



FACILITATION OF NATIONAL STRATEGIES FOR CONTINUOUS DEVELOPMENT AND SUSTAINABILITY OF HTA

Analysis and recommendations

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LIST OF AUTHORS

Marta Durczak, Agency for Health Technology Assessment (AHTAPol), Poland

Ewa Kiersztyn, Agency for Health Technology Assessment (AHTAPol), Poland

Krzysztof Orłowski, Agency for Health Technology Assessment (AHTAPol), Poland

Aleksandra Pajor, Agency for Health Technology Assessment (AHTAPol), Poland

Marta Stasiak, Agency for Health Technology Assessment (AHTAPol), Poland

Karolina Szewczyk, Agency for Health Technology Assessment (AHTAPol), Poland

Document was developed with the active contribution of external experts as well as partners involved in EUnetHTA Joint Action Work Package 8 activities:

Luciana Ballini, Regional Health Care Agency of Emilia Romagna, (ASSR-RER), Italy

Elisabeth Breyer, Gesundheit Österreich GmbH (GÖG), Austria

Mirella Corio, National Agency for Regional Health Services (AGENAS), Italy

Mirjana Huic, Agency for Quality and Accreditation in Health Care, Croatia

Inaki Imaz, Carlos III Health Institute (ISCIII), Spain

Panos Kanavos, London School of Economics, UK

Hege Kornor, Norwegian Knowledge Centre for the Health Services (NOKC), Norway

Neringa Kuliešiūtė, State Health Care Accreditation Agency (VASPVT), Lithuania

Sun Hae Lee Robin, French National Authority for Health (HAS), France

Marco Marchetti, University Hospital “A.Gemelli”, Italy

Sabrina Medici, Regione del Veneto, Italy

Gintare Miksiene, State Health Care Accreditation Agency (VASPVT), Lithuania

Montse Moharra, Catalan Agency for Health Technology Assessment and Research (CAHTAR), Spain

Renzo Pace Asciak, Ministry for Social Policy / Strategy and Sustainability Division(SSD/MSOC), Malta

Iris Pasternack, National Institute for Health and Welfare (Finohta, THL), Finland

Elpida Pavi, National School of Public Health (NSPH), Greece

Isabel Pena-Rey, Ministry of Health, Spain

Janeek Saluse, University of Tartu (UTA), Estonia

Antonio Sarría, Carlos III Health Institute (ISCIII), Spain

Kristina Tomekova, Slovak Agency for Health Technology Assessment (SLOVAHTA),
Slovakia

Eva Turk, Institute of Public Health of the Republic of Slovenia (IPH-RS), Slovenia

Marcial Velasco-Garrido, University Clinic Hamburg-Eppendorf and Technical University of
Berlin, Germany

Luca Vignatelli, Agency for Healthcare Regional Services (ASSR), Italy

Claudio Zaugg, Swiss Tropical and Public Health Institute (Swiss TPH), Switzerland

Document review was conducted by:

Marcial Velasco-Garrido, University Clinic Hamburg-Eppendorf and Technical University of
Berlin, Germany

Ana María Gálvez González, National School of Public Health, Cuba

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GLOSSARY

Capacity Building - the process by which individuals, organizations, institutions and societies develop abilities (individually and collectively) to perform functions, solve problems, set and achieve objectives.

Commissioner - a government official, representative in charge of a department or district or a person appointed as a member of a government commission.

Dissemination - any process by which information is transmitted (made available or accessible) to intended audiences or target groups.

Health technology assessment (HTA) is a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value.

HTA activity - an activity associated with HTA, including for instance: supporting the decisions of healthcare product companies regarding product development and marketing or investors, supporting regional and national allocation decisions for healthcare resources (planning and priority setting), providing information for regulatory decisions on market approval of a technology, helping healthcare payers and providers determine which technologies should be included in health benefits plans and helping them formulate coverage (whether or not to pay) and reimbursement (how much to pay) policies, helping managers of hospital healthcare networks, and other healthcare organizations, make decisions regarding technology acquisition or adoption, informing clinicians, providers, and patients about the proper use of healthcare interventions for particular health problems (for instance practice guidelines and

disease-management programmes), reporting gaps in scientific knowledge and health services research.

HTA organization - an organization providing relevant information facilitating evidence-based decision making in health care, supporting health care providers, payers and policy-makers.

HTA process - continuous procedure composed of a set of individual steps, including identification of technologies with potential for reducing burden of disease, assessment of clinical efficacy, harm/benefit ratio, economic efficiency, feasibility, followed by evidence synthesis via HTA products, monitoring and – if necessary reassessment.

HTA products: assessment reports (documents stemming from the process of assessment, based on systematic revisions of scientific evidence focusing on aspects such as the efficacy, safety, effectiveness and efficiency of medical technologies) or their short versions, primary research projects conducted to start up the assessment process, when the evidence is insufficient or there are no data, consultation to different health structures in the public and private sector, academic and training activities geared towards transmitting knowledge and skills in the methodology and practice of health technology and health services assessment, clinical practice guidelines.

Performance budgeting - budgeting that links the funds allocated to measurable results.

Stakeholders – groups or organizations which potentially will be affected by, or have an interest in, and may, in a consultative role, influence the actions or aims of an organization, project or policy direction.

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1 EXECUTIVE SUMMARY

Broad research which investigated the current experience, stage of development, needs, scopes and outcomes of HTA institutions, organizations or units all over the Europe, both experienced or inexperienced in HTA enabled identification of factors limiting HTA capacity. A cross-sectional study by means of a semi-structured questionnaire of HTA organizations was carried out. Results of this study reinforced formulation of **consensus recommendations on general strategy for continuous development as well as development of appropriate support systems for HTA capacity building**, overcoming common problems, improving structures and processes.

The results presented do not constitute a case-study of HTA condition in responding countries and revealed strategies are not institution-tailored. To facilitate sustainable development in national settings, the HTA organization should map its processes among opportunities, threats, strengths and weaknesses mentioned to derive solutions based on other entity's experiences. The barriers against HTA organization establishment as well as against performing ordinary HTA activities most frequently indicated by already experienced entities were: gathering trained staff, funding and reaching political interest. The results were consistent when analyzing the severity of abovementioned barriers. The barriers most frequently indicated by entities not yet performing HTA activities were: gathering trained staff, funding and reaching political interest. When analyzing the severity of barriers the results changed slightly, giving the greatest importance to funding, gathering trained staff and agreement with stakeholders. Recommendations how to overcome barriers against performing HTA as well as establishment of HTA organizational structures developed by WP8 are presented below.

Recommendations in brief

BARRIER: AGREEMENT WITH STAKEHOLDERS

- Identify relevant supporters and opponents regarding organization's place in health care system.
- Seek increased assistance of politicians, decision makers and scientists, establish an ongoing relationship between partners.
- Adjust communication strategy to particular target group.
- Endeavour to regulate the uneven data access by legislative initiatives.
- Establish formal processes to disclose conflict of interests.

BARRIER: REACHING POLITICAL INTEREST

- Strengthen trust between scientists and politicians and improve the use of scientific evidence in decision-making through continuous dialogue.
- Define clear position of HTA with regard to the specificity of health care system.
- Counteract improper or insufficient use of HTA, which may result in loss of political interest.
- Disseminate HTA products in order to prove their usefulness. Use transparency to make agreement with policy-makers easier to reach. Use different approaches that raise awareness of politicians as beneficiaries of the HTA processes and products.

BARRIER: FUNDING

- Involve HTA in decision making process to ensure stable funding.
- Prepare organization-specific business plan, that ensures the commitment of relevant parties, helps to minimize risk of a failure and facilitate acquirement of funding sources.
- Seek additional sources of funding.
- Use external financial advisors to manage organization's budget.
- Try to precisely determine resources consumed for organization's products. Consider implementation of performance budget or re-negotiations of work-load, regarding organization's stage of development. Avoid competition for funding among institutions by clearly divided responsibilities and seeking cooperation to share work-load.

BARRIER: SHORTAGE OF TRAINED STAFF

- Use various motivating factors to attract people to the organization and protect them from quitting i.e. encouraging salaries, friendly atmosphere at work, stability and prestige, intellectual challenges.
- Create an appropriate sense of mission.
- Invest in people, i.e. ensure appropriate external and internal trainings.
- Allow flexible hours or part time job.
- Employ people with experience in other areas and allow them to work part-time.
- Develop a new mindsets in the society encouraging building capacity.
- Exchange staff with other institutions, involve external experts, use achievements of others.

2 INTRODUCTION

Health technology assessment (HTA) is a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. It is aimed to inform health policy and decision making processes concerning health technologies precisely on these issues [1].

Over the last 30 years, many European countries – and particularly those in the European Union (EU) – have established or are currently developing HTA systems. Many of them, including France, Sweden and the United Kingdom, are also investing considerable resources to support the establishment and improvement of HTA and other evaluative activities. Nonetheless, health services research and HTA represent less than 0.05% of total national health care spending. Countries with social insurance health systems or national health services demonstrate the highest annual budgets for such activities [2].

Many projects have been carried out since the need to create a sustainable network for HTA process within European Union for both, those in the public sector and those working in other settings was identified. The EUR-ASSESS project (1994-1997) disclosed that an efficient system for sharing information and exchanging experiences among those involved in HTA across Europe was needed, the HTA-Europe project (1997-1999) further explored this issue and put emphasis on the need of the European Commission's assistance for the establishment of HTA coordinating structures, and the ECHTA/ECAHI (European Collaboration for Health Technology Assessment/ European Collaboration for Health Interventions) project (1999-2001) concluded that HTA has become “a political priority and there is an urgent need for establishing a sustainable European network on HTA” [3].

EUnetHTA was established to respond to the need for a sustainable European network for HTA that could develop and implement practical tools to provide reliable, timely, transparent and transferable information to contribute to HTAs in EU Members States. The European Commission and Member States co-funded the three year project (2006–2008) with the aim to develop a sustainable network and resources to inform health policy making. The project connected national HTA agencies, research institutions and health ministries, as well as enabled an effective exchange of information and support to policy decisions. The results of the project showed that there are common aspects and **barriers experienced by the HTA organizations** regardless of their geographical setting or years of experience in conducting HTA activities. The work to identify the possible indicators used to assess the development of HTA organizations or programs started in 2009 as one of the two main objectives of the Capacity Building Function of the EUnetHTA Collaboration 2009 [4].

EUnetHTA Joint Action and Work Package 8 (2010-2012)

The Joint Action takes into account and incorporates the achievements of the EUnetHTA Project (2006-2008) and EUnetHTA Collaboration. Its overarching objective is to put into practice an effective and sustainable HTA collaboration in Europe. Within EUnetHTA JA 2010-2012, the objective of the Work Package 8 (WP8) is to **develop a general strategy** as well as construct a **business model for sustainable collaboration on HTA**. Other tasks include: stakeholder policy development, facilitation of support by external parties for the sustainability of the European collaboration for HTA, establishing contacts with the European

institutions, governance and organizational structure development and development of working relationships with academic and research institutions.

A detailed business model for the HTA collaboration within EU will include the description of:

- already available and shared HTA know-how, procedures, tools, etc.,
- proposed common/shared HTA processes, practices, methodology,
- development and necessary supporting tools,
- facilitation in HTA training and capacity building activities connected to the process and tools employed in the collaboration,
- **facilitation of national strategies for continuous development and sustainability of HTA,**
- operational and management process,
- operational definition of stakeholders and process of their involvement,
- long term funding mechanism [5].

3 OBJECTIVE

The objective of the activity coordinated by the Agency for Health Technology Assessment in Poland (AHTAPol) (whose results are to be presented in this consensus document) was to **provide the set of recommendations on facilitation of short and long-term national strategies for HTA sustainability and development**, with emphasis put on **national strategic plans for the establishment and improvement of existing HTA organizational structures and processes**. It required active participation of the EUnetHTA JA partners involved in WP8 as well as commitment of identified third parties. This report may be used, in whole or in part, by organizations, units and individuals involved in HTA activities or planning to do so in the future, as well as commissioners and policymakers or any other potential beneficiaries of HTA while adjusted to particular health care and political system.

4 METHODS

The development of WP8 recommendations was a multistep process, consisting in:

- design of study exploring the current experience, stage of development, needs, scopes and limitations of HTA institutions, organizations or units all over the Europe;
- study execution within identified target group of organizations;
- data analysis with emphasis put on common barriers identified and proposed problem solutions;
- expert panel assembly with structured discussion on national strategies for HTA sustainability;
- formulation of recommendations in a consensus conference.

4.1 STUDY DESIGN

The methods used to reach the objectives were based on the literature review and work done in previous projects (EUnetHTA 2006-2008 WP8, EUnetHTA Collaboration), as well as EUnetHTA JA WP8 partners consultation.

A cross-sectional study by means of a semi-structured questionnaire of HTA organizations was carried out. The selection of questions to be included, questionnaire dissemination strategy and target group of HTA organizations were discussed during e-meetings and the workshop with HTA experts associated with WP8.

In order to ensure the study feasibility, a pilot questionnaire was reviewed in May 2010. Subsequently, in the period from 31th May till 4th October the final version of the questionnaire was administered via e-mails. Reminders were carried out between 1st July and 31th August 2010. Additionally, organizations with uncertainties concerning the e-mail address were phoned.

It was assumed that the survey should be completed by one person from each identified organization. The designated person should have filled the survey on behalf of the entire organization, although consultation was allowed. Participants were informed that individual responses would not be disclosed to any other organizations or third parties without their consent.

The questionnaire included three sets of questions: first for organizations that already perform HTA activities, the second for those who plan to start their HTA activities and the third for all the respondents. The survey included a total number of 68 questions (27 multiple-choice, 29 single-choice and 10 open-ended questions).

4.2 PARTICIPANTS

The list of HTA-related organizations that constituted the target group for questionnaire dissemination was compiled by merging the information from various sources: e.g. directory of EUnetHTA, INAHTA members, websites of existing HTA units directories, agencies or

programs and information from EUnetHTA partners. The Internet was searched for the organizations' homepages and further contact data. Any identified organization regardless its location, financial profile or HTA involvement status mentioned within one of these sources was included. The questionnaire was administered to 102 target organizations from 21 countries. Responses had been expected before the 5th October 2010.

4.3 MEASUREMENTS

All the questions were incorporated in seven sections, varying according to information to be obtained:

General Information: 12 questions concerning the profile, experience and background of the respondent's organization as well as the contact details;

HTA products: 7 questions (6 single-choice questions and 1 multiple-response question) concerning HTA products defined as assessment reports or their short versions, primary research projects conducted to start up the assessment process, when the evidence is insufficient or there are no data, consultation to different health structures in the public and private sector, academic and training activities geared towards transmitting knowledge and skills in the methodology and practice of health technology and health services assessment or clinical practice guidelines were included in this section;

Finances: 9 "yes or no" questions and 2 multiple choice questions about funding sources of the organization's current and/or future HTA activities and methods of financial management used to support sustainable realization of projects in field of HTA;

Legal aspects: 8 multiple-choice questions and one multiple response question about regulatory framework and legislative environment of HTA organization;

Management: 11 questions about management environment of the HTA organization, ongoing activities in the area of HTA and stakeholders' policy in respondent's country;

Human resources 10 questions about people employed in respondent's HTA organization;

Technical resources: 3 questions about technical resources in respondent's organization.

In the **summary part** of the questionnaire 5 questions enabled responder to rate in 0-5 Likert scale the common barriers against the process of HTA organization establishment and performing HTA activities as well as reveal problem solving strategies.

4.4 DATA ANALYSIS

Standard descriptive analysis was conducted to characterize the respondents' organizations and response rate. The content of open-ended questions was analyzed for each question separately. For other kinds of questions, distribution of responses as numerical and percentage rates was calculated.

The institutions were divided into two groups according to their commitment to HTA activities: those being already involved in formalized HTA activities ("HTA Doers") and those planning to perform HTA activities ("HTA Non-Doers"). Results for each group were analyzed separately.

Based on the Summary section of questionnaire, barriers against the process of HTA organization establishment and performing HTA activities were identified and rated.

The respondents were divided into three subgroups according to estimated strength of each barrier, which was graded in a 6 point scale (where 0 corresponded to “no barrier”, 1-2 to “moderate barrier” and 3-4-5 to “strong barrier”). Relationship between these barriers and corresponding questions has been investigated.

It was planned to choose three barriers occurring most commonly and three strongest barriers for further detailed analysis. Due to the fact that some barriers repeated in both groups the total number of different barriers for detailed analysis was four (gathering trained staff, funding, reaching political interest, agreement with stakeholders).

4.5 EXPERT PANEL ASSEMBLY AND CONSENSUS MEETING

In February 2011 the Expert Panel, consisting of WP8 partners and invited external experts assembled for WP8 workshop. Using the results of survey (which identified and characterized main barriers against HTA organization establishment and performing HTA activities) as the framework, the structured discussion was facilitated. Two parallel groups performed critical analysis and interpretation of the data focused around the four essential barriers. Subtopics for each of these four broad categories, as well as proposals for facilitation of national strategies for HTA sustainability were developed and incorporated in draft consensus document. During the meeting in June 2011, the WP8 partners conducted a thorough review of the report combined with discussion and reached consensus on the final recommendations.

5 RESULTS AND RECOMMENDATIONS

5.1 SURVEY RESPONSE RATE AND SAMPLE CHARACTERISTICS

In order to maintain broad spectrum of the survey, large number (102) of diverse organizations was identified as a target group. Out of 102 distributed questionnaires, a total of 35 responses were received (**34,3%**). Such moderate response rate might have resulted from the participant identification strategy employed, that required no verification of HTA involvement status and allowed inclusion of any organization **supposed to be involved or perceived as interested in HTA activities** at the time of study execution.

Among 102 primarily identified organizations 34 were involved in EUnetHTA project. 24 responses from this subgroup were received, thus representing **70,6% response rate for EUnetHTA partners**. From 35 answered questionnaires, 30 were obtained from organizations that already have formalized HTA and perform HTA activities, while 5 came from organizations planning to get involved into HTA. Responders originated from 20 European countries, with the distribution of study participants within each country as follows: Austria (3), Czech Republic (1), Croatia (1), Denmark (2), Estonia (1), Finland (1), France (1), Greece (1), Hungary (1), Italy (10), Lithuania (1), Malta (1), Netherlands (1), Poland (1), Romania (1), Slovakia (1), Slovenia (1), Spain (4), Sweden (1), United Kingdom (1).

Figure 1. Map of countries represented by study participants.



Tab.1. Characteristics of the survey respondents.

Organization's characteristics	HTA Doers		HTA Non-Doers	
	N	%	N	%
Organization perform HTA activities for				
>4 years	21	70	N/A	N/A
0-4 years	9	30	NA	N/A
Performing HTA as the main reason for organizations' establishment				
Yes	9	31	N/A	N/A
No	20	69	N/A	N/A
Profile of the organization				
Governmental agency	18	60	2	40
Academia/ University	4	13,3	1	20
Compulsory health care insurance (public)	1	3,3	0	0
Private medical insurance	0	0	0	0
Ministry of Health	4	13,3	1	20
Health care providers/ Hospitals	4	13,3	0	0
Other private company	1	3,3	0	0
Other*	5	16,7	2	40
Level on which organization works**				
International	16	53,3	3	60
National	24	80	4	80
Regional	13	43,3	0	0
Local	10	33,3	0	0

* "An academic department with a Government contract to deliver HTA", "Regional Board of Health", "NGO"; "Regional Specialized Centre"; "not for profit, independent scientific body with a broad scope of missions: HTA, clinical guidelines, public health guidance, hospital accreditation"; "NGO with academia, government and insurance as board members"; "Public, at national level"; ** multiple response question; N/A - not applicable

All the respondents that took part in the survey represented **not-for-profit** sector.

Need for performing HTA activities was the main reason for establishment of 31% existing HTA institutions. For the majority of respondents from this group (69%) reasons for establishment of the organization were not related to HTA activities. 70% of organizations had been already performing HTA for at least 4 years at the time of completing the survey. The WP8 study revealed that the organizations, either already involved in HTA activities or planning to perform HTA activities were mainly governmental agencies (60% and 40% respectively), academic departments (13,3% and 20% respectively) and units in Ministry of Health (13,3% and 20% respectively).

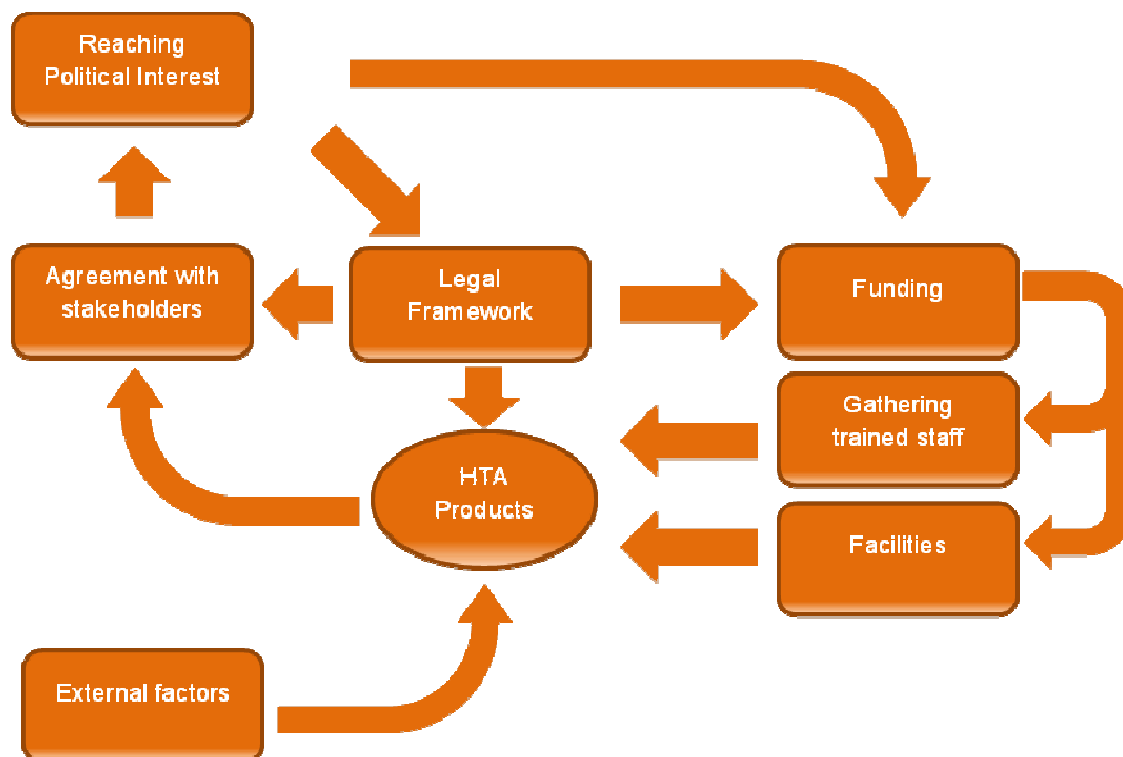
5.2 BARRIERS

The following barriers against establishment of HTA-dedicated organization and performing HTA activities were identified: reaching political interest, agreement with stakeholders,

impact on target group, legal framework, funding sources, gathering trained staff and facilities. The universal pattern existing between various obstacles has been observed (simplified Figure below). Moreover, it occurred that the significance assigned to certain barriers changes over time.

The identified limiting factors were interrelated, as they are part of a larger, intertwined system. Shortage of political interest may result from the lack of regulations that enforce HTA involvement. Legal framework ensure or clearly determine possible funding sources. Funding constitute a critical factor influencing capacity, regarding for instance available human resources. HTA products have or should have an impact on target groups (i.e. decision-makers) and relevant stakeholders. However other external, country-specific factors also may have an impact. Whereas multiple processes underlie certain barriers due to system complexity, investigating and addressing main causes at process levels does not result in sustainable solutions. As an alternative the techniques of Theory of Constraints demand greatest focus at **relationship** between several main causes of all the failures of processes in the system [6]. Therefore relations between indicated barriers were analyzed and discussed broadly in this document. Organizations perceive various aspects as a barrier of certain degree of importance and suggest different strategies for improvement (depending on the type of HTA institution and level on which the organization perform its activities). While seeking solutions it is advised to look globally, however explore one constraint – core problem that leads to most undesirable effects and prevents an organization from reaching its goal. The analysis of organization's current situation, which provides information about aspects to be changed and related relationships, followed by analysis of possible change directions should be incorporated into a strategy that through other processes (affecting the causes of main problem) in a system produce more **sustainable results**.

Figure 2. Universal relations between barriers concerning HTA process.



5.2.1 ORGANIZATIONS PERFORMING HTA ACTIVITIES

Respondents provided data on main barriers against the establishment of organization as well as against performing ordinary HTA activities.

The barriers against HTA organization establishment indicated most frequently by already experienced entities were: gathering trained staff (55%), funding (48%) and reaching political interest (48%) (Figure 3.). Other barriers identified were: impact on target groups (23%), legal framework (23%), agreement with stakeholders (16%) and facilities (6%). The results were consistent when analyzing the importance of abovementioned barriers (Figure 4.): the greatest percentage of organizations indicated gathering trained staff, reaching political interest and funding as the utmost problem.

Figure 3. Barriers during establishment of organization (experience of organizations currently performing HTA activities).

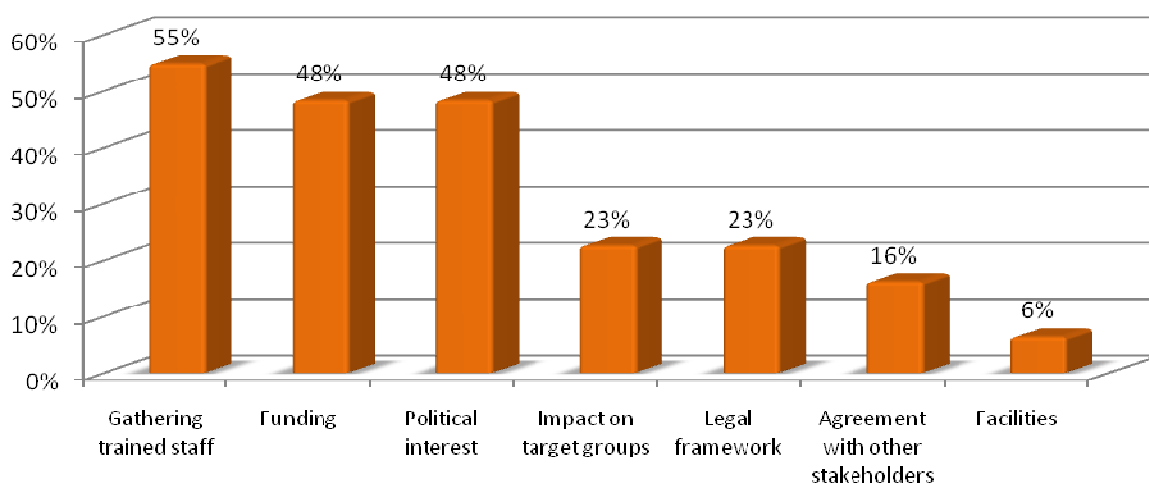
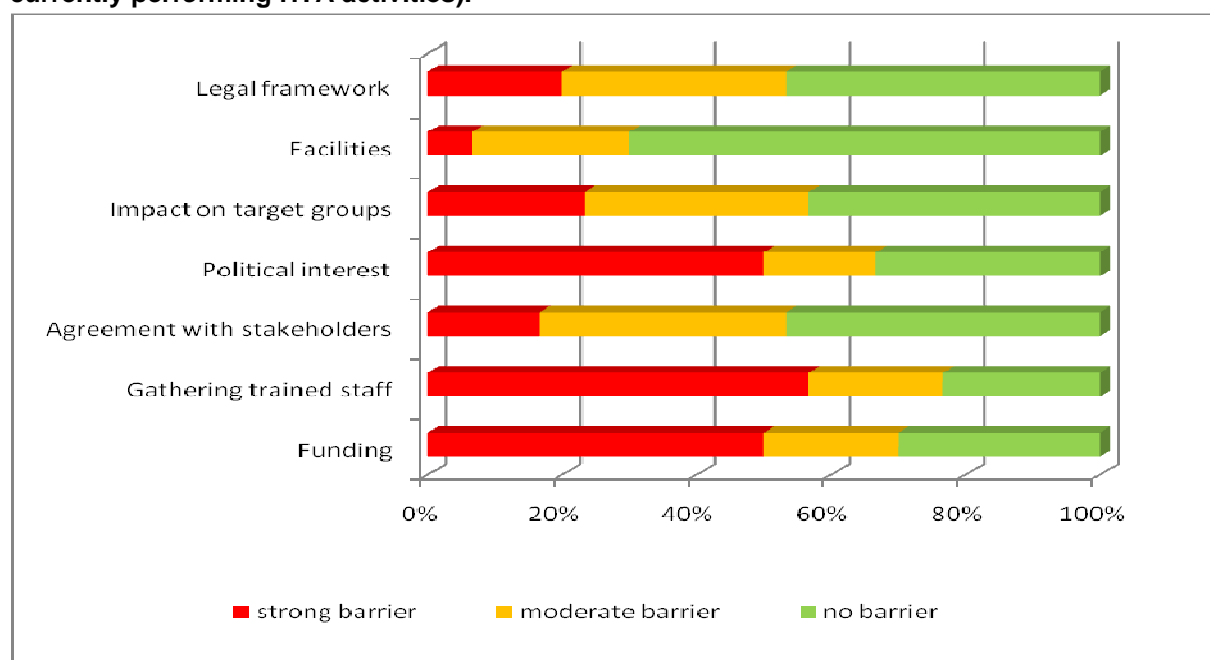


Figure 4. Barrier importance during establishment of organization (experience of organizations currently performing HTA activities).



The same barriers were identified against performing ordinary HTA activities by organization: the greatest incidence was observed in case of gathering trained staff (52%), funding (42%) and reaching political interest (42%) (Figure 5.). The results were consistent when analyzing the importance of abovementioned barriers (Figure 6.): the greatest percentage of organizations indicated funding, gathering trained staff and reaching political interest.

Figure 5. Barriers affecting ordinary HTA activities (experience of organizations currently involved in HTA).

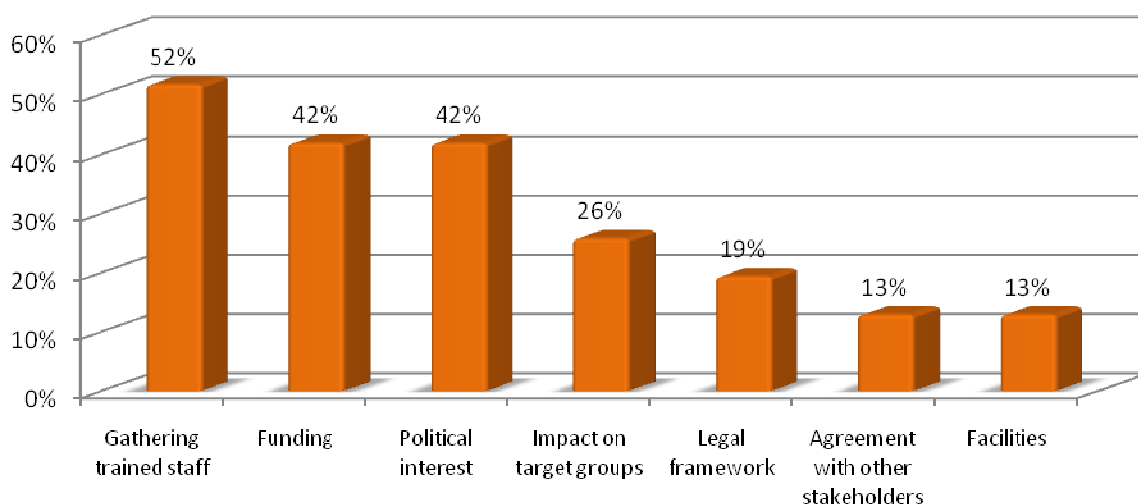
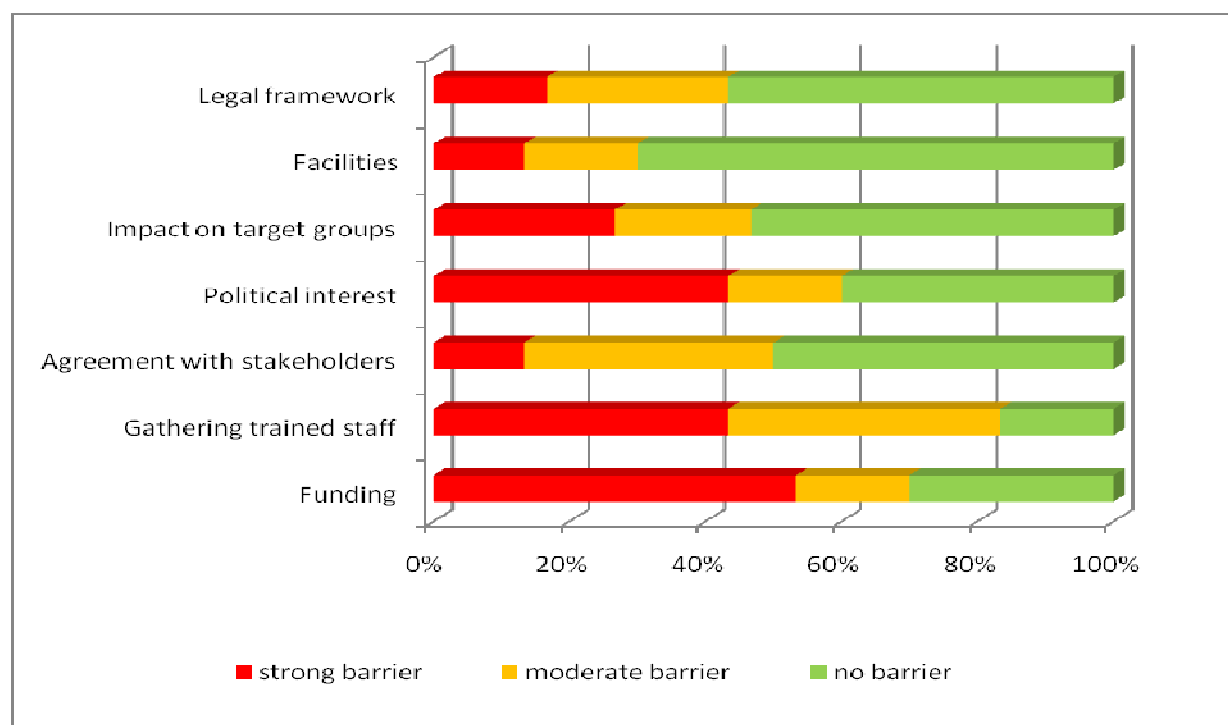


Figure 6. Barrier importance during performing HTA activities (experience of organizations currently performing HTA activities).



5.2.2 ORGANIZATIONS NOT PERFORMING HTA ACTIVITIES

Respondents provided data on main barriers against the establishment of organization. The barriers indicated by entities not yet performing HTA activities were: gathering trained staff (80%), funding (80%), political interest (80%), agreement with stakeholders (40%), legal framework (40%), impact on target groups (40%) and facilities (20%) (Figure 7.). When analyzing the importance of abovementioned barriers the results changed slightly, giving the greatest importance to funding, gathering trained staff and agreement with stakeholders (Figure 8.).

Figure 7. Barriers against establishment of organization (experience of organizations not yet performing HTA activities).

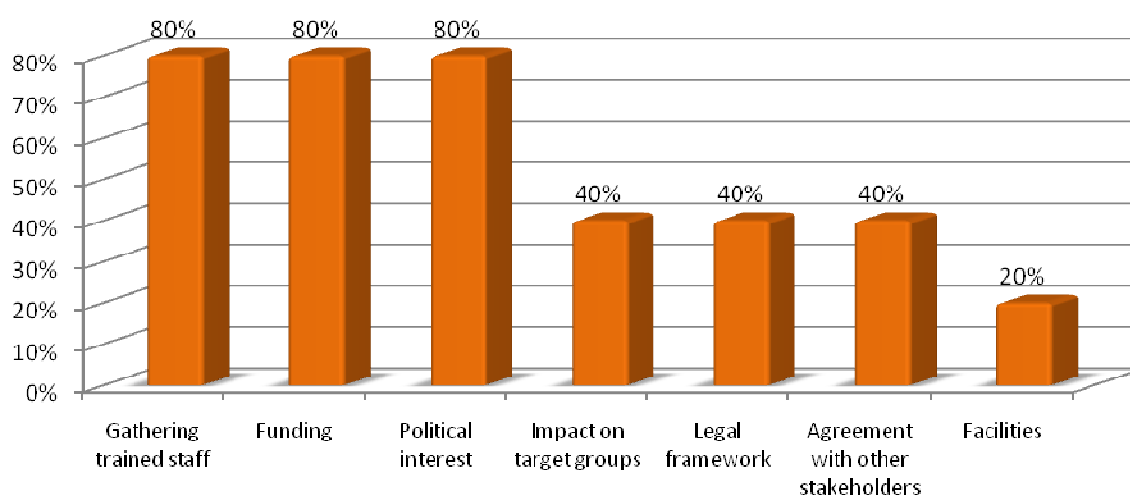
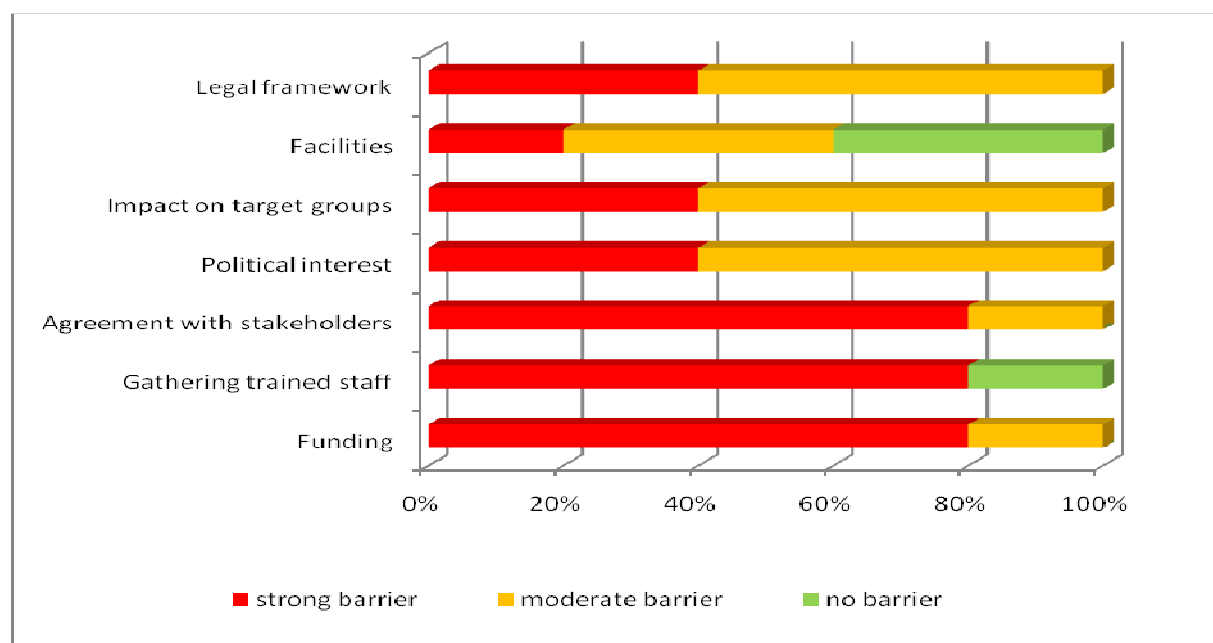


Figure 8. Barrier importance during establishment of HTA organization (experience of organizations not yet performing HTA activities).



5.3 RECOMMENDATIONS

5.3.1 BARRIER: AGREEMENT WITH STAKEHOLDERS

Agreement with stakeholders as those organizations or individuals who have an interest in, or are affected by HTA organization activities, products, services and associated performance is surely one of concerns. Increased stakeholder involvement throughout the HTA process can help capture and improve the real-world value and applicability of HTAs. Nevertheless, stakeholder involvement needs to be transparent and well-managed in order to ensure that the objectivity of assessments is not influenced [7]. Among organizations and units that are going to undertake HTA activities it was one of 3 core constraints, while established and experienced in HTA organizations do not consider agreement with stakeholders as a substantial barrier, but ascertain it has some impact on HTA products.

Agreement with stakeholders may denote the fact of agreeing, the harmony of opinion as well as an arrangement between parties regarding a course of action. The definition of agreement depends on the organization's profile and health system structure (including legal framework), especially in terms of relations between various institutions.

Relevant stakeholders identification

Stakeholder groups may include national, regional and local governments, non-governmental organizations, payers (i.e. insurance), industry, providers, clinical professionals, patients and communities. Identifying stakeholders, understanding who they are and why they interact, in what degree they are involved in decision making processes and what are their terms of reference require some elaboration on the nature and roles of each of these groups.

Identify relevant supporters and opponents regarding organization's place in health care system

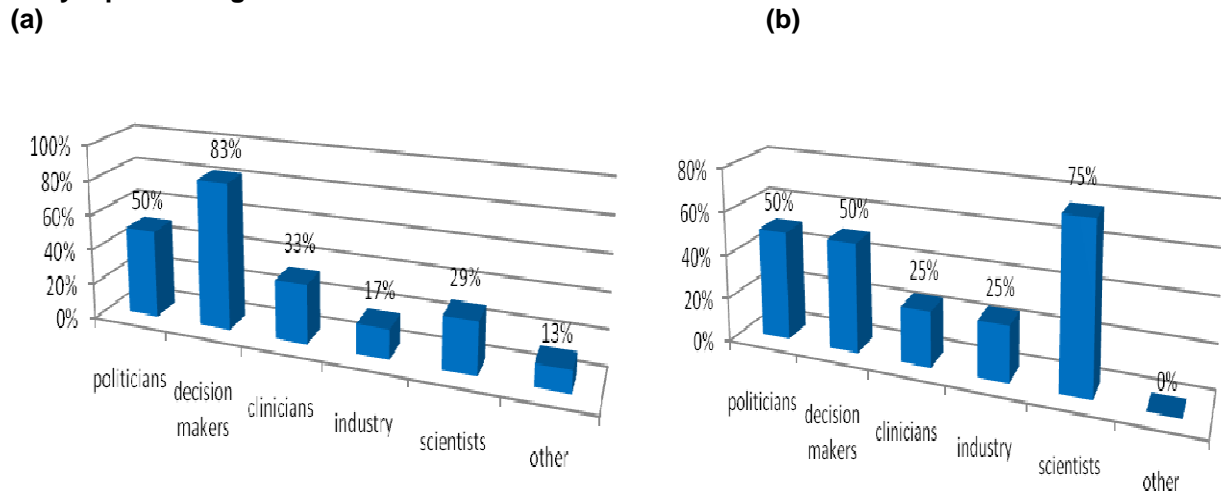
At the stage of establishing HTA organization and starting HTA activities it is especially important to identify stakeholders inclined to support the organization, including those who may benefit from HTA, as well as potential opponents. The agreement with expected supporters should be reached while establishing the organization, concerning i.e. the manner of setting up. Incomplete recognition of HTA organization's place in the health system may lead to inadequate stakeholders identification what further affect the inter-organizational relations.

In the past, politicians and decision makers represented the main supporters of HTA process establishment (as reported by 50% and 83% of responding organizations, respectively). It seems the conditions in countries with non-structuralized and non-formalized HTA nowadays are slightly different, with main support coming from scientific society, rather than decision makers: during early stage of HTA organization development scientists constitute the

Seek increased assistance of politicians, decision makers and scientists.

main driving-force for HTA process establishment, as mentioned by 75% of responding organizations. Support from pharmaceutical industry and clinicians seems invariable among past and present. In case of clinicians its meagre extent clearly shows the need for improvement. Thus it may be concluded, that increased assistance of politicians, decision makers and scientists is a key success factor during establishment of HTA processes.

Figure 9. Main supporters of HTA process establishment within organizations (a) already (b) not yet performing HTA activities

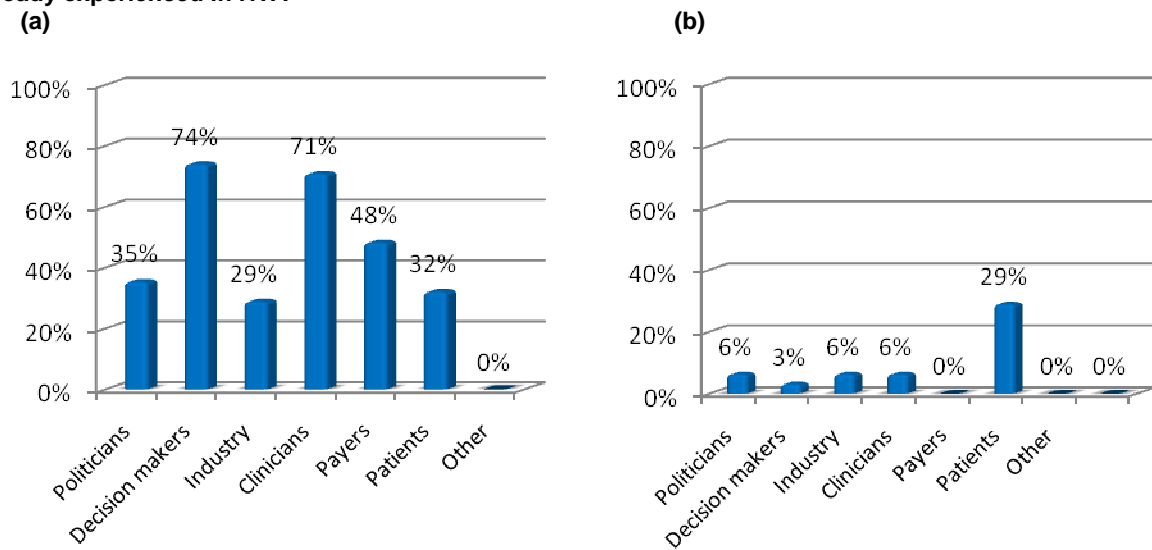


Extent of agreement and stakeholder involvement

The EUnetHTA Joint Action stakeholder involvement policy distinguishes between the involvement of stakeholders and the involvement of experts, depending on a context [8]. As indicated by WP8 study results, certain groups of stakeholders still do not contribute directly to HTA programs. For instance HTA organizations report difficulties in committing patient and citizens representatives. Obstacles to their participation may result from regulatory issues (i.e. composition of some Committees), shortage of resources, inefficient communication as well as from limited availability and willingness to participate. Overcoming these barriers requires structured and formalized policy for patients and public involvement in HTA. It can be achieved by means of providing comments during assessment, standard short-form questionnaires for stakeholders, possibility of active participation in board of health or citizens council sessions – for people chosen randomly from general population.

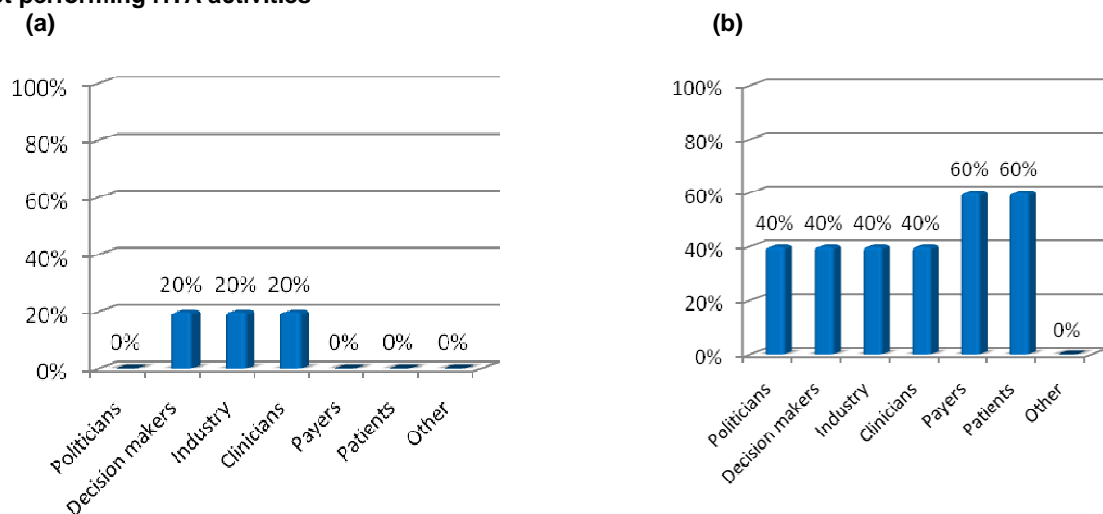
As revealed by WP8 study (Figure 10.), decision-makers and clinicians are perceived as key stakeholders and involved in processes in majority of entities already performing HTA activities (74% and 71%, respectively), while politicians, industry and patients participate to a lesser extent. Only patients are planned to be more involved in the process in the future, as mentioned by every third HTA organization. It may suggest that with time sustainable involvement is being achieved through well- established relations.

Figure 10. Stakeholders (a) involved or (b) planned to be involved in HTA processes within organizations already experienced in HTA



Within organizations not yet performing HTA activities, low level of stakeholders' involvement is being observed, although with an upward trend manifesting through increased percentage of entities planning to involve payers, patients, clinicians, politicians and decision makers.

Figure 11. Stakeholders (a) involved or (b) planned to be involved in HTA processes within countries not yet performing HTA activities



It must be emphasized that it is not necessary to reach the consensus with all the stakeholders, especially while establishing HTA system.

Further HTA organization functioning does not require full agreement on all its aspects as well - sometimes dialogue between partners or opponents is sufficient and adds value.

It is not necessary to reach consensus, dialogue also adds value.

During the assessment, depending on relevance of stakeholders and scope of task assigned, not all of them have to be engaged in HTA processes to an equal extent. Some of them play the consultative role, while others do not contribute to HTA. The general rule is to involve the representatives who increase the value of the report. As HTA processes are located in various places within each health system, in some countries stakeholders may be also involved in associated processes i.e. preparing evidence-based guidelines.

However, even if involvement of all relevant stakeholders is substantial for both political and scientific reasons and enhance the value of organization's research considerably, it must be balanced with task-specified timeframes and predefined scopes: giving the advantage of providing fair opportunities for input from stakeholders - thus increasing transparency, credibility and acceptance of reports and the results obtained versus longer process duration and threats to scientific independence from undue influence of external parties.

Communication strategy

Informed stakeholders foster and facilitate the collaboration and sharing HTA knowledge. To achieve agreement with them, a good communication strategy must be developed. That requires precise designation of HTA organization's short/long-term goals with respect to certain stakeholder groups, as well as circumscription of research elements appointed to be spread and the needs of potential partners.

Each of the target audiences (groups or individuals at the local, national or international level with whom HTA organization is seeking to develop a synergy and to share information) requires specific communication strategy due to its characteristics [9]. As for the direct beneficiaries and research partners, a good strategy encourages participation, secures the commitment to the project aims, ensures that the research results are perpetuated and reliable, while their impact in the field is extended. For political decision-makers, a strategy is needed to ensure that participatory development is better understood and adapted to needs of society, to influence policies or policymakers around key aspects, while for the community and funding agencies, a strategy must be aimed at gaining visibility, sharing the knowledge of HTA utility. Efficient channels of communication, dialogue and engagement with stakeholders may include public awareness actions (symposia, workshops, presentations, discussions within small working groups), as well as well-suited HTA product dissemination strategies. In general, more flexible modes of knowledge spreading are needed and adjustments need to be made, based on the receiver's feedback.

Communication strategy should be adjusted to each target group.

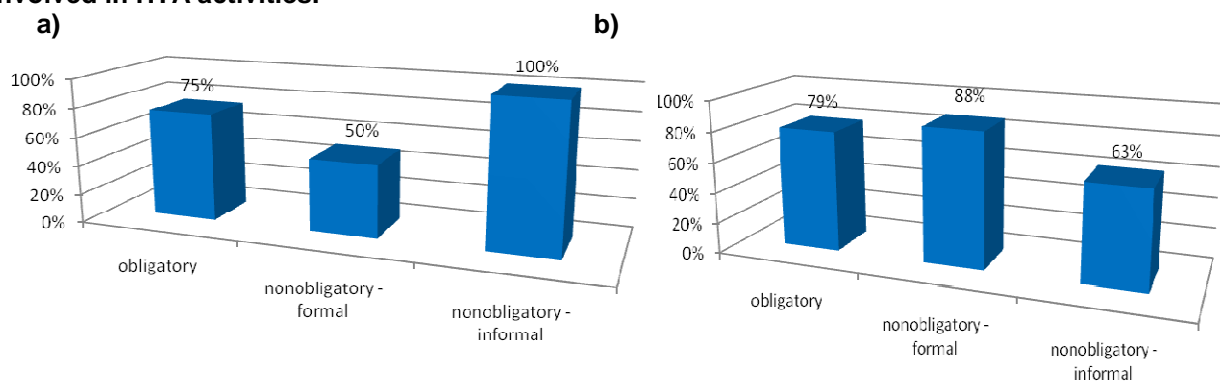
In general, decisions about health technologies are more likely to be accepted by a broad range of stakeholders, such as health professionals, industry and patient representatives, if the decision making process is regarded as transparent and based on evidence, and if it includes an appeals mechanism. Stakeholder acceptance of decisions seems to be a key determinant of whether decisions are actually put into practice within health systems [10].

Organization also has to assure that the different stakeholders and decision makers have trust in that organization and its products. As for establishing good relations with them, involvement of well perceived individuals or organizations can help build good perception of HTA organization.

Exchange of relevant information should be always incorporated into communication strategy. The results of WP8 study indicated that variety of institutions in health care sector collect clinical, epidemiological and economic data which are or could be used in HTA process, including: Ministries of Health or regional Health Boards, academic centers, national research institutes, hospitals, registration offices, payers, insurers. However in some cases uncertainties exist concerning what kind of data and by whom is collected due to confidentiality or lack of formal information and clearly designated roles of institutions, especially payers or insurers and academic centers. HTA organization should identify its data requirements, their limitations and availability from various sources, as well as fields for potential improvements (i.e. access to real world data) to enable further role-negotiations, research projects planning or legislative initiatives.

Among European countries access to the necessary data is warranted mainly through informal and non- obligatory relations or formal and non- obligatory, respectively in institutions planning and already involved in HTA activities (Figure 12.).

Figure 12. Relationship ensuring the access to data collected by other institutions in health care sector used in HTA processes in countries with (a) no formalized HTA, (b) already involved in HTA activities.



The growing incidence of formal relations may be considered as a positive phenomenon, as it results in increase of transparency and credibility of HTA products. However collaboration is relevant for sharing the data on health technologies, the special care is required for both incorporation and disclosure of data from industry.

Uneven data access may be regulated by legislative initiatives.

As the need for detailed regulatory framework referring to data access and exchange by health sector institutions has been identified, legislative initiatives in that field may constitute solution that secure robust and timely delivered information for HTA processes, independence of HTA organizations as well as trade secret and privacy protection.

Power issues and conflict of interests

Fragmented decision-making processes and overlapping competences allow disclosure of different interests. The key to prevention and resolution of conflicts is to anticipate them and develop appropriate management strategies.

Figure 13. Percentage of organizations already performing HTA activities that indicate the HTA processes are located in certain number of entities (including Agency, Ministry of Health, hospital, payer, academic centers, commercial companies, networks).

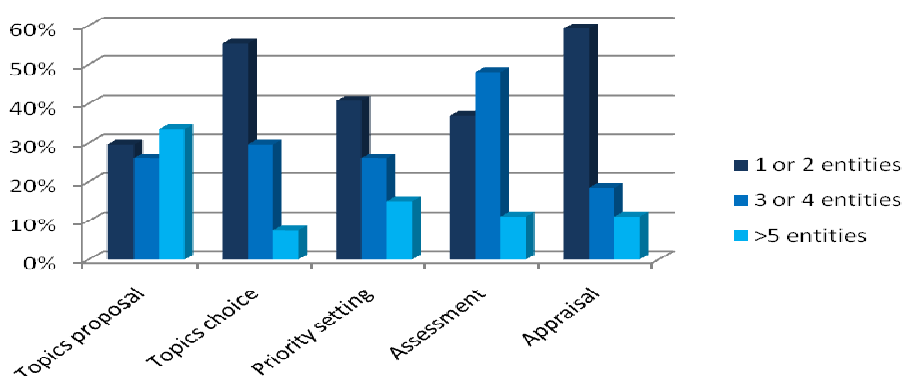
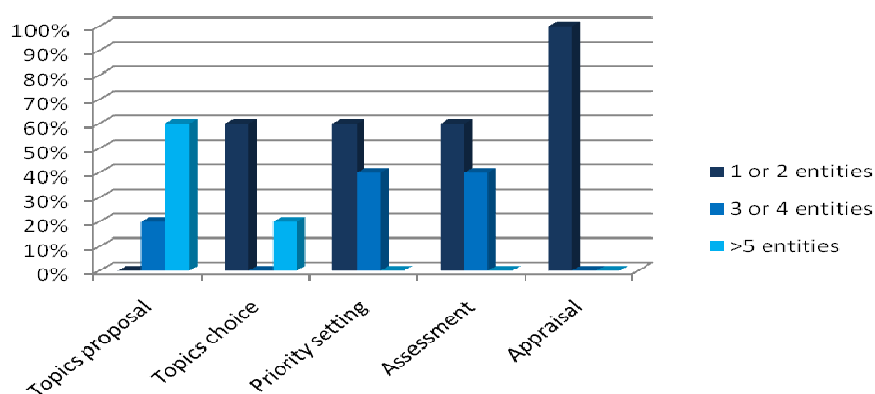


Figure 14. Percentage of organizations not yet performing HTA activities that indicate the HTA processes should be located in certain number of entities (including Agency, Ministry of Health, hospital, payer, academic centers, commercial companies, networks).



Groups involved in reimbursement and pricing decisions often differ from those affiliated with independent HTA assessment or clinical guidance development, and so do other entities involved in HTA processes. From the view of organizations not yet involved in ordinary HTA activities more entities should participate in topics proposal, while processes like priority setting, assessment or appraisal should be limited to single or few institutions (Figure 14.). The experience of those already performing HTA activities indicate, that diversity and decentralization of some processes (i.e. due to coexistence of national institution with

satellite institutions and many HTA projects) may not necessarily limit the development of national HTA. However, on decision-making level (topics choice, priority setting, appraisal) leading functions seems crucial.

If the country has a dedicated HTA body, but with somewhat unclear and miscellaneous role, divergent processes and responsibilities may hinder the efficacy of decision-making process and lead to unnecessary duplication of efforts and resource use. The interplay of responsibility and decision-making power extends also to the financing in health care system. Thus tensions between organizations due to non-precisely stated missions, overlapping tasks and benefits may occur. The strategies for improvement might include introduction of relevant regulations ensuring role clarity and well-prepared communication strategy, increasing transparency of the whole process, as well as addressing duplication, where it exists, including consideration of consolidating functions within the health care system.

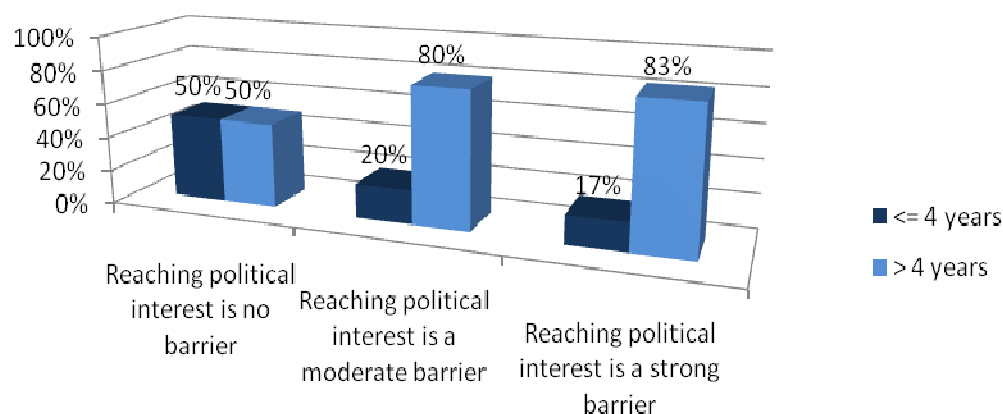
Regarding HTA process itself, many organizations introduced active measures to protect against potential conflicts of interest between industry (sponsors of the primary research, applicants for reimbursement etc), payers and government, health technology assessors themselves (analysts, panel members, experts involved in reviewing the evidence and making final recommendations), patients and society. It is important that HTA systems are as independent as possible, particularly as the findings from HTA reports are often controversial. Without sufficient independence, decisions might not be supported owing to perceptions that the process was driven by a particular agenda, most often associated with payers or industry [2]. WP8 study revealed, that in organizations experienced in HTA, formal processes are employed to disclose potential or existing conflicts of interest and their management, as well the thresholds for exclusion are set. It results in low percentage of organizations identifying threats endangering transparency of HTA processes, on the contrary to units still on stage of development. In that case the support of other institutions and disclosure of relevant personal, occupational, financial connections or interests may help preserving the objectivity and credibility of new HTA programs and processes.

**Establish formal
processes to disclose
conflict of interests.**

5.3.2 BARRIER: REACHING POLITICAL INTEREST

As Health Technology Assessment provides a broad spectrum of valuable information for decision-making in health care sector and primarily aims in supporting policy-makers in evidence-based decisions, its direct adaptation into policy and management might have been expected. There is a widespread agreement that the development of HTA requires that policy-makers become aware of, accept and ultimately support it. Although attempts have been made, not yet all countries managed to capture the attention and support of policy-makers, including politicians, and despite examples of successful applications coming from all over the world, reaching political interest was found to be important barrier among organizations already experienced in HTA and those planning to perform HTA activities, although it was observed that the importance of barrier differs between entities, depending on time since start of HTA activities (Figure 15.). Younger organizations, involved in HTA for less than 4 years seem to have fewer problems in that field, however no firm conclusions could be drawn with respect to reasons for that situation (i.e. political environment changing into more favourable, intensified pro-HTA lobby or some communication setbacks).

Figure 15. Problems with reaching political interest stratified according to time since start of organization's HTA activities.



Research society vs. policy-makers

Despite its policy goals, HTA must always be firmly rooted in research and the scientific methods. A main concern is that researchers and policy-makers comprise two very different communities with different values, ideologies, languages, backgrounds, institutional settings and reward systems etc. Evidence-based scientific information produced by researchers can be used by managers and health policy-makers to orient the decision-making process, as a result generating new research needs. Interactions observed between political and research

Strengthen trust between scientists and politicians and improve the use of scientific evidence in decision-making through continuous dialogue.

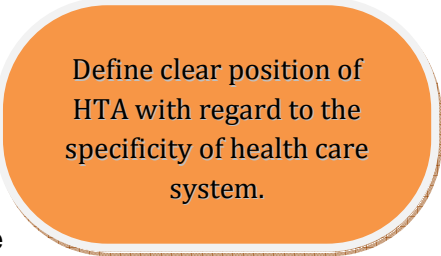
élites also manifest through crucial role of politicians among various factors affecting HTA capacity, concerning commissioning, funding and legal framework.

For reasons mentioned above HTA requires dialogue between policy-makers (having most involvement in setting inputs) and HTA producers (delivering the outputs). The utilization of HTA in policy-making depends very much on mutual understanding and responsiveness to user needs [4]. It's potential to function as a mediating mechanism between policy and research domains by providing a problem oriented systematic overview of research depends upon HTA producers having a thorough and detailed knowledge about policy-making and its conditions, and its users being aware (and having positive experiences) of the use of HTA.

Finding place for HTA in the system and defining its role in decision process

It should be noted, that in order to be most relevant, HTA activities must be undertaken within the policy context of a particular health care system taking account of national priorities and systems, including regionalization.

In order to reach and raise political interest (in case of planning to start HTA-related activities or being already involved in formalized HTA, respectively), a clear position of the HTA organization in health care system must be defined. HTA can potentially enter the policy process at different stages (e.g. agenda setting, policy formulation or evaluation), but always with the aim of informing the decision.



Define clear position of HTA with regard to the specificity of health care system.

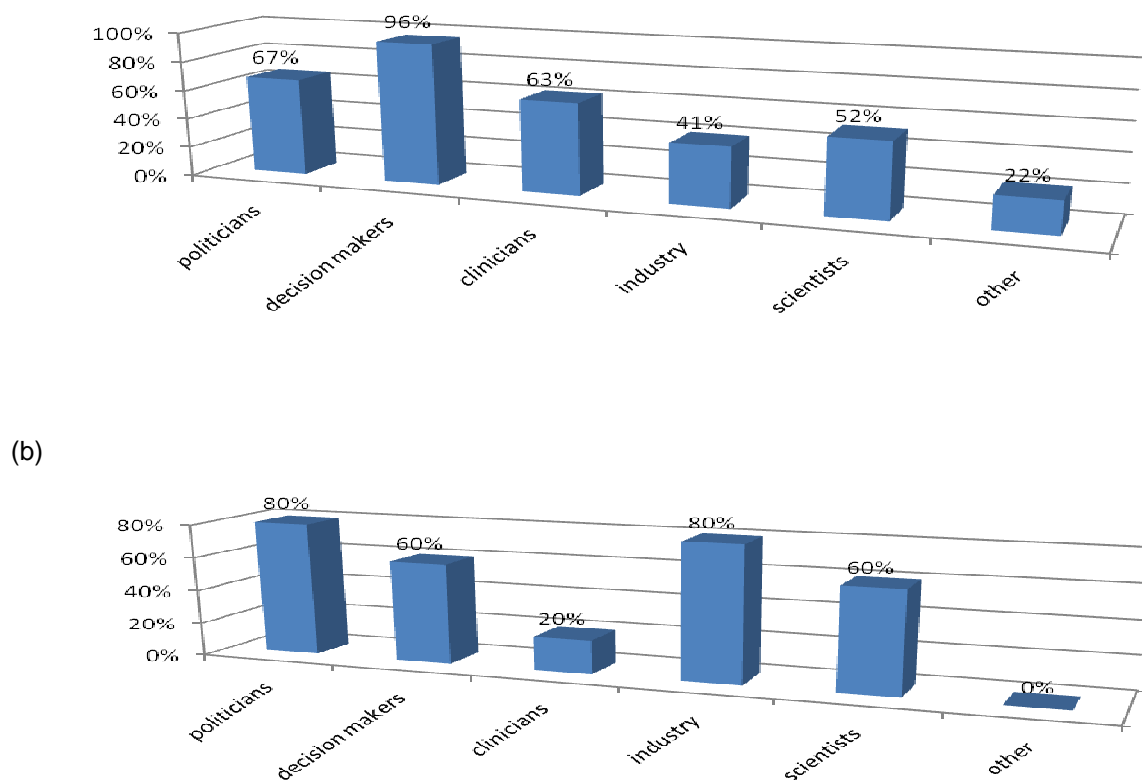
It is necessary to understand who are the key commissioners and decision-makers. Different bodies which participate in drawing up health policies and should be targeted by HTA are for instance:

- politicians: who are elected persons and those appointed by them (members of national, regional or local parliaments or assemblies; ministers; state secretaries; heads of departments),
- civil servants: technical experts in national, regional or local authorities,
- managers: in hospitals, primary health-care, sickness funds, private health insurance,
- members of corporations: persons operating in provider associations (e.g. medical or hospital associations); purchaser associations; self-governing institutions (e.g. joint committees of provider and purchasers, as in social health insurance systems),
- clinical and non-clinical staff involved in formulating both local and national clinical practice guidelines (CPGs),
- multidisciplinary decision-making committees on which several of the above are represented [4].

Different levels of commissioning constitute the rationale for broad spectrum of functions played by HTA organization. In many countries the governance and organization of any HTA entity depends on whether it is established primarily to serve the decision-making requirements of the government or a broader range of needs, despite the fact, that the whole HTA process is overseen by the Ministry of Health.

The variety of entities in health system guarantee that there are always needs unsatisfied by other institutions and competences in health care system. HTA organization may fill in these niches, so submission of specific projects focused on health needs /issues/ topics relevant to governmental bodies seems crucial. Various channels of communication should be identified and used (i.e. direct contact with politicians - official lobbying or using the opportunities resulting from other activities; contact through media, patient associations or other collaborating institutions; invitations to trainings and workshops).

Figure 16. Need for HTA in health care sector identified by certain stakeholders within countries (a) not yet involved in (b) already performing HTA activities.



In countries relatively experienced in HTA, the outstanding awareness of need for HTA within decision-makers can be observed.

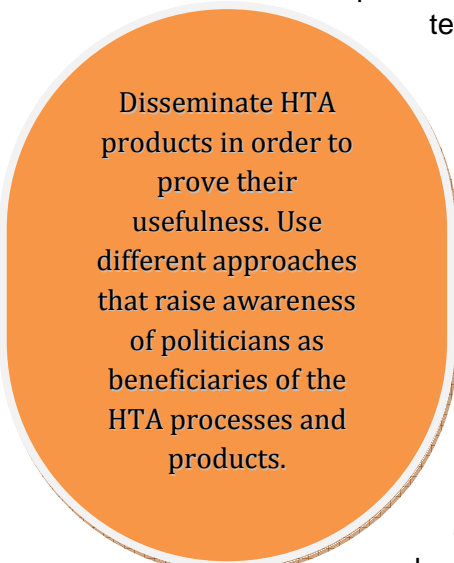
Continuously proved HTA usefulness and organization's expertise

Once the place for HTA in the health care system has been found or even the need for HTA identified and accepted by relevant decision-makers, the organization continuously has to prove its usefulness for the system and society.

Counteract improper or insufficient use of HTA, which may result in loss of political interest

The goal may be accomplished through several approaches that raise awareness of politicians as beneficiaries of the HTA processes and products.

- Since there is a desire to control public spending in health care, the fact that HTA can provide valuable information to assist politicians in prioritizing and allocating budgets to the most cost-effective activities should be underlined, also through the dissemination of HTA products. The information about HTA presented to policy-makers must emphasize reasonability of such approach and potential savings in the health care system. It should be also mentioned that by increasing the potential use of HTA, decision-makers will be able to implement decisions that capture the benefits of new technologies, overcome uncertainties and recognize the value of innovation, all within the constraints of overall health system resources [11]. Thus HTA can be used to justify the policy-makers' decisions to the society. Moreover HTA provides decision-makers with powerful management and evaluation tool that enables reassessment of decisions taken previously, after a technology has been used in practice.
- It should be highlighted that HTA can contribute to greater benefits related to international and intergovernmental cooperation in field of the European health policy agenda. Interest in collaboration among European HTA players has been already the impetus for a series of projects supported by the European Union [4]. In countries where EUnetHTA has been active, decision-makers and policy-makers have shown significantly more interest in the widespread use of HTA to inform policy over the last few years.
- Organization planning to start HTA activities should consider building capacity before establishing formalized national institution. Bottom-up strategy is time consuming, but in long run seems to be more effective, as it uses the value of strong competences and experience. Additionally the willingness to implement HTA built on lower levels is more stable and less prone to political changes.



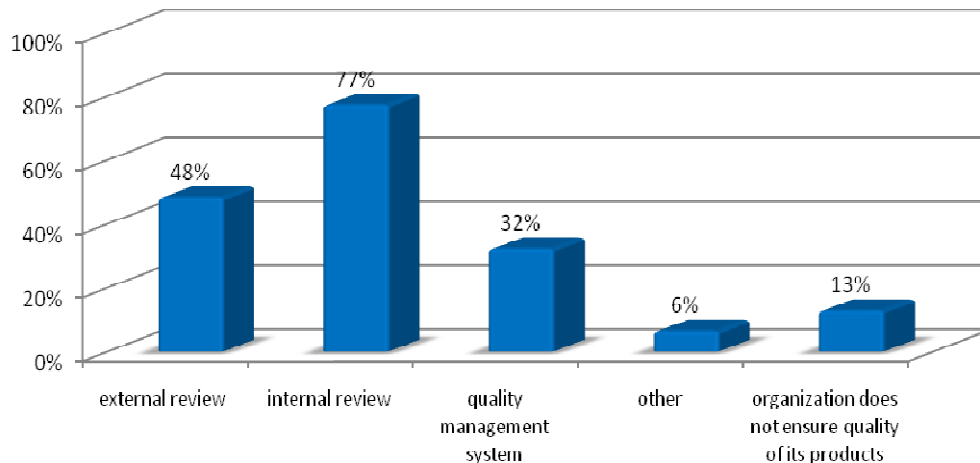
Disseminate HTA products in order to prove their usefulness. Use different approaches that raise awareness of politicians as beneficiaries of the HTA processes and products.

The **organization's expertise** usually directly translates into the quality of its products. Given the variety of impacts addressed and the range of methods that may be used in an assessments as well as general multidisciplinary character of HTA it should be stated that HTA must be based on clear and **standardized guidelines** that outline evidence and methodological requirements [2], for example the HTA Core Model, which offers a structured manner of creating and presenting HTA information, where some elements are prioritized over others to support European collaboration through defining them as "core elements".

Thus, initiatives increasing and revising the quality of products are welcome (i.e. reviews and quality management systems), as indicated by WP8 study results (Figure 17.). In less established HTA systems, due to similarity of principles and requirements, the international collaboration which facilitate knowledge transfer and development of methods could help overcoming the limited capacity and resources needed to implement comprehensive

assessments. Although the way HTA is conducted and impact recommendations and decisions on health technologies varies considerably among countries, international evaluation of HTA entity may increase its credibility, further used as an argumentation for funding negotiations.

Figure 17. Percentage of organizations ensuring the quality of their HTA products by certain means- experience of organizations performing HTA.



Need of transparency

Some HTA entities are still not recognized as important institutions, that deliver scientific, independent recommendation in a transparent process for evidence based decision making at national and regional level. Transparency can be defined as a principle that allows those affected by administrative decisions, business transactions or charitable work to know not

Use transparency to make agreement with policy-makers easier to reach.

only the basic facts and figures but also the mechanisms and processes [12]. It decreases the opportunity for the

authorities to abuse the system in their own interest.

Despite the quality of products, the impact of HTA depends to large extent on transparency of the assessment and decision-making process. If HTA's role in health-care decision-making is supposed to be valuable, it must be

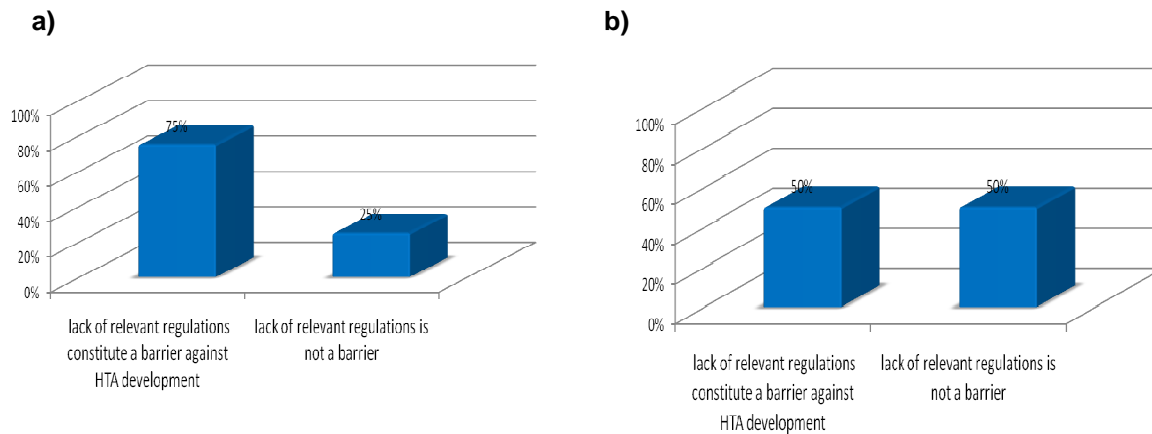
transparent, timely, relevant, in-depth and usable. However, politicians do not always consider clarity of processes as a favourable condition, so to increase the political interest on HTA, the expected system-specific level of transparency must be recognized and examples of benefits and added value resulting from HTA presented i.e. experiences with HTA gained from successful applications and disappointing encounters with uncontrollable political processes.

Political interest vs. legal framework

Problem with reaching political interest may be strictly related to the lack of legal framework concerning HTA, as it warrants political adherence. There is a common recognition that very little or none HTA regulations exist. Thus, it may seem important to put certain definition of

HTA in a law act, especially at the beginning of activity, although the views of experienced HTA organizations are inconsistent (Figure 18.).

Figure 18. Percentage of organizations (a) not performing HTA activities yet, (b) already experienced in HTA that perceive lack of relevant regulations as a barrier against HTA development.



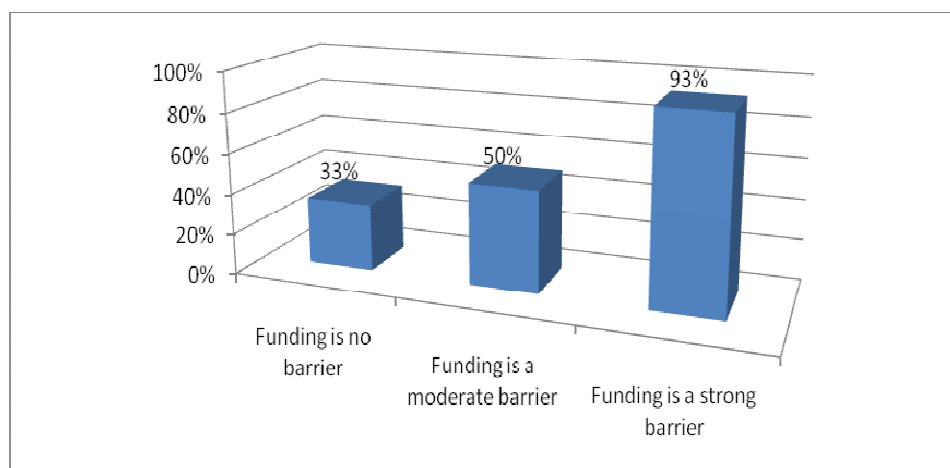
5.3.3 BARRIER: FUNDING

Funding was indicated as one of the most important barriers among both organizations that are already involved in HTA and those that are just planning to start their HTA activities. Essential problem with funding is caused by inadequate financing in relation to output that organization is planning/obliged to provide. Other state of affairs relates specifically to start-up of HTA institution and it concerns the fact that relatively large budget is required to establish new organization.

Funding as a result of reaching political interest

The results of WP8 study revealed that among organizations which indicated funding as a strong barrier and a moderate barrier respectively, 93% and 50% also considered reaching political interest as a problem (Figure 19.). It seems that reaching political willingness to introduce and further support HTA is crucial. The dependence of funding on political support is both direct (by achieving direct subventions and financing) and indirect (by facilitation of legal framework which provides continuous financing of HTA organizations).

Figure 19. Percentage of organizations for whom reaching political interest is a problem, stratified according to importance of funding barrier - experience of organizations performing HTA activities.



A universal solution for overcoming funding barrier that results from lack of political interest is inclusion of HTA in decision making procedures. The more HTA is linked to this process, the more likely large and permanent funding is provided. The inclusion may take the form of national policy for evidence-based health care, for instance.

Involve HTA in decision making process to ensure stable funding.

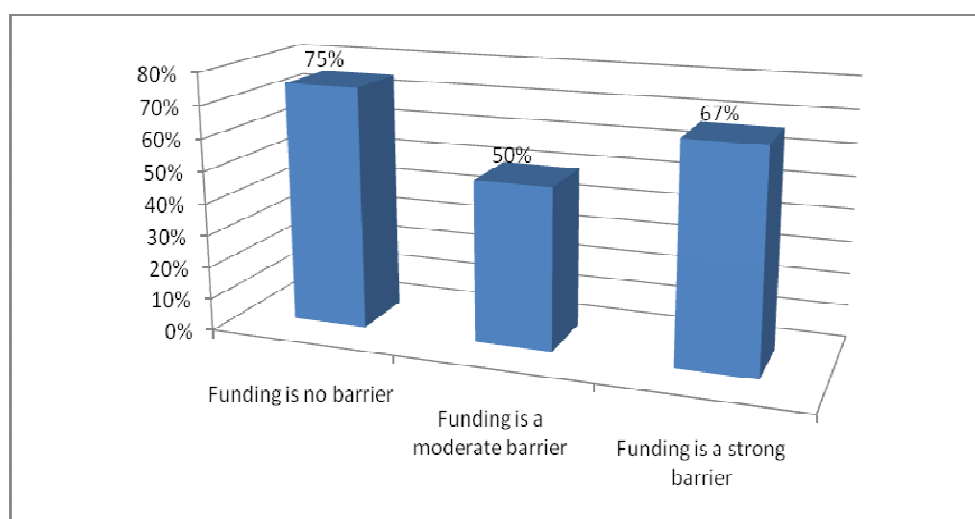
Fostering the knowledge of HTA usefulness through the dissemination of HTA products, as well as realizing projects in-line with the decision makers priorities may also lead to gaining support in form of financing.

Financial management of HTA organization

In case of new HTA organization lack of professional financial management may be a problem, because often supporters of organization's establishment are HTA fascinatees without relevant financial or managerial knowledge and experience. Also within already functioning HTA organizations this problem may arise. If needed - organization might employ a financial manager or hire a financial consulting agency (cost of hiring professionals should be balanced with increase of financial efficiency as a result of their work).

Use external financial advisors to manage your budget.

Figure 20. Percentage of organizations that have a specified budget within groups of certain importance of funding barrier– experience of organizations performing HTA activities.



As WP8 study revealed that having specified budget is not correlated with importance of funding barrier (Figure 20.), it seems that every organization should rather have a specified business plan – the formal statement of set business goals and the plan for reaching these goals. It allows to identify problems that may occur during plan realization, as well as facilitates clarification and synchronization of goals and strategies. A professionally prepared business plan ensures the commitment of relevant parties and helps to minimize risk of a failure, thus facilitating acquirement of funding sources.

Prepare organization specific business plan.

Diversification of funding sources

Having one single source of funding can put organization at risk because of two main reasons. First hazard is purely financial – sudden change or restraint of funding source can endanger organization's continuous HTA activity. Second risk

Seek additional sources of funding.

is caused by the fact that one payer as a funding source may influence or limit (directly or indirectly) organization's independence. Therefore diversification of sources might seem to be a solution, as the global impact of factors mentioned above is minimized.

Tab. 2. Percentage of the organizations with particular funding sources – experience of organizations performing HTA activities.

Source of funding	% of organizations
Government/administration	83%
Research funding bodies	37%
Self financing [charging fees for HTA products/services]	33%
International organization [i.e. world bank, European Union]	23%
Public health care providers	20%
Private industries [e.g. pharmaceutical industry]	17%
Self financing [charging fees for non-HTA products/services]	10%
Academic organizations/University	7%
Foundations [charity, others]	7%
Private health care providers	3%
Public health care insurance	3%
Patient associations	0%
Private medical insurance	0%
Other	0%

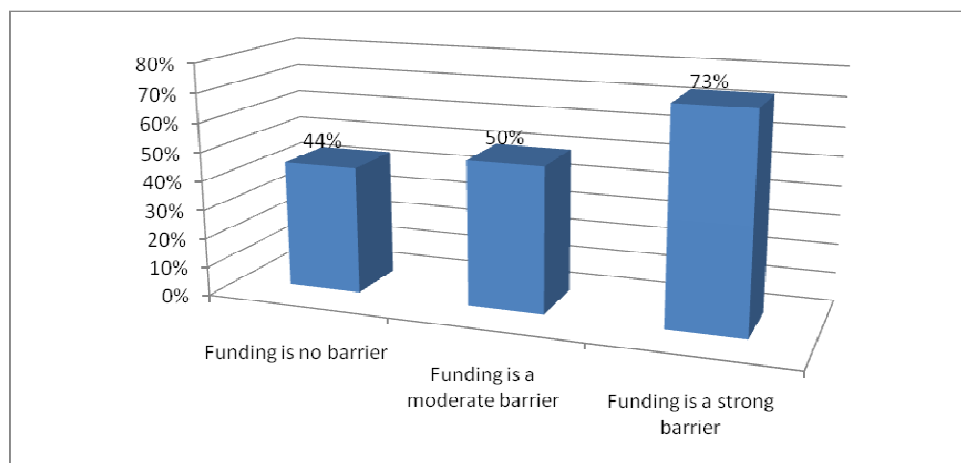
To increase its financial capacity, HTA organization should look for additional sources of funding to feed its general budget or secure funds for specific activities (however, it is always determined by the profile of organization and related regulatory framework, which in some cases can limit the possibilities). The approaches may include for instance:

- self-financing by charging fees for HTA and non-HTA products, services or sharing knowledge (i.e. organization of trainings, preparing reports, analyses, audits),
- application for research grants (if organization is eligible) offered by a range of organizations, including public and not-for-profit sector bodies or international organizations. Various funding streams may require research proposals that address specific topics, themed areas or HTA clinical trials and evaluation studies.
- financing from EU in different mechanisms, in most cases directed for specific targets as staff training. Especially appealing for new organizations may be to seek EU financing for the twinning projects by which the cost of technology and know-how transfer from more experienced in HTA countries is enabled.

On the other hand results of WP8 study (Figure 21.) show that organizations having more than one funding source tend to have higher barrier concerning funding. This situation may be caused by the need to fulfil too many requirements specific to different entities (especially difficult on the early stages of institution development) or inconvenience in managing complex budget. It occurs that the optimum degree of diversification should balance opportunities and threats mentioned to derive organization-tailored solutions. While seeking

new funding sources it has to be remembered that more sources of finances may lead to more and more complex expectations which organization has to face, so the responsibilities of the organizations must be clearly specified in order to avoid confusion and achieve agreement.

Figure 21. Percentage of organizations that have >1 funding source within groups of certain severity of funding barrier during establishment of organization.



Fixed budget vs. performance budget

Most of the organizations have fixed annual budget, while the amount of work output they are required to provide often changes during the year. It leads to situation, where financial resources are not sufficient for their activities. Performance budget can be a solution to this problem, as it balances outputs and resources (financing is correlated with specified deliverables organization is planning/obliged to provide). When implementation of performance budget is impossible, then attempts should be made to negotiate the work-load with the principal based on estimated cost. It should be explained that the limited fixed budget will result in possibility of delivering only limited amount of products and any exceeding expectation will result in lower quality or will be impossible to fulfil. It is always vital to precisely determine resources (work time, money etc.) consumed for organization's products. Without proper knowledge it is impossible to create a well balanced budget and to negotiate work-load.

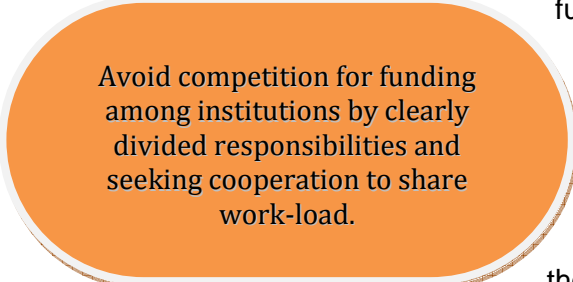
Consider implementation of performance budget.

However, in case of organizations that just plan to develop HTA activities it might be appropriate to have a fixed, secured budget due to their limited capacity to deliver products just after organization establishment. In that case implementation of performance budget should be postponed. Also in this case the negotiation arguments for raising budget should be different.

Competition or cooperation with other HTA organizations

In some countries there are few organizations that perform HTA or HTA related activities. It may trigger competition for funding, which results in inadequate money allocation.

In such situation it is vital to clearly divide responsibilities. This separation can be based for example on the type of product organization delivers (rapid reviews, full HTA reports, horizon scanning etc). Other possibility is to agree on division basing on the subject of work (drugs, procedures, organization of healthcare). If abovementioned situation is impossible and there are few institutions that cannot divide their responsibilities a solution may be to isolate



Avoid competition for funding among institutions by clearly divided responsibilities and seeking cooperation to share work-load.

funding sources. It is especially the case with organizations working on regional or local level, which are financed by their local governments. There are many HTA institutions that work on national, regional and local level, focused on similar topics. Sharing work-load and cooperation between those institutions can save much of organizations

own time by avoiding double track work and thus may lead to savings and better budget balance.

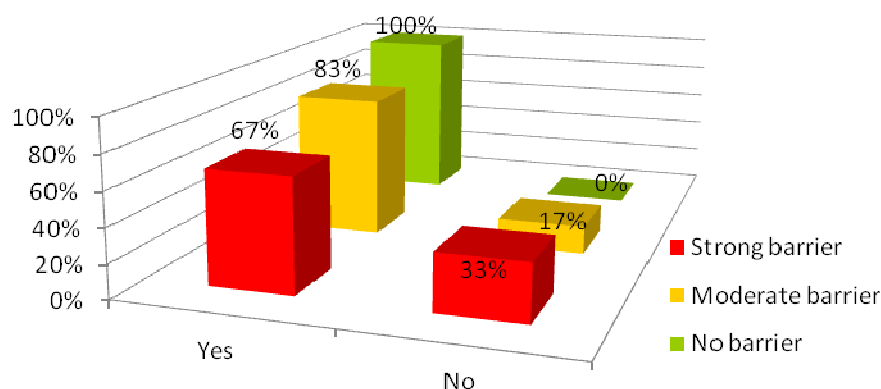
5.3.4 BARRIER: SHORTAGE OF TRAINED STAFF

Capacity building for HTA activities in terms of adequate human resources is an integral goal of either establishing new HTA organization or performing daily activities. Shortage of trained staff was the most frequently reported barrier among organizations that already perform HTA as well as among those that are just planning to start their HTA activities.

Shortage of trained staff in relation to insufficient funding

The barrier of shortage of trained staff seems to be greatly related to insufficient funding. Financial resources allow to provide employees with sufficient salaries, making organization competitive compared to other employing institutions, but also contributes to external trainings of staff members and encouraging them with other incentives.

Figure 22. Is budget sufficient to cover all existing HTA activities in the organization – experience of organizations currently performing HTA activities. Answers stratified according to importance of barrier.

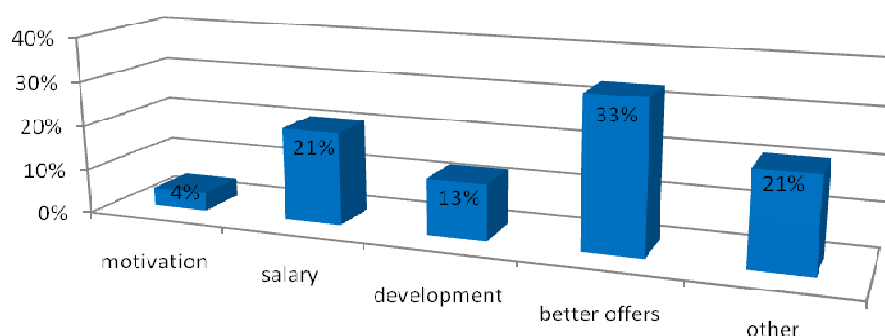


Results of WP8 study demonstrate that every single organization which didn't consider gathering trained staff as a barrier had sufficient budget to cover their existing HTA activities.

On the other hand 67% of organizations for which shortage of trained staff constituted a strong barrier had a sufficient budget as well. It suggests that finances are not the only problem underlying shortage of trained staff. It is also important to make sure that there are specific to HTA job positions, especially if there is one pool of positions for the whole organization. In this case, if HTA unit loses an employee, the newly recruited one doesn't necessarily has to fill in the gap.

Sufficient financial resources relieve problem with shortages of trained staff but does not solve the problem completely

Figure 23. Reasons for staff turnout – experience of organizations currently performing HTA activities.



The salary and social benefits for employees are of course an important factor to attract people to the organization. It helps to satisfy many needs (e.g. security, self-esteem, self-development). The value of sufficient financial employee appreciation was confirmed by results of WP8 study (Figure 23.), which indicated that among 21% respondents already performing HTA activities insufficient salary was the reason for staff turnout. Better offers from the market were reported by 33% of responders, becoming the main reason for staff turnout. Staff employing and retaining is a never-ending competition with the industry, universities, other entities within public services as well as other organizations performing HTA/EBM activities (i.e. clinical practice guidelines groups or Cochrane groups). The competition takes place not only within the same country, but worldwide as well.

Human resources management using non-financial incentives (i.e. atmosphere of work, stability, prestige and intellectual challenges)

Since public institutions and - in some cases - private sector also, are not able to provide more sources for remuneration packages in a particular point of time, solutions not engaging financial rewards, that provide other kinds of benefits should be incorporated in the organization as well to attract and motivate people [13]. As important as funding is also proper management, that takes into account and use other motivational factors described below.

Use various motivating factors to attract people to the organization.

Atmosphere of work is exceptionally important factor, which may result in employee's acceptance of some disadvantages, i.e. lower salaries. Atmosphere of understanding and team work helps an employee to develop a connection with the co-workers and the organization itself. A collaborative environment leads to staff's clear perception of shared common purpose, taking pride in their work and participation in decision making process.

Create atmosphere of understanding and team work.

Also stability and prestige of the organization should be highlighted. Working in the public services in most countries is associated with prestige, which can't be achieved in other sectors. Public sector tends to be more stable as well. Those are intangible benefits, which should be stressed as an advantage of an employment in the public sector.

Create career paths to ensure possibility of continuous personal development. Highlight the stability and prestige.

Possible way to attract people to the organization, as well as to assure their long-term dedication is to create career paths. Career path offers a solid foundation and possibility of continuous personal development within the organization. It gives employee a sense of purpose and safety. The career paths may be consistent with organization's goals and development directions, as well might allow certain careers in other fields than HTA to be continued.

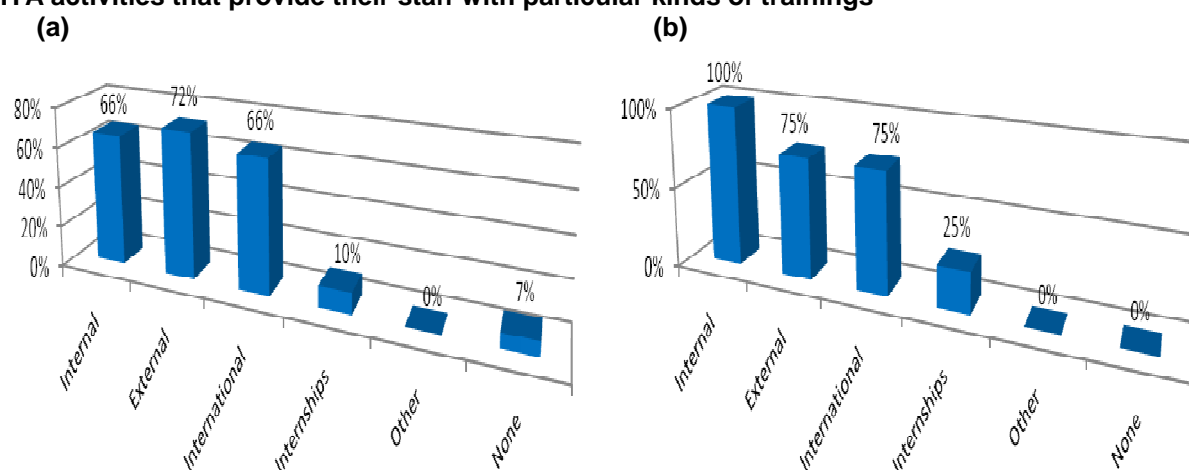
Another incentive using employees' ambition and need of personal development are trainings. Trainings ensured can constitute one of the strongest motivational factors for the employee. Availability of trainings shows the faith in the employees' ability to gain new qualifications, knowledge and skills, but also that employer believes they are worth investing in. On the other hand it makes the employees more valuable for the organization. There are two main approaches:

- on the job trainings, with employees trained at place of work. The most common methods are: demonstration or instruction; coaching, which involves a close working relationship between an experienced employee and the trainee; job rotation (within the same organization, but in several different units or departments); projects (involving employees with different backgrounds or disciplines in one activity). Advantages of this approach include: cost-effectiveness, less disruption to the work schedule, gaining direct experience by the employee in their own working environment, with equipment they are familiar with, lower stress level with training or supervision by people the employee knows, easier assessment of employees' improvement and progress, binding new employee with already hired staff during the training. Unfortunately on the job training present some disadvantages as well. Teaching or coaching requires specialist skills itself to achieve sufficient standard of the training. It's also a time consuming approach. It has to be assured that sufficient experienced employee time is allocated to guiding trainees [23].
- off the job trainings, that involve training courses away from employee's place of work. This is often also referred to as "formal training". The main types of off-the-job training courses are: day release (where the employee takes time out from normal working hours to attend a course), evening classes, sponsored courses in higher education, self-study, computer-based training. Advantages of off-the-job training include: use of specialist trainers, avoiding distractions at work which helps to focus on the training, opportunity to meet with people from other sectors or institutions. Disadvantages of off-the-job training are the higher costs and risk of training not being directly relevant to the employees' job.

Invest in people, i.e. ensure external and internal trainings that provide knowledge and know-how tailored to activities performed.

Figure below represents percentage of HTA organizations which provide their HTA staff with different kinds of training. Results of WP8 study demonstrate that almost 75% of entities experienced in HTA ensure external trainings, while 7% do not provide trainings at all. Within the organizations which do not perform HTA activities yet, 100% provide their HTA staff with internal trainings and 75% also with external ones.

Figure 24. Percentage of organizations (a) already experienced in HTA, (b) not yet performing HTA activities that provide their staff with particular kinds of trainings



Flexible model of cooperation with employees

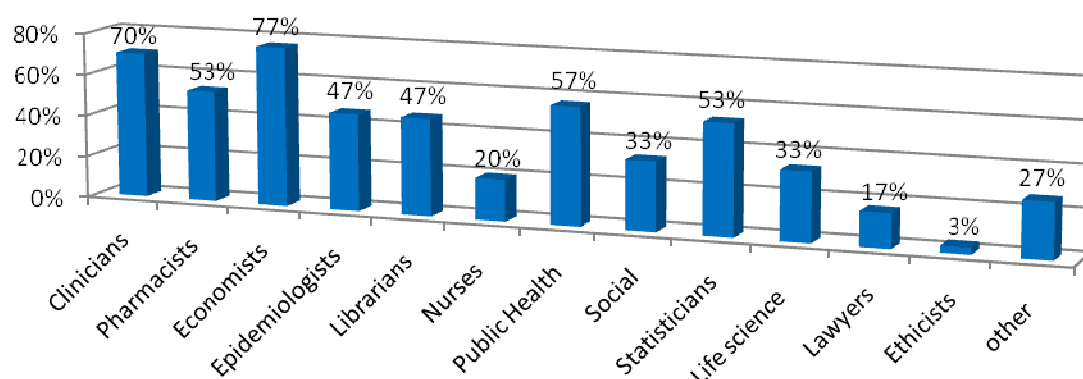
Employing temporary workers can ensure organization's flexibility due to the fact that number employed can vary to take account of changes in the work-load, as well as they offer specialist skills to carry out specific projects. Unfortunately temporary workers can lack motivation and commitment. It is important to avoid using temporary employees when the job is in reality permanent.

More flexible and soft model of cooperation could be a good strategy to make the organization attractive for people who already have a career in another field. Flexible working-hours system can help recruiting and retaining staff, since it provides an opportunity for employees to work hours consistent with their other commitments (i.e. child care or other occupation). However it requires care and needs to be carefully planned by all those likely to be affected - representatives of management and employees usually should be involved. Advantages of flexible working hours are: greater freedom for employees, avoiding commuting during the normal rush-hour, improved morale and reducing absence and lateness, reduction in overtime and less lost time. Disadvantages are: costs involved in administering the scheme, it may not be suitable for organizations where continuous cover is necessary. Along with flexible hours system, part time job can also be a good solution. This allows employees to be dedicated to other, primary profession simultaneously (i.e. clinicians in hospitals), thus assuring continuously improved knowledge and self-realization of personnel. Possibility of acquiring new knowledge and still not losing contact with their original

Allow for flexible hours or part time job.

occupation can attract them to HTA. This is exceptionally good idea for organizations which only start performing HTA activities. It allows to gather experienced (though not in HTA field) staff with only limited resources. It also can help solve the problem of low salaries.

Figure 25. Percentage of organizations with employees of certain professional background involved in HTA process



Given the multi-disciplinary nature of HTA that covers a wide range of issues concerning the use of pharmaceuticals, medical devices, clinical practices, health promotion and disease prevention variety of backgrounds of HTA staff should be a strength of the organization [23]. The diversified research topics stimulate the team to exchange of knowledge. Above Figure

Employ people with experience in other areas and allow them to work part-time.

represents professional background of employees involved in HTA process within the organizations which already perform HTA that had taken part in WP8 study. Over half of the organizations employ economists, clinicians, public health specialists, pharmacists and statisticians. Many of those people would welcome the opportunity to continue their original

occupation, while working in HTA field. Of course it has to be taken into account that conflict of interest may occur in this situation, and while career in Academia or other public services usually does not give rise to concerns, cooperating with the pharmaceutical industry is not allowed.

According to the shortage of trained staff two groups of individual problems need to be taken into account: recruitment of new employees and prevention of staff turnout.

New employees recruitment

Efforts should be made to spread the knowledge, rise interest about organization and increase its attractiveness to future employees. A way to promote the organization is to create a website devoted to the institutions work, as well as promoting access to relevant literature on HTA. The approach used in some countries is integration of health economics, HTA or EBM into the pre-graduate study plans in the

Develop a new mindsets in the society encouraging building capacity.

public health, economics, medicine or pharmacy field. It is also possible to include these disciplines in the framework of post-graduate studies (i.e. masters, PhD programs) in close cooperation with Academia. The problem is that's a solution for environments where HTA is already known, at least to some extent. It requires experienced people who can teach at the universities. This is a very good solution for organizations already performing HTA activities, which are concerned with the capacity building for HTA. For countries/ environments that do not perform HTA yet it may be possible to engage experts from other countries or environments. Other possible approaches to attract employees is to organize international workshops i.e. "HTA Camps", systematic reviews classes and promotional campaigns to increase overall awareness of HTA in the society or offer internships for students in the relevant areas of expertise, that can further become motivated and already trained to some extent employee.

Sometimes the solution is to look for people with none or just a little experience in the field of HTA, but motivated to work in public services. Possible strategy could be to employ specialists, with experience in different areas. Most of the organizations provide specific training in HTA inside the organization, often using on the job approach, described above. People who already have a career will be more prone to get motivated by new challenges and responsibilities, than with financial perspectives. Another advantage of this situation is that those people bring to the organization experience from various areas, which can be definitely used in HTA process.

Staff turnover prevention

Keeping stable workforce in the organization is a challenge. This issue especially affects organizations which already perform HTA, however in case of newly created or involved in HTA entities some preventive steps should be taken as well.

The organization should be attractive for both – juniors and seniors. Employers need to be aware that people will quit their jobs, if they are not

Create an appropriate sense of mission.

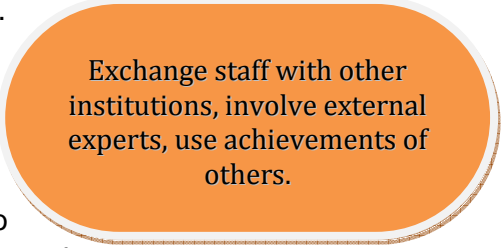
motivated enough through factors mentioned above. Experienced staff ought to be especially appreciated, given the opportunity to represent the organization in various settings (discussions with

commissioners, participation in conferences). It is also important to arouse an appropriate sense of mission and conviction of advantages of working in HTA (i.e. if employees involved in HTA perceive themselves as scientists they won't get attracted by greater incentives in a private sector). In countries with bad perception of public service, general attitude should be changed to emphasize the associated values.

Other possibilities to overcome the barrier of shortage of trained staff

Useful approach can be to exchange staff with other institutions within the same country or internationally. International collaboration among HTA bodies can facilitate the development of methods and more efficient assessment processes, and facilitate knowledge transfer and capacity-building in less established HTA systems and programmes [2]. Use contact networks to find partners to exchange staff and information. Exceptionally good example of this kind of collaboration is EUnetHTA project. Being involved in the project enables the organization to use the resources and tools elaborated by EUnetHTA. It also provides

EUnetHTA Summer School, where knowledge is spread and experience is shared. This is the field which EUnetHTA Joint Action 2 can expand. Maybe the need for a separate Work Package devoted to trainings should be considered.



Exchange staff with other institutions, involve external experts, use achievements of others.

Use reports from other countries.

It allows reducing repetition and thus may lead to savings with regard of work time. Use the achievements of other countries and institutions, only adjusting it to the needed circumstances and environment. Cross- agency collaboration can provide transfer of knowledge and help reduce number of people needed to perform a project. The reports of other organizations can also be used as a training tool.

Adjust activities to needs, expectations and possibilities.

Using different types of final products may be useful to overcome a barrier of shortage of trained staff. In some cases rapid review may be appropriate and it saves time and involve less people then full report. It is crucial though to know exactly who is the target group of the product and what are the expectations. For organizations which do not perform HTA activities yet it is useful to determine that at a very beginning.

Other way to overcome the barrier of shortage of trained staff is outsourcing work to external organizations, like academic centers. Subcontracting reports to another public or private institution is a way to finalize the product with limited number of trained staff employed in the organization. Unfortunately it is usually associated with sufficient financial recourses. It is also possible to cooperate with non-paid external experts (even only for one project or task), as they may get attracted by chance to promote their names, especially if the HTA organization has a good reputation.

6 STRENGTHS OF THE ORGANIZATION

Organizations may benefit from assessment of its **strengths, weaknesses, opportunities and threats**, as it could be incorporated in the development phase of strategic plan and used to gain impetus, competitive advantage and sustainability [14]. It is a valuable tool in organizations decision-making and may be used to assess development possibility, a potential partnership, an investment opportunities etc. Although weaknesses must be managed, organizations should rather focus on creating a tailored strengths-based development strategy, that ensures effectiveness and that all internal and external opportunities are seized.

Whatever capability an institution has it can be regarded as strength. An organization's strengths may lay in its structure or diversity of financing sources, may result from its ability to create unique products or to provide high-level service and satisfy the "market" needs. Crucial factors are also organization's staffing and training, as well as the quality of its managers.

Although managers are not provided with a guidance to identify the strengths of their organization, they may exploit the experiences of others. WP8 study revealed the main strengths that were of consequence for overcoming identified barriers against HTA organization establishment and performing HTA activities.

Human factors constitute a constraint for both: implementing new system and maintaining organization's activities. It relates to the interpersonal skills of the individuals involved in the project such as ability to work together toward a common goal, in the face of conflict etc. However, it occurred that the most critical factors are people's **commitment to work**, the **motivation** and **enthusiasm** of staff **to perform HTA activities**, also in long-term perspective due to project specificity, often expressed as "We believe in what we do!". A well-balanced combination of **experience** of the staff and social skills secures **good team spirit** as well as **responsibility** and willingness to **share knowledge** and help decision making. Key factors that also seemed to influence the ability to attract **ambitious**, creative and full of **initiative** personnel were: provision of sufficient training and continuous search for new sources of funding dedicated to new staff recruitment. Features mentioned above to a large extent are related to and depend on the **quality of organization's management**. European HTA organizations emphasized the role of respectful and encouraging management, the importance of good project leaders and need for assuring the **governance through continuous improvement** of the quality of management processes via inter-institutional or inter-units networks.

Other internal factor claimed to affect institutional performance is **flexibility**, which in the context of **HTA processes** can be defined as ability of an organization to effect changes in the process components (activities, inputs, resources, information etc.) in a timely manner usually in response to changes in environment and stakeholders' needs. It also refers to the accompanying **organizational structure**, that needs to be more informal in nature, based on leadership, knowledge and trust to enable changes in the processes, roles and

responsibilities [15]. Some manifestations of organizational flexibility in processes such as staff recruitment, choice of contracting partners and funding mechanisms likewise were mentioned (i.e. management of a formalized network of excellence encompassing public institutions, research centers, stakeholders and private financial supporters).

As for external factors supporting HTA organizations in their activities, the experience indicates the importance of **communication with relevant stakeholders, favourable legal framework**, good **inter-organizational management** and **international relations**. Detailed strategies and opportunities that contributed to institutional successes incorporated or were manifested through: support from Ministry of Health or government (i.e. decision to prepare and implement HTA strategy, also with mandatory status of HTA regarding reimbursement), legislative initiatives (i.e. legally stated mission of HTA organization, detailed legal framework describing financing sources) and finally – good relationships with stakeholders (including strong links to users of HTA products at the Ministry and hospital level, availability of HTA products for wider group of recipients, public presentations), conditioned by constructive feedback and impact analysis.

Especially young organizations, still at development stage of their HTA processes emphasized the importance of international support and collaboration (i.e. by means of international projects or evaluation that strengthen credibility), as well as national collaboration with academic and scientific institutions, and patient organizations. Expertise and independent position in healthcare system (i.e. resulting from academic background) or the capacity to involve scientific community occurred to be critical success factors.

7 DISCUSSION

The survey results presented in the previous chapter indicate that the majority of organizations contacted had been already performing HTA for at least four years at the time of completing the survey. For approximately one-third of existing HTA institutions need of performing HTA activities was the main reason for establishment of the organization. The profile of organizations, either already involved in HTA activities or planning to perform HTA activities was governmental, followed by academia and Ministry of Health. All of the respondents of the study represented not-for-profit sector, which is consistent with many previous surveys on HTA institutions [3, 16, 17, 18].

The study adds new information concerning barriers against establishment and performing HTA-related activities with respect to experienced HTA organizations as well as those with non-formalized HTA programs all over the Europe. Obstacles for HTA promotion as well as for initiation are similarly perceived across different context and cultures. All of the barriers, although, as it was explained at the beginning of the survey, may vary depending on the type of organization, years of conducting HTA activities or country-specific conditions. When analyzing the severity of particular barriers, among all barriers identified, the results gave the greatest importance to funding and gathering trained staff for both, those organizations which are currently performing HTA activities and those which are planning to perform HTA activities in the future. However, the severity of these two barriers was lower for organizations currently performing HTA activities when compared to the organizations which are planning to perform HTA activities. As it was already stated in the previous survey report on HTA organizations [16] this can be explained by the recall bias. The oldest agencies which are already experienced in the HTA activities cannot accurately report the situation at the time they were established. The perception of severity of the most important obstacles to initiate HTA organization has changed over time.

A major problem associated with the barrier funding seemed to be inadequate allocation of financial resources in relation to planned production. The results of the present study suggest that when it comes to institutions that plan to start the HTA, a relatively large budget is needed to establish a new organization. The findings are similar to other published survey [18] which reported that the financial resources are probably primary enablers to carry out HTA in established institutions in high income countries. Ensuring that sufficient funds are available to train HTA professionals is simply part of an overall budget secured to finance an HTA agency. These findings confirm the information found in the publication Kristensen 2007 [20], where it has been stated that newly established HTA organizations in countries without any institutionalized HTA will have to develop gradually, starting with activities that do not require a large amount of resources.

Abovementioned problem of insufficient funding is greatly related to the barrier shortage of trained staff, since financial resources allow to provide employees with sufficient salaries, making organization competitive compared to other employing institutions, but also contributes to external trainings of staff members and encouraging them with other incentives. According to the results of study performed by Rajan et al. [19], the concept of HTA has been implemented more fully in high income countries and trained HTA personnel

are more abundant than in low and middle income countries. It is important to consider that a relatively small number of experts are currently active in the field, in contrast with the large number of new and existing technologies to be evaluated. Successful HTA programs require appropriate education and training strategy targeted at expertise, organization and staff qualification [16]. Results of the previous survey report on HTA organizations showed that the higher number of staff the greater of specialization and multidisciplinary of teams [16]. Thus, there is a need of having a variety of staff expertise in order to ensure the capability of the institution to deal with the wide range of HTA topics.

Agreement with stakeholders as those organizations or individuals who have an interest in, or are affected by HTA organization activities, products, services and associated performance was found to be another barrier. There are examples in the literature on this topic confirming the importance of recommendations in the present survey. According to Sorenson 2008 both Sweden and the United Kingdom have sought to improve stakeholder representation and participation, most notably among patients and the general public. The National Institute for Clinical Excellence (NICE) encourages stakeholder comments in its technology appraisal and clinical guideline programmes, and has a Citizens Council that helps capture public views on key issues surrounding the development of guidance, especially in terms of social values and judgments. Feedback from the Council helps to create a framework of scientific and social value and judgments, which is used to guide the work of assessment groups and improve methodologies used to develop NICE guidance. In Sweden, the respective HTA agencies involve a broad array of stakeholders in their assessment and review groups, from health economists to representatives of health care organizations and patient groups. Stakeholders are also able to comment on SBU Alert reports once publicly available via the Internet. Given their role in producing and analyzing much of the clinical data employed in assessments, the greater and earlier involvement of industry representatives has also been promulgated. Typically, once they submit the required evidence, manufacturers are not involved until the assessment is complete. This can hinder the possibility of addressing any outstanding questions regarding the available evidence. Improved participation could result in greater efficiencies and ensure that the required evidence is integrated into continuing clinical studies. Nevertheless, the involvement of manufacturers raises concerns that greater collaboration between HTA entities and industry may influence the objectivity of the assessment process and following recommendations [2].

The development of HTA requires also acceptance and support of policy-makers. Unfortunately, as the results of the survey indicated, not yet all countries managed to capture the attention and awareness of policy-makers, including politicians, and despite examples of successful applications coming from all over the world, reaching political interest was a barrier among organizations already for both, organizations involved in formalized HTA and those planning to perform HTA activities. Younger organizations, involved in HTA for less than four years seemed to have fewer problems in that field, however no firm conclusions could be drawn with respect to reasons for that.

As it was stated in the OECD report [10], health technology assessments are more likely to be used by decision makers if policy instruments are available to act on the assessment, if prior commitments to make use of technology assessments are in place, and if the technology assessment methodology used is regarded as “appropriate”. The OECD survey results suggest that technology assessment largely needs to be tailor-made for the

characteristics of individual health systems, including where decisions about uptake and diffusion of technology get made as well as, in some cases, for the particular technologies being assessed. In general, HTA needs to be linked more comprehensively with innovation and other aspects of policy making. Twelve OECD member countries (Australia, Austria, Canada, France, Germany, Ireland, Japan, Mexico, the Netherlands, Norway, Spain and Switzerland) participated in the survey and respondents included government officials, health technology assessors, health care and hospital administrators, clinicians and researchers. Comparative information was collected on actual decision-making processes for five case study technologies: positron emission tomography, hepatitis C genotyping and viral load testing, telemedicine, prostate cancer screening, and technologies for dealing with stroke patients.

In order for HTA to influence decision makers, it has to produce the evidence that they require. This means ensuring the timely availability of information, in line with decision priorities, and recognizing the various dynamics of different technology markets. The involvement of decision makers early on in the assessment process may help deliver more valued and relevant information. However, there may be occasional tensions between HTA methodology and decision making. On the one hand, there is support for autonomous and rigorous HTA with sound methodologies. On the other hand, there is a recognized need to ensure that HTA is suited to the decision-making process and the decision makers' needs – which sometimes (although certainly not always) may be at odds. Timeliness of HTA production is good example where sometimes HTA producers and decision makers' needs diverge. This point underlines the need for better communication between the producers and users of HTA to ensure sound methodology and relevance. Furthermore, HTA can potentially be used to build better links between decision makers and the innovation community. For example, HTA highlights areas of uncertainty, suggests areas for further research, and outlines aspects of the technology where changes might be needed to improve, for example, its cost-effectiveness. This information is not only important to health-care decision makers but also to health-care innovators who can use such information as an input into the dynamics of medical innovation [10]. The need of continuous dialogue between scientists and politicians was confirmed in the publication Velasco-Garrido 2008 [4], where among the proposed actions for researchers and policy-makers in order to use HTA in the decision-making process were: to improve collaboration and ensure close, personal, two-way communication, as well as the to consolidate the mutual trust.

The importance of collaboration among agencies has been described in other previous surveys [16, 17, 21]. Networking, at regional, national, and international levels, can be very helpful for newly established HTA organizations with limited resources by avoiding repetition of HTA assessments made previously by other HTA organizations. Another words, it can be very helpful to overcome barriers.

Networking, at regional, national, and international levels, can be very helpful for newly established HTA organizations with limited resources by avoiding repetition of HTA assessments made previously by other HTA organizations.

Greater international collaboration when it comes to the synthesis of evidence may generate savings and reduce duplication and also raise important methodological issues around transferability. After all, many HTA practitioners use the same sources of evidence for their

reviews. The International Network of Agencies of Health Technology Assessment has achieved a great deal through its joint evaluations, database and development of an HTA checklist, but there is recognized need for further collaboration in this area. Countries that do not have extensive HTA programmes may especially benefit from such collaboration [10].

It should be noted, that results presented do not constitute a case-study of HTA condition in responding countries and revealed strategies are not institution-tailored. To facilitate sustainable development in national settings, the HTA organization should map its processes among opportunities, threats, strengths and weaknesses mentioned to derive solutions based on other entity's experiences. It is also important to look globally and focus not only on one limiting factor while seeking solutions to overcome the barrier.

Limitations

There are some limitations to the present study. It should be noted that the study sample used in the survey may not be representative of the general context of HTA. From some countries, none of the addressed organizations of the sample answered. The majority of organizations contacted had been already performing HTA for at least four years at the time of completing the survey. The response rate from countries without institutionalized HTA was very low.

8 CONCLUSION

It might be concluded, that the impact of HTA can be enhanced if key stakeholders are adequately involved, decision-makers give advance commitments to use assessment reports (and assessments meet their needs), necessary resources are available for implementing decisions, there is transparency in the assessment and decision-making processes, and collaboration, knowledge and skills are transferred across jurisdictions.

It should be noted, that in order to be most relevant, HTA in Europe must be undertaken within the policy context of a particular country taking account of national priorities and systems, including regionalization.

To accomplish the predefined, mutual goal of securing sustainability of HTA, the experiences of organizations participating in WP8 study should be taken into consideration. Particular solutions (listed below) which were developed for identified barriers in process of survey analysis and workshop discussions can be used to reach sustainability of HTA development. However it is important to remember that they are just set of propositions and every organization has to choose the ones that fit to its specificity because there's no universal solution for many different organizations.

Recommendations in brief

BARRIER: AGREEMENT WITH STAKEHOLDERS

- Identify relevant supporters and opponents regarding organization's place in health care system.
- Seek increased assistance of politicians, decision makers and scientists, establish an ongoing relationship between partners.
- Adjust communication strategy to particular target group.
- Endeavour to regulate the uneven data access by legislative initiatives.
- Establish formal processes to disclose conflict of interests.

BARRIER: REACHING POLITICAL INTEREST

- Strengthen trust between scientists and politicians and improve the use of scientific evidence in decision-making through continuous dialogue.
- Define clear position of HTA with regard to the specificity of health care system.
- Counteract improper or insufficient use of HTA, which may result in loss of political interest.
- Disseminate HTA products in order to prove their usefulness. Use transparency to make agreement with policy-makers easier to reach. Use different approaches that raise awareness of politicians as beneficiaries of the HTA processes and products.

BARRIER: FUNDING

- Involve HTA in decision making process to ensure stable funding.
- Prepare organization-specific business plan, that ensures the commitment of relevant parties, helps to minimize risk of a failure and facilitate acquirement of funding sources.

- Seek additional sources of funding.
- Use external financial advisors to manage organization's budget.
- Try to precisely determine resources consumed for organization's products. Consider implementation of performance budget or re-negotiations of work-load, regarding organization's stage of development. Avoid competition for funding among institutions by clearly divided responsibilities and seeking cooperation to share work-load.

BARRIER: SHORTAGE OF TRAINED STAFF

- Use various motivating factors to attract people to the organization and protect them from quitting i.e. encouraging salaries, friendly atmosphere at work, stability and prestige, intellectual challenges.
- Create an appropriate sense of mission.
- Invest in people, i.e. ensure appropriate external and internal trainings.
- Allow flexible hours or part time job.
- Employ people with experience in other areas and allow them to work part-time.
- Develop a new mindsets in the society encouraging building capacity.
- Exchange staff with other institutions, involve external experts, use achievements of others.

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10 APPENDIX

Questionnaire used during WP8 study