TA in Biomedicine and Healthcare – from clinical evaluation to policy consulting[1]

by Leonhard Hennen, Office of Technology Assessment at the German Parliament

In the light of the heavy media coverage of the race for sequencing the entire human genome in the last year and the expectations and promises of a break through in medical treatment and diagnosis connected with the Human Genome Project (HGP), it can not come as a surprise that the European Parliamentary Technology Assessment Network (EPTA) has chosen "TA in Biomedicine and Health Care" as subject for its Annual Conference in Berlin last year. But apart from its topicality the choice was also motivated by the growing importance of Biomedicine and Healthcare issues in the work programmes of the EPTA organisations in recent years. Parliamentary Technology Assessment as carried out by EPTA organisations always included TA on health care issues. This occupation of parliamentary TA with Biomedicine and Health Care has however, remarkably enough, developed in some distance from activities going on in what is internationally known as Health Technology Assessment (HTA). The choice of the conference subject thus also offers an opportunity to bring two perspectives on Health Technology – Parliamentary Technology Assessment (PTA) and Health Technology Assessment (HTA) together and see if (and if so how) these two perspectives can learn from each other. The paper will give a brief overview over the field of TA in Biomedicine and Health Care as carried out by parliamentary TA institutions as well as by HTA institutions in order to identify those features both approaches have in common and some peculiarities of each approach to health care issues.

Looking back into the history of Technology Assessment

The cradle of Technology Assessment has been standing at the US Congress in Washington, D.C. This is undoubtedly true for Parliamentary Technology Assessment. But it also applies to Health Technology Assessment as a particular branch of TA that developed rapidly and independently from parliamentary TA during the 80es and 90es.

Among the huge amount of projects carried out by the Office of Technology Assessment (OTA) of the US Congress during its 17 years of existence health care issues always played a major role. One of the first reports delivered by OTA to the Congress in 1975 was dedicated to the *Development of Medical Technologies: Opportunities for Assessment* (OTA 1976). This report is considered as the kick off point for their profession by the international community of professional HTA experts. Objectives, subjects and methodology of health technology assessment were outlined for the first time in this report, and the report nowadays still is referred to in debates on issues, objectives and procedures of HTA.

HTA and TA institutions at national parliaments both share the same origin and of course have objectives and some of their methods in common. But during the seventieth and eighties HTA developed into an international, word wide community particularly dedicated to TA on health care issues. Health technology is the only field of technology assessment so far which has gained a distinctive profile in the sense of a particular subject, client, expertise and specialised institutions. HTA like TA in general aims at supporting decision making by providing comprehensive information on the preconditions for, and consequences of the implementation of new technologies. Whereas parliamentary TA units do this for a broad range of technologies and fields of technology policy following the agenda of political discourse, Health Technology Assessment is restricted to a particular field of technology application and a particular set of problems. Generally the explosion of costs in the health care sector caused by expensive new technologies is seen as the reason why HTA continually gained in importance and has gradually been established at hospitals, medical research institutes, and at national health care administration bodies. What is generally called "High Tech Medicine" put the publicly funded health care systems under pressure, and increasingly led to demands to justify costly new medical applications.

As we can learn from the preface of the OTA report from 1976, the motivation of the Senate Committee on Labour and Public Welfare to charge the Office with tackling the issue of HTA was

> "to examine Federal policies and existing medical practices to determine whether a reasonable amount of justification should be provided before costly new technologies and procedures are put into general use" (OTA 1976, p. vii).

It was the expensiveness of new technological applications in health care (at that time, e.g. coronary bypass surgery, ultrasound foetal monitoring, computer tomography), which led to initiatives to assess new technologies with regard to their safety, effectiveness and costs before widely introducing them into medical practice.

A definition of Health Technology Assessment published in 1997 in the final report of a project on the role of HTA funded by the European Union underlines the importance of the cost versus medical benefit subject, when stating:

> Health Technology Assessment "... includes studies of ethical and social consequences of technology; factors speeding or impeding development and diffusion of health technology; the effects of public policies on diffusion and use of health technology and suggested changes in those policies; and studies of variation in use of technologies."

And then the report continues:

> "The *most prominent part* of HTA is to determine, insofar as possible, the benefits and financial costs of a particular technology or group of technologies. The main goal of such studies is to improve *'value for money'* in health care." (Introduction to the EUR-ASSESS Report 1997, p. 135).

Technologies and problems dealt with in Health Technology Assessment

HTA mainly has been and still is occupied with studies focusing on the one hand on the economic evaluation of costs caused by new technologies for the health care system, and on the other hand on the clinical evaluation of the efficacy and safety of new technologies and medical treatment with regard to the patient's health. The perspective taken by HTA studies when dealing with new diagnostic and therapeutic technologies is to a large extent determined by the clinical setting made up by

- the patient (his health, safety, right to know);
- the technology (its performance and costs)
- and by the medical expert, physician (his education, problems of medical decision making, questions of best medical practice).

To illustrate the broad range of medical procedures and technologies that have been scrutinised under the lens of HTA, some results of a survey which was carried out in 1995 on behalf of the Office of Technology Assessment at the German Parliament (Petermann, Sauter 1996) will be presented. This survey covered 815 HTA studies published between 1980 and 1995. The studies were classified according to the type of health care technology dealt with and the problems or dimensions of possible impacts examined.

Most of the studies covered by the survey deal with new therapeutic and diagnostic health technologies and medical treatments. Besides this however, HTA covers the whole range of technological innovations relevant for clinical practice as well as for hospital management (see Tab. 1).

Tab. 1: Classification of 815 HTA studies (1980-1995)

Subjects of studies	*Number of studies*
Technologies for Therapy	360
Technologies for Diagnosis	225
Management of Disease	85
General Subjects	80
Systems Management	40
Prevention	13
Critical Care and Survival	8

Looking at the *subjects* of the individual studies covered by the survey in greater detail there seems to be no promising new technology or procedure for health care which has not been covered by HTA. New technological trends and emerging chances and problems of the health care sector, such as the use of information technology for hospital management, exploding costs of health care etc. are the subject of a

great number of HTA studies. In all there seems to be a dominance of new technological applications induced by imaging, information and communication technologies. Biomedical technologies (e.g. genetic testing for prenatal diagnosis) also become a subject of HTA in the 90es. At least the range of studies covered in the TAB survey indicates that – interestingly enough – biomedical issues have for the most part been dealt with in studies carried out on behalf of parliamentary TA bodies.

Most of the studies categorised under *Therapy* deal with technologies and programmes for heart, liver, kidney and bone marrow transplantation. One also finds studies on surgery technologies like minimal invasive surgery, technologies for heart and vascular surgery. One of the most extensively studied field in this category is also the most expensive: new laser technologies. A great number of studies is devoted to oxygen therapy and cancer chemotherapy. There are, however, only four studies on gene therapy, and three of them were carried out by parliamentary TA institutions.

Among the studies dealing with technologies and procedures for *Diagnosis* imaging technologies and other technologies for records of diagnostic data make up the greater part – ranging from well known technologies like X-ray and EEG or ultrasonic monitoring to very special technologies like cell photography. The focus here again is on cost intensive technologies like computerised tomography and nuclear magnetic resonance imaging. We find 12 studies on DNA-diagnostics (genetic testing) in this field – again most of them were carried out in the context of parliamentary TA.

The sample *Management of Disease* contains studies which are not intended for therapy in the sense of healing but for the management of the quality of life of the patients such as hemo-dialysis technologies and acute pain treatment, implantable infusion pumps for insulin, and management of long-term care. The most extensive group here is made up of studies on technologies and management for home care.

The focus of the studies dedicated to *General Subjects* is on the development of costs in health care and health insurance. Apart from this a number of "self reflective" ("meta"-) studies dealing with the development of HTA itself, education and training for HTA, status reports on research on health care technologies are subsumed under this category.

The growing importance of information technologies for *health systems management* is mirrored by a great number of HTA studies dealing with hospital information systems, expert systems (Computer-Assisted-Decision-Support for Physicians) and medical smart cards.

In the survey only few studies were found on the *prevention* of disease (e.g. of aids, osteoporosis, and cancer). This is however changing in recent years. Statements of representatives of the International Society of Technology Assessment in Health Care indicate that the HTA community intends to re-orient its work by including studies on the opportunities for prevention of disease instead of therapy only.

Finally, under the heading *Critical care / survival* new technological options for intensive care for extremely pre-term infants, or live sustaining technologies for elderly people range most prominently.

Looking at the dimensions of possible impacts of health technology which are mainly paid attention to in HTA studies we can plainly see the above mentioned focus on questions of costs and medical efficacy (see Tab. 2).

It is however also plain to see, that apart from issues which could be said to be merely clinical ones, we also find studies dedicated to more general questions of ethics (such as, e.g. the moral status of brain dead patients), of social consequences (the acceptance of disease and disabled persons in society), social acceptance of new technologies for medical treatment (gene therapy), statutory regulation of application or studies dealing with the development of health care in general. In recent years the growing importance of this type of questions for HTA is widely discussed as a new challenge for the HTA community. It is held to be necessary to expand the scope of HTA studies by including social effects and the social objectives of the health care system (growing importance of prevention) and to include the different ethical perspectives held by social groups on the application of new health technologies (EUR-ASSESS Project Subgroup 1997).

Tab. 2: Dimension of effects/impacts of HT, Problems primarily discussed in HTA studies

Dimension	*Number of studies*
Effectivity and Efficacy Medical effectivity (medical benefit); Clinical efficacy, Feasibility, Quality Control; Clinical decision making; Patients benefits (quality of life)	**124**
Economic aspects Cost effectiveness Does Technology reduce costs for health care? Assessment of new costs for the health care system or health insurance Comparison of costs between alternatives of treatment	**80**
Technical and Management Aspects Implementation and diffusion of technology in the health care system, Technical Infrastructure; Optimisation of HT; Hospital management, Communication	**50**
Safety aspects Chances and risk trade off Technical security	**30**
Legal aspects Regulation of application, Health Insurance	**40**
Political Aspects Health care planing, Political options	**30**
Research, "reflexive" HTA Research and development of health technology (funding, status of research, institutions)	**30**
Social aspects Social benefits, Acceptance, Health education	**29**
Ethical aspects	**20**

It is however also plain to see, that apart from issues which could be said to be merely clinical ones, we also find studies dedicated to more general questions of ethics (such as, e.g. the moral status of brain dead patients), of social consequences (the acceptance of disease and disabled persons in society), social acceptance of new technologies for medical treatment (gene therapy), statutory regulation of application or studies dealing with the development of health care in general. In recent years the growing importance of this type of questions for HTA is widely discussed as a new challenge for the HTA community. It is held to be necessary to expand the scope of HTA studies by including social effects and the social objectives of the health care system (growing importance of prevention) and to include the different ethical perspectives held by social groups on the application of new health technologies (EUR-ASSESS Project Subgroup 1997).

Parliamentary TA and Health issues

Let us now turn to Parliamentary Technology Assessment: What are (or have been) the focal points of institutions carrying out TA studies for the support of parliamentary decision making when dealing with health care issues? To find an answer to this question the studies carried out in the field of health and healthcare by the member organisations of the European Parliamentary Technology Assessment (EPTA) Network* during the nineties were analysed by scanning their homepages and work programmes as far as available. This does not claim to give a systematic and comprehensive overview of what EPTA organisations have been working on in the medical field in the last decade but should nevertheless provide a rather reliable picture. Looking at the projects and publications of EPTA (without making a difference between comprehensive TA studies and short term projects) the following clusters of subjects which were dealt with comes up (see Tab. 3 and 4).

Tab. 3: TA studies related to health and health care issues carried out by PTA organisations

Subject	*Number of studies*
Environment, Technology and Health Risks	24
Information Technology and Health Care System	10
Health Care System	7
Health Technology / Diagnosis, Therapy	10
TA in Health Care / Methods, Objectives	7
Biomedicine / Human Genetics	32

Tab. 4: TA studies related to health and health care issues carried out by parliamentary TA organisations*

- *Environment, Technology and Health Risks (24)*
  Bacterial food poisoning (POST)
  Drinking water and health (OPECST, Teknologiradet, TAB)
  Allergy Policy (Teknologiradet)
  Environment and Health (TAB, OPECST)
  Genetically modified food (Teknologiradet, TAB, Swiss TA Centre, STOA, POST)
  Chemical substances in food (Teknologiradet)
  Infertility (Teknologiradet)
  Environment and health impact of aviation (STOA)
  Physiological and environmental effects of electromagnetic radiation (STOA, POST)
  PCBs and Dioxin: Environment and health effects (STOA)
  Deliberate release of GMOs (STOA, TAB, OPECST, Rathenau, ITA)
  Effects of heavy metals on environment and health (OPECST)
- *Information Technology and Health Care System (10)*
  The digital hospital (ITA)
  Tele-medicine (Teknologiradet, ITA, Committee for the Future)
  Medical card (ITA)
  European health card (STOA)
  Information Technology in Health care (Rathenau)
  Automation in the health care sector (Rathenau)
  Computer based medical dossiers (Swiss TA Centre, Rathenau)
- *Health Care System (7)*
  Socio-economic effects of Alzheimer disease (ITA)
  Geron-technology (Committee for the Future)
  Progress in pharmaceutical research and Technology and the ageing of Society (STOA)
  Prediction and prevention (Rathenau)
  Assisted Technology for Disabled Persons (Rathenau)
  Assisted technology and elderly people (ITA)
  Technology in extramural health care (Rathenau)
- *Health Technology / Diagnosis, Therapy (10)*
  Vaccines and their future role in public health (POST)
  Electronic and other implants (Rathenau)
  Shock-wave-therapy (ITA)
  EPO in Tumour Anaemia (ITA)
  CRP measurement (ITA)
  Ultrasonic prenatal diagnosis (Swiss TA Centre)
  Diet and heart disease (POST)
  Radiotherapy and cancer treatment (POST)
  Silicone Implants (STOA)
  Orphan drugs (STOA)
- *TA in Health Care / Methods, Objectives (7)*
  Education for TA in health care (ITA)
  Co-ordination and networking in HTA (ITA)
  HTA evaluation methods in Europe (ITA)
  Health Technology Assessment and evidence based medicine in www (ITA)
  Role of Health Technology Assessment (Rathenau)
  State and Perspectives of HTA (TAB)
  Towards a justifiable application of medical technologies (Rathenau)
- *Biomedicine / Human Genetics (32)*
  Genetic testing/genetic screening (TAB, Teknologiradet, Rathenau, POST, SWISS TA, ITA, Council of Europe)
  Xeno-transplantation (SWISS TA Centre, TAB, Teknologiradet, Rathenau)
  Gene Therapy (TAB, Teknologiradet, STOA, ITA, SWISS TA Centre)
  Reproduction and birth (Rathenau)
  Patenting Human DNA (POST)
  Life sciences and human rights / bio-ethics in general (OPECST, Rathenau, STOA)
  Cloning (Rathenau, TAB, Council of Europe)
  Therapeutically Cloning (OPECST)
  Prenatal Diagnostic, medical assisted fertilisation (OPECST)
  Research on human embryos (STOA)
  Bio-informatics (STOA)
  Sequencing the Human genome (STOA, POST, TAB)
  Reproductive Technologies (POST)

* Swiss TA Centre / Centre for Technology Assessment at the Swiss Science and Technology Council
Committee for the Future, Parliament of Finland
Council of Europe / Committee on Science and Technology, Parliamentary Assembly of the Council
ITA / Institute for Technology Assessment of the Austrian Academy of Sciences
TAB / Office of Technology Assessment at the German Parliament
OPECST / Office Parlementaire d'Évaluation et Choix Scientifiques et Technologiques, France
Rathenau Institute, Netherlands
POST / Parliamentary Office of Science and Technology, United Kingdom
STOA / Scientific and Technological Options Assessment Programme, European Parliament
Teknologirådet / Danish Board of Technology

Easy access to information on the EPTA Network and its member organisations is possible via the newly created common website at http://www.eptanetwork.org/

A first cluster consists of studies dealing with *health risks caused by technology and environmental problems*. This of course is a field of investigation which belongs to TA from its beginnings: Environmental pollution has been one of the first issues which caused demands for long term impact assessment of new technologies. The subject here is not health care as such but environmental and health impact assessment as a responsibility of governmental departments for environment and technology policy rather than health care departments. In some studies – as in more general studies on environment and health – problems of the health care system are involved when it comes to questions of prevention and diagnosis of environmentally induced diseases. In general however the studies are not related to the field of health care policy but to environmental policy.

The second cluster is related closer to subjects of classical Health Technology Assessment but with a focus on particular implications with regard to policy making. The perspectives opened up by *Information Technology* for health care go beyond problems of the clinical setting and relate health care to general problems of the so called Information Society. On the one hand information technologies like the medical electronic card for the storage of medical records of patients are a means to facilitate the exchange of information on the aetiology of a person's disease, on the treatment the patient has had so far, on known susceptibilities towards drugs etc. for the advantage of the patient. On the other hand technologies like the medical card might be a danger to the patient's privacy; it must for example be prepared for the patient's right to know what data are stored on his smart card and misuse by third parties (employers, insurance companies) should be excluded. The rights of a patient as citizen might be afflicted in these cases, so the problem at stake is directly connected with general political debates on data protection and privacy in the Information Society. In the case of the prospects of Tele-medicine the problems at stake go beyond the responsibilities of health care management and administration. Tele-medicine shows the way to a fundamental structural change in the health care system opening up opportunities for reducing costs, on the other hand however it leaves unanswered questions of medical responsibility, quality of information, commercialisation of health care etc..

The studies carried out by EPTA organisations include several studies on *general problems of the health care system.* Typically these are problems connected with the general demographic change in western societies. The ageing of society and the availability of technologies for home care (in order to take some load from hospitals and improve the quality of life for elderly people) are prominent here. We find as well some projects dealing with particular HTA issues in a more clinical sense. For example, HTA has been a main field of activity of the Institute of Technology Assessment at the Austrian Academy of Sciences from the beginning of the nineties. This might be due to the fact that a specialised institution for HTA is missing so far in Austria. The fact that projects on health technology in a narrower sense have

been carried out by EPTA member organisations in recent years (apart from Austria, this includes also the TA unit of the European Parliament, STOA; and POST, the TA unit of the British parliament) indicates that there is no strict separation between PTA and HTA with regard to the issues coming to the attention of the respective institutions.

The divergencies in the development of PTA and HTA but also indications for growing convergence are also illustrated by the fact that some of the PTA institutions recently carried out major studies dedicated to *objectives and state of the art of HTA*. In the last decade, some of the EPTA organisations have been exploring the field of HTA under the aspect of whether HTA should be more prominently included in their work programmes. This is done by some kind of meta-studies on HTA – the issue is not Health Technology but Health Technology *Assessment* (its methods, subjects, goals, forms of institutionalisation etc.). The motifs behind these activities is the realization of the growing importance of Health Technology in the social and political discourse. In a report by the Rathenau Institute from 1995/96 e.g., it is stated that the Rathenau institute's interest in the field of HTA is caused by "the specific need for public debate and national political opinion forming on health care issues".

These latter activities together with a growing number of projects on Health Technology in the work programmes of parliamentary TA institutions were initiated by the growing importance of health care and health technology on the political agenda. This is in part due to information technology entering the health care sector, but to a large extent also to budgetary constraints for funding public health care caused by a crisis of the welfare state. Besides this however the new interest in HTA is mainly caused by the fact, that the rapid advance of biotechnology and genetic engineering and its dominating impact in the field of diagnostics and therapy not only raises the problem of increasing costs for health care but also brings ethical issues on the agenda.

Since the beginning of the 90ies *Biomedicine* has been a field which is at the centre of activities of most European parliamentary TA units. Issues connected with the field of Biomedicine – the application of genetic engineering and in-vitro-fertilisation technology or more generally the application of results of research in human genetics, and molecular and cell biology in the field of medicine – can be regarded as a main field of interest of PTA units not only within the realm of their occupation with health technology issues but as a central part of their general work programmes during the nineties. Whereas we find issues like genetic testing being only scarcely dealt with by HTA institutions almost every organisation belonging to the EPTA network did carry out at least one major study on this subject in the last decade.

Biomedicine as a challenge for policy consulting

Biomedicine appears to be more of a task for parliamentary TA than for classical Health Technology Assessment. In all European countries biotechnology and genetic engineering have been and are vividly discussed not only by experts but also by the general public and the media as well as by parliaments. It is a characteristic feature of biomedical issues that as soon as a new milestone in basic genetic or biotechnological research is reported, fundamentally new prospects for medical applications immediately show up. For example, the cloning of Dolly the sheep two years ago immediately led to public debates about the implications for cloning of human beings for therapeutic reasons. As could be seen in this case and is typical for biomedical issues in general: medical promises, opportunities to defeat disease that could not even be thought of some years ago lay next to scenarios of altering and manipulating human nature in a way that could not only be misused but challenges our common understanding of human nature. With the beginning of the eighties, when the issue of genetic engineering (of recombinant DNA technology) first came to the attention of a broader public beyond expert communities, the promises as well as the risks and ethical challenges of the application of biotechnology in the field of medicine has been a contested subject of social and political debate.

Biomedical applications like xeno-transplantation, genetic testing, cloning of embryo stem cells induce impacts and ethical

questions which go far beyond the medical setting of a physician and his patient and thus reaches beyond questions of costs, medical effectiveness and possible unintended consequences – comparable e.g. to a new drug or new surgery method – for the patient. What is at stake with regard to Biomedicine are not only medical questions to be answered by medical experts but questions that need to be answered by society.

The fact that biomedical research is seen as a field of medical intervention which implies fundamental ethical, social and legal problems which exceed the realm of professional or medical ethics, is illustrated by vivid public debates on statutory regulation for embryo research, cloning, genetic testing, germ line therapy, stem cell therapy, patenting of the human genome and other issues in all European countries and last but not least by attempts to come to ethical and statutory agreements on biomedical research and biomedical treatment on a trans-national level.

The Council of Europe's Convention on Human Rights and Biomedicine (Council of Europe 1997) in its preamble makes clear what is at stake with the rapid progress in biomedicine: The Council is referring here to the fundament of the political constitution of all western democracies. The signatories – as is stated in the preamble – agree to the convention "conscious that the misuse of biology and medicine may lead to acts endangering human dignity". The articles of the convention then specify aspects of human dignity which might be endangered by misuse of biomedical treatments:

The principle of individual freedom is endangered by the fact that clients may undergo biomedical treatment without being well informed about possible risks and negative consequences for their future life and by the fact that there might be social pressure on individuals to undergo biomedical treatment. The principle of privacy is set against the possible misuse of knowledge about a person's state of health by third parties. The principle of equal rights of individuals is seen as endangered by the possible discrimination of a person because of his/her genetic heritage.

And last but not least there is one question implicitly dealt with in the entire text: This is, to what extend can we reconcile intervention in human nature with our understanding of human dignity? This of course is one of the most contested and debated concepts in society as well as in philosophy. It cannot come as a surprise that the Convention does not give a concise definition of what is meant by "human dignity". The cultural differences in applying this concept to political regulation is shown by the recent decision on cloning of human stem cells by the British Parliament which allows therapeutical cloning of embryos until the 14th day of their development – a decision which lead to criticism because human dignity is seen as being disregarded by this decision.

The Convention does not give explicit advice with regard to regulation, it is restricted to some general rules and ethical considerations (this caused some criticism especially in Germany). But nevertheless the Convention (including its weaknesses) shows quite well the challenge of biomedicine to society and politics. The debate on the Convention in different countries reveals the conflicts policy making has to deal with. Biomedicine opens up promising prospects for health care and treatment of disease. Biomedicine does so by making human life and the human body – its creation, its development and growth – amenable to human agency. What has been thought to be a matter of nature or fate – is now becoming a matter of choice or decisions that can be taken by parents, by patients and medical experts. Since in modern societies there is no common frame of reference (religious beliefs, traditions, uncontested authorities) to answer the ethical questions arising in connection with biomedical research, biomedicine is a challenge to governments and parliaments in their search for decisions which are acceptable to the values, beliefs and interests of a broad range of social groups. In contrast to most other health technologies biomedicine is subject to social discourse and thus subject to parliamentary decision making on the necessity and opportunities for legal regulation. Stakes are high, possible social impacts are uncertain and moral concepts for the evaluation of ethical implications are socially contested. This makes Biomedicine a candidate for a TA approach which is not restricted to a specific medical perspective but is open to a general societal perspective.

Biomedicine in Health Technology Assessment and Parliamentary Technology Assessment

Looking at this brief outline of differences between HTA and PTA in the field of health care technology and biomedicine it becomes quite obvious that there is no "competition" between both approaches to the issue; rather HTA and PTA approaches are complementary. Whereas HTA is mainly occupied with consequences and implications within the health care system, PTA is dealing with the wider social implications of the application of Biomedicine and other health care technologies. At the core of HTA are problems of the clinical setting, whereas PTA aims at social and cultural problems (inequality and discrimination, privacy and human dignity) caused by biomedical innovations. HTA is occupied with evaluating efficiency and costs, PTA has to deal with conflicting values and interests striving for fields of consensus with regard to legal barriers to medical applications. The outcome of HTA is knowledge to be fed into clinical decision making (best medical practice) or health care management; PTA provides knowledge for research policy, for legislation and for a well informed public debate (see Tab. 5).

Tab. 5: Complementarity of HTA and PTA

	HTA	PTA
Problem Area	Clinical setting physician – patient	Political setting technology – society
Issues at stake	Efficiency, costs	Contested values and interests
Outcomes	Clinical guidelines, recommendations for health care management	Input to public debate, research policy, legislation

This correspondence of both approaches might grow into a relation of co-operation in the future. With the further development of biomedicine, debates are likely to change (and already are about to change) from very general discussions (such as: what are the promises and risks of human genome research) to more differentiated discussions on a number of very particular medical applications stemming from human genome research. In the course of this development clinical information on cost efficiency or medical efficacy might gain more importance in public and political debates on new opportunities for diagnosis and treatment of disease. Political evaluation of, e.g., predictive genetic testing, its probable social consequences, its consequences for our general attitude towards disease has to include detailed information on the efficacy, and on possible benefits of genetic tests for cancer disposition for a patient which clinical Health Technology Assessment can provide.

Convergence can also be expected the other way around. In the course of bio-medical applications becoming more and more dominant in medical practice it might well become evident that HTA cannot but draw on findings from TA studies dedicated to the wider societal implications of bio-medicine. Clinical evaluation in the light of effectiveness, costs and benefit for the patient in the course of biotechnology entering the hospital necessarily will include more fundamental ethical questions. The time lag between the experimental test of totally new biomedical technologies and its applicability in the clinical context is getting shorter (see cloning). It is unlikely that HTA, e.g. on pre-implantation diagnostics for human embryos in the context of in-vitro-fertilisation could be done without referring to questions asked in the wider society: questions on the moral status of the human embryo or on the legitimacy of selecting embryos with respect to genetic features.

Note

1) Revised version of a paper presented at the EPTA Annual Conference, Berlin, November 10th, 2000

Literature

Council of Europe, 1997: Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine – Convention on Human Rights and Biomedicine, European Treaty Series, No. 164

EUR ASSESS Project Subgroup, 1997: Report on Methodology. Methodological Guidance for the Conduct of Health Technology Assessment. In: International Journal of Technology Assessment in Health Care, Vol. 13, pp. 186-219

Introduction to the EUR ASSESS Report. In: International Journal of Technology Assessment in Health Care, Vol. 13, pp. 133-143
OTA / Office of Technology Assessment, 1976: Development of Medical Technologies. Opportunities for Assessment. Washington: United States Congress
Petermann, Th.; Sauter, A., 1996: Stand der Technikfolgen-Abschätzung im Bereich Medizintechnik. Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag, Bonn: TAB-Arbeitsbericht Nr. 39

Contact

Dr. Leonhard Hennen
Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag (TAB)
Neue Schönhauser Straße 10, D-10178 Berlin
Tel.: + 49 (0) 30 / 28491 – 108
Fax: + 49 (0) 30 / 28491 – 119
E-Mail: hennen@tab.fzk.de
Internet: http://www.tab.fzk.de

»

Aktuelle Entwicklungen im Bereich Health Technology Assessment – das deutsche HTA-Projekt

von Matthias Perleth, Medizinische Hochschule Hannover

Für eine systematische Bewertung medizinischer Verfahren und Technologien hat sich auch im deutsch-sprachigen Raum der Begriff „Health Technology Assessment (HTA)“ eingebürgert. In diesem Beitrag soll die bisherige Entwicklung von HTA skizziert und insbesondere die Bedeutung des deutschen HTA-Projekts für die Entwicklung in Deutschland hervorgehoben werden.

Aus der Perspektive von rund 25 Jahren konzeptioneller und methodischer Entwicklung und nicht zuletzt der Erfahrungen von Tausenden von HTA-Reports erscheint der erste relevante HTA-Bericht, der OTA-Report *Development of Medical Technologies: Opportunities for Assessment* von 1976 (siehe auch den Beitrag von Hennen in diesem Schwerpunkt) als erste systematische Annäherung an HTA verblüffend aktuell. Derzeit intensiv diskutierte Fragen der Standardisierung der Methodik von HTA, Kurzassessments, Prioritätensetzung, Entwicklungsstatus einer Technologie, Implementation von HTA-Ergebnissen u. a. m. werden in der OTA-Darstellung ausführlich diskutiert (OTA 1976).

Beispielhaft soll hier nur die Diskussion der Umsetzung der Ergebnisse von HTA-Berichten zusammengefasst wiedergegeben werden. Als mögliche Konsequenzen eines HTA erwägen die Autoren zwei Extreme: Keine Änderung oder komplette Blockade einer Technologie. Zwischen diesen Extremen gibt es aber eine Reihe von weiteren Möglichkeiten (von denen einige in wenigen Ländern heute Anwendung finden). Zu diesen Maßnahmen gehören die Beschleunigung der Entwicklung einer Technologie, Änderung der Indikationen für die Anwendung einer Technologie, Nutzung der Informationen für die strategische Planung, stufenweise Einführung oder zeitlich begrenztes Aussetzen der weiteren Diffusion bei gleichzeitiger weiterer Evaluation der Technologie (!), Initiierung weiterer Forschung hinsichtlich Risiken oder Wirksamkeit, Monitoring der Nutzung der Technologie.

Die bisherige Entwicklung von HTA, sowohl in den USA wie auch in Europa, lässt sich anhand verschiedener Entwicklungslinien – ohne Anspruch auf historiographische Unangreifbarkeit zu erheben – grob in Phasen einteilen.

Hierzu gehören:

1. *1970 bis ca. 1980: Erste Konzeptualisierung der Bewertung gesundheitlicher Technologien*

Dies schloss die Untersuchung von Sicherheit, Wirksamkeit und Nebeneffekten ein, wenn auch der Fokus zu Beginn noch auf der Untersuchung der sozialen bzw. gesellschaftlichen Implikationen medizinischer Technologien lag. Dies beinhaltete v. a. die Untersuchung der Bedingungen der Innovation, Einführung in das Gesundheitswesen, Diffusion und Nutzung von medizinischen Technologien, meist aus sozialwissenschaftlicher und ökonomischer Perspektive u. a. anhand von Fallstudien (siehe Institute of Medicine 1985 für eine Übersicht). Ausschlaggebend für die Entwicklung und den zunehmenden Einfluss von HTA waren neben der Sorge um die Sicherheit und Wirksamkeit