health systems to support robust, evidence-based decision-making, support best practices and innovation for building and maintaining thriving agencies, and build communities of practice to enable the continuous exchange of knowledge and learning among our members. These objectives are in line with INAHTA's vision of having a network of strong, independent agencies, where each agency is an essential contributor to health system decision-making to achieve better health and better health systems for the people they serve.

Throughout the year, members collaborate in working groups on external partnerships, internal communication, the impact of health technology assessment, quality assurance, education and training, and industry relations. Membership is open to organizations that assess technology in health care, are non-profit, relate to a regional or national government, are funded at least 50% from public sources, and provide free access to their reports. The common challenges encountered in INAHTA are limited staffing and time constraints among its members, geographic distances, language, culture, incompatibility of methods, etc.

The by-laws of INAHTA include detailed information on membership criteria and the application and approval process for membership. The network has different levels of membership fee according to World Bank classification. As of June 2011, annual membership fees are: €700, €205, €1350 and €675 for high-, upper-middle-, lower-middle-, and lower-income-countries respectively. Candidate membership is also available for agencies that are just starting, have yet to produce health technology assessment reports, or are experiencing financial hardship. It is also possible to publish information and 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 necessary quality standards.

There is also a mentorship programme offered by INAHTA to WHO Member States. The programme is specialized in building the capacities of health technology assessment staff on the skills needed to develop valid reports. The programme was launched in 2014 at the request of WHO; its aim is to provide those looking for training with access to a global network of expertise, which is very much needed to overcome the challenges associated with implementing national health technology assessment programmes.

8.3 Panel discussion on networking and collaboration for overcoming implementation barriers and challenges to health technology assessment

The discussion covered a number of technical points related to membership of INAHTA and HTAsiaLink. Dr Werkö explained that the only difference in regard to membership status in INAHTA is on voting rights; other than that, candidate members receive the same set of

services as full members. It takes around 1–2 months for a new member to be approved. Countries which do not have HTA agencies can apply for membership: ministries of health in Asian countries are recognized as members of HTAsiaLink even if they do not have a formal health technology assessment body.

9. THE WAY FORWARD

9.1 Group work: developing national health technology assessment programmes within existing health systems in countries of the Region

Introduction

The main purpose of the group work session was to develop an action plan to institute a health technology assessment programme within an existing national health system. Participants were divided into 3 groups as follows: Group 1 comprised countries in emergencies or with low income levels (Afghanistan, Iraq, Libya, Pakistan, Palestine, Syrian Arab Republic and Yemen); Group 2 comprised non-emergency countries with high/middle income levels (Egypt, the Islamic Republic of Iran, Jordan, Oman, Sudan and the United Arab Emirates); and Group 3 comprised the French-speaking countries (Djibouti, Lebanon, Morocco and Tunisia).

The discussions in each group should result in:

- activities needed for establishing a national programme;
- location of the national programme in relation to current structure of decision-making framework;
- structure and composition of the unit/agency;
- required resources (human and financial);
- key partners (national and international);
- first activity to be undertaken by established unit/agency;
- products to be addressed (medicines, devices, vaccines, etc.) and priority-setting;
- networks to be linked to for gathering information (HTAsiaLink, INAHTA, HTAi, Euroscan, etc.);
- how to use the recently launched regional health technology assessment network and what is expected from it;
- how WHO can support.

Presentations and discussion

Group work deliberations called upon each country to perform a set of activities to start/enhance HTA programmes within their existing national settings.

Afghanistan

Although Afghanistan has a unit performing activities similar to health technology assessment (Health Economics and Financing Unit), changes in the structure and functions of

this unit will be needed to encompass assessment activities. A working group should be established to determine the required structure and terms of reference. The working group should also provide a detailed action plan for developing the health technology assessment programme in the country. The unit will be also working with the Ministry of Health and the Ministry of Public Health. The working group will comprise three professionals and will start working as an independent unit in relation to the two ministries. An estimated initial budget of US\$ 50 000 will be required for operational and managerial costs. External experts (WHO, health technology assessment agencies, etc.) will be needed to support the working group. A number of stakeholders (international donors, nongovernmental organizations, civil society, universities, etc.) can also be included in this plan. The first activity the unit should carry out is a detailed assessment on the cost–effectiveness of vaccines and drugs used for some of the diseases prevalent in the country. The regional network will be used for building long-term relations for the sustainability of the programme. Two types of support are needed from WHO: technical support (for establishing the unit) and financial support (for logistics). The Afghan Minister of Health signed an agreement with NICE International a few months previously, and therefore an initial agreement of collaboration is already in place.

Djibouti

The health technology assessment unit in the country will be developed by the Expert Committee on Health Planning, which will be tasked to organize the strategy, setup and processes of the HTA programme. This approach takes advantage of the wide recognition of the expert committee and its decisions. The unit will be located within the cabinet of the Minister of Health. The committee's first activity will be to increase awareness within the health ministry about health technology assessment and its potential benefits. The committee will also prepare a plan of action for five years. Human resources will be a challenge and the needed financial resources have to be planned by the Ministry of Health. Partnership with Tunisia will be helpful to initiate the project in the country. Technical assistance from WHO and other experts will also be needed.

Egypt

A concept paper incorporating objectives, needs, requirements, benefits, etc. will be the first activity towards establishing a health technology assessment programme in Egypt. The second step will be formalizing a committee to develop guidelines and terms of reference for the HTA unit. The third step will be defining the location of the unit within the Ministry of Health and Population. These three activities will comprise the preparatory phase of the project. Two workshops will also be needed in this phase; the first will be with public entities (academia, ministries, etc.) and the second with special stakeholders. All public entities in charge of healthcare facilities in Egypt (such as the health insurance organization, curative care institutions, etc.) should be involved and briefed from the beginning on the importance of health technology assessment and the steps that the Ministry is taking in developing this service in the country. It is suggested that the unit should fall under the direct supervision of the Office of the Assistant Minister for Financial and Administrative Affairs in affiliation with the national centre for health information in the Ministry of Health and Population. Experts are needed from many disciplines (epidemiologists, pharmacists, engineers, etc.) to establish

the unit and for training and guideline development purposes. National entities (such as universities, research centres, etc.) and support from international stakeholders (such as WHO, Centers for Disease Control and Prevention, etc.) will also be needed. Resources such as the regional network will be very useful at this stage.

Islamic Republic of Iran

The first step will be to integrate all departments currently carrying out health technology assessment into a single entity with the health ministry. The location of the unit should allow it to report to both the Ministry of Health and Medical Education and the Ministry of Social Welfare. It is suggested that the unit be split into subunits on medical devices, drugs, vaccines and preventable technologies, etc. Human resources are the prime need in establishing the unit, and therefore enhancing capacities should be emphasized (especially in the area of healthcare financing). Specialists and external consultants will be needed to develop the necessary guidelines to operate and conduct health technology assessment processes. The first activity to be undertaken by the unit will be on prioritization of technology needs, which should take all epidemiological, financial and technological parameters into account. Sharing country experiences through the newly launched regional health technology assessment network will be necessary, and WHO should provide financial, legal and international support to the country to develop this programme.

Iraq

The future of health technology assessment in Iraq depends on 3 major issues: political will, understanding its importance, and personnel. Though the will is present, the deep understanding of health technology assessment and the personnel are virtually non-existent. In Iraq the area of health technology is weak, and therefore training and education are crucial steps before initiating the programme. Within six months, the country will seek to get the necessary approvals to initiate a unit in the Ministry of Health. However, the model that fits Iraq best is to locate this unit within universities. Another six months will be needed to form the unit with the required personnel. Iraq will maintain contacts with WHO and all experts during this whole process. Involving universities, especially in the areas of research and literature search, would be very helpful.

Jordan

The first activity in Jordan will be to write a proposal for medium- and high-level managers in the Ministry of Health to meet to discuss health technology assessment and how it can be implemented. The location of this unit will be within the Ministry, and directly linked to the General Secretary or one of the deputies of the Minister of Health. The unit will initially include biomedical engineers, pharmacists and healthcare economists. Staff serving in the unit will be reallocated from existing staff in the concerned directorates so as to use their long experience in dealing with technologies. Key partners will be from universities, the private sector, social service organizations, Jordan Food and Drug Administration, the Standardization Council, and the Royal Medical Services. International networks and WHO support as external partners will also be required. Initially, the focus of the unit will be on

medical devices; drugs and vaccines can be included at a later stage. The regional health technology assessment network is needed for information-sharing, especially with international agencies and experts. Providing technical support, conducting national workshops, financing international meetings on health technology assessment and other learning-based activities will be needed and WHO can assist in providing them.

Lebanon

The health system in the country is dominated by the private sector and therefore the approach will be somehow different from that of other Member States. The first activity will be a mapping exercise to identify local structures, identify needs, and determine the most efficient location for the assessment unit. The Director General of Health is enthusiastic about health technology assessment and therefore political buy-in is not needed. However, the Ministry of Health still needs to meet with other stakeholders to ensure that they are in agreement. A proposal for the organizational scheme of work will be prepared before establishing the work process and legal framework to integrate it into national practice. Training will also be needed to enhance the capacities of nationals in this area. The unit will be located within the projects and health systems unit in the Ministry of Health, and staff will be recruited to carry out its functions. Based on the results of the mapping exercise, there might be a need for a steering committee, which would include representatives from all stakeholders for priority-setting. Key partners at national level will be health coverage funds, universities, and the syndicate of private hospitals. Rapid reports will be needed at the beginning, especially those covering comparative usage of different medical devices for specific clinical procedures. A cooperation protocol with the French government exists, and they can be approached to assist in developing the programme. The regional network, INAHTA, HTAsiaLink, and AP-HP will be contacted for support, information sharing, benchmarking, tools and adaptation of foreign health technology assessment reports. Support for training will be needed from WHO.

Libya

It has been suggested that health technology assessment activities for the Libyan Ministry of Health should be located in the Directorate of Pharmaceuticals, Medical Devices, Consumables and Narcotics. A proposal will be made for the Undersecretary for Technical Health Affairs to establish a health technology assessment department (not a unit or agency) within the pharmaceutical administration sector in the Ministry of Health. Human resources will be needed for the establishment of the department, especially biomedical engineers, pharmacists and health economists. The first activity of the committee should be to revise the cost-effectiveness of many of the technologies (especially drugs, devices and narcotics) in the country. WHO technical support, training and guidance will be needed to ensure successful implementation of the programme.

Morocco

Before establishing a unit in the country, the usefulness of health technology assessment within the context of universal health coverage in Morocco will need to be

demonstrated. Also, regulations governing the initiation of health technology assessment may have to be adopted. It is suggested that a committee be established along the lines of various existing health technology committees. Existing staff will be used to initiate the programme and produce needed reports. No funding will be available until health technology assessment is proven to be a worthy tool to invest in. The Ministry of Health, universities, engineering firms, hospitals and health technology assessment networks will be the potential partners of this initiative in the country. The first activity will be to evaluate the usefulness of health technology assessment and to determine its standard procedures; reporting on this will be shared widely with all stakeholders to demonstrate what it is all about. Support from WHO and the existing networks will be needed in promoting health technology assessment and securing the necessary political buy-in.

Oman

The first activity will be to appoint a focal point who will be responsible for initiating the development of the health technology assessment programme in the country through proposals, discussions or meetings. Capacity-building of staff and WHO guidelines on the initiation of the programme will also be needed. The location of the unit should be within the primary health care cluster in the Ministry of Health. At its inception the unit will need two permanent dedicated staff, supported by part-timers. A primary health care guideline and associated technologies will be the first activity of this unit, and the focus will be on diabetes medicines in particular. The regional network will be very helpful in this respect. Data and support from WHO will be required in twinning with HTA agencies and countries to establish the unit.

Pakistan

The health system in Pakistan is divided among the provinces and it is considered that health technology assessment is required in each province and in the health ministry to aid decision-makers. Though the main focus of the federal government is currently on regulating health technologies, health technology assessment should be considered at this stage as a second step towards ensuring the effectiveness and quality of the services provided. The first activity to be conducted will be a report on the effective use of certain drugs compared with others in several districts in the country. As in the case of many other Member States, WHO technical support in the form of funding, training and guidance will be needed to ensure the successful implementation of the programme.

Palestine

The starting point to instituting a health technology assessment programme in Palestine will be through the development of a committee with a clear action plan. A meeting with the Minister of Health will be required to seek his endorsement for the establishment of the committee, which will report directly to the Minister. The committee will comprise only 3 national professionals as a start (from the directorates of drugs, biomedical engineering and planning). Two subcommittees may be formed, the Drugs and Therapeutics Committee (already existing) and the Medical Devices Committee (to be established). Financial

resources will be required at the beginning of the programme for consultancies and training of staff on the health technology assessment committee and the sub-committees. Partners can be local universities, large private-sector organizations, international donors and nongovernmental organizations, and UN agencies such as WHO. The first activity of the committee will be to conduct an awareness workshop for all national and international stakeholders and Ministry of Health staff to explain health technology assessment and its benefits. The first type of technology to be addressed will be medical equipment and how to manage it more effectively. WHO will be needed to contact other Member States and experts for sharing of experiences and knowledge as well as to provide training and mentorship programmes for national staff.

Sudan

The first activity in Sudan will be dedicated to health technology assessment advocacy and orientation to key officials inside the health ministry (such as the Director General of Planning and International Health, the Undersecretary of Health, etc.). The location of the unit will be inside the Planning and International Health Department in the Federal Ministry of Health. The unit will have four staff (coordinator, health economist, technical analyst and secretary). Universities, the private sector, medical specialist councils, health insurance, the army and police civil department, and others can be considered national counterparts and partners. Also, international partners (global funds; Gavi, the Vaccine Alliance; WHO; Japan International Cooperation Agency; etc.) should be involved for funding purposes. Within this unit, four committees will be formed on medical devices, drugs, vaccines and clinical guidelines. Members of the committee will involve national and international experts as needed. The regional health technology assessment network and WHO technical support will be valuable assets.

Syrian Arab Republic

A national orientation workshop for all stakeholders should first be conducted in the Syrian Arab Republic. This step is important to raise awareness and gain the political commitment and support needed to establish the unit in the country. It is suggested that a health technology assessment committee be established within the central administration of the Ministry of Health. The committee should involve representatives from several directorates (medical equipment, food and drugs, public hospitals, primary healthcare, health economics and information, etc.). The first activity should be a research study on rationalizing expenditures on medical devices. Support from WHO will be required for training and in communicating with other agencies. The experience of the Islamic Republic of Iran can be a good resource for the country. Also, a letter of support from WHO is needed emphasizing the importance of health technology assessment, especially in the area of health care expenditure and prioritization of needs.

Tunisia

A health technology assessment unit, INASante, already exists in the country. It is an independent body with a defined structure and procedures. To promote health technology

assessment in the country, INASante has used national health meetings to explain its potential benefits and has presented many examples demonstrating the impact of assessment in the decision-making process. It is already working extensively in the area of pharma-economics evaluations, and hopes to extend the activities to other products such as medical devices. The unit now needs to examine the existing models to select the one that best fits the Tunisian health system. The reports produced will impact decision-making in issuing market authorizations for medical devices as well as pricing and reimbursement. For hospitals, health technology assessment can be helpful for making the right procurement decisions. The team in INASante will include statisticians, pharmacists, physicians, epidemiologists, economists, and engineers. It is expected that the functions of INASante will develop over time, and partnerships will be needed to achieve their targets. It is already a member of INAHTA, but other memberships will be considered as well. Technical support from WHO will be needed.

United Arab Emirates

A health technology assessment unit already exists in the country; however, what is needed is to increase the reliance on this unit in the decision-making process. A workshop is needed to achieve this aim. The unit is located in the health policies and regulation sector in the Ministry of Health. The unit has about seven staff (mostly pharmacists and biomedical engineers), however, the number of products should be increased; international cooperation and assistance is needed to improve the work. The focus of the unit is on devices, vaccines and drugs. The country might need WHO support to recruit consultants and share country experiences. A website with all published reports already exists.

Yemen

Initially a meeting with leaders in health in Yemen needs to be conducted to discuss health technology assessment and how it can be developed in the Ministry of Public Health and Population. It is suggested that health technology assessment starts as a committee with the intention of transforming it into a unit after preparing the framework, regulations, structures, and resources needed to establish it within the health ministry. The committee should comprise representatives from five disciplines: pharmaceuticals, biomedical engineering, health economy, planning, and procurement. Financial resources needed annually will be around US\$ 100 000, which is a small amount compared with the amount spent on technologies. The first activity of the committee should be on the cost-effectiveness of drugs and devices in the country and how this can be improved. The Ministry of Finance, universities and other national entities can be partners in this initiative. In addition, international organizations such as WHO/Yemen, the European Union and others operating in Yemen should be involved. Support is needed from WHO to convince the health ministry of the importance of the topic. In addition, training and technical guidance will be needed during the establishment of the unit; the services of HiTAP and NICE are particularly required.

9.2 Launch of the Eastern Mediterranean regional network on health technology assessment

Mr Hazem Sakr, WHO

The regional health technology assessment electronic network links members and content using the WHO EZcollab platform. This network supports the WHO concept of collaborative learning and knowledge sharing. It is a moderated community, accessible only to members, which provides an online archive of discussions, documents, contacts, announcements and a calendar of events. It also allows users to exchange resources, research papers, guidelines and other publications.

The network is seen by WHO as an opportunity to discuss health technology assessment issues with other experts. All participants and experts at this meeting were invited to be part of the network. Members can initiate discussions and contribute documents and other content.

9.3 Regional Director's closing remarks

Dr Alwan expressed his confidence that this meeting would motivate Member States to develop national plans of action to institute health technology assessment into their existing health systems, and towards this end he encouraged participants to share the outcomes of the meeting with their governments. The WHO is fully committed to supporting the implementation of these national action plans. As a result of the efforts made during the past year, HTA will be one of the topics to be discussed with Ministers of Health in the next Regional Committee meeting in October 2015.

10. NEXT STEPS

The following activities were identified by the experts and participants in the meeting as important steps towards developing health technology assessment programmes within existing health systems for countries in the Eastern Mediterranean Region.

- Encourage support for health technology assessment at national level; a brief on the proceedings of this meeting will be coupled with a letter from the Regional Director (addressed to ministers of health urging them to support the setting up of a national programme within their existing health systems) as advocacy for policy-makers.
- Those countries which currently do not have a formal health technology assessment structure should conduct national orientation workshops for key officials and stakeholders in the country to raise awareness and advocate for adopting health technology assessment. Participation of the WHO and external experts in these events will be needed to share other countries' experiences and demonstrate the potential benefits.
- Countries should be committed to the establishment of health technology assessment units along with the necessary processes/rules/regulations to ensure the transformation of purely scientific evidence into rational implementable decisions. Generally, the units

should start small in terms of staffing and budget. They are usually located within the health ministry and their work is mostly technical (literature search, surveys, etc.).

- Each country will be required to conduct a national mapping exercise to identify areas where health technology assessment reports will be needed. This will help in expediting the acceptance of the tool as a valid approach that will facilitate resolving many of the technology-related problems in the country.
- The selection of the initial activity for the health technology assessment unit is important. The first report should be carefully chosen so as to ensure acceptance and wide recognition for health technology assessment. It is recommended that the first activity of the newly developed unit should address lower levels within health care delivery (hospitals, primary health care centres, etc.) before moving to the national level.
- Countries should try to link health technology assessment activities to important ongoing initiatives (benefit packages, universal health coverage, etc.) or programmes (maternal and child health, noncommunicable diseases, etc.) in the country. The first products should be related to these initiatives or programmes.
- Countries need to identify areas where specific technical support is required (training on the health technology assessment process, literature survey, format and production of reports, etc.). This will help in enhancing the capacities of staff in specific areas related to their work.
- International donors such as the Global Fund, and Gavi, the Vaccine Alliance, etc. are willing to fund health technology assessment products related to their special areas of interest. Countries are recommended to approach such organizations to seek financial assistance, especially in the early stages of the development of their programmes.

Annex 1**PROGRAMME****Monday, 1 December 2014**

08:00–08:30	Registration	
08:30–08:50	Address by Dr Ala Alwan, Regional Director for the Eastern Mediterranean	
08:50–09:10	Introduction and meeting objectives	<i>Dr Marthe Everard, WHO</i>
09:10–09:30	Challenges and opportunities of HTA in the Eastern Mediterranean Region: results of a mapping survey	<i>Dr Adham Ismail, WHO</i>
09:30–09:40	WHA resolution on health technology assessment	<i>Dr Adriana Velazquez, WHO</i>
09:40–10:00	Health technology assessment for universal health coverage: the experience of the Islamic Republic of Iran	<i>Dr Majid Davari, HTA Islamic Republic of Iran</i>
10:30–10:50	Health technology assessment for universal health coverage: the experience of Thailand	<i>Dr Yot Teerawattananon, HiTAP</i>

Session 1: Prerequisites for a successful health technology assessment programme

10:50–11:10	Ingredients of a successful health technology assessment programme	<i>Dr Iñaki Gutiérrez-Ibarluzea, HTAi Spain</i>
11:10–11:30	Good governance of health technology assessment programme: strategies and concepts	<i>Dr Sophie Werkö, SBU Sweden</i>
11:30–11:50	Human and financial resources required to establish a health technology assessment programme	<i>Dr Yot Teerawattananon, HiTAP Thailand</i>
11:50–13:00	Discussion	

Session 2: Possible structures and organizations of health technology assessment systems

14:00–14:20	Organizational differences in health technology assessment frameworks across countries	<i>Dr Adham Ismail, WHO</i>
14:20–14:40	Health technology assessment in the United Kingdom: National Institute for Clinical Excellence (NICE)	<i>Dr Derek Cutler, NICE United Kingdom</i>
14:40–15:00	Health technology assessment in the Islamic Republic of Iran: the Iranian Health Technology Assessment Unit	<i>Dr Majid Davari, HTA Islamic Republic of Iran</i>
15:30–15:50	Health technology in Malaysia: The Malaysian Health Technology Assessment Section (MaHTAS)	<i>Dr Rugayah Bakri, MaHTAS Malaysia</i>
15:50–16:10	Health Technology assessment in Thailand: Health Intervention and Technology Assessment Section (MaHTAS)	<i>Dr Inthira Yamabhai, HiTAP Thailand</i>
16:10–17:00	Discussion	

Tuesday, 2 December 2014*Session 3: The HTA process*

09:00–09:20	Key principles for conducting health technology assessment process	<i>Mr Reiner Banken, INESSS Canada</i>
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09:20–09:40	Identification of technologies to be assessed and setting priorities for health technology assessment process	<i>Dr Iñaki Gutiérrez-Ibarluzea, HTAI Spain</i>
09:40–10:00	Pre-analysis phase: collection background information	<i>Dr Andres Freiberg, NICE United Kingdom</i>
10:30–10:50	Stakeholders, health technology assessment process products and project processes	<i>Dr Sophie Werkö, SBU Sweden</i>
10:50–11:10	Conducting a successful health technology assessment process	<i>Dr Rugahah Bakri, MaHTAS Malaysia</i>
11:10–11:30	Elaborations of recommendations of health technology assessment process: strategies for dissemination and implementation of results	<i>Dr Jeonghoon Ahn, NECA Republic of Korea</i>
11:30–12:30	Panel discussion on work process of health technology assessment (NICE, HiTAP, MaHTAS, OSTEBA, and SBU)	<i>Moderated by Dr Marthe Everard, WHO</i>

Session 4: Outcomes of HTA process

12:30–13:00	Effect of health technology assessment on policy-making and clinical practice	<i>Dr Sophie Werkö, SBU Sweden</i>
14:00–14:20	HTA and social health insurance: impact on pricing, reimbursement and market access	<i>Dr Adham Ismail, WHO</i>
14:20–14:40	HTA for pharmaceuticals, devices and other technologies: impact and applications	<i>Mr Reiner Banken, INESSS canada</i>
14:40–15:00	Hospital-based health technology assessment: concept and impact	
15:30–16:30	Discussion on impact of health technology assessment process	<i>Mr Bjorn Fahlgren, AP-HP France</i>
16:30–17:00	Introduction to group exercise: using health technology assessment for universal health coverage benefit package development	<i>HiTAP & NICE</i>

Wednesday, 3 December 2014

09:00–10:10	Group exercise
10:30–11:10	Group exercise presentations

Session 5: Integrating health technology assessment into public policies

11:10–11:30	Integration of health technology assessment into public policies: introduction	<i>Dr Adriana Velazquez, WHO</i>
11:30–11:50	Health technology assessment for adding value to innovation: from research to use in health systems	<i>Mr Reiner Banken, INESSS, Canada</i>
11:50–12:10	Promoting production of evidence and dissemination of information	<i>Mr Majid Davari, HTA Islamic Republic of Iran</i>
12:10–13:00	Discussion on how to formalize health technology assessment in the Eastern Mediterranean Region	

Session 6: Networking and collaboration

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|-------------|---|-------------------------------------|
| 14:00–14:30 | Implementation of health technology assessment in low- and middle-income countries: challenges, opportunities and networking | <i>Dr Jeonghoon Ahn, HTAsiaLink</i> |
| 14:30–15:00 | INAHTA strategies and mentorship programme | <i>Dr Sophie Werkö, INAHTA</i> |
| 15:30–16:00 | Panel discussion on networking and collaboration for overcoming health technology assessment implementation barriers and challenges (INAHTA and HTAsiaLink) | |

Session 7: The way forward

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|-------------|--|-------------------------------|
| 16:00–16:10 | Introduction to group work: developing national HTA programmes within existing health systems in the countries of the Eastern Mediterranean Region | <i>Dr Marthe Everard, WHO</i> |
| 16:00–17:00 | Group work | |

Thursday, 4 December 2014

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|-------------|--|-------------------------------|
| 09:00–10:00 | Group work (cont.) | |
| 10:30–11:30 | Group work presentations | |
| 11:30–12:30 | Discussion on group work and recommendations on a framework for development of national health technology assessment programmes in countries of the Eastern Mediterranean Region | |
| 12:30–12:50 | Launch of the Eastern Mediterranean regional network on health technology assessment | <i>Mr Hazem Sakr, WHO</i> |
| 12:50–13:00 | Closing session | <i>Dr Sameen Siddiqi, WHO</i> |

Annex 2

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