

On-site Visit of LBI-HTA

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Visit Report

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Introduction

The Ludwig Boltzmann Institute for Health Technology Assessment/ LBI-HTA was founded in April 2006 for a period of 7 years. The long-term idea of the LBG research initiative to found new institutes is ultimately to pass on sponsorship and to transfer the LBI-HTA into the responsibility of other institutions. Before the negotiations with the “other institutions” (MoH/ Ministry of Health, Federation of Austrian Health Insurances/ HVB-Hauptverband der Sozialversicherungen, 9 regions/ Länder) start, the “Ludwig Boltzmann Gesellschaft” invited three experienced HTA-experts from European insurance-based health care systems (DE, BE, NL) to an on-site-visit by in order:

1. to support LBG in their decision how to frame the transformation process
2. to give inputs for the practical organisation of “independence”
3. to provide basis for negotiations with 3 “pillars” (future financial contributors, see Strategy paper LBI-HTA 2013+)

It was the wish of the LBG to obtain input on

1. Appraisal of RESEARCH PROGRAMME in the context of international methodological and collaboration-developments/ trends.
2. Propositions for the GOVERNANCE-STRUCTURE: functions, activity descriptions, competences, appointment-procedures, effects of different models of governance.
3. Propositions for transparent PROCESSES in the execution: work-division and communication processes between HTA-institute and financiers/governance-committees: definition of work-program, publication policies, primary data-access policies etc.
4. Long-term FINANCING depending on role/status: core area of HTA-institute, optional activities in stakeholder-management etc. quantity-structure of resources (time) for core-area and optional activities, expectation on input-output relation.

CRITICAL ELEMENTS: What to watch most carefully in handling the gateways of influence on HTA-results.

Summary of the viewpoints contributed by the invited experts

In limited time, LBI-HTA has become a reference in Austria

Since its creation in 2006, LBI-HTA has produced over 100 project reports and other scientific advice documents. The organization has reached a fair level of visibility and is respected for the quality and credibility of its output.

... but also a respected partner in a European context.

Although every country will still, for an undetermined amount of time, have to go on with national (or regional) decision making on whether or not to include and fund health technologies (in the most broad sense of the word), the issues and the ways to address them can only adequately be approached in an international context. Collaboration between HTA institutions is of vital importance for reasons of quality and efficiency, and LBI-HTA has during the past few years earned a place as a pioneer and role model in this respect.

Although being a relatively small institute, it has had a decisive impact on a number of the most important achievements by the EUnetHTA network so far, including the POP database (planned and ongoing projects), and a number of actual collaborative projects in the field of cancer drugs. Moreover, by showing what is possible, even with comparatively small resources, it can definitely be a role model for similar endeavours in the new EU member states.

Main message 1 : time has come to scale up

The first important message the external experts want to convey is that time has come for Austria to have its own HTA agency that can take up and expand its role, both in the country and in the European or international network. In order to be on more or less equal foot with other western countries of comparable size, we recommend a yearly budget of at least 8 mio €. This would give LBI-HTA a similar size per population as what is seen in countries where HTA has reached a good degree of maturity.

The reasons for this advise are

- 1. Increasing demand for independent scientific advice in healthcare decision making*
Most healthcare and public health insurance systems are and increasingly will be under pressure as the budgets will not be able to hold pace with the ageing population, the ever increasing demands and expectations from society regarding health care and the ever more expensive technological advances. When having to take cost-cutting decisions or refusing reimbursement for certain innovations, politicians will turn to scientist to give them evidence-based and unbiased advise. Although this requires a cultural change, the evolution seems inevitable in the long run.
- 2. Concerns about corruption, including in healthcare*
The above-mentioned need for independent scientific advice is even more urgent in the light of the never stopping stream of allegations about fraud with research results, concerns about publication bias, non-disclosure of unfavourable trial results, ...etc. Facing these concerns as well as the complex funding in health care in Austria including the Bund, the Länder and statutory health insurances, and the heterogeneous composite of health care providers it is inevitable that the LBI-HTA should become a strong and independent authority based on a legal mandate.

In the context of the recent public debate on corruption in Austria the organisational perpetuation and autonomous funding of the LBI-HTA as an independent, international highly accepted HTA institutions is mandatory.

3. *Becoming an equal partner in an international context*

Starting from the fact that the different partners in the EUnetHTA joint action have in total some 1000 different planned and ongoing projects on their programmes, it is clear that a national institute will never be able to provide answers to all pending questions. Unless strong networking and collaboration is set up, all HTA agencies will eventually collectively fail. A good network needs strong, credible partners, with the capacity to contribute own specific know-how to the network. Also for this reason, a critical mass is needed, as the longevity of collaboration within such voluntary networks also entails an acceptable level of reciprocity between partners with comparable strength. In this respect, it is to be feared that, in the long run, a too small LBI-HTA will not be able to live up to the expectations .

Main message 2 : becoming an integrated part of the healthcare system.

LBI-HTA should become part of the healthcare system (not purely academic) and as such it should obtain an official statute and have a role in the system. For this a legal basis is an important prerequisite.

Yet, to be able to fulfill its role in an efficient and credible way, it should keep a high level of independence, amongst others guaranteed by an autonomous, long-term funding (see below).

The specific role of an HTA institute in a healthcare system is not to define policy, but to contribute independent, objective, scientifically sound analyses (assessment), and, when appropriate and feasible, to formulate policy advice on the basis of the assessment (appraisal). The latter could be a specific role for the Board (see below).

By taking up this role as a strong, independent and evidence-based oriented institution and well-respected agent/mediator in the system of Austrian stakeholders, LBI-HTA will actively contribute to the shaping and evolution of the health system towards more evidence-based policy making.

Building a strong central HTA institute will logically require stronger coordination and rationalisation among HTA-producing actors in Austria. This could, a.o. entail more outspoken profiling/specialisation, and collaboration rather than competition

Main message 3 : stable, non-conditional funding

A. Stable funding

Building up a team of highly competent scientists, which is essential for a credible HTA agency, takes time, and asks for the possibility to offer a longer-time perspective in order to attract valuable candidates. Moreover, the set-up and development of scientific procedures and the elaboration of the highly needed network of external experts (both national and international) is also a long-term enterprise. For these reasons, a stable funding with a long-term perspective should be warranted, based upon a formal agreement between all funding partners.

Mechanisms must be put in place, that those financial contributors consisting of more than one representative (the regional partners) speak with one voice.

Industry funding is to be avoided by all means, and an open conflicts-of-interest policy is highly recommendable.

B. Non-conditional funding

One element of stability, but also of independence, is that the funding allocation is not directly linked to the execution of specific studies or tasks. This means that the financial contributions are not earmarked and should not be bound to specific projects. The rationale is that the advices produced by LBI-HTA, and, consequently, its activity programme, cannot only be defined by financial contributors (and their

singular perspective) but should respond to a broader societal agenda. Of course, If regions are a strong financial contributor/ partner, then hospital topics will play a stronger role.

But, even so, the managing Board of the renewed LBI-HTA agency should consist of more than the representatives of the financial contributors, but also incorporate Medical Associations, Hospital and Patient Associations .

Main message 4 : priority setting for activity programme is independent from funding

Another consequence of the preceding is that the priority setting of the activity programme of the HTA agency is not exclusively done by the sponsors, but by the Board, so as to incorporate the broader societal perspective. Mechanisms must be in place that “harsh” discussions are possible, but with no financial consequences (see non-conditional funding).

It should be performed on the basis of well-defined procedures. Priority setting criteria might be: access issues, social accountability, affordability, feasibility, frequency of disease, severity of disease, room for improvement.¹

With regard to the **scope of the work programme**, the current work of LBI-HTA reflects the methodological trends and tendencies of all international HTA-agencies (Horizon-scanning, conditional coverage, complex interventions etc.).

Both specialized or a broad spectrum of the work-programme have pros and cons, and will heavily depend on the role of the new institute.

Production of guidelines for good clinical practice could be envisaged next to evidence analysis and evidence generation. The latter will depend on the future distribution of roles between the different Austrian advisory bodies.

In order to be responsive and reactive to urgent health/political issues, some resources should be reserved for unforeseen questions requiring a quick response.

Main message 5 : stakeholder involvement

The interaction with stakeholders should not be considered only as “political correctness”, but as essential, providing a real added value to the assessments. “Inclusive” assessments are informed by views and visions of different stakeholders and therefore are more likely to give answers that are ‘audible’ or intelligible by the stakeholders. This is not to be intermingled with “negotiated or compromised” results.

Stakeholder involvement mechanisms should be put in place and be considered early in setting up the new institute. These interactions are part of the standing procedures, fitting on a regular basis in the timelines of HTA-production. They can help to make the issues tangible, to define the right scope and to identify the real issues at stake, to make the methods acceptable as well as the main messages resulting from the study, and they can be very valuable for the dissemination of the end product. With respect to the latter, there is also the work with the media and press, which is of increasing importance and can be quite rewarding.

For certain (types of) subjects, part of the assessments can be to show transparently and systematically the controversies of certain topics, lay the controversies open.

¹ At KCE, project proposals (incl. own proposals) are scored by a panel of KCE experts and managers according to five criteria: (1) frequency and (2) severity of the problem, (3) room for improvement, (4) policy relevance and (5) feasibility. A classification by activity domain (HTA, HSR and Guidelines) is proposed to the Board, which can amend the classification, e.g. ‘scale up’ a project for policy reasons.

Involvement of stakeholders is to a certain extent time-consuming, and a trade off should be made in terms of costs and benefits.

Remaining challenges

- Not only to assess effectiveness and cost, but ...
- ... also incorporate such issues as equity, access and social distribution
- Organisation of ever increasing knowledge within institution and within country
- Organisation of collaboration between competences within the country
- Published research is often not of relevance and gives no answers to the actual questions: single answers of single questions do not provide full picture. It is the challenge for HTA to create full pictures.
- How to secure support/funding for a *central* institute from the *regional* authorities/partners?

Possible next steps

Agreement on a specific role for LBI-HTA within the Austrian health care system and an outspoken commitment by all relevant partners, sanctioned by

- a legal basis (law: e.g. 15 a agreement) for national HTA activities and international collaborations and
- a non-conditional budget (not easily to be withdrawn)

A national 'round table meeting', with the minister and all important partners, on the future of HTA in Austria could be a way to make this commitment 'crystallize'. ?