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# HEALTH TECHNOLOGY ASSESSMENT IN DENMARK

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Abstract

The Danish healthcare services are mainly provided by public sector institutions. The system is highly decentralized. The state has little direct influence on the provision of healthcare services. State influence is exercised through legislation and budget allocations. The main task of the state is to initiate, co-ordinate, and advise. Counties, which run the hospitals, also decide on the placement of services. The hospital sector is controlled within the framework of legislation and global budgets. General practitioners occupy a central position in the Danish healthcare sector, acting as gatekeepers to the rest of the system. The system works well, and its structure has resulted in steady costs of health care for a long period. There is no regulatory mechanism in the Danish health services requiring use of health technology assessment (HTA) as a basis for policy decisions, planning, or administrative procedures. However, since the late 1970s a number of comprehensive assessments of health technology have formed the basis for national health policy decisions. In 1997, after years of public criticism of the quality of hospital care and health technologies, and on the basis of a previously developed national HTA strategy, a national institute for HTA (DIHTA) was established. There seems to be a growing awareness of evidence-based healthcare among health professionals and a general acceptance of health economic analyses as a basis for health policy decision making. This progress is coupled with growing regional HTA activity in the health services. HTA seems to have a bright future in Denmark.

**Keywords:** Technology assessment, biomedical, Delivery of health care, Denmark

Denmark is a Scandinavian country that covers 43,094 $km^2$ and has 5.2 million inhabitants. Eighty-five percent of the Danish population live in urban areas, including 1.75 million people living in the region of Copenhagen (11).

Denmark is a constitutional monarchy in which all federal political power rests with an elected parliament. The central administration consists of 21 ministries, one of which is the Ministry of Health. The health area is also related to the Ministry of Social Affairs, the Ministry of Food, Agriculture, and Fisheries (provisions), and the Ministry of Labor (working environment).

Denmark has a two-tier system of local government, with 14 counties, the Copenhagen and Frederiksberg municipalities, and 273 local authorities. There are three levels of taxation: the state level, the regional level, and the local level. In the Danish healthcare sector, each level of authority has political responsibility for tax levels (financing) and level of service provided.

The main areas of production are industry, agriculture, and service trade. Denmark has an open economy and is very dependent on international trade. About two-thirds of Danish foreign trade is with other European countries. Compared with most other countries, the wealth in Denmark is very equally distributed among social groups (11).

The total public and private expenditure on healthcare corresponds to about 6–7% of the gross domestic product (GDP), and the citizens' own expenditures amount to about 19% of this figure (2). The increase in the population's average lifetime expectancy that was seen during the century has slowed over the last 10 to 20 years, and Danish lifetime expectancy is no longer among the highest in Europe. While most other European countries experienced an increase in life expectancy from 1980 to 1994, life expectancy in Denmark had almost no increase. The main causes of death among men and women are cardiovascular diseases and cancer (42).

## DESCRIPTION OF THE HEALTHCARE SYSTEM

### Brief History

The Danish healthcare services are mainly provided by public sector institutions, and the healthcare system is highly decentralized. Administrative reforms in the 1970s resulted in fewer and larger local government entities and gave them more responsibility. In 1977 the county councils assumed responsibility for psychiatric hospitals. By the late 1970s, the main features of the current Danish healthcare system were in place. The county councils and the two city councils are responsible for hospitals and healthcare reimbursement, and the 273 municipalities are responsible for home nursing and a number of preventive programs (e.g., school health and child dental services). The state therefore has little direct influence on the provision of healthcare services. State influence is exercised through legislation, budget block allocations, and other budget allocations.

In the 1980s, a growing public budget deficit and an increasing tax burden brought about a change in economic policy toward more restricted growth in public expenditure. In health care, growth was restricted mainly through general cost-containing measures on the part of the counties and the municipalities. At the same time, however, demands upon the healthcare sector did not diminish. Demand for healthcare services increased as a consequence of an aging population as well as patients' continuing expectations of high-quality services and access to new medical technology. General cost-containment measures, therefore, were accompanied by specific initiatives and reforms aimed at improving effectiveness and efficiency in health care through better management and accountability at all levels (50).

These combined efforts seem to have been fairly successful, since growth in the healthcare sector was kept at an average of less than 1% per year in the 1980s, and the healthcare sectors' share of GDP remained fairly unchanged.

In Denmark, three recent initiatives in hospital services have been introduced (2). Free choice of hospital was introduced in 1993. Experiments with a 3-month waiting time guarantee for two selected diagnoses were conducted in 1993 (the money follows the patient). Finally, a new budgeting scheme called "contracting" has been introduced in some places. The contracts are based on negotiations between the county and the hospital management. All activities that the hospital has to perform are listed in the contract, each with a set budget and a time frame (2).

### Constitutional Basis and Legislative Background

Health care in Denmark is considered to be a public responsibility. Healthcare services are financed mainly through general taxation. There is free and equal access to almost all

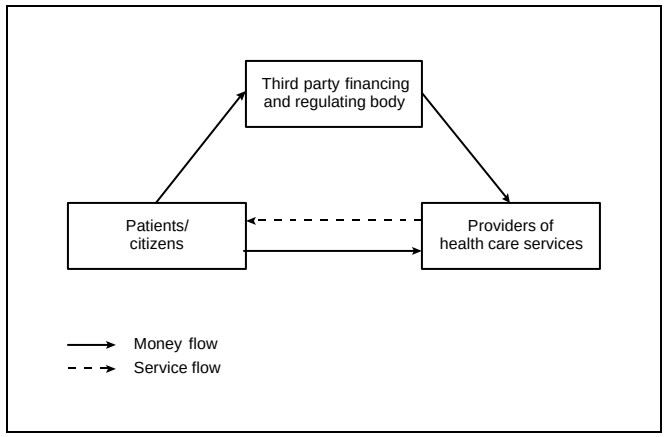


**Figure 1.** The Danish healthcare system. From OECD (50).

healthcare services, regardless of sociodemographic parameters. All residents are covered by the public Health Care Reimbursement Scheme in case of illness.

Legislation passed by the Parliament and the government defines the services that local authorities must provide. Normally, however, tasks are described in rather broad terms that give plenty of room for the counties and municipalities to decide how to deliver the services. The economic responsibility is decentralized to counties and municipalities, which have to balance services against their own tax revenues.

## Organization and Administration of the Healthcare System

The Danish healthcare system is characterized by the features outlined in Figure 1, the basic triangle (53).

The three actors are patients or citizens, providers of healthcare services, and an intermediate third party with the dual role of financing the services through collected taxes and insurance premiums and paying the providers (1). The healthcare services are organized so that responsibility for providing and financing health services lies with the lowest possible administrative level.

## Providers

Providers of healthcare services are organized in two sectors: primary health care, and the hospital sector. The primary healthcare sector can be further divided into one part that deals with treatment and care (general practitioners [GPs], specialists, dentists, etc.) and another part that is predominantly preventive and deals with preventive health schemes, health care, and child dental care (22). The GP acts as gatekeeper for hospital services and visits to most specialists (50). The intent of the GP system is that the GP serves the entire family to increase his knowledge of family circumstances and thereby improve his ability to treat family members. The hospital sector deals with medical conditions that require more specialized treatment, specialized equipment, and intensive care. There are four decision-making levels in the Danish hospital sector: the state, the counties, the hospitals, and the clinical departments (5).

Hospitals are given global budgets by the counties. The budgets are set mainly on a historical basis, that is, on last year's budget. Also, municipal healthcare services are given global budgets from the municipalities. Services under the Health Care Reimbursement Scheme are provided by independent professionals such as GPs, specialists, dentists,

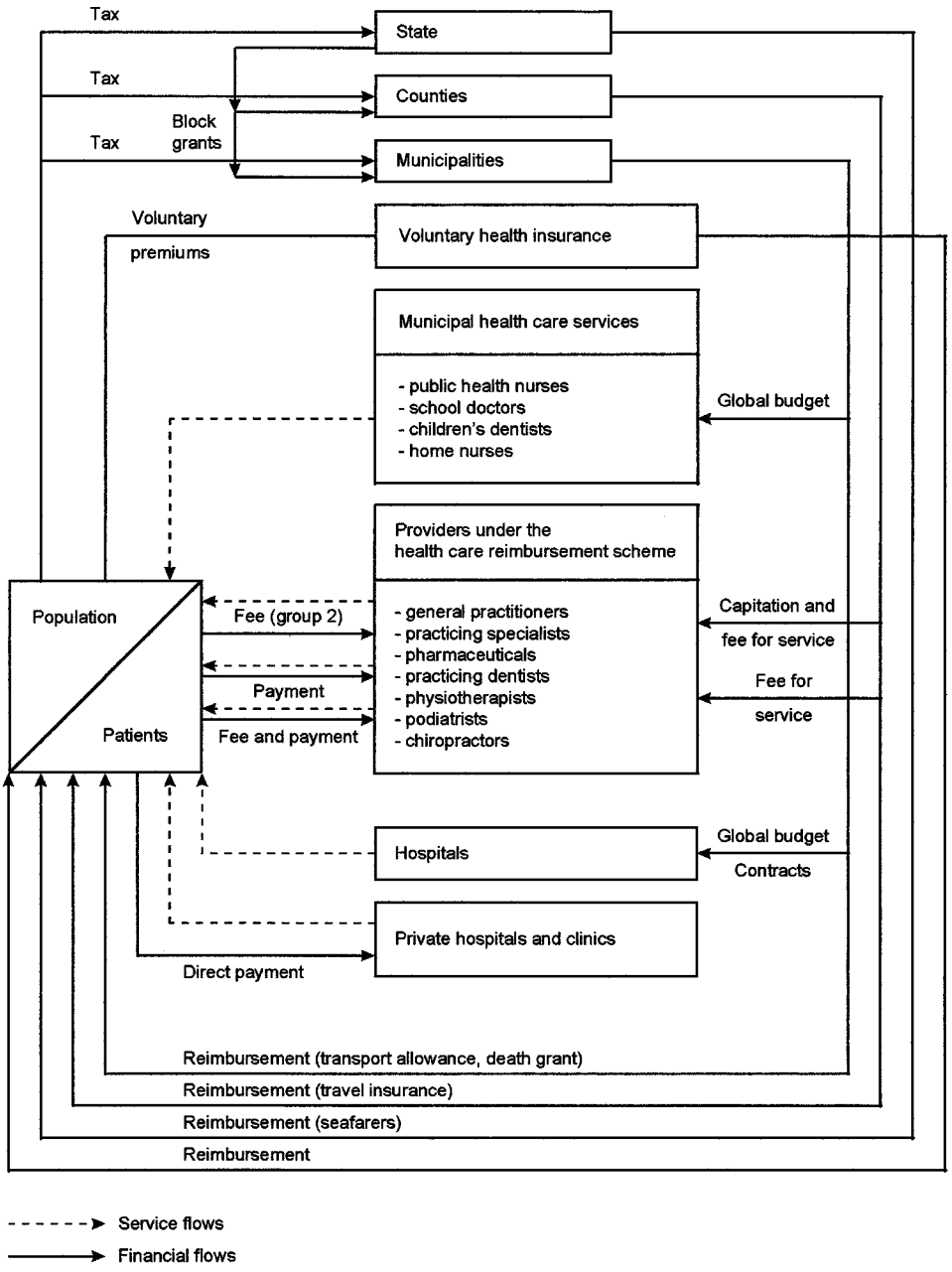


**Figure 2.** Services and financial flows in the healthcare sector. From National Board of Health (48).

physiotherapists, etc. GPs are paid partly on a capitation basis and partly by fee for service. Specialists, dentists, and other professional groups providing services under the reimbursement scheme are all paid by fee for service.

Figure 2 depicts the main features of delivering and financing health care in Denmark (50). The providers are divided into municipal healthcare services, providers under the Health Care Reimbursement Scheme, public hospitals, and private hospitals and clinics.



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## Third-party Financing and Regulating Body

The third party is divided into public authorities at the national level (i.e., the state), the regional level (i.e., the counties), the local level (i.e., the municipalities), and private insurance. The local governments, besides being the financing body, are also the regulating body.

The task of the state in healthcare provision is, first and foremost, to initiate, coordinate, and advise. One of the main tasks is to establish the goals for a national health policy. The Ministry of Health is the principal health authority responsible for legislation on health care, which includes legislation on health provision, personnel, hospitals and pharmacies, pharmaceuticals, vaccinations, prenatal care, child health care, and patients' rights. The Ministry of Health also occasionally sets up guidelines for the running of the healthcare service. The Minister of Health is the final decision maker on the state level.

The counties and the local authorities finance the healthcare services partly through local taxes and partly through relatively small block grants from the government. Block grants are allocated according to objective criteria, which among other things include demographic factors.

Hospital services and the primary practicing sector are financed by the counties. The hospitals operate within the politics or framework of the county. The county loosely defines the hospitals' role according to the catchment area it serves. Hospital services and municipal healthcare services are provided by salaried employees. Outpatient services outside hospitals (GPs, dentists, etc.) included in the Health Care Reimbursement Scheme are supplied by independent practitioners working under contract with the counties. Furthermore, the counties finance a part of the private expenditure on pharmaceuticals.

Besides being responsible for hospitals and healthcare reimbursement, county councils are also the final decision makers on whether a new technology is to be adopted. The Association of County Councils acts as the counties' common representative in external relations. The association has an ongoing dialogue with the government and Parliament on economic and legislative matters. In addition, the Association of County Councils handles the counties' interests in matters such as wages and employment conditions, including pay negotiations with the trade unions.

The municipalities are local administrative bodies responsible for home nursing, public health care, school health care, and child dental care. The local administration of the Health Care Reimbursement Scheme lies with the municipalities. City councils are the final decision makers in the municipalities. Local authorities have set up a National Association of Local Authorities. The municipalities are also responsible for primary and social care (e.g., nursing homes) and for a majority of the social services, some of which have great influence on the functioning of the healthcare services.

Outside the three formal decision-making levels, there are several nongovernmental organizations that have the power to influence the decision-making process and to put health issues and technologies on the agenda. Some of the most influential nongovernmental organizations are the Danish Cancer Society and the Danish Heart Association. Finally, the trade unions, in particular the Danish Medical Association, and some of the scientific societies are influential parties of interest as well.

## Patients/Citizens

All citizens are covered by the Health Care Reimbursement Scheme in case of illness. Citizens pay state, county, and local taxes, which are not earmarked for healthcare services.

User payments include both copayments or user fees and 100% user payments. Patient copayments or user fees are charged at visits to practicing doctors, dentists, physiotherapists, etc. Payment for pharmaceuticals varies from a 100% user payment for over-the-counter

**Table 1.** Activities per 1 Million Inhabitants

| | 1985 | 1995 |
|---|---|---|
| Discharges | 191,538 | 209,423 |
| Ambulatory visits | 679,610 | 872,093 |
| Visits to GP[a] | 4,479,805 | 5,937,227[b] |

***Source:*** Sundhedsstyrelsen (65).
[a] Personnel information from the Central Negotiation Committee.
[b] The number is from 1994.

(OTC) products to a 100% subsidy for insulin. A few private hospitals/clinics are financed through private payments. Most private health insurance is supplied by the private insurance company Danmark, and most reimbursement from private insurance companies covers drugs and dental care not fully reimbursed by the Health Care Reimbursement Scheme.

## Production of Health Services

The hospital sector produces a number of different services (e.g., treatment and care of patients, research, and education). Activity in somatic hospitals, measured as the number of discharges and the number of ambulatory visits, increased from 1985 to 1995, while both the number of hospital beds and the number of bed-days decreased. These changes led to a reduction in the average length of stay from 8.4 to 6.5 days, a reduction of 29.2% (70).

There has been a trend toward less and shorter hospitalization and more outpatient activity, as shown in the Table 1. The number of providers in the primary healthcare sector has increased, partly due to shorter lengths of stay in hospitals and partly due to improved possibilities of treating patients outside hospitals in private practices (2).

## Industry

The pharmaceutical branch includes manufacturers and distributors (pharmacies). The highest authority is the Ministry of Health, which is responsible for legislation on pharmaceuticals concerning both production and sales. The pharmaceutical industry consists of several small companies and one large company (Novo Nordisk). The annual gross turnover was 14.7 billion Danish crowns (DKK)[1] in 1996 compared with DKK 8.3 billion in 1990 (40;41).

Pharmaceutical manufacturers and importers are organized in the Danish Association of the Pharmaceutical Industry (*Lægemiddelindustriforeningen* [LIF]). The objective of LIF is to promote the pharmaceutical industry's interests at both the national level and the international level, with their interests including research and development of pharmaceuticals, production, sales, legal protection, and issues related to business, politics and public opinion. LIF is a member of the European Federation of Pharmaceutical Industries' Association and a number of other international organizations (41).

There are around 300 pharmacies in Denmark, with a total annual gross turnover of DDK 7.1 billion in 1996 (41;56). All pharmacies are organized in the Danish Association of Pharmacies. A special characteristic of the pharmaceutical market is the division between consumer choice, consumption, and financing in different situations. All consumption in the hospital sector is fully financed by the regional governments. In the primary health sector, expenses paid by the public are divided between regional governments according to the public healthcare insurance law and local governments according to pension and social security laws. The private insurance company Danmark covers most pharmaceutical expenditures for its members. The rest of the expenditures are paid by the patients directly. Costs for most OTC medicine are not reimbursed (41).

Official control of medicines is carried out according to the Medicines Act by the National Board of Health (48). The fundamental purpose of the Medicines Act is to ensure that all medicines, whether manufactured in Denmark or imported, are of high quality and that they meet the safety and other requirements and specifications laid down by the National Board of Health. The main requirements of the act are that every pharmaceutical business in Denmark must obtain an authorization from the National Board of Health and that all pharmaceutical products must be authorized by the National Board of Health before they can be marketed in Denmark. From January 1, 1997, the Drug Department was designated by the National Board of Health as an independent agency under the name of the Danish Medicines Agency.

The medical device industry in Denmark is characterized by a few large and many small enterprises. Compared to the size of population, the Danish production of medical devices is among the largest in the world (33). From 1993 to 1996, the economic turnover in the medical device industry increased by almost 30% to about DKK 9 billion. Ninety-eight percent of the production is exported (51).

The medical devices manufactured in Denmark are a rather heterogeneous group of products, ranging from simple dressings and syringes to hearing aids, blood-gas analyzers, and monitoring equipment for intensive care. With regard to hearing aids, Denmark is clearly leading, with a world export share of approximately 30% (share of total production is about 25%) (35). Coloplast, the Danish medical device manufacturer with the largest turnover, produces colostomy bags and products for wound care (51). There is a close connection between the biomedical research sector and the medical device industry. Examples include audiology, urology, and acid-base metabolism (35).

## MECHANISMS FOR CONTROLLING HEALTHCARE TECHNOLOGIES

### Regulations

***Pharmaceuticals.*** Registration of pharmaceuticals is performed by the Danish Medicines Agency. The criteria for registration are efficacy and safety. Although pharmacists are independent entrepreneurs, they are under considerable public control. The Ministry of Health decides the number and location of pharmacies, appoints new pharmacists, and negotiates with the Pharmacists' Association to determine pharmacists' total gross profit and a corresponding mark-up scale for pharmaceuticals.

Expenditures for pharmaceuticals have increased significantly in recent years. A number of different measures have been implemented to limit the increase. Generic substitution has been introduced to promote sales of lower-priced pharmaceuticals. As a means of enhancing competition among drug producers, a new scheme of cost-sharing was introduced in 1993. Under the new scheme the public contribution to a product in a generic group of drugs is a fixed amount calculated as a percentage (100, 75, or 50%) of the mean price of the two cheapest products in the generic group available on the market (50).

In 1994 the Minister of Health and the pharmaceutical industry agreed to put a ceiling on the price of pharmaceuticals. This agreement was renewed in 1995 by a 2-year agreement. It was agreed that prices of all pharmaceuticals subject to a subsidy would be reduced by 5%. The price of other pharmaceuticals was reduced by 2% (41). From January 1, 1996 the public subsidy of antibiotics was reduced from 75 to 50%. It is anticipated that this shift will lead to a shift in consumption from the relatively expensive, resistance-inducing, wide-spectrum antibiotics to relatively cheaper, narrow-spectrum antibiotics. These changes in subsidies are also intended to help curb growth in public expenditure on pharmaceuticals (43).

There has been much political attention to Danish drug prices, which are among the highest in Europe. In early 1997, the industry negotiated with the Ministry of Health for a voluntary price agreement that would replace the existing agreement when it expired

on April 1, 1997. The ministry's proposal was turned down by industry representatives, although they knew the rejection would lead to legislative intervention. The new act gives authorities more power to intervene, including the authority to establish a scheme with analog substitution that allows pharmacies to replace a prescribed pharmaceutical with a less expensive analog product, unless the doctor has indicated on the prescription that the prescribed pharmaceutical must be dispensed. The act also includes a price freeze and a so-called G scheme. The G scheme means that the doctor must actively reject the option of dispensing the cheapest pharmaceutical. Finally, the subsidy-granting authorities have the right to base the allocation of subsidies to new pharmaceuticals on health criteria and socioeconomic criteria and to bring prices and subsidies to the average level of the European Union (EU) (41).

***Utensils and Medical Devices.*** The market for medical devices is regulated by directives from the EU. The European directives must be enforced by Danish laws. There are three EU directives: one for medical devices in general, one for active implants, and one for in vitro diagnostic substances. The basic principle of the European directives is that devices are allowed on the market only if they comply with harmonized European standards; compliance is indicated by the so-called European Community (EC) mark (39).

Requirements for medical devices mainly concern safety. The extent of control exercised over a medical device depends on the risks associated with use of the product. There are four categories of risk (I, IIa, IIb, and III). An example of category I is adhesive bandages, while an example of category III is a heart–lung machine. The classification of a medical device governs the type of evaluation the manufacturers must undertake to demonstrate that the device conforms to the essential requirements of the relevant medical device directive (39).

Control of medical devices in category I is carried out by the manufacturers or providers themselves. Products in categories II and III must be certified by a Notified Body. From June 14, 1998, a medical device may be marketed within the EU only if it is certified. However, products bought before this date may still be used without certification.

The National Board of Health is the responsible authority for problems associated with the use of the medical device (e.g., side effects, malfunctions, or technical shortcomings). It is compulsory by law to report any such problems to the National Board of Health (39).

Besides the three EU directives, there is a special law for the use of x-ray equipment.

***Placement of Services.*** Hospitals are run by the counties, which also decide the placement of services. For example, county councils determine the degree of specialization (i.e., how many and which specialties at which hospital) (2). Together with the National Board of Health, the counties, within the framework of the so-called National Health Function Agreement (*Lands- og landsdelsfunktioner*) negotiate the appropriate distribution of specialties and of some expensive health technologies requiring highly specialized personnel, such as radiation therapy, neurosurgery, and heart and lung transplantation (65).

In additon to agreements governing the distribution of specialties and technology, there are a number of agreements among counties on sharing certain technologies (e.g., a magnetic resonance scanner or a mobile ultrasound shockwave lithotripter).

Primary healthcare practice is considered a free enterprise, but it is highly regulated and admission to practice is severely restricted in two ways. First, the physician needs to qualify as a GP. Second, once the physician qualifies as a GP, he or she has two possible ways to get a practice: a) to purchase an existing practice from a retiring GP; or b) to obtain permission from the county Joint Committee of the Public Health Security Service. This practice planning was implemented in 1976, and since then it has generally been possible to obtain permission to practice only in so-called open-practice areas, as determined by the Public Health Security Service. In general, the geographic distribution of GPs is uniform

because of this planning process (22). Unlike GPs and specialists, dentists are free to set up clinics in Denmark (43).

***Medical Personnel.*** Medical training is controlled centrally by the Ministry of Education, in association with, among others, the Health Training Council and the Social and Health Training Council, in cooperation with the Ministry of Health, the National Board of Health, and others. Further training in the healthcare sector (e.g., for specialists or nurses with diplomas) is the responsibility of the Ministry of Health and is adjusted continually to meet the needs of the health sector with regard to subjects, contents, and capacity (43).

## GPs as Gatekeepers

GPs have a central position in the Danish healthcare sector, partly because they participate in 90% of the population's contacts with healthcare providers and partly because GPs act as gatekeepers to the rest of the system. It has become possible for both GPs and specialists to treat an increasing number of patients in primary health care. Hospital admission and specialist treatment require a GP's referral. The GP is thus the person who ensures that the patient is given the correct treatment and is referred to the proper professionals in the healthcare sector. Moreover, GPs increasingly coordinate the care of patients who receive both primary health care and hospital care. Finally, the introduction of free choice of hospital in 1993 gave the GP an important role to play as the patient's adviser in the decision-making process.

For several decades, the Danish healthcare system has been characterized by universal coverage. Citizens may choose between two reimbursement schemes: group 1 or group 2. A majority of the population (97.96% in 1996) has chosen group 1. The choice of a GP rests with the individual, who must choose a physician within a 10-km radius of his or her residence.

Group 1 patients are registered with a general practice that can be visited free of charge. A person who has been registered with the same GP for at least 6 months has a guaranteed right to change GPs within a month. This requirement is intended to support a continuous relationship over time between the patient and the GP in order to improve the provision of health care to the individual. To see a specialist without charge, group 1 patients need a referral from their GPs. Group 1 patients may, however, see an ear, nose, and throat specialist or an opthalmologist without a referral. A group 1 patient who wishes to see another specialist without a referral is liable for the entire fee. Group 2 patients are free to visit any GP or specialist without being referred. People enrolled in group 2 receive reimbursement equivalent to that given to those enrolled in group 1, but doctors are allowed to charge group 2 patients more (22). The private insurance company Danmark covers about 26% of the population (50).

The counties, which have financial responsibility for the primary care sector, face budgetary uncertainty because only the capitated part (approximately one-third) of the GP fees can be determined with accuracy in advance. Furthermore, GPs operate their independent enterprises, and therefore the counties cannot impose global budgets on the primary care sector. While the combined capitated fee-for-service system might create the best possible set of incentives, it is not the best instrument to control costs (22).

## Control and Regulation of Production of Providers

In principle, capacity is determined by what the financing authorities (i.e., the counties) choose to supply quantitatively and qualitatively. Changing supply therefore requires a political decision, particularly if an increase in the overall economic framework is necessary.

The policy instruments currently in place to regulate the supply of medical services in the primary care sector are of two types: regulatory and economic. Because the GPs run

private practices, it is not possible to regulate their activities directly. The indirect regulatory instruments include a requirement that all counties engage in a GP planning process that in part determines the number of GPs allowed in private practice. Furthermore, the maximum number of group 1 patients a GP can be assigned is 2,095. These regulations serve to limit the GP's ability to generate demand for services. Other regulatory instruments include limiting free coverage of group 1 patients to a specific set of services and negotiating a fee schedule for the services that are covered. The fee schedule is negotiated between the Public Health Insurance and the Association of General Practitioners (*Praktiserende Lægers Organisation* [PLO]) periodically. Finally, another instrument for controlling the cost of health care is the prohibition of balanced billing for group 1 patient care (22).

Another control mechanism in the primary care sector is that GPs register their services with the Health Care Reimbursement Scheme to record the cases for which they are paid a fee for service. In this way the GPs cannot get reimbursed without registration. Furthermore, GPs' pharmaceutical prescriptions are registered by the pharmacies, and patients are assigned Central National Register numbers, which means that it is, in principle, possible to determine a patient's medication usage over time and a GP's prescribing behavior.

Another regulatory mechanism in the hospital sector is the budget. Hospitals' budgets are fixed by the counties, and the hospitals are expected to organize and conduct their affairs within the limits of these budgets. The county may change the budget or specify certain demands for production (quantitatively or qualitatively) in the budget (i.e., contracts). There are usually a number of supplementary and incentive funds that the hospital or department can apply for as well. In the hospital sector, patients' diagnoses and treatments are recorded in the National Patient Register.

Qualitatively, production providers are controlled indirectly in a number of ways. A number of clinical databases have been established at the national level to survey clinical outcome (e.g., hip replacement, stroke, wound infections, and laparoscopic surgery) (61). The clinical databases are accessible only to the database contributors, not to public authorities. The databases are therefore not used for public control of production. Rather, they serve as sources for research and internal quality control.

Another control mechanism is patient surveys. For hospital services, it is now common to use surveys to assess patient satisfaction. The issues covered in the surveys are usually process-related. These patient surveys may not be a means to evaluate the quality of care, but they give an impression of how patients experience their stay at the hospital.

To ensure patients' legal rights, a number of laws have been passed in Denmark regulating patients' rights and the possibility of making complaints and receiving damages. The aim of these laws is to create a set of rules to ensure patients the best possible treatment and care in all situations. A complaint system has been established regarding professional treatment in the health service. The Patients' Board of Complaints is an independent public authority that can express criticism toward the medical staff or submit particular cases to the public prosecutor with the aim of taking the cases to court. Patients may also claim damages in connection with treatment in public hospitals, through the Patient Insurance Scheme that was set up in 1992. Finally, patients may also receive compensation for harm as a consequence of using pharmaceuticals (43).

## Attempts to Channel Research

Research is carried out under the auspices of a number of different bodies: at universities, at national research institutes within the health sector, in the hospital sector, in the primary care sector, and in private firms. This arrangement means that responsibility for and financing of health service research are divided among a number of official authorities and private companies. Overall responsibility for health science research lies with the Danish Ministry of Research, through the Danish Council for Research Policy. The Ministry of Health,

which is responsible for health service as such, also plays an important role in health science research.

In the Danish Council for Research Policy, there are six research councils, one of which is the Danish Medical Research Council (DMRC) (17). The DMRC functions as a public research fund, and every year the council grants support to medical research. It also gives independent, professional advice on medical problems to the Danish Parliament, the government, the Danish Council for Research Policy, and other public authorities, as well as international research organizations and, to a certain extent, private foundations. It is the purpose of the DMRC to ensure that Danish medical research has a basis for renewal and stability. It is a long-term goal of the DMRC to allocate half of its research budget solely on the basis of quality, within all areas of importance for the health and treatment of patients. The remaining half of the budget is to be allocated to research for which the subject or organization has been determined beforehand. During the current period (1998–2002), the council has decided to allocate half of its budget to priority activities. The priority areas are consistent with the priority areas recommended in the National Strategy mentioned below, except for health services research. The rest of the budget is allocated partly to other research areas affecting the promotion of health and treatment of patients and partly to intercouncil programs.

In 1994 the Ministry of Research appointed a committee to develop a national strategy for Danish health research. This National Strategy Committee for Health Research proposed a national strategy characterized by, among other things, the following elements (46):

1. Securing human resources through a deliberate investment in recruiting researchers, educating researchers, and forming positions for researchers;
2. Selection of research topics in areas that have been given specific priority, encompassing:
   - *Genetic research*, which covers genetic epidemiology, genetic diagnostics and therapy, and treatment based on gene technology;
   - *Clinical intervention research*, which aims at establishing a foundation for direct improvements in prevention, diagnosis, treatment, and care;
   - *Brain research*, which encompasses basic biomedical research, clinical research, and public health research;
   - *Preventive research*, which aims at explaining both how people stay healthy or develop diseases and die, and how diseases can be prevented in the population in general. Preventive research also includes evaluating the effectiveness of all methods and interventions in question; and
   - *Communication* of the results of research as an integrated part of the research activity.

## Problems with the Controlling Mechanisms

Extensive use of medical technology may have resulted in better care, but it has also caused a steady increase in the cost of health care. Through new medical technologies the medical profession has generated and promoted a range of new demands to be met by hospitals. New pharmaceutical products have made it possible both to treat more patients and to treat patients more successfully. Examples of new pharmaceutical products are beta-interferon used for treatment of patients with multiple sclerosis and a new combination treatment for patients with HIV. Both products are very expensive, and their long-term effects are not known.

In past years the Danish health sector has rarely been an early adopter of new medical technology, and often new medical technology has seemed to diffuse more slowly here than in many other industrialized countries. This has been shown in a number of individual cases of expensive or controversial medical technology (e.g., computed tomography, heart transplantation, shockwave lithotripsy, and mammography screening) but has never been

subject to a systematic evaluation when it comes to new generic medical technologies. However, an appraisal of the hospitals' need for replacing medical equipment estimated a national unmet need for investment and reinvestment of DKK 1.8 billion in 1995 (27). This finding might indicate an underutilization of certain modern health technologies.

Waiting time for hospital services, and in particular for surgical procedures, is another problem. The average length of waiting time for an operation has increased from 86 days in 1992 to 102 days in 1995. About one-third of patients with nonacute conditions have a waiting time longer than 3 months (59). For political purposes, a waiting time of less than 3 months has been guaranteed for two selected diagnoses; this action is mainly a quality improvement initiative. Patients may choose either shorter waiting times and longer distances to the treating hospital or longer waiting times and shorter distances. Whether this initiative will lead to improved efficiency in the long run is uncertain.

Free choice of hospital introduces regulated competition into Danish health care service. The emphasis here is on incentives rather than controls. Free choice of hospital might lead to decreased allocation efficiency in hospital services if the capacity to decrease resource utilization in hospitals experiencing less demand is not matched with an increase in resource utilization in hospitals experiencing more demand. Another possible drawback with this initiative is the uncertainty in planning. Whether a hospital or a department will be able to maintain its level of expertise and its investments in technology depends on its ability to attract patients.

The hospital sector is controlled within a framework of legislation and global budgets. Being responsible for more than half of the counties' budgets, hospitals have always been the target of cost-containment initiatives based on the idea that such a large area has great potential for increasing efficiency and reallocation of resources. Faced with stagnating or even decreasing revenues to spend on hospitals, county councils have increasingly focused on the expenditure side. The possibilities have been rationalizations (e.g., new medical technologies), structural changes (e.g., greater emphasis on outpatient care), reallocation of resources, and/or general reductions of expenditures (e.g., not filling posts) (5).

An increasing number of patient complaints should be considered a major problem in health care. In recent years, the quality of hospital services has been debated repeatedly in public. In addition to waiting time problems, medical technologies such as bone cement, kits for HIV testing, and blood-based products for hemophiliacs have been criticized.

Finally, there are two general problems with the control of healthcare technologies. The first problem occurs when the decision-making process is initiated by the media; for example, a patient's need for a treatment not yet provided is presented on television, which leads the Minister of Health to decide to implement this particular treatment. In such examples, of which there have been quite a few, the normal control mechanisms might be bypassed and comprehensive assessments cannot be used. The second, and more common, problem occurs when there is a broadening of indications.

## Recent Policy Reports and Papers and Future Proposals

In 1995 the government and the Conservative Party agreed to establish a hospital commission (*Sygehuskommisionen*) with the following objectives (59): a) to examine whether the Danish hospital sector can be organized in a more suitable way; and b) to examine whether a change of structure or better utilization of resources will reduce the total waiting time.

The commission finished its report at the end of 1996. It did not recommend any change in the overall financial structure of the Danish healthcare system. Neither did it put the introduction of new copayment arrangements on the agenda. The recommendations included: a) the use of global budgets should be further developed (e.g., by the use of incentive funds); and b) a continuing development of contracts, where activity and economics are linked

together. There is a need for an investment policy and an improved coordination of technical equipment among the counties, which should be backed up by strengthening the national effort in medical technology assessment.

In 1995 a group of health economists prepared an economic evaluation of pharmaceuticals on the behalf of the Danish Medicines Agency (at that time a part of the National Board of Health) (3). The report recommended that, in principle, economic analysis should be pursued for all pharmaceuticals, but only simple price comparisons should be undertaken for generic medicines. Danish health authorities have now decided to introduce economic evaluation of new pharmaceutical products on a voluntary basis for 2 or 3 years. It was further recommended that later guidelines for economic evaluations be introduced in a harmonized and mandatory version (4).

There are a number of recent, more specific policy reports on issues such as breast cancer, maternity care (ultrasound scanning and amniocentesis), cervical cancer, newborns, immunizations, gene technology, in vitro fertilization, and transplants.

## POLICIES RELATING TO SPECIFIC TECHNOLOGIES

### Screening

Implementing new screening programs and stopping ongoing programs are frequently subject to political as well as professional debate. The Danish Cancer Society appears to have considerable influence when it comes to the question of whether a certain screening program for cancer should be implemented or stopped.

There are numerous examples of increased screening activity outside public health programs (e.g., ultrasound scanning of pregnant women). This is so-called opportunistic screening, as the screening is not always made in response to an indication. The screening takes place without any official agreement or recommendation from the health authorities. Opportunistic screening may involve a substantial use of resources without a corresponding benefit for the population (20).

Until recently, pregnant women were offered a test for HIV. Today only certain risk groups are offered an HIV test.

### Breast Cancer

In 1989 a subcommittee of the National Board of Health recommended—on the precondition that the demands for capacity and organization were fulfilled—that mammography screening be implemented in Denmark according to certain criteria. These criteria are that women in the age group from 50 to 69 years should be regularly examined by mammography and the first examination should include two pictures of each breast. The women should as a rule be offered a repeated examination after 2 years with one picture of each breast (60).

In 1997 the National Board of Health recommended in a status report on breast cancer to the Ministry of Health that women in the age group from 50 to 69 years should be offered a mammography screening every second year. It recommended that mammography screening be organized so that women are called in every second year. The report was prepared by a group of professionals appointed by a committee concerning breast cancer under the National Board of Health. The National Board of Health finds it necessary to monitor mammography screening and breast cancer treatment (69).

To date, the county of Funen and the municipalities of Copenhagen and Frederiksberg have implemented mammography screening. The last couple of years have seen repeated discussions of whether mammography screening should be offered as a screening program or on indications only. The focus has mainly been on the positive consequences of screening. The negative consequences have been given less attention.

### Cervical Cancer

Cervical cancer is the only form of cancer submitted to systematic screening in Denmark. In 1986 the National Board of Health recommended that tests should be offered to women every third year and should include primarily the age group from 23 to 59 years. Women in the age group from 60 to 75 years should be offered the test for a specific period of years. Furthermore, it was recommended that the smear method be used and that the program be computerized and coordinated with invitations to women not previously tested (58). Today almost all counties are offering systematic screening for cervical cancer. The lower age limit is 23 years in all counties, whereas the upper age limit varies from 45 to 70 years (58).

### Ultrasound Scanning of Pregnant Women

Screening by ultrasound is currently offered by half of Danish birthing facilities. Approximately 90% of all pregnant women are scanned, typically during 16 to 18 weeks of gestation. Recently, the National Board of Health concluded that ultrasound scanning of pregnant women should not be performed on a routine basis. If, in spite of the recommendation, the county chooses to carry on with ultrasound scanning of pregnant women on a routine basis, then it is requested to inform the women about the aim and content of the ultrasound scanning. This request was formulated because many women believed that only if they had ultrasound scan could they be assured that nothing was wrong with the fetus. It was recommended that ultrasound scanning be offered only for indications such as uncertainty about gestational age and suspicion of multiple fetuses or fetal malformations (66).

### Amniocentesis

Women past age 35 are offered amniocentesis, as are women who have had a stillborn or handicapped baby or at least three miscarriages. If someone in her immediate family has had a stillborn or handicapped baby or if the father is over age 50, (67) the woman is also offered amniocentesis.

### Newborns

Newborns are tested for phenylketonuria (PKU) and congenital hypothyroidism. All newborns whose family history suggests an increased risk of developing allergy have a test to determine whether they actually have an increased allergy risk.

### Immunizations

Young people below the age of 18 who are Danish nationals or residents in Denmark can be vaccinated against whooping cough, diphtheria, tetanus, polio, measles, mumps, and Hib infection (*Haemophilus influenzae* B, meningitis, and epiglottis). Females over the age of 12 who are Danish nationals or residents in Denmark can be vaccinated against German measles (43;68). The vaccinations are given by GPs, and the cost is covered by the counties (43).

### Biotechnology

***Gene Technology.*** Within the area of gene technology, the Danish Parliament has passed an act on the employer's right to require health information in relation to employment. According to this legislation, the employer is not allowed to require any gene diagnostic test from the employee (18).

***In Vitro Fertilization.*** When new methods of treatment within the area of reproductive technology are begun, they must be reported to the National Board of Health and the

Danish Council of Ethics. The National Board of Health and the Danish Council of Ethics then make a report to the Minister of Health, who supplies the Parliament with information about the statement. It is then determined whether the new treatment method is ethically acceptable (33). In vitro fertilization treatments are carried out both in the public health sector and in private clinics. Because of long waiting periods, many people go to private clinics. Normally, women who satisfy a number of criteria are offered three attempts in the public health sector. Just recently, an act was adopted that made it illegal for lesbians and women over the age of 45 to have in vitro fertilization treatment.

***Transplants.*** In Denmark, kidney transplants on patients with end-stage kidney disease have been performed since 1963, and pancreas transplants since 1987. After introduction of brain-death criteria in 1989, transplants of hearts and livers began in 1990. In 1992 transplants of lungs were also included (49).

Organ transplantation is organized in a few transplant centers, that is, transplants of heart/lung and lungs are performed only at one hospital, while transplants of hearts are performed at two hospitals (49).

Generally, there is a shortage of organs despite a number of public campaigns aimed at getting people to decide whether they want to be organ donors. People can set up a so-called organ will, but relatives may refuse to comply with the will. The organs come from Danish donors and from foreign donors through the international exchange schemes Scandia-transplant and Euro-transplant. The largest number of transplants are kidney transplants from living donors (49).

## HEALTH TECHNOLOGY ASSESSMENT

In Denmark there now seems to be general agreement on the definitions of health technology and health technology assessment (HTA) (47): Health technology encompasses prevention, examination, treatment, care, and rehabilitation—within and outside the health service. The term "health technology" should not be limited to a narrow definition of equipment, but should also include drugs, examination methods, treatment, care, rehabilitation, health education, and health promotion interventions. A health technology assessment is a comprehensive systematic evaluation of the assumptions for, and consequences of, the application of health technology.

HTA was originally adopted from the United States, and international cooperation has influenced its development. However, the concept has also been adapted to some extent to Danish culture and health services. As it appears from the following sections, the Danish view of HTA seems to differ from the European trend by being slightly more oriented toward the public and more decentralized, and perhaps slightly less science based, than is the case in a majority of countries with active HTA.

HTA in Denmark is oriented toward the public in the sense that various parties of interest participated in developing HTA over the years and in subsequently formulating a national HTA strategy, and that statements issuing from Danish consensus conferences are directed mainly at the public and decision makers in politics and administration. In Denmark HTA is decentralized, as demonstrated in the national strategy for HTA, which explicitly states that HTA should be applied not only centrally but at all levels in the health service as a systematic process in planning and operational policy and as an underlying process for the routine clinical decisions of health professionals (47). Here HTA is based less on hard clinical evidence, since data on clinical effectiveness in Danish HTAs are often gathered through their own clinical trials, expert opinion, and occasionally a limited literature review. Comprehensive and systematic reviews of scientific literature (not to mention meta-analyses) are still uncommon in regional HTAs, and have been used in a limited number of national HTAs.

## History of HTA in Denmark

The following description of the historic development of HTA in Denmark is based on literature and interviews with a number of (former) key actors. To the extent possible, it is presented in chronological order. HTA organizations and programs that still (i.e., in 1997) exist are mentioned here and discussed later in detail, whereas previous organizations and programs are only briefly described in this section.

The concept of HTA was apparently introduced in Denmark in 1979–80 by Dr. Per Buch Andreasen, a general internist. Its appearance was strongly influenced by the success of the U.S. Office of Technology Assessment (OTA), but its development in Denmark has roots that can be traced back to the early 1970s. After some initial university studies in the late 1960s and early 1970s on such topics as macro-economic analysis and financing of health care, the concept of health economic analysis was introduced in 1972 by a medical doctor in his thesis on traffic accidents (29), and shortly thereafter followed by the first Danish textbook on health economics (30). It took a decade before the concept started diffusing in the Danish health service, and another decade before it was more or less generally accepted by the medical profession.

In 1973, based mainly on Anglo-American literature, modern methods of medical statistics, rational clinical judgment, and medical decision making were introduced in Denmark in a textbook (74). These concepts were accepted faster by the medical profession than was health economics, but 15 years later they were still insufficiently represented in the syllabus for medical students. It took 5 years after its origin for the conceptual successor, evidence-based medicine, to be introduced in Denmark in 1996 (32;38).

Throughout the 1970s an extensive public debate took place on the potential consequences of new technology for the individual, society, and the environment. Generally the debate or criticism concerned energy technology, production technology, information technology, and genetic engineering. The debate was often initiated by grassroots movements and academics. The government supported some information campaigns and technology assessments. The concept of technology assessment was adopted from the OTA in the mid-1970s (36), but the assessments were often so-called advocacy assessments (i.e., technology assessments performed by only one interested party, and thus—at least in the aspects to be evaluated—potentially biased). In 1978 the Council of Technology (Ministry of Industry) appointed a committee to discuss and suggest how to organize technology assessment in Denmark more systematically. The committee suggested the establishment of a Council of Technology Assessment to initiate, coordinate, and grant technology assessments to be carried out in a decentralized manner at already existing research institutes, but it gave the assessment of products and consumer goods (including medical technology) low priority (72). It then took two bills, another committee report, much public debate, and five more years for the Danish Board of Technology to be established.

During the extensive public debate on the potential consequences of new technology in general, Ivan Illich's thought-provoking book *Limits to Medicine* (21) was published in Danish in 1977. This led to informal discussions among members of Parliament, in which members of the Research Council also participated. Eventually the subject was raised in the Parliament's Standing Research Committee (*Folketingets Forskningsudvalg*). In 1978 the Research Committee formed a subcommittee called Limits to Medicine (*Lægevidenskabens grænser*), which included medical experts from bodies such as the DMRC. One of the members of the subcommittee was Per Buch Andreasen, who in May 1979 was commissioned to produce a background paper for the Research Committee, while the Research Council granted him leave and a study visit to the OTA. After articles in a newspaper and a journal in late 1979, Andreasen's white paper—regarded as the official birth of HTA in Denmark—was published on April 9, 1980 (6). At the same time, the first Danish HTA concerning laboratory automation was undertaken and published (23).

In light of efforts to limit the resources allocated to health care, the necessity of HTA was obvious. The above white paper strongly emphasized the need for HTA initiatives to be taken within research communities and at political and administrative levels, and different models were suggested to institutionalize HTA at a national level. In particular, the institutionalization of HTA was debated within the health services, and this debate coincided with a discussion in wider circles on establishment of the above-mentioned Council of Technology Assessment. As a result, two HTA committees were formed.

Through a decree of state in 1982, the National board of Health was formally given the responsibility for HTA in Denmark (12). The board's Standing Committee on Health Planning (*Planlægnings- og visitationsudvalget* [PVU]) consequently formed a subcommittee on HTA with members from a variety of disciplines and backgrounds. The subcommittee's objective was to support PVU in establishing and developing HTA in Denmark, including to disseminate information concerning HTA. It published an HTA model with ultrasound screening of pregnant women as an example (19) and widely distributed easy-to-read booklets explaining the content and methods of HTA (1984 and 1987). The subcommittee apparently also influenced PVU and other committees under the National Board of Health, for a number of comprehensive assessments (but they were not called HTAs) were performed, for example, on transplantation of heart, lung, pancreas, and liver (1985), and on vaccination against mumps, rubella, and measles (1985). However, comprehensive assessments of medical technologies were also published prior to establishment of the subcommittee, for example, on treatment of hemophilia (1978), cardiac surgery (1978), and neonatal screening (1980).

Also in 1982, the DMRC formed a subcommittee on health services research and medical technology assessment, with the aim of mapping the need for research, stimulating research, and supporting the DMRC in these areas (31). This subcommittee arranged a number of research seminars within the field of HTA, and arranged and cofunded a series of consensus development conferences, the first of which took place in 1983 and was on mammography screening.

The World Health Organization's (WHO) Europe office in Copenhagen had, since the early 1980s, a program on appropriate technology, and it was at the WHO Copenhagen office that the International Society for Technology Assessment in Health Care (ISTAHC) was founded in 1985. Both of these activities were barely noticed in the Danish health services, and they had little influence on the development of HTA in Denmark. The Danish adoption in 1984 of section 38 of the WHO program "Health for All: Year 2000," which recommends the establishment of a national mechanism for HTA, also had no visible impact.

In the mid-1980s a number of HTA seminars were arranged by the trade unions and others, and the Danish Hospital Institute arranged HTA courses and published a textbook (26). On a number of occasions, decentralization of HTA and the involvement of different parties of interest were discussed.

The Danish Board of Technology was set up by the Parliament as an independent statutory body in 1986 (71). The first president of the board was also the president of the Danish Nurses' Organization, which indicates the trade union's interest in the consequences of health technology and in HTA but which did not lead the Board of Technology to give a higher priority to HTA than to other technology assessments.

Following a public debate on organ transplantation and death criteria, the Danish Council of Ethics was established by the Danish Parliament in 1987.

At that time (1987–88) there was growing interest and activity in HTA in many places both inside and outside the health services, but there was no coordination or central force in the Danish National Board of Health or elsewhere. Then, for a period of about 5 years, just when other European countries experienced increased interest and activity in HTA, there

was a fading interest in HTA in Denmark. There are several reasons for the decline, the four most dominant being:

1. In exactly the same period of time, there was a Director General of the Danish National Board of Health who was not interested in HTA. Consequently no major initiatives were taken by the Board of Health to further this area.
2. In 1988 the board's Standing Committee on Health Planning, and therefore its active HTA subcommittee as well, was dissolved. A new HTA committee under the Board of Health was established in 1990, but it was given no power or resources.
3. The idea of clinical guidelines and of quality assurance was introduced by the Danish National Board of Health in 1988 and 1989, respectively, and interest in these other tools for quality improvement deflected for some years the focus away from HTA.
4. There was a need for oversight, coordination, and development of methods for the—to some extent—dispersed development of HTA, but no central body took the initiative.

In 1993 the Danish National Board of Health published a National Strategy for Quality Development in Health Care, which had been developed by the board together with the Danish Ministry of Health and WHO Europe (44). The strategy emphasizes the role of HTA. Concomitantly, a Standing Committee on Quality Development in Health Care was established, consisting of representatives from all major stakeholders. During the years since its establishment, a number of publications have been produced to inspire and coordinate activities. Individual publications address issues such as reference programs (clinical practice guidelines), standards and indicators, patient surveys and consumer involvement, and clinical databases for quality improvement.

In 1993 the Nordic Cochrane Center was established in Copenhagen.

In his opening speech to the Parliament, in October 1993, the Prime Minister noted the need to preserve and improve the quality of the Danish health services. The government then took the initiative to discuss a financial agreement with the counties. As a basis for these discussions, an ad hoc committee produced a report on the economy of hospital care (57). The aim of the report was to describe the recent development of production, resource consumption, and management tools in hospital care, and to analyze the main factors influencing future development, including the cost consequences of demographic and technological development.

The committee concluded that prior to implementation of a new technology in hospitals, there ought to be well-documented knowledge about its clinical effectiveness and comprehensive assessment of its social consequences. Furthermore, the committee recommended the establishment of an independent standing HTA committee under the National Board of Health, and that the county councils should give a higher priority to regional HTA (57).

As a consequence, the Danish National Board of Health in 1994 appointed a standing Health Technology Assessment Committee to strengthen the development and application of HTA. This committee consisted of 15 representatives of different parties of interest (i.e., the Ministry of Health, the Association of County Councils in Denmark, the DMRC, the Danish Hospital Institute, and the trade unions for medical doctors, nurses, and other health professionals). However, trade and industry were not represented. The committee was allocated DKK 1 million per year for its work. It existed for 3 years, until the Danish Institute for Health Technology Assessment was founded, during which time it managed to put HTA on the agenda in the Danish health services by publishing items such as:

- A revised brochure on HTA that was as widely distributed as its 10-year-old predecessor (62);
- A guideline for an administrative procedure based on the HTA concept (application for medical equipment) (63);

- A report on early warning of emerging medical technologies (52);
- A report on beta-interferon for the treatment of multiple sclerosis (64);
- A report on back pain (37); and
- The Danish national strategy for HTA (47).

The Ministry of Research appointed in 1994 a committee to develop a national strategy for Danish health research. In its report, the strategy committee—probably as a consequence of contact with the above HTA committee—explicitly mentions HTA and the Cochrane Collaboration, which also appear in the subsequent budget of the DMRC (46).

In early 1996, based on publication of the national HTA strategy and other Danish and international HTA reports, the time seemed to be appropriate for establishing a national HTA institute. The catalyst was public criticism of the quality of some kits for diagnosing HIV. With the recent experience of a scandal concerning bone cement, the Minister of Health felt strongly the need for better control of medical technology. Discussions in the Ministry of Health and with the new Director General of the National Board of Health led to a proposal, and in December 1996 the Parliament decided, by the adoption of the Finance Act for 1997, to establish the Danish Institute for Health Technology Assessment (DIHTA) (15).

Until the mid-1990s there was very little HTA activity within the regional health services, but since 1995 interest has generally grown and some HTA projects have been launched (described below). In an effort to coordinate these regional activities, in 1997 the Association of County Councils in Denmark established a network of HTA contact persons, one from each county and from DIHTA.

## A National Strategy for HTA

In 1996 Denmark was the first country to formulate an official national strategy for HTA (47). The strategy contains chapters on HTA—why, how, and where to get further information—and a main chapter on the strategy. Selected parts of the latter are reproduced in this section.[2]

## Background and Objective

Following a national analysis of the economy of the Danish hospital sector, a committee appointed in 1994 by the Danish Ministry of Health concluded that, prior to adoption of any new medical technology in the hospital sector, an assessment of the effect of the technology on health and a general assessment of its wider social consequences should be available. The committee emphasized the need to strengthen HTA both centrally and regionally in the individual counties. As a result of the committee's recommendations, the development of HTA within the National Health Service has been given a high political priority. In 1994 the Danish National Board of Health appointed a standing committee, the Health Technology Assessment Committee, to strengthen the development and application of HTA. The committee and its secretariat prepared the first Danish strategy for HTA.

The principal objective of the strategy is to establish a comprehensive basis for decision making for the introduction and utilization of medical technology at all levels of the health service. The aim is to ensure that, as far as possible, a HTA is undertaken for any new technology and that the concept of HTA becomes an integral part of routine decision making for planning and operational policy in the health service.

The strategy includes a number of overarching elements. An action plan has been developed for each of these elements, and a number of activities are planned centrally, at the county level, in the municipalities, in local hospitals and primary care facilities, and

within professional bodies. It is therefore intended that local strategies will be developed following the national strategy.

The elements of the strategy are:

1. HTA will be incorporated into planning and operational policy at all levels of the health sector, both centrally as well as locally, at the institutional level and at political, administrative, professional, and research levels. Relevant trade and industry will be invited to take part in a dialogue about HTA;
2. Criteria will be developed for priority setting and selection of HTA projects, and areas for independent Danish HTA projects will be identified;
3. Denmark will ensure that international HTA initiatives are monitored and the results applied to the Danish National Health Service;
4. The need for research and development of HTA methodology will be identified to strengthen the development of the HTA research program;
5. The National Board of Health will ensure national oversight and coordination of the development of HTA;
6. Financial resources will be allocated to ensure the viability of the strategy; and
7. The strategy will be regularly reviewed and amended, if necessary.

In the following section, the first four items will be discussed.

## HTA at All Levels of the Health Sector

A coordinated effort is necessary to implement the individual strategy elements and to reach the principal objective. The first task is to define roles and responsibilities at the individual levels of the health service.

The central government's health organizations have the following roles and responsibilities:

- To ensure that the concept of HTA becomes an integral part of the central administrative function. For example, the HTA Committee could assess the terms of reference for committees and task forces, health and health-related reports, and the basis for decisions in relation to HTA, highlighting potential need for incorporation of elements of the HTA strategy.
- To contribute to cooperation and coordination of HTA on a national scale, including central and local health departments, medical professionals, medical organizations, and research institutions (see also strategy element no. 5);
- To contribute to the development and establishment of a Danish early warning system for new health technologies and to cooperate with international centers for continued development and operation of such a system;
- To communicate HTA results;
- To contribute to the incorporation of the HTA concept in research planning; and
- To contribute to the incorporation of training in HTA principles and methods, in, for example, the basic medical curriculum, and to contribute to the development of educational programs on HTA for counties, municipalities, hospitals, primary care, and other health institutions to use in training managerial and other staff groups (multidisciplinary and monodisciplinary programs). In addition, a multidisciplinary network of HTA experts could be developed to provide training and advice in the use of HTA to managers, health staff, and clinical researchers.

DIHTA will be responsible for a number of these functions.

As those directly responsible for running the health service, county councils and municipal authorities have a special obligation to ensure that HTA is incorporated in the planning

and running of the health service. Their roles and responsibilities are outlined in the following:

- To integrate the HTA procedure into the decision-making process for the operation and planning of services;
- To integrate HTA as a routine decision-making tool, to be used when decisions are made concerning purchase of new equipment, major alterations, or the introduction of new methods of treatment or service;
- To coordinate all HTA activities with other quality development activities.
- To incorporate the concept of HTA into research planning.
- To provide necessary training in utilization of HTA (principles and methods) to all staff groups.
- To ensure that knowledge of HTA results is compiled, communicated and implemented.
- To participate in a Danish and international early warning system.

Suggestions for specific activities will be developed through discussions and further initiatives by DIHTA.

Professional organizations centrally and locally have a responsibility for defining activities within their own fields of interest, across institutional, municipal, and county boundaries. Included are medical colleges, the professional associations of nurses and professions allied to medicine (in the following, designated as medical scientific societies), specialist boards, and practice boards. Roles and responsibilities include:

- To identify the need for technology assessment of new and existing technology;
- To initiate and possibly implement HTAs;
- To contribute to a Danish and international early warning system; and
- To establish training opportunities in HTA principles and methodology.

Managers of research institutions have responsibility for incorporation of the HTA concept into the identification of research projects. Efforts will be made to encourage and inspire implementation of more HTA projects.

HTA will be promoted in Danish trade and industry that have interests in the health sector. In the long term, preference will be given in the competitive contracting process to medicines, medical equipment and technology, and utensils that have been developed and marketed based on an HTA concept. The global development of evidence-based medicine will accelerate considerably in the years to come. More and more professionals and decision makers in the health service will demand HTA for new products and methods.

A dialogue with the Ministry of Business and Industry and with Danish trade and industry interests will be developed to determine how HTA is to become known and applied in the private business community.

### Priority Setting and Selection of HTA Projects

Staff at all levels of the health service are responsible for identifying and drawing attention to areas where there is a need for HTA. This responsibility includes both the need for assessment of new health technologies as well as the need for evaluation of existing technologies. An early warning system for emerging health technologies will be established in Denmark in collaboration with an international early warning system.

In areas where there is a need for an independent national intervention, HTA projects will be undertaken as a basis for planning and operational decision making. Implementation of independent national projects should take place in cooperation with research councils, health authorities, and professional organizations. Comprehensive HTAs are extremely

demanding of resources. It would therefore be a global advantage if arrangements could be developed to spread the burden of HTA internationally. In some cases, international HTA projects that have already been implemented can be used by adapting them to Danish conditions.

A description of the areas of potential intervention will be compiled to enable the necessary priority setting and selection. Preliminary studies in the form of prepared data sheets for potential areas of intervention will provide an important basis for the selection and priority setting of health technologies for HTA projects. A data sheet should describe the importance of a possible assessment, the nature and extent of the clinical problem, the health technology and its alternatives, aspects important for patients, and basic information about organizational and economic consequences.

DIHTA will identify areas for HTA intervention following wide consultation with the medical colleges and societies, the counties, and research institutions. An early warning system will be developed after wide consultation with relevant stakeholders. DIHTA will ensure the initiation of, and will monitor the implementation of, HTA projects. Furthermore, DIHTA will contribute to the preparation of action plans for the implementation of the HTA results. These plans may involve communication of the results to decision makers, suggestions for the initiation of reference programs, and proposed initiatives regarding supplementary training.

## Criteria for Selection of HTA Intervention Areas

Appropriate areas for HTA could be:

- A common illness/condition that affects a large group of patients;
- A health technology whose adaption has specific ethical implications;
- Healthcare provision of acknowledged poor quality;
- Professional uncertainty in relation to indications and effects;
- Acknowledged or presumed inappropriate use of procedures;
- Major unexplained variations (e.g., regional variations in treatment patterns); and
- Actual or expected high cost.

The criteria for HTA coincide with the criteria for other quality assessment and development activities, such as reference programs (guidelines) and clinical quality databases.

An evaluation of the "value for money" of performing the technology assessment must be undertaken when setting priorities and selecting areas for intervention. The following are criteria for the expected outcome of the technology assessment.

*Expected positive effects of an HTA*:

- Improved outcomes for patients, including quality of life;
- Improved patient acceptability;
- Improved basis for planning/decision making;
- More effective utilization of resources; and
- Benefits from development of the methodology for conducting the technology assessment.

*The time scale for the positive results of an HTA to be realized*:

- Time required to conduct the technology assessment;
- Time required to introduce changes in practice;

- The importance of an early HTA, i.e., the assessment is undertaken prior to the adoption of the method.

Experience shows that once a health technology has been adopted, it may be difficult to withdraw it. This is the case, for example, with screening programs.

## International Cooperation

HTAs already undertaken in other countries, for areas of specified intervention, will be adapted to national conditions and utilized wherever possible, for example, published HTA reports and reports from consensus conferences. The results of these analyses will be implemented using methodologies such as the preparation of reference programs (guidelines).

An HTA database will be established for national and international HTA projects, which will allow systematic retrieval of information. DIHTA will establish cooperation with the Cochrane Collaboration and will apply for membership in the International Association of Health Technology Assessment Agencies (INAHTA) in 1998.

As part of the national Information Technology Action Plan (45), international databases will be made available in Denmark. This should provide the opportunity for individual hospital departments or practices to make routine use of information in the databases on specific methods for examination, treatment, or care.

## Research and Development of HTA Methodology

There is a need to identify and agree on the methodology to be used in HTA and to develop methods for early warning of emerging health technologies and for implementation of HTA outcomes. There is therefore a need to strengthen the contribution of research in developing new and existing methods for HTA, and it is important to develop the necessary research environment in the universities and research institutions to support this. Therefore, DIHTA will:

- Assist in identifying significant HTA research subjects, for example, through contacts with medical colleges and societies;
- Communicate with the DMRC, possibly by setting up a contact committee for this purpose;
- Evaluate the need for research on HTA; and
- Assist with the initiation of HTA research projects. An HTA research project on the development of an early warning system for new technology has been set up.

## Organizations and Programs Involved in HTA

***Danish Institute for Health Technology Assessment.*** DIHTA, was established in 1997 with an annual government grant and a budget of DKK 25 million. DIHTA is the state HTA organization and is placed in the National Board of Health.[3]

The purpose of the institute is to promote the application of HTA in Denmark, to manage information, to advise and provide training in the area of HTA, and in doing so to contribute to quality development in the health services. In cooperation with the county health care systems, the institute will carry out analyses and assessments in relation to new and existing equipment, remedies, treatment and care methods, methods for rehabilitation, health education, and prevention.

The board of the institute consists of major healthcare stakeholders. The aim of this board is not only to act as adviser to the director of the institute about existing activities but also to suggest new activities and supply new ideas.

A Scientific Board consisting of researchers from a multitude of medical and social sciences has been established. The aim of the Scientific Board is to act as research and methodology adviser to the institute.

The institute sees as its prime task to implement the National Strategy for Health Technology Assessment, which was developed and published by the National Board of Health in 1996. DIHTA will cooperate on HTA with partners in clinical departments and practices, administrative bodies, research institutes, internally with the National Board of Health, and with HTA institutions abroad. The purpose of this cooperation is to ensure the implementation of HTA in the running and planning procedure at all levels—central, regional, and local levels of institutional, political, administrative, professional, and scientific entities. Furthermore, DIHTA will develop a dialogue on HTA with relevant industries and business organizations.

At the moment, DIHTA consists of an interdisciplinary group of 10 persons. The group includes doctors, economists, and academically trained professionals with experience in HTA and scientific experience in relevant disciplines. Strategy and activity plans are continuously revised, and staff members visit various institutions, hospitals, and administrations as well as arrange meetings and give lectures on HTA. DIHTA is establishing an early warning system in Denmark, preferably in an international collaboration. DIHTA will pay special attention to the dissemination and implementation of HTA results at relevant levels of health care.

To assess the general interest in HTA and to raise the level of HTA activity, DIHTA first set aside DKK 10 million and called for proposals. The reaction was overwhelming: 110 applications for support of HTA projects were received from all levels of the health services and from the universities. DIHTA decided in the first round to support 26 projects, the results of which are expected in 1998–2000. Subsequently, a new call for proposals led to the support of about 30 new projects.

DIHTA has published a number of reports since the institute was established. Among these are beta-interferon treatment for multiple sclerosis, incidence, treatment, and prevention of back pain, and management of gallstones (10;25;54;55). Furthermore, the institute has other ongoing projects that deal with influenza vaccination of the elderly, diagnosis of colorectal cancer, rheumatoid arthritis, and positron emission tomography.

***DSI–Danish Institute for Health Services Research and Development.*** DSI–Danish Institute for Health Services Research and Development (*Dansk Sygehusinstitut*) is an independent research and development organization established in 1975 by the Danish government, the Association of County Councils in Denmark, and the city councils of Copenhagen and Frederiksberg.[4] The aim of the institute is to find better solutions to the problems faced by the planning and governing authorities within the healthcare services.

As of 1998, DSI had a multidisciplinary academic staff of more than 20, including doctors, nurses, economists, planners, sociologists, a lawyer, and a biomedical engineer. In addition to its permanent staff, DSI has a network of associated external consultants. DSI runs the only public Danish health services research library.

The institute has an annual budget of approximately DKK 25 million, one-third of which is covered by a block grant from the county councils and Copenhagen Hospital Trust.

The Institute carries out research and development and provides advisory services within a number of areas under the following headings: health economics, including economic evaluation, measurement of productivity and efficiency, and financing; health and hospital planning; health management, including implementation of clinical guidelines, quality assurance, consumer involvement, and human resource development; health informatics; and technology assessment. DSI publishes its research in a report series and in journal articles. The institute arranges and contributes to postgraduate courses and seminars for various health professionals, administrators, and politicians.

DSI has managed and participated in a number of national and international HTA projects and activities, with international examples including EUR-ASSESS and HTA Europe, activities within INAHTA, European projects on the assessment of medical informatics, and publication of *Changing Professional Practice* (73).

***The Danish Board of Technology.*** The Danish Board of Technology is an independent body established by the Danish Parliament (the Folketing) under the Board of Technology Act No. 375 of June 14, 1995.[5] The first Board of Technology was set up as a statutory body in 1986 (72). In the Parliamentary debate on the bill, the need for comprehensive assessment, especially of medical technology, was emphasized, but it was made clear that the board should deal with all kinds of technology (16). The statutory body was replaced by the present board on July 31, 1995.

The Board of Technology is composed of a Board of Governors, a Board of Representatives, and a secretariat. It is self-governing but organizationally attached to the Ministry of Research and Information Technology.

According to its legislative mandate, the Board of Technology's tasks, covering any kind of technology, are:

- To organize independent technology assessments and carry out all-round assessments of the potentials and consequences of technology;
- To initiate activities relating to public enlightenment, education, and communication; and
- To advise the Danish Parliament and government.

The Board of Technology builds on the democratic traditions in Denmark. The board must therefore:

- Help inform and generate debate on as broad a basis as possible;
- Use the insight, experience, and credibility of lay people in its assessments of technology;
- Make use of expert knowledge and contribute to basing the debate on factual and relevant arguments; and
- Support democracy by initiating relevant and important technological debates among the public and among policy makers and decision makers.

The board applies different methods of assessing technology. An interdisciplinary group of experts may conduct analyses offering an overview of the issue and strategic policy options. Citizens also may formulate objectives, visions, requirements, and needs. This can be achieved by, for example, scenario workshops and consensus conferences. It is an essential task to contribute to the development of methods for assessing technology, especially methods involving the citizens affected by the technology in question.

An important part of the board's work is to provide advice to the Danish Parliament and government. This consultancy can be provided in several different ways. The board can, of its own accord, draw politicians' attention to problems that they need to address, or it can take on assignments that the politicians wish to have performed. The board is in direct contact with Parliament to answer concrete questions and organize hearings at the request of politicians.

An annual appropriation of approximately DKK 10 million is set aside for the Board of Technology.

Health issues may be an aspect of any assessment made by the board. Examples of assessment activities specifically in the health field are: infertility, a consensus conference (1993); gene therapy, a consensus conference (1995); estrogen-like substances and men's capacity for reproduction, a hearing (1995); telemedicine, an assessment and hearing (1997);

and medical technology assessment, a (planned) workshop centering on how to ensure that medical technology assessment has a real impact on decisions concerning the health sector (viewed as a preliminary project for a possible major project in the future).

## Consensus Conferences: Danish Models

In 1983 the DMRC, in cooperation with the Danish Hospital Institute,[6] launched a series of consensus conferences that continues to this day. So far 13 such consensus conferences have been held; the most recent (March 1997) was on laparoscopic surgery (14).

The original concept of consensus conferences was adopted from the U.S. National Institutes of Health (NIH) but slightly changed because the objective differs. In many countries the consensus conferences aim at influencing the quality of clinical practice and thus are dominated by medical experts (24). Statements from Danish consensus conferences are directed mainly at the public and the decision makers in politics and administration, whereas influencing the medical profession has been a secondary goal. This emphasis is demonstrated not only in the identification of topics for the consensus conferences but also in the composition of the panels, which produce the consensus statement on the basis of technology specific expert papers. To establish a clear distinction between experts and the panel, experts in the technology to be assessed are deliberately not included in the panels. Panels include distinguished medical scientists, experienced clinicians, and representatives from the ranks of healthcare administrators, economists, and the informed public (e.g., journalists, politicians, and consumer representatives) (7). Apart from that, the process is similar to that of the NIH.

The Danish Board of Technology successfully adopted the idea of medical consensus conferences and applies it both inside and outside the field of medicine. The board goes even further in avoiding expert dominance of its consensus conferences. It publishes newspaper invitations for lay people to participate as panel members, and it selects a representative group of citizens for the panel. Prior to the conference the lay panelists are introduced to the topic and define the questions to be answered (28). The board also has a close connection to decision makers, in particular to the Parliament and government, so the results of its consensus conferences are more likely to be utilized.

The Danish experience demonstrates that consensus conferences may be a forceful social technology with a strong potential to influence decisions about medical as well as nonmedical technology (7).

## Odense University, Center for Health and Social Policy

The Center for Health and Social Policy (CHS) at Odense University was founded in 1991 as an interdisciplinary center within both the School of Business and Economics and the faculty of health sciences. The research staff consists of 7 senior researchers and 12 junior researchers from the fields of economics, statistics, demographics, and health sciences. Teaching is carried out at the master and doctorate levels. Besides research on demography and aging, CHS has a strong interest in research and education in HTA, particularly with the focus on health economics. This research can be divided into two main areas: a) HTA and economic evaluation; and b) economic health services research.

The research carried out under the heading of HTA and economic evaluation includes such topics as the methods and practice of HTA in other countries, diffusion research on selected technologies (e.g., laparoscopic surgery), guidelines for economic evaluation, applied economic analyses, and research on methods of estimating of costs and benefits. Examples of applied economic analyses are cost-effectiveness analyses of screening for colorectal cancer, breast cancer and cervical cancer, cost-benefit analyses of injury prevention, and cost analysis of interferon treatment for hepatitis C and of diagnosis and treatment of back pain, dementia, and injuries.

CHS is also responsible for the economic analyses in several ongoing HTA projects financed by the Danish Institute for HTA (e.g., an HTA of the treatment of patients with cholelithiasis in Denmark, and a Nordic multicenter HTA of a new kidney stone therapy). Research on methods of estimating costs and benefits focuses on measuring direct and indirect costs (friction costs versus human capital costs), willingness to pay, design and modeling, revealing preferences, and discounting life-years gained.

In the other health economic research area at CHS, economic health service research, the topics are the organization and financing of the healthcare sector, econometric models of human production during a lifetime, analyses of preferences and attitudes of the population toward healthcare services, models of early warning of emerging health technologies, equity in the delivery of healthcare services, and health economic and econometric models of aging.

### Other Universities

Other university institutes have some HTA activity, albeit not very much. For example, the Institute of Social Pharmacy at the Royal Danish School of Pharmacy has conducted a few HTAs and imparts undergraduate and postgraduate training in HTA. At Aalborg University, the Department of Development and Planning works on proactive HTA. At the Copenhagen University Institute of Social Medicine, HTA is becoming part of the Master of Public Health training, and at the Technical University of Denmark undergraduate students in biomedical engineering receive short courses in HTA.

### The Danish Institute for Clinical Epidemiology

The Danish Institute for Clinical Epidemiology (DICE)[7] is an independent sectoral research institute under the Danish Ministry of Health. DICE's principal purpose is to carry out research and reviews in the field of health, diseases, and mortality of the population and in the field of health promotion, prevention, and treatment (13).

With a cross-disciplinary academic staff of more than 20, the main work of the institute comprises research on the health of the population, health services research and evaluation, methodological and development projects, and reviews.

Epidemiologic studies are often an important part of HTA. DICE produces epidemiologic figures and has access to individually based epidemiologic registers such as the Danish Register of Causes of Death. The institute also manages several disease-specific registers. In its health services research and evaluation program, DICE has also carried out comprehensive assessments on topics such as technology assessment of the treatment of gallstones, evaluation of the effect of a statutory 3-month waiting guarantee for knee replacement and slipped disc surgery, equalities/inequalities in the population's utilization of health services, and rates of surgery in the Nordic countries, including the variation between and within nations.

### The Nordic Cochrane Centre

The Nordic Cochrane Centre opened in October 1993.[8] A network with collaborators in the five Nordic countries has been established, and contacts have also been made with researchers in Lithuania and Russia. The Center is the Cochrane Reference Centre for Nordic countries (Denmark, Finland, Iceland, Norway, and Sweden) as well as other countries (Estonia, Latvia, Lithuania, Mongolia, Poland, Russia, and the Ukraine).

The objectives outlined in the strategic plan for the Nordic Cochrane Centre and Network are:

- To facilitate the preparation of high-quality, up-to-date systematic reviews across a broad range of healthcare topics.
- To promote awareness of, access to, and use of Cochrane Reviews;

- To provide central coordination and a focus for Cochrane activities within the countries serviced by the Nordic Cochrane Centre;
- To provide central coordination for software development within the Cochrane Collaboration;
- To contribute to research relevant to systematic reviews, especially on bias and on nonspecific (placebo) effects of health care;
- To contribute to the efficient operation and sustainable growth of the Cochrane Collaboration; and
- To achieve financial sustainability for the Nordic Cochrane Centre.

On behalf of the collaboration, a number of tasks are undertaken, such as: collaborative review groups, including hepato-biliary, colorectal cancer, and anesthesia (Copenhagen); Methods working groups, including empirical methodological studies (Oslo), and placebo, and nonrandomized studies (Copenhagen); and coordinate software development within the collaboration.

About half of the funding sources are Danish public or private organizations, and the rest are located in the other Nordic countries.

## The Danish Council of Ethics

The Danish Council of Ethics[9] was established by Parliament under Act No. 353 of June 3, 1987, on the establishment of an ethical council and the regulation of certain forms of biomedical experiments. The act was amended in 1990 and 1992. The council is under the organizational jurisdiction of the Minister of Health, but the minister has no instructional powers toward the council, and the minister also has no obligation to follow the council's recommendations.

The task of the Danish Council of Ethics is to provide the Danish Parliament, official authorities, and the public with ongoing advice and information about ethical problems raised by developments in the national health service and the field of biomedicine. This work is accomplished by submitting reports and statements in specified areas and by mounting debate-generating activities in various forms. Some published reports are on the ethical aspects of death criteria (1989), fetal diagnosis and ethics (1991), genetic screening (1993), assisted reproduction (1996), cloning (1997), late induced abortions (1997), treatment of psychiatric patients (1997), prenatal diagnosis (1998); organ donation (1998), and screening (1999).

Reports from the Council of Ethics are not HTAs, but they could constitute an important contribution to a comprehensive assessment of the technology in question. The report *Priority Setting in Health Service* takes a broader view (9). It describes how decisions are made in the health service, the priority-setting tools available (including health economics and HTA), and the values and goals for the health service; the report also recommends how priority setting ought to be done.

## HTA Activities in the Regional Health Services

With the aim of introducing HTA at all levels of the Danish health services, one of the first activities of the National Board of Health's first HTA committee was to publish in 1984 an easy-to-read booklet explaining the concept of HTA. Although this was followed by more teaching material, courses, and numerous lectures and talks, the implementation and diffusion of HTA in the regional health services progressed very slowly for a decade. Suddenly in 1995–96, the level of regional HTA activity apparently rose, boosted among other things by the new national HTA strategy and the decision to establish DIHTA.

To the extent that it has been verifiable via the Association of County Councils in Denmark's HTA network, the status of HTA activity in the 15 counties in autumn 1997 seemed to be:

- Five counties had or were working on a formal regional HTA strategy, policy, and/or activity plan;
- Four counties had or planned in 1998 to have one or more staff members fully engaged in HTA;
- Six counties reported that they have performed or are performing actual HTA projects;
- Eleven counties reported that they use the HTA concept in administrative and other procedures; and
- Only one county expressed no interest at all in HTA.

A number of HTAs are (at the end of 1997) in progress in the regional health services, mainly in university hospitals, on topics such as nutrition therapy for head-neck cancer patients, colon and rectum cancer screening, rehabilitation after stroke, compression stockings, drug prescription in a department of internal medicine, and use of the gamma knife for brain surgery. Often a clinical trial is a major part of these regional HTAs, whereas critical literature surveys and meta-analyses are rare.

## Appraisal Activities in Industry

In the Danish pharmaceutical industry most of the companies are very interested in health economic analyses, and in total about 10 health economists are employed. Following a round-table discussion among industry and Danish health authorities, the latter have decided to introduce the economic evaluation of new pharmaceutical products on a voluntary basis for 2 to 3 years, as part of applications for public reimbursement (4). Some of the pharmaceutical companies have also shown interest in HTA, for example, by financially supporting HTA projects performed at Odense University and at DSI, and by arranging HTA seminars.

The Danish medical device industry has only lately shown a modest interest in health economics, evidence-based medicine, and HTA. The pharmaceutical as well as the medical device industry are, however, represented on the governing board of the new DIHTA.

## Level of Interest and Involvement

The level of interest and involvement in HTA has varied in Denmark since HTA was introduced in 1980. Denmark was among the first countries in Europe to introduce HTA, and the country's interest in HTA increased, as did that of other countries, until late in the 1980s. As mentioned before, it then decreased to a very low level for about 5 years. Since 1994–95, there has been a sudden increase in interest and involvement at all levels of the health services.

On the national level, the attitude of the Parliament and the Ministry of Health toward HTA is clearly positive, as reflected by the founding and support of DIHTA and financial support of comprehensive assessments of the consequences of medical informatics. DMRC, in its strategy plan for 1998–2002, designates health services research as a high-priority activity. In this area, DMRC will analyze the decision processes that exist within the health sector and evaluate the services that are chosen (i.e., DMRC will continue to support HTA projects).

A 1996 questionnaire to all heads of regional and local hospital administrations also showed great support for HTA (34). Seventy-seven responded, corresponding to an overall response rate of 90%. The questionnaire results are summarized in Tables 2 and 3. As the perception of what HTA is might vary (in spite of a national definition), these results should be taken with some caution, as they are indicative only.

As one would expect, HTA is regarded as less relevant and is less used by small hospital administrators than by large hospital and regional hospital administrators.

The cause "lack of knowledge" is ranked highest by the small hospitals, whereas the causes "demands resources" and "political realities" are ranked highest by regional hospital administrators, who are closest to the political level of decision making.

**Table 2.** The Perception and Diffusion of HTA in Danish Hospital Administrations

| | Yes (%) | Don't know (%) | No (%) | Total (%) |
|---|---|---|---|---|
| Do you regard HTA as a relevant tool for decision support in health planning? | 96 | 4 | 0 | 100 |
| Do you formally apply the HTA concept in purchasing expensive medical equipment? | 68 | 5 | 27 | 100 |
| Do you formally apply the HTA concept in connection with other planning/projects? | 38 | 9 | 53 | 100 |

***Source:*** Larsen (34).

**Table 3.** Causes for Lack of Interest and Involvement in HTA

| Causes for the current lack of interest and involvement in HTA | Responders (%) |
|---|---|
| Lack of any knowledge of HTA | 61 |
| View of HTA as demanding resources | 53 |
| Political realities minimize the importance of HTA | 38 |
| View of HTA as difficult to comprehend and use | 23 |

***Source:*** Larsen (34).

Until now only a few Danish researchers have participated in specific European HTA projects. The national strategy emphasizes the need for Danish involvement in international collaboration, and DIHTA will give priority to encouraging and funding participation by Danish researchers, and especially by university researchers.

## Use of HTA Results

There is no regulatory mechanism in the Danish health services requiring the use of HTA in policy decisions, planning, or administrative procedures. On the national level, a number of comprehensive assessments of health technology since the late 1970s have, without being labeled HTA, formed the basis for health policy decisions at the National Board of Health. In some cases, HTAs have had a distinct influence on the decision, such as:

- HTA of beta-interferon for the treatment of multiple sclerosis (64) was clearly the basis for the counties' voluntary limited use of this technology and for national monitoring of its clinical effectiveness;
- The Danish Board of Technology's consensus statements are usually debated in Parliament and are often used as a basis for policy decisions; and
- Based in part on a Nordic report on mammography screening in 1988 (8), the Ministry of Health decided to postpone a recommendation concerning this technology, on the grounds of the then lack of documented effect.

However, as HTAs have rarely been requested explicitly by decision makers, and as policy making is often a long and complex process, it is usually difficult to trace the extent to which an HTA was important in the decision. The extensive decentralization of HTA activity further impedes central appraisal of the use and success of HTA. There has been no attempt to evaluate the effectiveness of HTA in Denmark.

In general, there is no doubt that too little attention has been paid to the implementation of HTA results. The national strategy, however, presents an action plan for monitoring the implementation of HTA results.

## DISCUSSION AND SUMMARY

Health care in Denmark is generally considered a public responsibility. More than 98% of Danish hospital care is provided by public hospitals, whereas primary healthcare providers are professionals such as private GPs, specialists, dentists, physiotherapists, and public visiting nurses, and school dentists. The expenditure on Danish health services is relatively low, amounting to approximately 6% of the GDP. More than 80% of health services are publicly financed through taxation, while one insurance company covers a substantial part of the privately financed health services.

The health services are decentralized politically, administratively, and financially. The role of the state is mainly to establish the goals for a national health policy and to initiate, coordinate, and advise professionally. On the regional level, counties are responsible for the provision and financing of hospital care and for reimbursement of most of the privately provided primary care, while on the local level municipalities are responsible for public primary care, social care, and elder care.

A number of mechanisms have been applied and specific initiatives taken to regulate the provision of health services, quantitatively and qualitatively, the intent being to control the implementation and use of health technology. Important, usually well-functioning, general mechanisms are, in the planning phase, the individual county's budgetary allocation and all the counties collaboration, led by the National Board of Health within the framework of the so-called National Health Functioning Agreement (*Lands- og landsdelsfunktioner*). In the execution phase, GPs play an important role as "gatekeepers" to hospital care and private specialists.

National health programs on in vitro fertilization, prenatal care, immunization, cancer screening, and transplantation are examples of specific initiatives in which the National Board of Health usually plays a pivotal role in establishing goals for a national health policy and providing professional advice. Over the past 20 years, in a number of cases comprehensive assessments of medical technology have formed an important part in health policy decisions, usually, however, without being labeled as HTA. Examples of this broad-based advice from the Board of Health are guidance on treatment of hemophilia (1978), cardiac surgery (1978), transplantation of heart, lung, pancreas, and liver (1985), vaccination against mumps, rubella, and measles (1985), prenatal genetic information, counseling, and examination (1994), and early detection and treatment of breast cancer (1997).

In practice, health providers' decisions on implementing new health technology are often made either politically or de facto by clinicians on a much narrower knowledge basis. Problems with the control and use of technologies are often related to broadening of indications and the agenda set by the media. Due to occasional stories in the media about a patient's need for a treatment that is not yet available, rational decision-making processes are now and then bypassed for political reasons, as, for example, in the case of the introduction of liver transplantation at two places in Denmark rather than in just one.

The process of deciding to introduce new health technology is often complex, involving a variety of stakeholders with different interests and responsibilities. A successful application of HTA depends on sufficient knowledge about the actors and the mechanisms and processes of decision making, which have not yet been adequately studied. Therefore, it is encouraging that DMRC, in its strategy plan from 1998–2002, calls "analysis of the decision processes that exist within the health sector" a high-priority activity.

Compared with the HTAs in a majority of European countries with HTA programs, Danish HTAs seem to be: a) slightly more decentralized, because HTA is used not only at the national level but also at the regional level in health policy and planning decisions, and because the HTA concept (i.e., the comprehensive multidisciplinary approach) is intended to be used, and to some extent is used, as a basis for routine administrative decisions at all

levels in the health service; b) slightly more oriented toward the public, in the sense that various parties of interest participated in developing HTA over the years and in subsequently formulating the national HTA strategy, and that statements from Danish consensus conferences are directed mainly at the public and decision makers in politics and administration; and c) perhaps slightly less based on hard clinical evidence, since data on clinical effectiveness in Danish HTAs are often gathered through expert opinion and occasionally through limited literature review. A comprehensive and systematic review of scientific literature (not to mention meta-analyses) is still uncommon in regional HTAs and occurs in only a limited number of national HTAs.

HTA was introduced in Denmark in 1980 but has its roots here in clinical decision making, health economic analysis, and a general public criticism of technology back in the early 1970s. Until the late 1980s, there was a growing interest in HTA and activity in many places both inside and outside the health services, but there was no national coordination. Then, just when other European countries experienced increased HTA interest and activity, health authorities and funding bodies in Denmark lost interest in HTA. In 1994, however, after a period of about 5 years of almost "national HTA silence," the Danish National Board of Health appointed a standing Health Technology Assessment Committee that managed to put HTA on the agenda in the Danish health services and research communities, in part by publishing a Danish national strategy for HTA. In early 1996, after years of public criticism of the quality of hospital care and medical technologies and based on the national HTA strategy and other HTA reports, the time seemed to be appropriate for establishing a national HTA institute. DIHTA was established in 1997.

It might be wishful thinking, but there seems at present to be:

- A growing awareness among health professionals of evidence-based health care;
- A more general acceptance of health economic analyses as a basis for health policy decisions;
- Growing regional interest and activity in HTA for the health services;
- Mechanisms in place that can to some extent coordinate HTA activities nationally; and
- Much better possibility of funding HTA activities.

Although the effect of HTA on policy decisions and clinical practice remains to be documented, today it is hard to maintain a pessimistic view of the future development of HTA in Denmark.

## NOTES

[1] One Danish crown (DKK) = 0.13 ECU.

[2] At the establishment of the Danish Institute for Health Technology Assessment (DIHTA), the HTA Committee of the National Board of Health was dissolved and the responsibilities were taken over by DIHTA. Consequently DIHTA's implementation of the strategy is reflected in the text.

[3] Further information can be obtained at: http://www.dihta.dk.

[4] Further information can be obtained at: http://www.dsi.dk.

[5] Further information can be obtained at: http://www.tekno.dk.

[6] Now called DSI—Danish Institute for Health Services Research and Development.

[7] Now called National Institute of Public Health. Further information can be obtained at: http://www.dike.dk.

[8] Further information can be obtained at: http://www.cochrane.dk.

[9] Further information can be obtained at: http://www.etiskraad.dk.

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