

- Der Zugang zu EPO sollte jedenfalls auf die zugelassenen Indikationen – Tumoranämien – beschränkt sein.
- Innerhalb der Indikationsbereiche ist es notwendig, die Anämie genau abzuklären, Fehlindikationen auszuschließen, und Richtwerte für Beginn und Dauer der Behandlung, bzw. Kontrolle zur Respondenz sowie Abbruch der EPO-Gabe zu definieren.
- Eine Anwendungsbeobachtung, ob EPO in der verbesserten Tumor-Oxygenierung auch außerhalb klinischer Studien zum Einsatz kommt, ebenso wie eine Evaluierung zur Wirksamkeit in verschiedenen präoperativen Indikationsbereichen scheint notwendig. Es besteht die Vermutung, dass EPO in zahllosen medizinischen Bereichen fehlverwendet wird.

Evaluation medizinischer Intervention als relevantes Politikinstrument

Die Evaluation medizinischer Interventionen – Health Technology Assessment – muss heute in Deutschland und Österreich gegen das „Stigma“ ankämpfen, Patienten bislang erbrachte Leistungen nunmehr vorenthalten zu wollen. Das Ziel von HTA ist aber, Ineffizienzen, d.h. überflüssige und unnötige Leistungen, in den Griff zu bekommen und, bei gleichbleibender Qualität der Gesundheitsversorgung, sogar noch zu einer Qualitätssicherung beizutragen. Optimisten glauben, dass aufgrund der Beseitigung von Ineffizienzen der Einspareffekt so groß wäre, dass bei gleichbleibenden Sozialversicherungsbeiträgen die Qualität sogar noch erhöht werden könnte. Klar ist jedenfalls, dass die Evaluation des medizinischen Leistungsgeschehens nur dann einen Effekt zeigen kann, wenn sie als Gesundheitspolitikinstrument auch ernst genommen und eingesetzt wird.

Literatur

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Possibilities for partial integration of Health Technology Assessment (HTA) and Technology Assessment (TA)

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In the light of the growing impact of biomedicine and health care issues possible areas of co-operation are discussed. Mutual exchange of information and partial integration of training in HTA and TA would have to play an important role.

Introduction

As has been pointed out by Leonard Hennen in his contribution on page 13, HTA and TA should be regarded as complementary rather than competitive. The fact that HTA has developed its own methods and approaches over the past 25 years should not give reason to ignore the achievements of TA and vice versa.

From a methodological point of view, HTA employs nowadays quite sophisticated methods to assess the costs and benefits of a given technology in a quantitative way whenever possible. However, it falls short if it comes to the assessment of social, ethical and legal consequences of the application of health technologies. The data-driven approach in HTA should not be taken as an excuse to neglect topics that cannot be “measured” easily. HTA tends to limit its scope to a single tech-

nology or a certain procedure. Typical examples are laser treatments for short-sightedness, magnetic resonance angiography for renal artery stenosis and anticoagulation regimens after heart valve replacement. HTA aims at decision-making, most often for coverage decisions, of particular technologies on the level of social insurance.

On the other hand, TA in biomedicine is often concerned with similar technologies albeit in earlier development stages. TA uses the approach of policy analysis and employs rather qualitative methods. Both approaches, TA and HTA have their focus on the discussion of emerging technologies or technology areas, which do not always translate into practical applications at the time of assessment. Typical current examples include xenotransplantation, the Human Genome Project, information technology. TA is concerned with the implications of technology for policy-making. This is a fundamental difference to HTA: While HTA aims at decisions that are usually outside the political level (exceptions exist!), TA is located exactly at that level and aims at informing the law-making process. Consequently, TA considers the perspectives, interests and values of social groups while HTA assesses technologies from different perspectives (including the clinical perspective, payer, patient and societal perspectives).

Thirdly, TA and HTA cover different aspects of the same technologies. This is for example the case with telemedicine applications. While HTA explores the dynamics of diffusion, possible health benefits, organisational impacts and costs of such applications, TA might concentrate on the implications for the patients' privacy, data protection and commercialisation. Both approaches are necessary but may lead to different consequences or decisions taken. While the result of a HTA may favour a specific telematic application, a TA could raise serious concerns with regard to existing legislation. In such cases, politics needs information from the perspective of TA (is the technology consistent with existing laws / conventions, does it raise ethical concerns etc.) *and* from HTA (does the technology benefit the patient, who benefits most from it, how costly is it etc.).

In the following, some areas of useful and necessary co-operation of TA and HTA will be discussed. It should be stressed that such co-operation could be of mutual benefit for both the TA and the HTA community and for the multitude of decision-making processes in health care as a whole. The areas of co-operation outlined below should also be regarded as focal points of possible joint assessments of technologies that affect both decision-making at the level of health insurance and health policy in general. The Austrian Academy of Sciences with its Institute of Technology Assessment may serve as an example which fully integrates HTA as well as TA in one institution: since researchers from various disciplines are part of a (H)TA team, an interdisciplinary approach is more likely than in pure HTA institutions.

Possible areas of co-operation between HTA and TA

Innovation research

Traditionally, Health Technology Assessment is initiated after an innovation has entered the market already. In this situation, an assessment should take place in the early phase of diffusion. This is often the case when new technologies are limited to specialised centres, such as university hospitals. However, this approach is limited in that it may only *react* to developments. Apart from marketing studies, only few attempts have been made to evaluate innovations during their developmental stages for their potential effects on patients' outcomes and costs. Marketing studies are usually designed to estimate whether products will be profitable. However, this approach falls short of the aim of HTA to assess the potential of new technologies for public health in a scientific manner. The impact of innovations on societal or ethical issues (such as innovations based on fetal tissue or the screening of hereditary diseases) apart from their potential clinical benefits, is often outside the scope of HTA. Thus, a framework for assessing the social impacts of health technologies beyond a (certified) clinical benefit is clearly needed to complement the picture of a technology in its social context. Such a framework could be

developed and provided by a TA project. Since the innovative status of a technology is not always clear, a link to priority setting activities should be maintained.

Priority-setting

While many topics for assessment are determined by the regular tasks of HTA agencies, others may be chosen more freely. The criteria for choosing topics for assessments may differ between HTA and TA, but the methods of how these criteria are applied are probably similar. In HTA, epidemiologic criteria such as prevalence, mortality, costs and burden of disease are regarded as important. In addition, the need for making a decision about a specific technology and the anticipated impact in terms of change in management and costs and possible outcomes are used increasingly. From this perspective, HTA could be regarded as technology in itself and thus is required to prove its usefulness.

Priorities in TA are set by the political agenda. Important criteria include possible impacts of a new technology on public goods, such as health, safety, environment, costs; competing interests or values within the society; distribution of costs and benefits within the society – in sum, the relevant question here is: is there a public interest in a given technology?

One possibility of co-operation would be the exchange of information in order to better understand relevance and interest in specific topics, e.g. epidemiological relevance, ethical issues or long-term consequences of health technologies.

Public participation

HTA tends to ignore media and public interest in health technologies as long as these do not result in a demand for a specific technology which might entail an increase in health care costs. Even if the public interest is considered in HTA, it is usually used only as an argument for initiating a HTA. There are, however, also a few examples where public participation has a role in HTA. This could be explained in part by the role of HTA in elucidating the risks and benefits of a technology for patients and for the

health care system, but not in informing the public opinion.

In contrast, as Hennen describes in his article, TA seeks answers for questions which are beyond clinical considerations but affect the society as such and, therefore, should be answered by society. The involvement of the public in such broader considerations has led to the development of methods of public participation in TA, i.e. the participation of “lay people” in TA (e.g. Consensus Conferences according to the Danish model; expert-stakeholder TA as developed in the Netherlands). HTA could supplement the information provided in such participatory TA projects. It should be discussed, how the lay perspective elucidated in participatory TA approaches could be integrated into HTA and vice versa.

Implementation and impact research

While implementation research is concerned with methods of successful translation of TA results into practice, impact research focuses much more on the issue of the effects of a TA report. Within a comprehensive TA programme which includes all steps from priority-setting to impact research, criteria for implementation and measuring the impact of TAs should be defined. This may not be an easy task, since sometimes the impact is on the level of awareness or aims at providing input for the informal decision-making processes and no clear relation between a decision and a TA may exist or become evident. Such problems are probably similar for TA and HTA, and there is obviously a need for further research and conceptualisation in both areas.

How could closer co-operation be achieved?

Information

One of the most important prerequisites of closer co-operation is information. HTA and TA institutions should exchange their reports on a regular basis. This could be achieved by feeding results of the TAs into a database. In HTA, a major database has been established which covers structured abstracts of HTA reports from most of the publicly funded HTA

institutions (<http://agatha.york.ac.uk/welcome.htm>). The TA database of ITAS (<http://www.itas.fzk.de>)¹ covers TA projects in Europe (mainly Germany) but also worldwide, including TAs in biomedicine but only occasionally HTAs. These limitations could be overcome if there were an exchange of structured abstracts of projects to be included in the respective databases. A common database is also possible but carries the difficulty that both databases have their own history, use different sources and methods and aim at a different audience, therefore a continuation of the established databases with regular mutual exchange of abstracts seems to be more promising.

Training and education

With regard to training and education in TA, especially two issues should be kept in mind:

- a relatively small number of academics and other experts are currently active in the field;
- a large number of new and existing medical technologies need evaluation.

Successful TA programmes require an appropriate education and training strategy. For example, training and education in HTA through effective educational means is targeted at expertise, organisation and staff qualification. It is therefore important to distinguish between career researchers who need full technical skills, temporary researchers who may need training for specific skills, commissioners who need appraisal and implementation skills, and the clinical work force, which needs awareness. It is no longer just the implementation of findings which is important, but increasingly it is also the integration of HTA into the implementation of the technology which is essential.

To date, few opportunities exist for training in TA. It would be an interesting option to partially integrate training in TA and in HTA. This could be realised by exchanging junior staff between agencies, inviting experts to workshops and – in the medium term – work out a curriculum in TA / HTA that specifies the requirements for carrying out TA studies.

Joint projects

A number of joint projects between HTA institutions have been realised in the International Network of Agencies for Health Technology Assessment (INAHTA) with some success. Joint projects between TA and HTA institutions are possible on topics that encompass both clinical and societal aspects of technologies. If technology assessment is perceived as a multidisciplinary task, such joint assessments would benefit both the TA and the HTA community and would also serve as a training opportunity for researchers.

Conclusions

TA in biomedicine and HTA are tools for knowledge management in order to prepare health care decisions on different levels. Taking the limited financial resources of health care systems into account it can be foreseen that the demand for TA and HTA will grow enormously. While HTA may be used to filter out ineffective but costly interventions TA may play a greater role in steering health care technologies in a socially more acceptable and desirable direction.

TA and HTA are complementary rather than competitive tools based on the shared intention to give input for a more needs-based R&D health technology policy and a more patient-oriented health care provision.

Note

- 1) The TA-database of ITAS is no longer available online, but only on CD-ROM. For further details see the ITAS homepage at <http://www.itas.fzk.de>.

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