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Guidance for the development of a National HTA-strategy

Claudia Wild[a,*], **Marius Stricka**[b], **Nikolaus Patera**[a]

[a]*Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA), Garnisongasse 7/20, 1090 Vienna, Austria*
[b]*Lithuanian University of Health Sciences (LSMUNI), Preventive Medicine, Lithuania*

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Abstract
Background: Health Technology Assessment (HTA) has gained importance and is emphasized as instrument to guide health policy in rational decisions on resource allocation on health technologies. In 2015 the development of a National HTA strategy in Lithuania was undertaken. It is the intention of this paper to offer generic guidance for similar future initiatives.
Methods: A mixed-methods and multi-perspective approach was used to collect data and information: a detailed health care system analysis of the regulative and legislative environment, complemented by international experiences on possible linkages between decision making and HTA, extensive interviews on existing decision making processes and specific system needs for HTA.
Results: The guidance for the development of a National HTA strategy follows a step-wise approach: The first step is the definition of specific strategic objectives that can be operationalized in concrete activities that can be monitored in their implementation. Next - in a detailed system analysis - data and information are collected. The collected information is assessed according to an analytical framework within four areas: assessment of system needs, assessment of potential benefits of and challenges in the utilization of HTA, analysis of human resources and capacities as well as need for training and analysis of options for institutionalization and financing. During the final step concrete activities guided by the pre-defined objectives are planned based on the identified needs.

*Corresponding author. Fax: +43 1 236 81 19 99.
E-mail address: claudia.wild@hta.lbg.ac.at (C. Wild).

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Conclusion: The implementation of HTA with transparent processes and products may take years. Careful planning, monitoring and eventual adaptation of the National HTA strategy will be needed.

Introduction

Health Technology Assessment (HTA) – defined as a multidisciplinary process that summarises information related to the use of a health technology in a systematic, transparent, unbiased, robust manner and aiming to inform health policies to achieve best value [1] – has increasingly gained importance and is emphasized as an important instrument to guide health policy in rational decision making and in planning resource allocation [2]. Internationally the World Health Organization (WHO) [3,4], Global Development Agencies [5] and in some cases also the World Bank [6] are encouraging or even requiring HTA as a tool for priority-setting for the allocation of scarce resources for health care. In Europe the Cross Border Healthcare Directive (2011/24/EC art.15) [7] has formed not only the legislative prerequisite for a voluntary network of established HTA agencies in countries with a long-standing HTA tradition, but also the context for developing HTA activities in new Member States (MS) with no or little knowledge on how and when to use HTA. Box 1 clarifies the intended role of HTA in health policy decisions.

In 2015, the development of a National HTA strategy for one of the new European MS, Lithuania, was supported by a grant of the EU-structural fund aiming at "providing high quality and affordable health care services" and was conducted in a collaboration between the Austrian Ludwig Boltzmann Institute for HTA and local Public Health experts from LSME University, Kaunas [8,9]. Little (published) knowledge on the development of a National HTA strategy – such as on process, structure and methodology – is available for high-income countries [10,11]. At the same time a growing interest in HTA can be observed in low- and middle-income countries that are in the process of introducing universal health coverage. Experiences with the development of HTA from six countries in Asia were recently published [12]. On a similar note effective capacity-building strategies for HTA for Sub-Saharan Africa were the subject of a review [13]. In this context it is our intention to provide information on how we proceeded in Lithuania and to offer a generic guidance for future initiatives with similar aims.

Aims of a National HTA strategy

The development of any strategy involves the definition of well-defined goals, the determination of actions to achieve these goals, and the mobilization of resources to execute these actions. A National HTA strategy intends to support (future) health policy decisions on health interventions supported by research-based assessments with the goal of a more rational use of resources. A well-performing HTA system will give decision support across the life cycle of technologies in order to facilitate patient access to cost-effective health technologies that improve health outcomes; to minimize the use of technologies that are ineffective or harmful; to contribute to value for money investments in health technology in the context of limited health care resources; to keep pace with evolving technologies, clinical practices and HTA methodologies [14]. A National HTA strategy therefore pursues two general aims [11,15]:

- to establish a solid and comprehensive ("evidence-based") foundation for decision making for the introduction and utilization of health technologies at all levels in the health care system;
- to ensure that HTA becomes an integrated part of routine decision making for planning and operational policy within the health care system.

More specific strategic objectives that can be operationalized either as short-term or as long-term activities are:

1. to establish a political framework to promote (enforce, facilitate) HTA uptake;
2. to establish structures for timely, efficient and good-quality provision of HTA information that satisfies needs;
3. to increase acceptance and demand for HTA information;
4. to boost the utilization of HTA information for decision making.

Methods for the development of a National HTA strategy

The methodological approaches for the development of a National HTA strategy should be based on data and information enriched by multiple sources. A mixed-methods and multi-perspective approach is most likely to achieve results that can actually be implemented in practice [8]:

Health care system analysis: a detailed description of the health care system and the (formal and informal) decision making processes, the division of power in specific (investment, reimbursement, tariff-setting) decisions as well as existing capacities and possible training opportunities for HTA. The description is based on published legal and regulatory sources as well as on interviews with national experts. Components of the system analysis are

- Description of the legislation and regulation of health care,
- Description of responsibilities and the decision making processes on public health interventions, hospital services, drugs/devices,

Box 1 "HTA in a nutshell" [13].

> Health Technology Assessment (HTA) is one of the tools that supports the policy formulation process. Using multidisciplinary analyses, it examines the health, economic, social and ethical implications of the use of new (and existing) 'technologies,' broadly defined as any interventions to improve health. These analyses inform the development of clinical protocols, the composition of benefit packages and reimbursement mechanisms for health care providers, for example. To have policy impact, the findings of these evaluations need to be inserted into government's priority-setting processes, where they are weighed against numerous other concerns. Participation in certain stages of these processes is also a function of HTA practitioners.[1]

- The landscape of advanced training/capacity building for HTA,
- Resource estimation of staff already working in HTA or needed.

Analysis of international experiences: a systematic presentation based on publications on experiences and lessons learnt from comparable health care systems and deductive conclusions derived from such international knowledge. Components of the presentation of international experiences are

- Examples of legal and regulatory linkage between health policy and HTA,
- Utilization and applications of HTA in comparable health systems,
- HTA processes and products,
- Barriers to use of HTA and potentials to overcome them,
- Institutional embedding of HTA,
- Financing of HTA activities,
- Capacity building in countries with little tradition: needs, characteristics and amount of training needed.

Analysis of multiple stakeholders' perceptions: structured interviews on major characteristics and perceived problems, on formal and informal processes in decision-making, on perceived barriers to utilize HTA, on existing expertise and needed capacities, as well as on priorities for HTA products for the most urgent decisions provide valuable information complementing the system analysis and the knowledge gained from international experiences. Different stakeholder in health care – be it national (health care insurance, ministry of health) or regional payers (municipalities, local bodies responsible for certain health care and public health services), health care providers (hospitals, clinicians), suppliers (manufacturer of drugs, devices, equipment) or patients usually have very different perspectives on the health care system and its needs. Box 2 presents selected quotes from stakeholders in Lithuania as an illustration of results of such structured interviews.

[1]Taken verbatim from p. i. in: Doherty, J. Effective capacity-building strategies for Health Technology Assessment: a rapid review of international experience. International Decision Support Initiative iDSI Discussion Document: June 2015

Available from: http://www.idsihealth.org/knowledge_base/effective-capacity-building-strategies-for-health-technology-assessment-a-rapid-review-of-international-experience/.

Analytical framework for the development of an HTA strategy

Based on the thorough description of the health care system in question, the next step to the formulation of a strategy is the analysis of the collected information and data within four areas of interest:

System needs for implementing HTA: the description of the process of decision making in the health care system reveals detailed information on which institutions are responsible for what kind of decision and which regulatory instruments are in place to implement the decisions (Table 1). HTA develops the most impact if it is carried out for concrete decisions [16]: Some international examples are HTA for the in-/exclusion of interventions in benefits-catalogues [17,18], for investment decision in regional hospitals or infra-structural planning [19,20], for national drug benefit assessments and corresponding price-negotiations [21], for regional disinvestment decisions [22] or for national guidelines [23].

Ideally the system analysis identifies policy areas with a high need of decision-support and for transparent processes, where there are already strong regulatory instruments in place for facilitating the implementation of HTA. Table 1 reveals examples for the linkage between policy actors, their areas of decision-making and possible policy instruments. Part of the analysis is also to identify the need to establish new processes and to define carefully the HTA products needed.

Assessment of chances and challenges for HTA

Utilization: HTA can be utilized by a wide range of decision-makers: the actual utilization of HTA for evidence-informed health policy decisions is stimulated by the information need and the demand of decision-makers for tailor-made timely HTA products of good quality (reliable, valid, clear in message) and relevance. The following HTA utilizations are prevalent (figure 1); not all of them will be equally important.

The barriers to HTA utilization are organisational factors such as poor dissemination of HTA, lack of material and personnel resources (skills of politicians to understand the need of evidence and its potential, and skills of HTA staff to understand the needs and priorities of politicians), staff turnover, but also resistance of professional (clinical) bodies or lack of managerial will for change in the organizational decision making culture. Strategies to increase the use of research evidence are the development of permanent

Box 2 "Lithuania's own voices" [8].

HTA needs

- *"We need a rational system of decision making on investment and reimbursement."*
- *"Decisions on investments above a certain threshold would need to be evidence based."*
- *"Our expectation is to learn from an HTA if the technology is appropriate for Lithuania, for whom it should specifically be provided and if Lithuania can afford to pay for it."*
- *"Against the background of the constant flow of new innovations: Which technologies to consider? Which technologies to reimburse? And when to reimburse: right at market entry or later? Ideally the first step would be to make an HTA."*
- *"In the devices market, there are many similar products, for us it is not clear what the respective advantages are, also the value for money is unclear."*
- *"Proactive choice of HTA topics by public agents, not reactive to industry application or in response to industry pressure."*
- *"There is an indecisiveness about who is in charge of HTA in Lithuania."*

Challenges to legitimacy of HTA

- *"All present HTA doers in Lithuania have direct or indirect contacts to policy makers, which result in some degree of conflict of interest."*
- *"An institution that has a regulatory function is not well suited for an HTA function."*
- *"Pharmaceutical companies applying for the reimbursement of a drug should not be the ones commissioning evaluations/ HTA of the drug themselves."*

Profile building for HTA

- *"Identify local HTA champions in university hospitals and support them."*
- *"Realize high-impact flagship projects that generate quick results/ savings."*

Quality assurance of HTA

- *"Danger that possible poor quality of present HTAs will discredit HTA among the professions."*

relationships with health politicians and administrators, but also trust and mutual respect for each others' professional needs. To increase the utilization and impact of HTA a good understanding of the processes, the context and competing priorities as well as of political pressures is of advantage [24].

In the best case the analysis identifies not only the fields of HTA utilization, but also potential barriers in order to be able to develop activities to overcome them early on.

Analysis of human resources and capacities: Even though decision making on new technologies is part of the operational routine of health authorities and health service providers, such decisions are frequently based on single source (e.g. manufacturer, medical experts) information. The challenge is to change the decision making culture towards transparent and evidence-based decisions. This change requires sufficient national capacities to carry out HTA [25]. Even though a formal HTA program might not be in place in most countries, all countries offer academic training, continuing professional education and eventually post-graduate course in hospital management, health sciences or Public Health from which coordinated HTA activities can take roots. The concept of capacity building encompasses not only the training of HTA core staff, but also the involvement of existing (relevant) capacities in academic institutions, and awareness-raising for HTA among the key stakeholders.

Besides the basic academic education in the respective disciplines of the researchers, training in HTA specific methodologies is required. Also, to understand and implement HTA findings training of and targeted communication with the decision makers is of essential importance for the actual utilization and implementation of HTA findings. Finally, since especially small countries can never have the capacities to assess all new technologies themselves, skills to use other countries´ assessments or to produce collaborative assessments are essential for national efficiency. Strong external partnerships within HTA networks (EUnetHTA, INAHTA, RedETSA, HTAsiaLink) are of utmost importance, but need time and resources for their establishment and for fostering a working environment of mutual trust.

The analysis must identify existing capacities (human resources) to carry out HTA, and of established academic

Table 1 Decision-Makers, Policy content and Regulatory Instruments (with examples[a]).

Responsible Institution	Policy content	Potential regulatory instruments	Examples
Ministry of Health	Immunisation schedule	(General or age-group specific) In-/exclusion in public immunisation schedule,	HPV-vaccination, Seasonal influenza vaccination
	Prevention programs	Investments in prevention programs	Mother-child care health checks
	Screening	Investments in early detection	Mammography or colon-cancer-screening
	Infrastructure	Investments in medical infrastructure	Hospitals, polyclinics, outpatient services
Ministry of Health	Hospital financing	DRGs or capitation	Re-calculation of DRGs for new surgical interventions or procedures
	Hospital services catalogue	In-/exclusion of additional services hospital catalogue	Planning: TAVI, PET, ...
	Additional investments in equipment	Tariffs	Rare interventions: neurosurgery, transplantation
	Planning of big equip ment/ specialized services	Conditional coverage/coverage with evidence development (research)	Quality indicators for frequent interventions: elective surgery in orthopaedics, birth clinics,
	Inpatient drugs	Infra-structural requirements for planning Minimal quality-volume requirements for specialized or frequent services Inpatient drug-commissions	positive/negative list for inpatient drugs (e.g. onco drugs)
Social Insurance Institutions	Outpatient services catalogue	Outpatient drug-commissions	Positive/negative list for inpatient drugs (e.g. rheumatism drugs)
	Outpatient-drugs	In-/exclusion of additional services Outpatient services benefit catalogue/basket In-/exclusion of new services Fee-for service tariffs Capitation Quality audits/pay-for-performance Conditional coverage/coverage with evidence development (research)	Quality indicators for chronic conditions: asthma, diabetes, breast cancer
Social Insurance Institutions	Planning of rehabilitation	Infra-structural requirements for rehab services	Severity of illness indicators as appropriateness-criteria for long-term care
	Planning of long-term care facilities	Access-regulation (thresholds) Outcome measurement	Quality indicators for outcome assessment after cardio-rehab
Medical Association/ Chamber of Physicians	Quality assurance CME/continuous medical training	Clinical guidelines Clinical pathways Auditing, benchmarking	Guidelines for chronic conditions Pathways for stepped care in diagnostics
Regions	Maintenance of hospitals and services	Quality assurance + control Clinical risk-management	Hygiene management CIRS/critical incident reporting system-installation

[a]simplified analytical tool based on Austrian examples [27].

institutions to train in HTA methodologies, but also analyse potential networks for organizing the necessary additional training and capacity building at home or abroad.

Analysis of options for institutionalization and financing: Most HTA agencies are advisory bodies and have no regulatory function [26]. This segregation of functions is

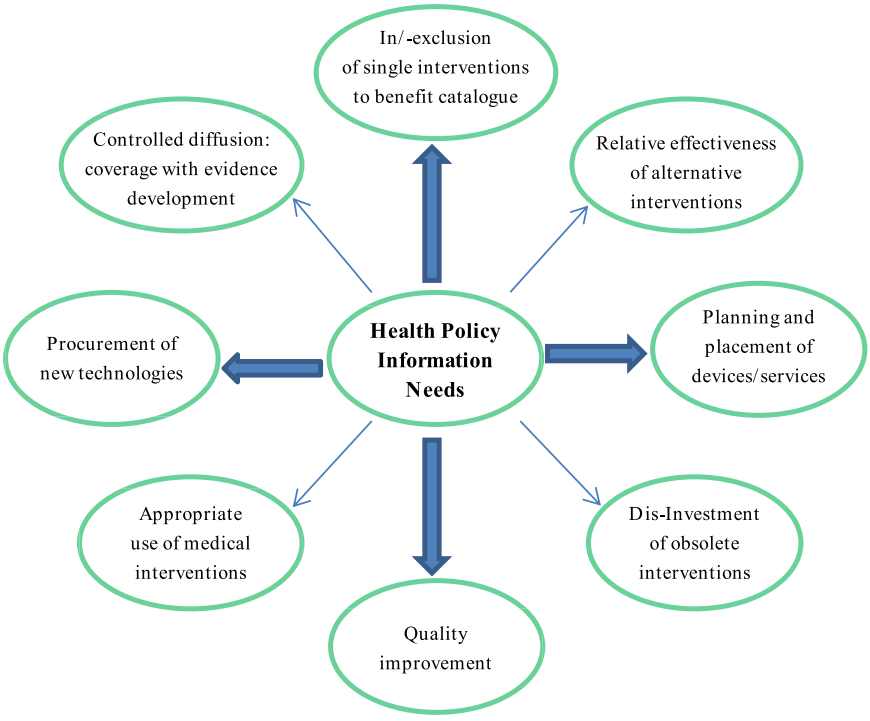

Figure 1 Common utilizations of HTA.

rooted in the HTA value of independence of interest and influence from system partners of any kind. This independence from interest-groups as well as from political interference is an essential prerequisite for objective HTA information. At the same time as HTA needs to stay at arm´s length from health policy, it needs to be connected enough to provide relevant and timely answers to policy questions. HTA is one component of the decision making process that can best be described as a synergistic division of work between health policy, regulatory approval, HTA and reimbursement.

There is not one "best practice" model of HTA institutionalization, but many different models. Nevertheless, the vast majority (e.g. in EUnetHTA, INAHTA) is publicly funded and closely associated with the national health authorities [25]: Institutionalization of HTA does not necessarily mean that a national HTA institute is founded, but that HTA is given a defined role in decision making. The analysis must therefore identify (public) funding options and (best) placement of HTA in the health care system.

From HTA strategy planning to implementation

The next step on the pathway from description and analysis of the given conditions is the planning of the operationalization. Concrete activities are planned in accordance with the pre-defined objectives with an eye on their practical implementation. The detailed configuration and nuancing of the following four strategic objectives is highly context-specific. Box 2 sketches the Lithuanian context with quotes from local stakeholder interviews.

Strategic objective 1: To establish a political framework to promote (enforce, facilitate) HTA-uptake

Operationalization 1: Regulatory embedding, ensuring legitimacy of HTA

To ensure the uptake of HTA, a regulatory linkage with policy decisions is important. In the case that a ministry´s action plan has already expressed its political wish to introduce HTA to improve health care efficiency and quality or if some regulations for mandatory HTA ahead of larger investment decisions have already been passed but are at present not actually executed or if initiatives (by the ministry of health or by health insurances) have already set up certain structures (e.g. a HTA committee) for the introduction of HTA to decision making, the first steps for the implementation are already set. If no such initiatives are yet in place, their initiation would be the first step.

Examples for strategic activities to reach objectives:

- Minister of health approves the HTA strategy as a priority.
- List of pending decisions by decision makers on programs or technologies is collected as basis for prioritization. Major payers are involved in the topic list and in decisions on the HTA work program.
- Prioritization tool is used for deciding an annual HTA work program: criteria such as technologies with high cost/ high volume/ high uncertainty or low cost interventions with the potential for the improvement of health of many citizens are applied.
- Rules of governance (roles, functions and rules for interaction) to secure HTA independence are defined and agreed.

Strategic Objective 2: To establish structures for timely, efficient and good-quality provision of HTA information that satisfies needs

Operationalization 2: Financing and organization of HTA production

HTA can be organized in a single centralized HTA agency or in decentralized and regionalized (but coordinated) HTA institutions. If HTA activities are highly fragmented across institutions, horizontal coordination (common methodologies, dissemination and implementation plans, awareness-raising) should take place. Even if there is not one single role model for the institutionalization of HTA, specific features such as public funding and established procedures to keep distance to interest-groups including payers define national HTA [8]. For this, stable long term funding of HTA activities and mechanisms against political interference are essential.

Examples for strategic activities to reach objectives:

- An earmarked budget for HTA activities is ensured and funding for existing trained HTA staff (e.g. in international projects) is safeguarded.
- Task force or HTA coordinator supporting the HTA strategy is appointed to enforce and monitor the activities. The tasks are clearly defined (e.g. prioritization criteria, governance principles securing independence, coordination of methodology standards, set-up of internet platform for public access to HTA reports, policies to include stakeholders, conflict of interest management etc.)
- For promoting the concept of HTA and for increasing visibility of HTA "flagship projects" (high impact on patient safety or cost savings) are conducted. Local HTA champions are supported through innovative projects.
- Eventually external (e.g. research grants) funding to foster good governance/ transparency for HTA is applied for.

Strategic Objective 3: To increase acceptance and demand for HTA information

Operationalization 3: Quality assurance of HTA: transparency in processes and products

A clear HTA process is one key success factor for trust and acceptance among stakeholders. The process has to include the pathway from the topic selection, conduction of research, completion of an HTA report towards a decision on implementation (or not) and then on to implementation. The quality of HTA products is the other success factor. Poor quality assessments will discredit HTA among decision makers and professionals.

Examples for strategic activities to reach objectives:

- Methodological and procedural standards (peer-reviewing, quality criteria for reporting etc.) are agreed and adhered to.
- Public access to HTA reports (for the general public, clinicians and media, for health policy and reimbursement institutions) is established.
- Impact of HTA on health policy decisions is evaluated regularly.
- International HTA activities, including horizon scanning activities, are monitored and regularly communicated to the ministry of health and statutory health insurance.

Strategic Objective 4: To boost the utilization of HTA information for decision making

Operationalization 4: Capacity building, networking and collaborating

Transforming the decision making culture towards evidence-based decisions demands a firm commitment from health policy makers and sufficient national capacities to carry out HTA. The diversity of HTA topics requires a broad range of different competences. Covering the full range is not always possible. Therefore a strong network for national and international cooperation, including external specialists, is a pragmatic necessity. For countries new to HTA and/ or small in size cultivating the skills to translate assessments done by others to the national context and fostering relations for collaborative assessments are both essential.

Examples for strategic activities to reach objectives:

- National in-house capacity conducting HTA is built (e.g. training of seniors to guide juniors). Students in Public Health, epidemiology, health economics are invited to participate in assessments and/or to conduct an evidence analysis as an academic thesis.
- Short educational programs on HTA for government, health care management, clinical staff and media representatives, to distinguish good quality information from biased information and to increase awareness of options to apply HTA, are offered.
- HTA staff members collaborate in international and in bilateral HTA projects as training opportunity and as start for network-building.

Box 3 illustrates how these four strategic objectives have been operationalized with milestones in a defined timeline for the National HTA strategy for Lithuania.

Guidance for the development of a National HTA strategy: multi-stepped approach

Many countries, not only those that already have established HTA programmes in their countries, increasingly use HTA as support for their decisions. This is rarely based on an explicit HTA strategy, though in recent years – especially encouraged by international agencies (WHO, World Bank, Centre for Global Development) – a more systematic approach to HTA implementation is being sought. Based on the development of a National HTA strategy for Lithuania, we tried to generate a generic procedure as guidance for the future development of HTA strategies in other countries. To our knowledge no such guidance exists yet for higher-income countries already enjoying universal health coverage and the one derived from the Lithuanian experience can therefore be a valuable contribution.

A change of culture (in decision making) takes years. There will be resistance from established vested interests fearing loss of influence. There will be inertia to

Box 3 Suggested Timeline and Milestones of HTA Strategy for Lithuania.

Timeline and Milestones

Short-term activities (2015, 2016)

- Minister of Health approves National HTA Strategy with a MoH order
- Continued funding for HTA staff trained in EU projects is safeguarded
- HTA Coordinator supporting the MoH HTA Committee is appointed
- The tasks of the HTA Coordinator are clearly defined and public annual reporting of achievements is provided
- A "Community of Practice" is established as forum for regular exchange all HTA actors
- List of pending decisions by decision makers on programs or technologies is collected as basis for prioritization
- Major payers are involved in the topic prioritization list and in decisions on the HTA work program
- Prioritization tool is used for deciding HTA work program
- "Flagship projects" are conducted
- Local HTA champions are supported with challenging projects (e.g. evidence-based planning)
- An analysis of the obstacles to filling already existing HTA regulations with life is conducted
- Rules of governance to secure HTA independence are defined and agreed
- A Website with information from all HTA actors is launched
- National methods handbook is compiled and published
- Standards for peer-reviewing, quality criteria for reporting, CoI/conflict of interest management are agreed and adhered to
- International HTA activities are monitored and regularly communicated
- Staff members collaborate in European (EUnetHTA) and in bilateral HTA projects

Medium-term activities (2017-2019)

- Further EU funding to foster good governance/ transparency for HTA is applied for
- Multi-disciplinary HTA teams across institutions doing HTA are established
- Staff at SMCA is trained in HTA
- In-house capacity to guide juniors in institutions conducting HTA is built
- Communication, dissemination and implementation plans are prepared for each HTA report
- Educational programs on HTA for government, health care management, clinical staff and media representatives are offered
- English language as working language is accepted to facilitate international collaboration
- Baccalaureat and Master students in Public Health, Epidemiology, Health Economics are invited to participate in assessments to conduct an evidence analysis as thesis

Long-term activities (2020 +)

- Minister of Health publishes decisions on HTA implementation and regularly reports to public on progress of implementation
- Separation of functions (policy or funding decision, regulatory, HTA) is implemented
- Standardized submission templates (based on EUnetHTA) are introduced at SHAA and SMCA
- Impact of HTA on health policy decisions is evaluated regularly
- Courses for evidence-based medicine and HTA are part of the basic curriculum of medical schools

overcome in a system set in its traditional ways. So it is best not to be overly impatient. Involving clinical experts and other stakeholders (in the initial scoping, later as external peer-reviewers or even in actually carrying out assessments) is not only an option to gain trust in each others' methods, but also a vehicle for inclusiveness and to teach and disseminate the concept of evidence-based medicine intrinsic to HTA. Raising awareness for HTA works best by successfully realizing "flagship projects" that increase the quality of patient services, decrease inappropriate or even harmful interventions or create savings that can be re-invested for other services.

Eventually transparent, reliable and replicable HTA products develop their own convincing language and begin to speak for themselves. Developing an HTA strategy can only be considered an initial contribution to making decisions on the health care system in question more evidence-based. The ultimate success of an HTA strategy is strongly dependent on if and how the health sector stakeholders take the ownership of the strategy and establish a process for evidence-based decision support.

We propose a multi-method stepped approach starting with

- defining the country specific goals that should be achieved with a HTA strategy,
- analysing the legal and regulatory aspects of one´s health care system and the existing and potential additional future pathways to implement HTA in given processes of decision making,

- identifying the prioritized needs for HTA introduction in decision making,
- defining short-term as well as long-term achievements in step-wise implementation.

The implementation of HTA with transparent processes and products may take years. Careful planning, monitoring and an eventual adaptation of the strategy will be needed.

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Conflict of interest

There is no conflict of interest for any of the authors.

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