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Austria: History of health technology assessment during the past 20 years

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Objectives: The aim of this article is to describe and analyze the stages toward recognition and implementation of health technology assessment (HTA).
Methods: System analysis of structures and institutions and their use of HTA.
Results: Austria is a latecomer in implementing evaluations/HTA as decision support. It can to a certain degree absorb the increasing international knowledge. Austria had a long time to observe the successes and failures of HTA in other countries and to learn from other countries. The implementation of HTA within the Austrian healthcare system ran through stages of uptake: starting 1989 with a systematic review on international activities, first international networking and collaboration since 1991, proposed assessments until the late 1990s, followed by reactive assessments on demand mostly on high volume and costly technologies since then. Since 2000, HTA is used on a regular basis for investment and reimbursement decisions by several players, namely the Ministry of Health, the Social Insurance and hospital cooperations. In 2006, the Austrian HTA-institute was founded.
Conclusions: It took approximately 15 years from first research activities in HTA to an institutionalization. HTA in Austria is not only product- but also process-oriented: The actual production of assessments for decision support is as important as the structuring and accompanying of the process of decisions making. In addition, shaping the public understanding of science (characterized by the intrinsic belief that all new medical interventions provide added value to the healthcare system) is part of Austrian HTA.

Keywords: Health policy, History, Reimbursement, HTA in hospitals, Planning, Resource allocation

THE AUSTRIAN HEALTH CARE SYSTEM

As in almost all European countries, health care in Austria is considered as the responsibility of public policy: 100 percent of the population is covered by the Austrian healthcare system, which is financed partly (45 percent) by the mandatory social (health, pension, and unemployment) insurance levied through employers, partly by taxes (32 percent), and partly by private co-payments (24 percent) (Figure 1) (13;18). A total of 10.2 percent of the gross national product goes to health care: with it, Austria, lies at the European peak (together with Germany, France, and Belgium) both concerning expenditures and private contributions (11). The healthcare delivery system is highly decentralized and regionalized and within the responsibility of the "Länder" (the 9 states of Austria): public hospitals (49 percent of all hospitals and 68 percent of all acute care beds) are owned and managed by regional hospital cooperations, or by social insurance (15 percent of all hospitals and 9 percent of all acute care beds) or confessional nonprofit providers (19 percent of all hospitals and 18 percent of beds); private hospitals (17 percent of hospitals, but only 6 percent of beds) are rare in Austria (13). In hospital care, physicians (60 percent of all Austrian physicians) are paid by salaries and they are employed by one of the regional hospital providers.

Outpatient care is delivered by physicians in private practice (8,300 self-employed physicians, which is 40 percent of all practicing physicians in Austria) and reimbursed by regional health insurance (12). In outpatient care, physicians in private practice are entrepreneurs and have (lifelong and not-redeemable) contracts with the health insurance. They are reimbursed mainly by fee-for-service, only

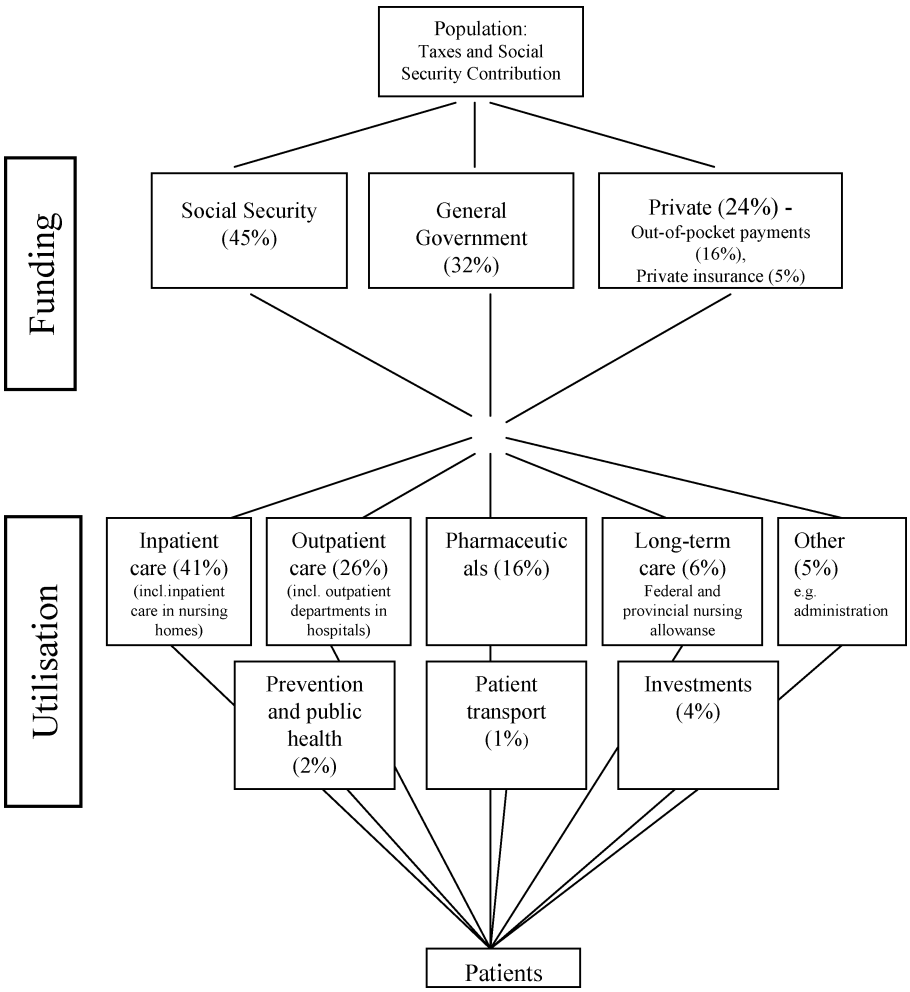

Figure 1. Financial flows in the Austrian healthcare system.

in a few cases (visits at general practitioners or pediatricians) by capitation. The twenty-one (nine bigger regional and twelve smaller company-operated) mandatory social and health insurance corporations cooperate within the Federation of Austrian Social Insurance Institutions that is responsible for negotiating with the Federal Chamber of Physicians on the reimbursement of and tariffs for new services. Nevertheless, as many different "service benefit baskets" and routes into those baskets exist as there are health insurance corporations. Only for pharmaceuticals/drugs does a positive list and a clear and pre-defined process for new drugs to be incorporated exist. The insured cannot chose between the mandatory insurance corporations. There is no competition or risk-selection of patients possible.

The Federal Ministry of Health (Women & Youth) oversees only general strategies in health policy and prevention (e.g., vaccination) and is responsible for framing the legislature and enforcing reforms especially on hospital care. In 1997, the Performance-Oriented Hospital Financing System (LKF), an adapted diagnosis-related group (DRG) system, was implemented for retrospective reimbursement of hospital services (6). Additional specific benefits for "highly specialized" services are covered by the Single Medical Procedures (MEL-) Catalogue (7) taken care of by the Federal Health Agency (FHA), composed by representatives of the nine regional health agencies. The FHA is also responsible for an Austrian-wide capacity planning of hospital services, including the Austrian Major Equipment Plan, covering computed tomography, magnetic resonance tomography, emission computed tomography, positron emission tomography, digital subtraction angiography, coronary angiography, and radiotherapy (5).

Healthcare reform initiatives focus on the major problems within Austrian health care. Austria has the highest density of hospital beds in acute care and the highest rate of hospital admissions per capita in Europe. Because of the highly decentralized and regionalized and sector (extra- and intramural) specific organization of provision and decision making, patient care is uncoordinated and efforts are duplicated. Since 1997, major reforms based on the "15a agreement"

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(4) between the Federation and the provinces has been implemented to lessen the extremely sharp distinction between intramural and extramural (or private practice) care and to control rising costs. These reforms intend to shift the emphasis from hospital to outpatient care and nursing homes by building alternative institutions of provision, integrate social and medical services, and reduce hospital costs through the reimbursement of performance-related cases instead of flat-rate payment for hospital days. In 2006, in a renewal and prolongation of the 1997 "15a agreement" on reforms in the organization and financing of health care (8), the implementation of "instruments for enforcing quality and efficiency" is mentioned explicitly, although health technology assessment as such is not named. Nevertheless, for 2009 a "national strategy" on health technology assessment is in planning by the Federal Ministry of Health (Women & Youth) (9).

Public Policies Intended to Control Practice and Hospital Care

The principles of "effectiveness" and "efficiency" for regulating and controlling practice and hospital care are anchored in two legal acts: in the General Social Insurance Law (2) it is stated that the "act of care must be sufficient and appropriate, but the extent of inevitable required not exceeding". The equivalent legal act for hospital care is the Federal Hospital Law (4), in which it is written in a paragraph on quality assurance: "a high-quality, effective and efficient health care has to be ensured. A quality assuring system serving the improvement of efficiency must be introduced." Although only general statements on the necessity of supporting effectiveness and efficiency of health care as part of an improvement of quality in different sectors, those laws lay the foundation for a necessity of evaluating the need, appropriateness, and effectiveness of healthcare delivery and especially medical interventions before investment, service delivery, or provision, although no systematic and obligatory enforcement is legally stipulated or demanded. Table 1 shows the different policy instruments of the different players in Austrian health care and the actual utilization of HTA within the pre-existing repertoire of regulating healthcare interventions.

Because of the fragmentation of responsibilities, the desire to create a functional control and planning instrument resulted in 1978 in the establishment of the Hospital Cooperation Fund, re-named to Federal Health Agency (FHA) in 2004. Within FHA'S responsibility is the capacity planning of hospital services and the Major Equipment Plan (5). The main instruments to control diffusion and regulate the use of health technologies, mostly techniques (surgical interventions), in hospitals are the catalog for Single Medical Procedures (7) within the DRG-refunding system and structural and volume-quality requirements for some/a few highly specialized interventions. On the other hand, within intramural care, Austria is considered to be among the most rapid "uptakers of innovation" (25), especially in offering cost-intensive oncologic treatments even long before approval, because there is no effective regulatory instrument for drugs. Additionally, regulating big devices with the Major Equipment Plan proved to be ineffective. Austria is among the best-equipped Organisation for Economic Co-operation and Development (OECD) countries concerning magnetic resonance imaging and computed tomography per capita (11). In outpatient care, physicians in private practice are reimbursed by fee-for-service, and it is well known that such reimbursement increases rather than decreases expenditures per patient with no influence on quality of care. A positive list for drugs (10) defines what is reimbursed within the mandatory health insurances and distinguishes between free prescribeable drugs and those with restrictions (only for certain patient groups, indications, by specialists). In contrast to the inclusion process of drugs in the positive list, there is no transparent predefined process for including non-drug interventions into the healthcare basket of the regulated health insurance.

EVALUATION AND ASSESSMENT: INTRODUCTION OF HTA TO THE COUNTRY AND INSTITUTIONALIZATION

Austria recognized HTA later then other Western industrialized countries as a valuable instrument to support decision makers in health policy. Compared with many other countries Austria is a latecomer in using the tool of HTA, but Austria has learned a great deal from the experiences of other countries. In 2005, the Health Quality Act was released and the Federal Institute for Quality in Health Care (BIQG) (3) was founded in 2007 for the development and enforcement of different measures: Clinical Guidelines, Clinical Pathways, Health Technology Assessments, and so on. The BIQG has not become operational as of fall 2008, so it is unclear if this Federal Institute will become a coordinative unit for commissioning and overseeing activities or if it will carry out research activities itself. Also, in 2005 the Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA) (16) was founded, based on a decision made by the research society Ludwig Boltzmann (a famous Austrian physicist) and consulted by international experts to invest in this promising field of applied research.

For a long time, HTA activities were not recognized by national health policy, but already internationally were well noticed. Retrospectively seen, Austrian HTA activities ran through different phases:

1989–1991: Orientation. In 1989, a small group of researchers at the Institute of Technology Assessment at the Austrian Academy of Sciences was working in the field of HTA, starting back then with a systematic review on international activities in this field of policy support (19;20). This phase can be called orientation.

1991 Until Today: International Networking and Collaboration. Getting engaged in the early

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Table 1. Players and Regulatory Instruments in Austrian Health Care

Institutions	Policy content	Regulatory instrument	Factual role of HTA (!! of relevance/impact on policy)
BMGFJ/Federal Ministry of Health, Women & Youth	Immunization schedule	In-/exclusion in public immunization schedule,	e.g., human papilloma virus excluded based on HTA
	Prevention programs	Investments in prevention programs	—
FHA/Federal Health Agency	DRG/Diagnosis-related groups	Annual allocation of "points" to DRGs,	
	MEL/Single Medical Procedures catalog	In-/exclusion of individual services into MEL catalog,	!! Since 2008, only interventions for which efficacy is scientifically proved get the MEL position
	Federal hospital services planning incl. big equipment	Determination of structural & minimal quality-volume requirements for specialized services	e.g., Vertebro-/Kyphoplasty was restricted to specific centers
		Health/ Hospital Plan & Major Equipment Plan	—
Ö-HVB/Federation of Austrian Social Insurance Institutions & EBM/Evidence Based Medicine at Ö-HVB	Drugs	Positive list/ register defining reimbursement in 3 categories/ boxes– open or restricted or not at all	HEK/Drug committee decides based on effectiveness and cost-effectiveness
	Interventions/treatments	Health services catalog/basket from social insurances defining reimbursement	EBM-HVB on individual services, !! HTA on performance evaluation of complex services (e.g., rehabilitation) or programs !! Development of algorithm for maintenance of service catalog
ÖÄK/Austrian Chamber of Physicians	Quality assurance basic education, advanced training	Guidelines,clinical pathways	—
Regional hospital cooperation in the 9 "Länder"	Investment/-disinvestment planning	Service planning and decisions, Investment decisions, Structural and minimal quality-volume decisions	!! HTA on effectiveness or cost-effectiveness of individual services !! HTA in strategic topics, e.g., profile of outpatient services in university hospitals, development of early warning system for oncologic drugs, pragmatic data collection; registries, monitoring studies, etc.

international cooperations, Austria changed its role of an external observer (EUR-ASSESS 1994/95) to active international collaboration (HTA-Europe 1996/97; ASTEC 1999; ECHTA 1999/2000; InnoHTA 2007/08; membership in INAHTA and ISTAHC/HTAi since 2004) and to setting initiatives for further European HTA-collaborative activities (EUnetHTA 2006–08) (23). In 2009, Austria is among the Founding Partners of the permanent European HTA-Collaboration EUnetHTA.

1991 Until Late 1990s: Assessments Based on Project Proposals, Applying for Third-Party Financing. Within this phase, the term "health technology assessment" was introduced into research proposals, first singular projects on topics partly associated to the broader, more comprehensive and less directly to policy decisions linked mother-discipline "technology assessment" and partly approaching clearly defined policy issues on investments were carried out: projects on the "shaping" of information technology (IT) technologies were on "Medcard/e-card" (1991), PACS/Picture archiving and communication system (1996/97), and genetic diagnosis of monogenetic-caused diseases and its implication to society (1995) (1).

1998 Until Today: Reactive Assessments on Demand for Reimbursement Institutions. Releasing research funding, investing them into HTA and demanding that HTA assisted in pending decisions marked the next phase of introducing HTA in Austria, moving HTA close to actual decisions and having an impact in individual institutions. Some examples: a report on extracorporeal shock-wave therapy (1998) (22), led to the decline of a reimbursement application (by orthopedics and manufacturer) by the Social Insurance corporations, a report on near-patient C-reactive protein (CRP) testing (2000) led to the coverage of CRP testing at outpatient pediatricians, a report on invasive aspergillosis in immunosuppressed patients (2001) led to diagnostic algorithms and step-wise therapy with anti-mycotica, and so on. Other reports, such as predictive genetic diagnostic testing for hereditary breast and colon cancer (2002) (15), had no direct impact on policy, but received increasing attention by the medical science community.

Since Approximately 2000: a Breakthrough in the Belief in HTA as an Applicable and Useful Instrument for More Rational Use of Resources and Especially of Health Technologies and

Simultaneously the Containment of the Overuse of Some Interventions. A report on erythropoietin (2000) (21) in tumor anemia led to response-control regulations and clinical guidelines in several Austrian institutions and, with it, to reductions in spending on erythropoietin of up to 21 percent of former expenditures. By then, even many clinicians were convinced that HTA is not meant to be an instrument for radical rationing, but for a systematic approach to take "a closer look." This marked the breakthrough of HTA in the relations to clinicians, industry, and reimbursement institutions.

Also Since 2000: Knowledge Transfer and Increased Public Understanding. An important role in the awareness of HTA concerned the efforts put into building up relationships with journalists, starting a monthly HTA newsletter (14) on international HTA results for a broader audience (academia, healthcare administration, research and development [R&D] funding agencies) offering seminars and advanced training on the methodology of HTA in general and on systematic searching for "secondary sources," such as assessments, reviews, and so on. Especially the latter supported reimbursers, and administration and funding agencies to become aware of the enormous international HTA and evidence-based medicine (EBM) outputs and the knowledge already available free of charge.

Since 2002 and Developing Hand in Hand With the Awareness of the Availability of International Knowledge: Challenge With More Difficult Topics. With the increasing awareness of the potentials of HTA, some institutions started to built up small units for EBM analyses and the topics demanded by policy from HTA became more complex, such as "evidence-based service planning" issues. Starting with the research question of "evidence-based intensive care unit planning" (2002) (24), followed by "regional planning of pediatric services for newborns in peripheral regions" (2007) (26) and defining "ambulatory services in university hospitals" (2007) (17), the idea of HTA of questioning the given, to reflect upon need rather than demand, was a challenge to move toward virgin soil in terms of methodology.

Since 1999: HTA as Catalyst for Networking Activities of Decision Makers. In the late 1990s, part of the Austrian HTA activities was to catalyze the exchange of evidence-based information between groups of decision makers having to deal with the same issue. The establishment of a middle-European network of representatives of health insurance entities meeting once a year (attended by Germany, the Netherlands, Austria, Luxembourg and Switzerland) (20) and the establishment, coordination, and scientific mentoring of a network of Austrian hospital managers "HTA in hospitals" meeting three times a year since 2002 led not only to the mere exchange of information and its effect of vigor and mightiness for decision makers in hospitals to enter negotiations with increased knowledge, but also led to a certain harmonization of nationwide decisions and policies on health interventions. Additionally, because the format of the "HTA in hospitals" meetings was/is that of a moderated dispute (a clinical protagonist of a new healthcare intervention characterizes the "innovativeness," while an HTA methodologists presents the synthesis of the state of knowledge and the critical appraisal of the given clinical studies in a broader context), the invited clinicians were increasingly motivated to present their perspective in a more systematic, less selective, and more critical manner. This network caused the explicit demand of reimbursers on health policy for a more transparent way of in-/exclusion of new interventions into the hospital service catalogue.

Since 2004: Inclusion of HTA as Vocational Module in Postgraduate Education and Academic Training. Within the Public Health postgraduate program and in Health Care Management Master programs, HTA has been a module for years. In addition, with the foundation of colleges of higher education in health management, HTA has become a demanded field for internships and first work experience as much as for topics for master theses. Inherent in this capacity building, the knowledge in HTA and its application is diffusing fast to healthcare managing institutions.

In 2005: Institutionalization of HTA. The founding of an academic Austrian HTA institute was initiated by the tender of one of the main research societies (the Ludwig Boltzmann Society) to found a new research institute in promising fields of translational research. One of the requirements for the foundation was/is that the translation of the applied research findings into practice must be guaranteed by means of the partly cofinancing of those in need of knowledge. In coherence with this research policy, the financing of the Ludwig Boltzmann Institute of Health Technology Assessment with 12 FTE staff is based on 60 percent national and regional R&D funds and of 40 percent raised by the research applying institutions, namely the Ministry of Health, the Federation of Health Insurances, several regional hospital cooperations, and (private) medical universities. The institutionalization brought along not only increased public awareness, but also, going along with the commitment of the funders, an increased demand for HTA knowledge especially in three fields: (a) "hot" and interest-group driven political topics, that need so be based on sound and highly credible research (human papilloma virus vaccination, folic acid supplementation, off-label use of Avastin in age-related macular degeneration); (b) development and evaluation of policy instruments to implement HTA (methodology of monitoring interventions in their early deployment [monitoring studies, registries]), development of transparent processes for in-/exclusion, and maintenance of interventions in clinical practice and reimbursement (catalogues for single procedures in hospitals, algorithm for processes for health insurance basket, development of "early warning" system for oncologic drugs in hospitals); and (c) enforcing public understanding and discussion on ethics in resource allocation, not only on the direct

Table 2. HTA Initiatives in Austria: Academic- and Administration-Associated Institutions and Working Groups

Ludwig Boltzmann Institute for Health Technology Assessment/ LBI-HTA Wien: http://hta.lbg.ac.at/
Inst. Public Health, Medical Decision Making and HTA/ Hall in Tirol: http://phgs.umit.at/
EBM Review Center/ Graz: http://apps.healthgate.at/ebmrc/index.jsp
Department for EBM and Clinical Epidemiology: http://www.donau-uni.ac.at/de/department/evidenzbasiertemedizin/index.php
Working Group on research-based health services: http://www.arwig.at/
EBM-unit at the Federation of Austrian Social Insurance Institutions: http://www.sozialversicherung.at/
Federal Institute of Quality in Health Care/BIQG: http://www.goeg.at/

Note. See Reference 1.

reimbursement (micro-) level, but also on meso- and macro-levels on priority setting within the healthcare budgets.

Since 2005: Many Other HTA Initiatives and Working Groups Start Working. In 2005, the Institute for Public Health, Medical Decision Making and HTA was founded at the private University of Medical and Information Technology (UMIT) in Hall/Tirol (Table 2). The institute mainly works in the field of modeling and decision analysis and is in the process of setting up an international HTA Mastercourse. A small EBM working group at the Federation of Austrian Health Insurance in Vienna is considered to be a service unit for internal requests on the efficacy of health interventions for regional health insurances. The EBM Review Center at the Medical University of Graz as much as the working group evidence-based health services research (ARWIG) carry out systematic reviews and meta-analyses on national (BMGFJ, regional requests) and international (IQWIG, DAHTA) demand (third-party projects). A small unit at the Danube University in Krems was founded in early 2008, focusing on EBM in preventive medicine. Finally, the Department of Health Economics at the BIQG will build an HTA unit in the near future.

DISCUSSION: UNIQUE FEATURES OF AUSTRIAN HTA DEVELOPMENTS

Austria, as a small country and as a latecomer in implementing evaluations/HTA as decision support can to a certain degree absorb the increasing international knowledge. Austria had a long time to observe the success and failures of HTA in other countries and to learn from other countries. However, it was not the wish for a more evidence-based, rational or equity-based healthcare system that was the primary motivation for finally turning toward HTA. It was the pressure on the healthcare budgets that increased such that the administrations have been forced to react and to incorporate instruments in favor of "appropriateness" of resource allocation: There is a huge and inflationary need for synthesized knowledge about the effectiveness of new or established healthcare interventions, the production of evaluative and interest-free knowledge, and enforced implementation of evaluations/assessments in the decision-making process in health care. These factors finally led to HTA receiving the political attention HTA was given in other Western countries years ago.

In the first years of HTA's recognition as a valuable tool to synthesize knowledge and to support health policy, HTA was used for a long time only in a retrospective manner, such as (i) naming inappropriateness, over- and misuse of interventions, and supporting evidence-based prescribing and the development of appropriateness criteria for reimbursers; (ii) pointing at regional variances with equal clinical outcome and supporting harmonization/standardization and, with it, the least resource-intensive intervention.

In the latter years, since approximately 2002, HTA is more often used in a prospective manner, such as (i) supporting drug purchasing policies by distinguishing between original and me-too products, (ii) distinguishing between need and demand and supporting evidence-based planning, (iii) evaluating new and emerging technologies and supporting only "mature" technologies and those with added value to diffuse, (iv) building up an "horizon scanning program" for oncology, (v) enforcing the public discussion on quantitative and qualitative thresholds for distinguishing between new and innovative, effective, and cost-effective.

HTA in small countries has a different profile than in bigger countries: the focus is rather on (i) putting international effectiveness knowledge in a national context (style of practice and application, quality assurance, economic analysis, etc.); (ii) reacting to specific national requests (over- or underuse of in-/effective interventions); (iii) making international knowledge available, that is, knowledge transfer and science and research communication (public understanding); (iv) structuring and accompanying the implementing process; and (v) moving toward further exploiting the potential of HTA methodology for complex issues (evidence-based planning, monitoring of real-life application). In any case, for smaller countries, international cooperation and collaboration is even more important, because of the limited resources and the need to reduce redundancy to react quickly to policy's demand for evaluative knowledge.

LESSONS TO BE LEARNED: CONCLUSION

HTA started as an academic activity by initiative and efforts of individual researchers in the late 1980s, not yet recognized

by national health policy, received international regard long before national attention, convinced with early singular projects on over- or misuse of health technologies with some/good impact in the mid 1990s, received increasing attention until approximately 2005, and was then, after 25 years of small-scale activities rewarded with an institutionalization in the form of an academic institute, namely the Ludwig Boltzmann Institute of Health Technology Assessment. In recent years, HTA has been used as a method to support policy preferably where there are already existent policy instruments for implementation. Those are:

- The Single Procedure Catalogue on interventions offered in hospitals: all new interventions that receive reimbursement have to go through an evaluative process. Some HTAs have been used for such decisions first in 2008, the role of HTA will be enforced.
- The Basic Benefit Catalogue of the health insurances and the "positive" list of the interventions and medicaments that are reimbursed: HTA has been used for evaluations of pharmaceuticals that are under "access-control."
- Institutional Hospital Drug Commissions are using HTA increasingly as the basis for "consensus-conferences" on decisions about the appropriate use of pharmaceuticals.
- Hospital Departments on Investment Planning, including for ITs, are increasingly using HTA for considerations on organizational changes coming along with IT implementations (e.g., Telestroke).
- In the Planning of Preventive Programs (Screening and Vaccination), HTA has been used (predictive genetic testing or colon screening) to define requirements and measures for quality assurance.
- In the Regional Planning of low-frequency elective surgery ("concept of minimal-frequency") or high-cost interventions (e.g., intensive care) HTA has been used.
- The Development of Clinical Guidelines by clinicians is accompanied by HTA teams in systematic methodology.
- The demand for HTA as a management skill is increasing, especially in the peer group of "young university professors" striving for management positions.

Health Technology Assessment Is Product- and Process-Oriented

The actual production of assessments for decision support is as important as the support of the process of decisions for change. Additionally, shaping the public understanding of science (characterized by the intrinsic belief that all new medical interventions provide added value to the healthcare system) is part of Health Technology Assessment. The next steps already foreseen to come are a formal and obligatory linking to reimbursement decisions and a national comprehensive strategy for HTA in Austria.

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