

**Gent Conference, December 7 – 9, 2001**

**European Integration and Health Care Systems: a challenge for social policy**

Paper to be delivered in Work-Shop I, Saturday, December 8:  
**Final draft.**

**Medical Technology Assessment – co-ordination role for the European Union**

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**Health Technology Assessment  
- a co-ordinating role for the European Union**

## **Introduction**

Health technology is an indispensable part of any nation's health care system. During the past 50 years all member states have increased their technological base for health care, both in terms of knowledge and by investments in equipment, devices and pharmaceuticals. This process has basically gone well. However, several problems have emerged related to the acquisition, diffusion and use of modern health technology. Also, concerns have been raised about the effectiveness and efficiency of already established procedures in health care.

Many innovations in medicine transform into applicable medical technology with potentially great benefits for patients. Although a new technology could prove to be more effective and cost-effective in comparison with established practices, it may face certain obstacles in finding a place in the practice of medicine, particularly if it carries high and clearly visible investment costs.

At the same time, the effectiveness and cost-effectiveness of many established medical technologies have never been assessed. In a sense, these technologies may block the market for other, better proven, innovations. Some estimates show that as many as 90% to 95% of the procedures used in health care have never been evaluated as to their relative cost-effectiveness.

In all countries, the medical profession has traditionally been left free to select technologies for diagnosing and treating patients. This has usually worked satisfactorily, due largely to the general sense of responsibility among the medical profession, accompanied by in-depth training and specialised skills applied in an environment of strong social control overseen by peers.

Nevertheless, the rapid growth of medical technology and the increasing volume of new knowledge from basic and applied clinical research have made it virtually impossible for even specialists to keep up with advancements in the field. Many inappropriate practices have crept into health care, while ineffective and obsolete technology may survive and be in frequent use despite overwhelming evidence of ineffectiveness or, even worse, of doing more harm than good. Examples of such poor investments are found in all member states.

## **Health technology assessment**

There is, in principle, no such thing as a need for medical technology. What is needed is the end outcome of a technology, i.e. what it may do for health and quality of life. The traditional definition of medical technology, applied in the past mainly to equipment and devices, does not enable one to assess anything else than its technical features. Therefore, medical technology needs to be broadly defined. Furthermore, it is impossible to assess the value of a single drug, a medical device or a piece of equipment in pure isolation from other contributions to the end outcome for patients. All medical technologies form parts of a chain of measures in the process of prevention,

diagnosis, treatment and rehabilitation. Hence, medical technology is defined generally as:

*The equipment, devices and drugs and the medical and surgical procedures used in prevention, diagnosis, treatment and rehabilitation of disease as well as the organisational and support systems used in the delivery of health care.*

Thus, technology assessment not only concerns machines and devices. It concerns all measures for preventing disease, such as programmes for mass screening of disease, and technologies for diagnosing disease, such as routine laboratory testing and the use of imaging techniques. It concerns technologies for treatment, such as bypass surgery, artificial lens operations, hip implants, the management of hypertension, diabetes and stroke and the indications for using different pharmaceuticals. It also concerns assessments of rehabilitation programmes, such as those used for alcohol and drug abuse. Finally it concerns the organisation and delivery of care since assessments, by definition, include issues about the use and diffusion of technology. Hence, it is in this context that we use the term “health technology assessment”.

### **Aim of health technology assessment**

Governmental interest in health technology assessment has paralleled the growth in health care spending. It is important to emphasise that the main purpose of assessment is not to save money by denying services or to sacrifice the needs of the individual for some “public good”.

The aim of health technology assessment is: *to improve quality of care by promoting effective and cost-effective technology and protecting the patients from ineffective health interventions.*

### **Health technology assessment in the member states**

Nearly all of the European Union governments have established agencies for health technology assessment. Their purpose is to provide policy makers, the medical profession and the general public with syntheses of findings from research on the relative effectiveness and cost-effectiveness of different medical technologies. Several examples show that HTA has substantially impacted both health policy making and clinical practice.

In general, these agencies are funded by the national health ministry or by local governments. Most of the agencies have no regulatory function, but are

advisory bodies. In addition, many research institutions are involved in the field. In the UK, a major activity of the National Health Services research and development programme is aimed at "assessments of the effectiveness, costs and broader impact of all procedures used by health care professionals to promote health and to prevent or treat illness". This includes not only synthesising the evidence, but also commissioning primary research to help fill gaps in the evidence.

Different models are used at the operational level, especially in the methodology of synthesising evidence and in the dissemination of findings. Obviously, scientific evidence needs to be interpreted in the light of each country's system for health care, its culture, demography, disease panorama, health care organisations, resources and wealth.

### **Illustrative examples**

Many of the assessments performed by different agencies are strengthening the evidence of current health practices. However, there are many examples of the contrary. A few such findings will be used as illustrative examples here.

The Swedish agency for health technology assessment (SBU) was established in 1987. Since then it has produced assessments of more than 500 different health technologies. Table 1. This agency usually selects major public health problems, such as obesity, stroke, depression, chronic pain, dementia, as a starting point for their assessments. All measures for prevention, diagnosis and treatment are identified. Then a systematic review of the entire international scientific literature is performed to obtain evidence, which is graded according to the scientific strength of the studies. The following five examples are all taken from the SBU:

- 1) In a recent review of the scientific findings of the effectiveness of different technologies used to diagnose and treat back pain it was found that quite a few of these have no scientific support and that some technologies used are actually producing more harm than good for the patient. Table 2.
- 2) A thorough assessment of the technologies used in the treatment of alcohol-and drug abuse demonstrate that the resources spent on the many unstructured support programs in this field either lack evidence of benefits for the patients or are scientifically proven to be useless.

3) In the assessment of screening for prostate cancer the evidence showed that there are no compelling reasons to recommend neither mass screening nor opportunistic screening.

4) As to the value of preoperative routine testing it was found that there is no evidence of benefit to the patient, nor to the surgeon or the anaesthesiologist, to do routine examinations by x-ray of heart and lungs, by ECG, and by blood analysis, before elective surgery in otherwise healthy patients.

5) There is no scientific basis for recommending bone density measurement in mass screening, selective screening, or as an extra component in health check-ups of asymptomatic individuals.

Such findings may be used in health policy making for the purpose of allocating resources more effectively, i.e. to get value for money.

### **Collaboration at the European level**

The Commission of the European Union is supportive of health technology assessment as a means of establishing best health practice in the member states.

During 1994 to 1997, the Commission funded a collaborative project called the EUR-ASSESS project, which aimed at:

- 1) Harmonising the methodology for assessments,
- 2) Exploring mechanisms for efficient dissemination of results,
- 3) Investigating the possibilities of linking the results of assessments to financing and reimbursement and
- 4) Developing a process for setting priorities in health technology assessment.

In 1997 to 1998 the EUR-ASSESS project was followed by the HTA Europe project, also supported by the Commission, which included the following aims:

- 1) Contribute to the effectiveness and cost-effectiveness of health care in Europe through improved HTA,
- 2) Contribute to the development of institutions for health care technology assessment in Europe,
- 3) Strengthen co-ordination of health care technology assessment in Europe,
- 4) Contribute to the development of methods of information transfer among European countries and

- 5) Furnish guidance to the European Commission concerning how to strengthen and aid co-ordination of HTA activities in Europe.

In 2000, the European Commission signed an agreement for a project aimed at developing a means of collaboration for health technology assessment activities in Europe.

The project, *The European Collaboration for Assessment of Health Interventions and Technology* (ECHTA/ECAHI) used six working groups to address subjects of importance for networking at the European level, namely:

1. To assess health promotion and disease prevention activities in terms of benefits, risks and economic, social and ethical implications as a complement to community health indicators.
2. To develop systems for routine exchange of information between programmes on:
  - Emerging technology issues
  - Priorities for future evaluation
  - Conduct and timing of ongoing evaluations, including findings from evaluations.
3. To identify possible joint assessments and to co-ordinate findings and existing resources within the community to support joint assessments.
4. To develop and disseminate best practice in undertaking and reporting assessments. To identify needs for methodological development.
5. To develop and co-ordinate education and support networks for individuals and organisations undertaking or using assessment of health interventions. To identify needs in the field and assist in the establishment of new provisions.
6. To identify and share successful approaches to link findings of assessments, their contribution to health indicators and health care decision-making.

All 15 member states of the European Union and observers from 8 other countries were involved in the project (about 110 medical and health policy experts in total). A Steering Committee representing all member states guided the project, and an Executive Committee was responsible for system design and integration. A key challenge for the working groups was to take full advantage of relevant expertise within Europe.

The main goal of the project was to promote European co-operation. The project intended to promote evidence-based health care in the European Community and explore opportunities to strengthen the network throughout the member states.

### **Findings of the ECHTA/ECAHI project**

The main finding of the project is the need to establish a permanent Network mechanism, European Collaboration for Health Technology Assessment (ECHTA), built on the considerations and following recommendations of the six working groups:

- Identify and prioritise needs and opportunities for assessment of health interventions and technology (including those in the area of prevention).

- Gather and disseminate information (e.g. by way of a clearinghouse using an Internet portal providing access to information and advice).
- Enable and encourage collaborative work.
- Develop skills in health technology assessment (e.g. by developing a common framework for training and education in the field, including a Masters degree in health technology assessment).
- Help in further development of methodologies in assessments and “best practice” in assessments. The development of measures for community effectiveness is a particularly pressing task.
- Improve ways of communicating the results of health technology assessment to policy makers, clinicians, industry, patients and the general public to ensure effective implementation of results and realise health gains.

### **Co-ordinating role for the European Union**

All member states of the EU are forced to balance biomedical advances and the promises of innovations with available resources for health care. Difficult choices must be made, and priorities must address the care of ageing populations, soaring costs of health care and public and professional demand for new medical technology – which may or may not substantially improve the quality of care.

Since knowledge is limited about the relative effectiveness of both new and established technologies in health care, there is a need for evidence-based, rather than opinion based, information about the medical, economic, social, ethical and organisational implications of the diffusion and use of health care technology. This need is shared by many parties including industry, researchers, clinicians, health policy makers, patients and the general public. These issues are by no means restricted to the technical capability of health technology. Rather, they are about value for money, equity, access and quality of care, including questions of financing and payment for health services.

Both medical technology and health technology assessment are international in scope. Few differences are found among countries as to the technological arsenal used by the health services. Furthermore, all agencies in the field of technology assessment use essentially the same sources to compile evidence, namely the body of international, scientific literature. The overall findings from systematic literature reviews, performed in any country in the EU, will apply to other member states, but some issues will remain country-specific. Health policy for investments in medical technology cannot be based on scientific evidence alone. Much of what is needed in health policy-making has not been, or cannot be, addressed by research. It goes without saying that

governmental priorities, the ethical and social implications of technology and issues of cost-effectiveness cannot be dealt with by a co-ordinating mechanism at the EU level. These must be addressed by each individual member state.

No mechanism has yet been established within the European Union that could regularly and systematically support the decision-making processes with critical facts from the many health technology assessments performed in the individual member states. However, this is of increasing importance, considering the fact that the mere availability and diffusion of a technology may determine its use, rather than population needs, the appropriate indications for use or the true effectiveness of the technology.

## **Proposal**

Many agencies and institutions within the European Union are currently working on assessment of different health care practices, interventions and technology, including evaluations of health care systems and structures.

The aim is to produce evidence-based information for health policy-making and practice. Such information focuses on effective and cost-effective procedures, technology and delivery of health care, taking account of social and ethical issues. There is evidence of successful improvement from this work, both in terms of the cost and quality of health services.

The European Commission has funded several projects to stimulate collaboration in this field. The ECHTA/ECAHI programme is the latest of these. An informal network has been established among the people involved in this project, mainly to:

- Work together,
- Share information about finished, ongoing and planned evaluations in different countries,
- Share best practice in doing assessments,
- Share experiences and methodology for successful dissemination and implementation of the results into policy and practice, and
- Provide education and training in the field.

There is now a need to strengthen this collaboration and create a sustainable Network within the European Union.

The objective of the Network would be to assist the European Union, its member states and the candidate countries to plan, deliver and monitor health services effectively. Strong commitment and funding from the Commission would allow such a Network to achieve this objective.

The Network should involve those working actively on assessments in health care in Europe, focusing on those in the public sector, but welcoming those working in other settings.

The Network should be based on an agreed workplan, developed within the ECHTA/ECAHI project. A Steering Committee should oversee the Network and should be supported by a Secretariat, initially placed at an existing HTA agency in a member state. The Network should work closely with global collaborative efforts in the field, such as INAHTA (The International Network of Agencies for Health Technology Assessment).

Table 1. A selection of SBU projects

- Treatment of back pain
- Screening for prostate cancer
- Treatment of obesity
- Treatment of osteoporosis
- Prevention of disease by physical exercise
- Prevention of disease by antioxidants
- Prevention of disease by community health programs
- Prevention of caries
- Estrogen treatment
- Smoking cessation
- Radiotherapy for cancer
- Mild hypertension
- Bone density measurement
- Preoperative routine testing
- Magnetic resonance imaging
- Gastroscopy
- Bone marrow transplantation
- Venous thromboembolism
- Screening for diabetes retinopathy
- Treatment of stroke
- Routine ultrasound examination during pregnancy
- Surgical treatment of rheumatic disease
- Asthma
- Urinary incontinence
- Stomach ulcer
- Home care
- Bypass surgery
- MRI
- Minor head injury
- Patient–doctor relationship
- Cytostatics
- Hearing Aids
- Placebo
- Sick-leave as a method of treatment
- Treatment with neuroleptics
- Dementia
- Alcohol and drug abuse
- Anxiety
- Depression

Table 2: Evidence of methods to treat back pain