

Health Care Technology in the Netherlands

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OVERVIEW OF THE NETHERLANDS

The Netherlands is a small country in Western Europe, located on the North Sea coastal area at the mouth of the rivers Rhine and Meuse, bordering Belgium and Germany. The territory of the Netherlands covers 41,574 km² of which 7,636 km² are water. About one-quarter of the country, especially the western part where land has been reclaimed from the sea since the 16th century, actually lies below sea level. In the south and the east, some hills rise to a maximum height of 321 m (above sea level).

In 1992, the Netherlands had a population of 15.1 million inhabitants (table 6-1). Due to high population growth during the 20th century, population density in the Netherlands is the highest in all Europe: 446 inhabitants per km² of land area in 1992. The western part of the country, with the three major cities (Amsterdam, Rotterdam, and the Hague), is the most densely populated. In 1992 there were 758,000 foreigners living in the Netherlands (5 percent of the population), plus another 650,000 people with a Dutch passport who were born in another country. Immigration (1 18,000 in 1992) has been increasing since 1985, and the number of refugees (22,000 in 1992) requesting asylum for political or humanitarian reasons is growing.

Government Structure

The Netherlands has been a kingdom since 1806, first as part of the French Bonaparte empire (1806-1813) and afterwards as an independent state under the royal House of Orange-Nassau. The hereditary monarch is the constitutional head of state, but the governmental power is executed through a Parliamentary democracy. The Parliament (*Staten Generaal*), which represents the people,



TABLE 6-1: Netherlands Population Statistics

Total population (Jan. 1, 1992)	15,128,604
Males	7,480,111 (49.4%)
Females	7,648,493 (50.6%)
Age 65 years and older	1,960,474 (13%)
Net population growth in 1991	118,700
Population growth rate in 1991	0.79%

SOURCE Central Bureau of Statistics, *Statistical Yearbook of the Netherlands for 1993* (The Hague SDU Publishers, 1993)

consists of two chambers. The Second Chamber (*Tweede Kamer*), which is politically the more important one, has 150 members who are elected directly by the people under a system of proportional representation (there are no electoral districts). As a result, in the Second Chamber the major national political parties are represented. Since no one party has a majority, a coalition of several parties is usually necessary to form a cabinet. The government consists of the Queen and the Cabinet Ministers (under a Prime Minister), who retain the executive power. The First Chamber (Senate) has 75 members who are elected by the Provincial Councils (*Provinciale Staten*). The two Chambers together with the government have the power to legislate. The major role of the Second Chamber is to amend and approve bills put forward by the government. The First Chamber can only approve or reject laws that have already been passed by the Second Chamber—it acts as a “second opinion.”

Provincial Councils are elected in each of the 12 provinces. Each council implements central state policy on the provincial level and supervises the day-to-day municipal administration. Each of the 647 municipalities has an elected municipal council headed by a mayor. During the last decade, more and more executive administrative power has been handed over by the central government to the provincial authorities, and the four largest cities have been given more responsibility to govern their own internal affairs.

1 The Economy

The Dutch labor force consists of 6.6 million people (65 percent of all people 15 to 64 years old). This labor force is on the small side compared with other European countries (75 percent in United Kingdom, 71 percent in Germany, 66 percent in France, 81 percent in Denmark) due to the traditionally low percentage of employed women (about half of women age 15 to 64), but the number of employed women is now growing fast. Although the labor force is modest, average productivity per worker is very high.

In general, the Dutch economy is based on free enterprise, but there is a certain degree of control and influence from the government, especially in times of economic recession, when large private enterprises (sometimes with state participation) are threatened. In the last decade the economy has been influenced more and more by the regulations and forces of the European Community internal market. Under the current economic recession the Dutch economy has been weakened by high unemployment (600,000 workers in 1993), but the Dutch currency¹ is among the strongest and most stable in Europe.

Despite the small percentage of the population that is employed in agriculture (6 percent), this sector is of major importance for the Dutch economy. After the United States, the Netherlands is the second largest exporter of agricultural products.

Industrialization started in the Netherlands only after World War II, somewhat later than in the rest of Western Europe. The most important industries in 1993 include (petrochemicals, electronics, and food). They are located mainly in the south and west of the country. Industry employs over a quarter of the workforce.

Because of its location at the mouth of the rivers Rhine and Meuse, trade and transport have been important for the Dutch economy throughout history. The port of Rotterdam is the biggest in the world. In the last decades, an increasing propor-

¹SUS 1 = Dfl 1.90 in 1994.

TABLE 6-2: Health Status by Subjective Rating

Rating	1981	1985	1991
Excellent	—	32.1	27.2
Good	80.2	50.4	53.7
Reasonable	12.2	10.7	12.1
Precarious	5.6	4.8	4.7
Bad	1.9	1.9	2.2

SOURCE Central Bureau of Statistics, *Statistical Yearbook of the Netherlands for 1993* (The Hague SDU Publishers, 1993)

(ion of the cargo is transported by air, and Schiphol International Airport (near Amsterdam) has become one of the busiest airports in Europe.

HEALTH STATUS OF THE POPULATION

The Dutch people have a very high standard of health, both according to their own subjective standards (table 6-2) and by objective data on vital health indicators. The good health status of the population is also reflected by the modest (in comparison to other countries) use that is made of medical services (see ch. 10).

The favorable figures for the Netherlands are the result of high standards of living, good nutrition, good sanitary and housing conditions, and the availability of reliable drinking water for most people since the first decades of this century. And for the last 50 years, the Netherlands has also had an excellent health care service. As a result, illness and death are to a large degree influenced by factors related to the affluent society (overconsumption and degenerative disorders) (table 6-3). Heart disease predominates, but cancer is a close second. Cancer is expected to be the number one cause of death in the future because of the advancing age structure of the Dutch population.

Aging of the population is one of the main concerns of the health care authorities. The proportion of people over 75 years of age is predicted to grow from 5 percent now to almost 15 percent in 2010, increasing the demand for medical services. Although people can stay relatively healthy to an advanced age, the need for homes for the elderly and care for handicapped people and for psycho-geriatric cases will grow. Waiting lists are now becoming a visible problem in the Netherlands.

THE DUTCH HEALTH CARE SYSTEM

The Dutch health care system has been described as a “patchwork quilt”—it has no master plan at its base. Rather, it is a complicated system that has evolved from a constant adding and changing of institutions, regulations, and responsibilities. This method of evolution is in the best tradition of Dutch pluralism. Yet, what has emerged over the years is a system in which high quality health care is provided with reasonable efficiency, and is equally distributed over the population (12).

Every citizen in the Netherlands has an entitlement to health care. Since 1983 the Constitution has contained an article under which the central authorities are obliged to take measures to promote public health (Article 22). Authorities (central and regional) are assigned the responsibility of ensuring that the whole Dutch population has access to high-quality care at an affordable cost and provided through a system that operates throughout the country. However, this principle has not been translated into a “National Health Care System,” as in the United Kingdom or the Scandinavian countries. Public health care, the control of infectious diseases, environmental protection, and the regulation and recognition of the health care professions have traditionally formed part of the activities of the central government. When it comes to the actual provision of care, the authorities have focused on creating favorable conditions in which the already existing private sector could expand in the fields of hospital care, nursing care, and social services. Thus, the Dutch health care system is a mix of public and private initiatives under the umbrella of the central government.

Brief History

Before World War II there was no true health care system in the Netherlands. All care was provided by private institutions, charities, or municipal organizations. There was no universal health insurance, but many private and public insurance agencies were operating throughout the country. In the late 1930s, progressive political and societal circles demanded reform of the health care

TABLE 6-3: Five Leading Causes of Death in Dutch Population, 1975–1990

Cause of death	1975		1980		1985		1990	
	Male	Female	Male	Female	Male	Female	Male	Female
Heart/vessels	43.5	46.2	43.4	46.7	43.2	45.6	38.9	41.4
Cancer	26.9	24.6	29.1	25.0	29.4	25.1	30.3	25.1
Accidents, violence and poisoning	6.2	5.5	5.7	4.8	5.1	3.9	4.6	3.6
Respiratory tract disease	7.6	4.8	7.0	5.1	8.4	6.2	9.4	7.1
Digestive tract disease	2.9	3.4	3.0	4.0	1.9	4.1	3.1	4.2

SOURCE Central Bureau of Statistics, *Statistics Yearbook of the Netherlands for 1993* (The Hague: SDU Publishers, 1993).

system, but **action was** prevented by the outbreak of the war.

After the war the new conservative government, rejecting a national health care system, left the initiative with private institutions and organizations, and limited themselves to overall control and regulation of hospital building activities and reimbursement fees. In 1956 new legislation delegated the principal authority for coordinating health care to Provincial Health Councils (who were representatives of the regional private care organizations).

The 1960s were a period of economic and social expansion in the Netherlands. The private foundations and organizations that controlled inpatient and outpatient care increased the number of new facilities, beds, and personnel, but without any regional or national coordination. The cost increases associated with these developments (and the resulting disparities and inefficiencies) troubled the government. However, the government had virtually no instruments for controlling or guiding these activities. It became clear that there was a need for legislation and administrative provisions to control health care.

The Hospital Tariffs Act (*Wet Ziekenhuislarieven*) of 1965, which regulated price-setting for all intramural institutions, and the Hospital Provisions Act (*Wet Ziekenhuisvoorzieningen*) of 1971, which regulated all building and renovating of intramural institutions, were the first steps. The first real planning of health care started when the government (a coalition dominated by the Socialist Party) drew up a Memorandum on the Structure of Health Care (*Structuurnota Gezondheidszorg*) in 1974. This document described a coherent and

coordinated regionalized system of health services, built up in stages, which could be directed and controlled. A major starting point was reform of the financing structure, under which the public health system as a whole would be financed out of general revenues and other facilities out of a separate health insurance scheme.

The strategy and the expectations of the policy outlined in the memorandum have not been completely fulfilled. The legislation required was introduced only partially, and was applied only to a limited extent. Nevertheless, the reforms started in 1974 did create a more coherent structure for the Dutch health care system and enabled the government to become a major player.

In the 1980s pressure on the health care system grew with rising costs, higher insurance premiums, new medical technologies, a growing range of services, and increasing administrative costs, all during an economic recession. It appeared that excessive demand for care combined with an oversupply of care could not be controlled with the existing system. The elaborate administrative system, inflexible through the large number of rules and regulations, proved incapable of checking the virtually autonomous growth of the health care sector.

In 1986 the government published a policy document, "Health 2000," which identified future health problems: aging of the population, growing dependency on care, consequences of alcohol and tobacco consumption, the social cost of accidents, and the predominance of cancer and cardiovascular disease alongside new infectious diseases. These future health problems could only be met with new, forward-looking policies, signaling the

need for yet another major reform of the health care system (described later).

Legal and Legislative Background

The legislative structure of the existing health care system in the Netherlands (until the recent reforms, described later) rests on four pillars: health care insurance, regulation of health care providers, control of health care costs, and accreditation of health care professionals.

Health Insurance

A compulsory national health insurance scheme (originating from a scheme introduced in 1941) was implemented in 1966, when the Sick Fund Act (*Ziekenfondswet*) was passed in Parliament. Part of the social security system, Sick Fund insurance covers about 62 percent of the population. Members of the scheme include employees and self-employed persons whose income falls below a certain level (US\$28,500 in 1992) and those over the age of 65 with no income of their own. Sick fund insurance covers all acute care provided by hospitals, general practitioners, and specialists; all costs of drugs and appliances; and transportation. For all public employees of provincial and municipal governmental bodies there is a similar insurance scheme (covering about 6 percent of the population). The remaining 32 percent of the population is insured through private schemes. Private insurance companies are represented by the National Society of Private Health Care Insurers (KLOZ), which participates in health care administration.

The national social insurance scheme is executed by independent sick funds. All of these are members of the Society of Dutch Sick Funds (*Vereniging van Nederlandse Ziekenfondsen* or VNZ), which plays a dominant role in shaping general health care policy. The sick fund scheme is supervised by the Sick Fund Council (*Ziekenfondsraad*), representing government, employers, employees, sick funds, care institutions, and health professionals. The Council approves arrangements between sick funds and health care providers, controls and defines the benefit pack-

age, and advises the Ministers of Health and of Social Affairs concerning the level of the insurance premium, which is fixed by the central government.

Neither the VNZ nor the KLOZ has a director legal role in health care administration or planning at the national level. However, they represent their members in the national negotiations over tariffs and budget guidelines that take place in the COTG (see below). They also participate in budget negotiations with each hospital, giving them potential influence over the introduction and utilization of health care technologies—for example, they may block a hospital's initiative to introduce a new technology by withholding financing.

In 1968 another social security law was passed to cover the costs of "exceptional medical expenses." This insurance scheme (AWBZ) covers the most expensive forms of care, including long-term care in hospitals, home care, nursing homes, homes for mentally and physically handicapped, and ambulatory mental care. It is compulsory for all Dutch citizens, and financed out of premiums under the fiscal system.

Regulation of Institutions

The provision of health care is regulated under the Hospital Provisions Act (1971), which covers acute care hospitals, nursing homes, mental health institutions, and institutions for the handicapped. Regulation includes the number and location of the institutions, building and renovation, the number of beds, certain equipment, number of specialists, etc. The capacity of the institutions is planned and approved by the provincial health authorities, but legal authorization is given by the central government. The central government provides guidelines to the provincial health authorities to assure equal distribution and access to care over the country. One of these guidelines concerns reductions in the number of hospital beds (table 6-4).

Health Care Costs

In 1965 the Hospital Tariffs Act (*Wet Ziekenhuistarieven*) was passed to control price-setting for all inpatient care institutions and was later ex-

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TABLE 6-4: Hospital Care Data

Data	1988	1992
Number of hospitals	181	162
General	130	112
University clinic	9	9
Specialized/category 1	42	41
Total number of hospital beds	68,020	63,744
Hospital days (x 1,000)	18,164	16,986
Admissions (x 1,000)	1,531	1,547
Outpatient visits (x 1,000)	20,119	21,718
Average hospital stay in days	11.5	10.6

SOURCE Central Bureau of Statistics, *Statistical Yearbook of the Netherlands for 1993* (The Hague SDU Publishers, 1993)

tended to all health care sectors (see table 6-5 for a breakdown of health care spending by class). The law is executed by the Central Board of Health Care Tariffs (COTG). In 1984 a hospital budget system was introduced; these global budgets, which are negotiated between hospitals and health care financiers, also must be approved by the COTG.

In practice the COTG creates a formula for calculating global hospital budgets, which is used in local negotiations over hospital budgets in which the different payers participate. The complexity of this process is reduced by the fact that each region usually has one dominant social insurance agency. The private insurers that operate on a national scale are represented by a KLOZ negotiator. The COTG monitors the end results of each local negotiation to see that they are consistent with the general guidelines.

The Tariffs Act also regulates the total volume of capital investment in the health care sector. Hospitals organizations are, in principle, free to acquire the money they need for building or enlarging their hospital facilities through loans on the capital market. However, the resulting costs for interest and depreciation will only be included in the budget and in the per-day price of a hospital bed if the hospital can secure a “certificate of need” from the central authorities. Another form

TABLE 6-5: Health Care Spending, 1993

Sector	Expenditure (in million Dfl)	% of total
Hospital care	15,272	27.1
Medical specialists	2,435	4.4
Ambulance transportation	537	1.0
Mental health care	3,899	6.9
Care for handicapped	4,883	8.6
Care for the elderly	10,568	18.7
Extramural care (incl. GP's)	9,664	17.1
Pharmaceuticals	5,466	9.7
Preventive care	763	1.4
Administration	2,845	5.0
Total	56,333	100.0

SOURCE Ministry of Welfare, Health, and Culture, *Finacial Reveiw for Health Care 1993* (The Hague SDU Publishers, 1993)

of control through this act is on the diffusion of health care technology. Both buying and use of expensive technology by hospital authorities is dependent on approval to accommodate the extra cost in the budget.

Certification of Health Professionals

Physicians and nurses must be certified by the government. A new system for enhancing professional standards and quality control in health care, a result of the 1994 Medical Professions Bill (*Wet-sontwerp* BIG), is to be introduced over a period of four years: certification and registration of nurses and physicians, description of “restricted medical acts (i.e., restricted to qualified physicians only), and reform of the professional disciplinary law. The volume of physicians is regulated in two ways: enrollment in basic medical training is limited by a central government quota at the level of the medical schools; and specialist education is regulated by the professional specialist organizations.

Administering the System

Health care administration under the current system in the Netherlands is very complex. It is a combination of elaborate government regulation

and the provision of care by mainly private health institutions and practitioners. As of 1994 the government's agent is the Ministry of Health, Welfare, and Sports.

The government has ultimate control over the planning of care facilities, the pricing of provisions and the macroeconomy of health care expenditures. It is directly responsible for prevention, health promotion, health protection, and intersectoral action in the health field. More and more, the government is striving for a comprehensive health policy.

The daily provision of health care is mainly in the hands of hospitals and institutions that have a private legal status. They originate from private foundations, charities, etc. Although private they all function in a nonprofit setting since all reimbursement of health care provisions is centrally regulated. This means there are nationally uniform reimbursement fees and charges, leaving little room for free enterprise and market force competition.

Individual patients are in principle (on the basis of health care legislation) free to choose their own physicians and their own hospital; however, since all referral to specialist care is done by general practitioners, this choice is limited. Professionals are free to select treatment for their patients, within the limits set by the insurance packages. Physicians are also free to settle and practice where they like, although there is more and more regulation in this respect from regional and municipal authorities.

Reimbursement of Services

Charges for health care services are uniform throughout the country. COTG is an autonomous body that sets out guidelines for the composition and calculation of charges and tariffs. Representatives of the providers and insurance agencies use these guidelines as the basis for negotiating the actual charges, which must be approved by COTG.

Before 1984 the health care reimbursement system in the Netherlands was open-ended. As part of the cost-containment policy all hospitals are required to have a global annual budget, which

is calculated prospectively. There is no possibility of recalculation or compensation afterwards if the hospital exceeds its budget.

General practitioners are paid on a cavitation basis for sick fund patients and on a fee-for-service basis by privately insured patients. In general their fees for sick fund patients and private patients are the same. Specialists are paid exclusively on a fee-for-service basis for all patients (except physicians in University Hospitals, who are salaried). Specialist fees for sick fund patients are negotiated between the representative organization of physicians and the sick funds. Specialist fees for private patients are negotiated with the insurance companies and are usually higher. All physicians' fees are controlled and approved by the Minister of Economic Affairs, as part of a general incomes policy.

Reform Proposals and Implementation

The introduction of global hospital budgeting in 1984 proved effective in containing the rising costs. Between 1984 and 1992 total health care expenditures remained stable at 8.3 percent of Gross Domestic Product (GDP). However, the Dutch government wanted to introduce further reforms to impose greater control over health care expenditures, to change the insurance system, and to enhance the efficiency of the system by introducing a competitive market system. In 1987 a special committee was asked to produce a blueprint for comprehensive health care reform and in 1988 it published its report, *Willingness to Change*. The central recommendations for reform were:

1. provision of health care and social care should be integrated;
2. the efficiency and flexibility of health care should be improved through the application of market forces, without sacrificing the principles of equality and equity; and
3. there should be a shift from government regulation to market regulation and self regulation.

The important innovative element was to be a central health insurance fund, covering the whole population and providing insurance against more

than 90 percent of health expenditures. The fund would receive income-related contributions from the population and would pay out risk-related premiums to competing sickness funds and private insurers. There would be sharing in the cost of premiums (no more than 15 percent of the cost) by consumers to encourage cost-conscious choice of insurers.

In 1990 the Dutch government started to implement these changes in a somewhat revised form with less emphasis on market orientation. The new proposal tries to integrate enhanced efficiency with a more regulated national insurance system based on solidarity. In this approach the differences between social and private insurance agencies would disappear and solidarity would be extended to all insured patients. This has been proposed because under the existing system the high financial burden on privately insured patients prevents market forces from acting. However, there is almost no place for competition between insurance agencies in the new scheme. Step-by-step introduction of the new system was planned over a period of four years beginning in 1991.

However, it is now becoming clear that such a system has significant effects on incomes and may be more costly in the long run; the medical associations are strongly opposed to measures directed at controlling and lowering the incomes of specialists. In late 1994 a new government decided not to go forward with all the reforms. There will not be a national health insurance scheme, but differences between social and private insurance schemes will be diminished. Priority will be given to moving consumer demand for and physician supply of care toward greater cost-effectiveness.

CONTROLLING HEALTH CARE TECHNOLOGY

Until the 1980s the Dutch health care authorities had no clearly defined philosophy of controlling the development and use of health care technology. In some areas (e.g., drugs) regulation had always been very strict, but in others, such as the licensing of new medical devices, control was almost lacking. Equipment could be introduced and

become part of established practice without decisionmaking, evaluation, or cost-calculation. The resulting problems have led to a wide range of regulatory instruments, each developed for a specific sector, with different procedures and varying degrees of control. Compared to other European health care systems, the Dutch system is usually considered to have a high degree of regulation; coordination, however, is rather poor.

Research and Development Efforts

In the Netherlands, research and development (R&D) related to medical technology falls into four broad categories:

1. *University research*: basic, strategic, and applied research in all fields of biomedical science. University research in the field of biomedical science is mainly concentrated in the eight medical faculties, the university-related research institutes, and in some of the technical universities. Overall responsibility lies with the Ministry of Education and Science, which covers the cost of the research infrastructure (buildings, facilities, and equipment) and takes on a large part of the R&D funding. Universities are no longer completely free to choose their own research areas and priorities. Since the mid-1980s the Minister of Education and Science has successfully implemented a policy of creating centers of excellence (*zwaartepunten*) to put an end to the considerable overlap in research efforts.
2. *Nonuniversity related research institutes within the public domain*: mainly applied research under contract to the government, industry, or societal organizations. Infrastructure and funding is mainly through the Ministry of Education and Science, and other ministries. The foremost institute with an interest in biomedical technology is the Netherlands Organization for Applied Scientific Research (TNO; see below).
3. *[dependent research institutes (not-for-profit)]*: basic, strategic, and applied research according to self-chosen mission. Infrastructure and funding is from their own sources, cover-

ing such topics as blood transfusion, mental health, and rehabilitation.

4. *Industrial R&D*: basic, strategic, and applied research according to self-chosen mission. Infrastructure and funding is from their own sources. Since 1986, the Ministry of Economic Affairs has implemented a policy to stimulate cooperation between research institutes and industry, with the aim of strengthening the position of the Dutch industry in this area internationally.

Total expenditure on biomedical R&D in the Netherlands was Df1975 million in 1991, excluding industrial spending (on which no data are available). Biomedical R&D is approximately 15 percent of all expenditure on R&D.

An important role in developing and implementing research policy is played by the Royal Dutch Academy of Sciences (KNAW), an organization with a longstanding tradition of advising the government and fostering cooperation and coordination between scientists and scientific institutes. The KNAW presents a periodic inventory of all biomedical research, judging the quality of the institutes and identifying future research areas (*Disciplineplan Geneeskunde*). Also important is the Dutch Organization for Scientific Research (NWO), which does not conduct research itself, but supports efforts of the universities by coordination, priority-setting, and funding. NWO allocates research funds made available by the government and acts as an intermediary between the government and the universities. Finally, the Council for Health Research (RGO) advises the government on future health research priorities.

The structure for biomedical R&D the Netherlands has always been confusingly complex with many overlapping organizations and different funding arrangements. However, for several years the government has been implementing policies to coordinate the research efforts of the universities, the independent research institutes, and industry. Factors such as burden of disease in the Dutch population are used more and more in determining research priorities. Applied research

(including technology assessment) has also been given a higher priority than in the past.

Regulation of Drugs and Biological Substances

Like other countries, the Netherlands regulates drugs and biologics for efficacy and safety. The Dutch program follows the usual system of requiring proof of efficacy and safety before the drug or biologic material can be marketed and used (pemarketing approval).

From an international perspective, it is fair to say that the Dutch system for regulating drugs and biological substances is one of the strictest in the world. The independent status of the organizations involved helps assure the integrity of these processes. The system works well in assuring safety and efficacy of the products on the market.

The Drugs Act of 1963 (*Wet op de Geneesmiddelen-voorziening*) is the legal basis for the pre-market surveillance and approval of drugs. The pharmaceutical industry itself has the responsibility for establishing safety and efficacy of any new drug. The law requires them to submit these data to the Board for the Evaluation of Drugs (*College ter Beoordeling van Geneesmiddelen*), an independent body of experts appointed by the Minister of Health. The Board has autonomous authority to grant, refuse, or revoke drug marketing licenses, and its decision is binding. The Board considers evidence of efficacy, safety, and quality, but does not consider societal need for the drug. Admission of a new drug usually leads to reimbursement by the sick fund insurance agencies. Refusal means the drug cannot be sold or used in the Netherlands.

All pharmaceutical products, as defined by the European Community (EC), and pharmaceutical preparations (medical products marketed in bulk or without a brand name) are subject to the registration procedure. Since 1978, new drugs that already have been approved elsewhere may be imported under a simplified procedure ("parallel imports"). Specialized drugs on the market before 1963 and generic drugs on the market before 1978 usually have not been submitted to careful evalua-

tion. They are given temporary licenses and will be assessed during the coming years, mainly by post-marketing surveillance.

The establishment of the European single market will profoundly influence the drug registration policy in the Netherlands. Registration through the Brussels office will mean automatic registration in all member states.

The use of drugs is not regulated, but a committee formed by the Sick Fund Council issues guidelines for their appropriate use. Since 1982 the Sick Fund Council has published a prescription guide (*Farmacotherapeutisch Kompas*) that gives recommendations on the use of drugs based on comparisons of price and therapeutic efficacy of equivalent products. This guide has been very influential in changing prescribing patterns of general practitioners in the Netherlands, since the guidelines are linked with payment decisions.

Blood and blood-derived products are strictly controlled in the Netherlands, regulated by the Committee for the Regulation of Blood and Blood Products (*Commissie ex artikel 1, van het Besluit bloedplasma en bloedproducten*). Vaccines and sera are regulated by an independent committee (*Commissie ex artikel 14 Sera- en Vaccinsbesluit*) that functions in a similar manner to the Drug Board. Vaccine trials in humans outside the laboratory must be approved by the Committee. As with drugs, vaccines are monitored after they are approved for use.

Regulation of Medical Devices

The introduction of biomedical devices and medical appliances in the Netherlands is poorly regulated. There is no systematic control or uniform procedure to establish the safety, efficacy, or quality of new equipment. Although the Medical Devices Act (1970) gives the Minister of Health the authority to evaluate and regulate any device or medical appliance, this law has not been effective. Only in cases where problems have arisen (as in the case of cardiac valve implants and rubber condoms) has the government introduced specific measures for quality control. But in general any newly developed medical device can be

introduced without proof of safety, efficacy, or cost-effectiveness.

This does not mean that no quality control at all takes place. Some activities are usually carried out by the health care providers themselves (as the users of the medical devices) or their representative organizations, on a voluntary basis. Examples of these activities include the following:

- *Sterilization equipment*: sterilization equipment must be produced according to good manufacturing standards set by the National Control Laboratory of the National Institute for Health and Environmental Hygiene (RIVM).
- *Electrical safety standards*: all electrical devices in the Netherlands must meet minimum safety standards; however, there are no specific standards for medical applications, with the exception of cardiac pacemakers. The National Hospital Institute tries to fill this gap with recommendations for testing and performance criteria.
- *X-ray equipment*: under EC directives, the Dutch government is committed to developing standards for x-ray machines and x-ray therapy. Regulation in this field is rather complicated, involving a number of advisory boards; licensing is by the Minister for the Environment.
- *Evaluation of technical performance*: some evaluation of medical devices is undertaken by the Dutch Organization for Applied Scientific Research (TNO) at the request of the National Hospital Institute. However, only a limited budget is available, and many devices are left untested. The majority of the technical evaluations of equipment are carried out by the hospitals themselves. The University Hospitals have put together a working party that will undertake evaluations and make the results available to other hospitals.

■ Planning and Regulation of Medical Services

In the 1960s and 1970s the expansion of medical technology and care resulted in a steady increase in the cost of health care. The Dutch government

saw the prolific building of new hospitals and institutions as one of the main contributors to rising costs. The Hospital Provisions Act of 1971 was introduced both to enable the government to regulate and coordinate the creation of inpatient facilities throughout the country, and as a planning instrument. It allowed the government to create a national network of hospitals and other health care institutions to ensure maximum access of the population to medical care. The provincial health authorities had responsibility for implementing this plan.

Article 18 Regulation

Article 18 of the Hospitals Act relates specifically to the planning of supra-regional, "high-tech" medical facilities. The law requires hospitals wishing to provide specific supra-regional services to seek approval from the Minister of Health (not the provincial health authorities), much like a "certificate of need" (CON) system. When the Minister decides that a specific technology or supra-regional service should be governed by Article 18, the Minister will publish a planning document (*Pluningsbesluit*) with general planning guidelines, an estimate of the need for that service, quality criteria to be met by a hospital, etc. In order to produce a planning document, the Minister asks the Health Council to report on the scientific state-of-the-art of the technology, on safety and efficacy aspects, cost-effectiveness, appropriate USC, and so on.

When a hospital puts in a request for a specialized service under Article 18, the application is put before the Hospital Planning Board (*College voor Ziekenhuisvoorzieningen*) which evaluates whether the hospital meets the criteria, what extra facilities are needed, and what the cost will be. When a service is approved the cost of the new service is met by an increase in the hospital budget. Funding of new equipment and technology by the hospital is usually through loans on the capital market. The cost of the loan (interest and depreciation) can be included in the hospital budget and is reimbursed by the health insurers, making it pos-

sible for hospitals to keep up (in a reasonable way) with technological improvements and ensure timely replacement of equipment.

When Article 18 regulation was introduced in the 1970s it was used mainly to regulate the diffusion of new expensive technology by limiting the number of facilities and the number of procedures (e.g., computed tomography (CT) scanners, cobalt radiation units, linear accelerators, and dialysis machines) and was largely an instrument for cost-containment. But gradually the central government began to use Article 18 as a real planning instrument: to ensure geographical distribution, to promote concentration of facilities, to enhance expertise and quality, and to increase the cost-effectiveness and appropriate use.

Emphasis in the Article 18 program shifted from controlling the purchase of equipment to regulating the use of specialized medical services as a whole. Today even supra-regional services that use almost no costly equipment (e.g., genetic screening and counseling and in vitro fertilization) are regulated through Article 18. Since 1984, when the global budget system in hospitals was introduced, the government no longer attempts to regulate the number of treatments or procedures. (Such regulation is part of the local negotiations over the annual budget between hospitals and insurance agencies.)

In general, Article 18 regulation has worked quite well. Most new, costly technologies that have been introduced over the past 20 years diffusion has been controlled in such a way that oversupply has been prevented and effective use has been stimulated (table 6-6). Regulation has been effective because hospitals that break the law are confronted with severe sanctions; when a hospital offers a specialized service without obtaining approval, it is considered to be an economic offense. The hospital may be fined and the new service will be closed down. Secondly, without approval, the service will not be reimbursed by insurance agencies and patients will not be referred to that institution. Also, interest and depreciation on capital loans will not be included in the budget.

TABLE 6-6: Technologies Regulated Under Article 18

Type of service	Year brought under Article 18	Current status
Radiation treatment	1979	Regulation continued
Computer tomography	1984	Regulation lifted 1988
Renal dialysis	1976	Regulation continued
Kidney transplantation	1976	Regulation continued
Nuclear medicine (diagnostic and therapeutic)	1984	Regulation lifted 1988
Genetic screening	1984	Regulation continued
Cardiac angiography	1984	Regulation lifted 1991
Interventional cardiology (PTCA, Implantation)	1984	Regulation continued
Cardiac surgery	1984	Regulation continued
Neurosurgery	1984	Lifted for "simple" interventions 1991
Neonatal intensive care (IC)	1984	Regulation continued
In vitro fertilization (IVF)	1988	Regulation continued
Heart transplantation	1991	Regulation continued
Liver transplantation	1993	Regulation continued
Lung transplantation	1991	Regulation continued
New candidates for Article 18 regulation:		
Allogeneic/autologous bone marrow transplantation	1994	—
Pancreatic transplantation	1994	—

SOURCE Ministry of Welfare, Health, and Culture, Financial Review for Health Care 1994 (The Hague SDU Publishers, 1994)

Experience with Article 18 has not been totally positive. Procedures are rather bureaucratic and time consuming. In some cases (e.g., CT scanners, cardiac bypass surgery) diffusion had already taken place before regulation was in operation. Recently the procedure has been adapted to be more flexible; it can now be applied almost overnight when the situation requires a rapid response. Also, regulation can be applied as a temporary measure (maximum of four years) to control the early stages of diffusion of a technology. Finally, when it is considered that a new technology has become established or has lost its supra-regional function, regulation under Article 18 can be lifted.

The total expenditure for specialized services under Article 18 regulation is calculated prospectively every year by the Minister of Health in his annual Review of Health Care Costs (*Financieel Overzicht Zorg*). There is only limited room for expansion of hospital budgets for these services (approximately Df125 million), so priorities must be set.

During the recent debate on health care reforms, the need for and effectiveness of strict regulation by the central government has been questioned. However, the Minister of Health has emphasized that Article 18 regulation as an instrument to control the introduction and use of new technology will be continued under any new system.

Control of Health Technology Through the Payment System

The major explicit control that the government and the insurance agencies have over the diffusion and use of technology is the health care financing system. The system for global budgeting introduced in 1984 includes allowance for investment in new equipment and technology, but to a limited extent. Approval for a specialized service under Article 18 will lead to a budget increase.

The Sick Fund benefit package includes so-called "closed" benefits and "open" benefits, such as specialist care. The benefit package covers only

treatments or procedures considered established and accepted. Since 1984 the Sick Fund Council (which develops and controls the benefit package) has used this system more and more as a tool to control the introduction and use of health care technology. Services can be excluded from the benefit package until efficacy and cost-effectiveness are demonstrated (as in the case of *in vitro* fertilization) or the level of reimbursement maybe lowered (as with CT scanning) when the technology becomes less complex. Some treatments are reimbursed only for specific, limited indications (e.g., autologous bone marrow transplantation only for acute leukemia). Using these methods, the Sick Fund Council has begun to effectively influence the use of health care technology, including the “appropriate” use of established technologies that are already included in the benefit package.

Influence of the Public

The public gets information on new medical technologies and their assessment mainly through the media. Television programs in the Netherlands on medical issues are frequent and very popular. However, most of these programs (often imported from the United States, United Kingdom, and Germany) take a rather uncritical view of medical technology, sometimes claiming effectiveness where this has not yet been proven. In more recent years, some series by Dutch producers developed in cooperation with the medical associations are highly informative, discussing both pros and cons, and avoiding sensationalism. One award-winning program presented the medical and ethical dilemmas in liver and bone marrow transplantation. Another highly praised series discussed the public use and abuse of DNA-based genetic information. Through these programs the media do influence the demand for some new technologies (e.g., organ transplantation, *in vitro* fertilization (IVF), cancer therapies). The same holds true for the information that some patient organizations provide to their members. The demand for lithotripsy and erythropoietin grew significantly after the Dutch Kidney Foundation

informed patients of these developments at an early stage. In 1993 the Minister of Health sponsored a series of television programs on “making choices in health care,” intended to involve the general public in a discussion on the limitations of health care.

HEALTH CARE TECHNOLOGY ASSESSMENT

Development of Interest

In the Netherlands one institution has traditionally had an interest in medical technology assessment: the Health Council (*Gezondheidsraad*). The Health Council, established in 1902, reports to the government on the state of science regarding issues of health care, public health, and environmental protection. The Council evaluates the efficacy, efficiency, and cost-effectiveness; and ethical, legal, and social aspects of new medical technologies including devices, drugs, diagnostic tools, surgical therapies, and also the health system as a whole. The Council does not carry out or fund medical research, but uses literature review (meta-analysis and synthesis of the international scientific literature), expert committees, and consensus meetings. Although technology assessment had always been used by the Health Council as a research tool, it had not been an explicit issue in the policies and decisionmaking process of the government or the health insurance agencies. This situation changed in the early 1980s, when both the government and the Sick Fund Council became concerned about the tremendous development of medical technology and its impact on health care and society (especially in terms of cost).

At that time the Minister of Health could control the diffusion of medical technology (to a certain extent) through the use of Article 18, but only as far as established technologies were concerned. There was no such regulatory instrument for innovative, emerging technology. At that time, new technologies automatically became part of the social insurance benefit package and were reim-

bursed on the basis that the medical profession judged these technologies to be useful.

Around 1982 the Sick Fund Council was confronted with patients who demanded that the costs of heart and liver transplantations that had been performed abroad be reimbursed by the sick funds. The debate focused on the question of whether these procedures should be considered established or still experimental. The outcome of the debate was that these therapies were excluded from the benefit package until they had been formally evaluated. Following this decision, the Sick Fund Council took the position that the introduction of new technologies into the benefit package should be more actively controlled.

In 1983 the Council outlined its new policy in a paper, "Limits to the Expansion of the Benefit Package." In the future all major new medical technologies were to be assessed, regarding efficacy and cost-effectiveness, and were to be admitted to the package according to their priority. When the annual budget was debated in Parliament later that year, one of the topics was the impact of technological development on health care in the light of limited money. The spokesman of the Democrats '66 Party made a plea for systematic evaluation of new medical technology in order to be able to make political choices in a more rational way. By 1984 the interest of policy makers in medical technology assessment had been roused, but there was still little expertise in the country and no coherent procedure. This gap has been filled by practical experience with technology assessment.

The First Technology Assessments

The year 1985 saw the start of three medical technology assessment projects: heart transplantation, liver transplantation, and IVF. The initiative was taken by the Sick Fund Council and the Ministry of Health. Funds came from the Sick Fund Council research budget and the actual research was carried out by the Universities of Maastricht (IVF) and Rotterdam (heart and liver transplantation).

These first projects were full-scale prospective technology assessments, aimed at evaluating the medical, social, economic, and ethical aspects of the technology. The final reports were completed in 1988 and 1989. Based on these reports, the Minister of Health and the Sick Fund Council decided to cover heart transplantation and IVF, and the decision on liver transplantation was held until further research (on long-term survival) was carried out.

The lack of expertise and experience in medical technology assessment in the Netherlands led the Minister of Health to ask the Steering Committee on Future Health Scenarios (*Stuurgroep Toekomstscenario's Gezondheidszorg*, or STG) in 1984 to recommend a long-term policy on medical technology. In its 1987 report (3), the STG raised the possibility of developing an "early warning system" for future health care technology. Six areas of emerging medical technology were described in more depth, looking at their future health and policy implications. The main policy conclusion was that if the Netherlands wanted to have greater control over the development and diffusion of medical technology, it would have to create a coordinated system for identifying technologies and assessing their benefits, risks, financial costs, and social implications. Technology assessment could then be a useful tool in making the necessary choices in a political context of increasingly limited resources.

Creating a National Fund for Medical Technology Assessment

The message from the STG was well taken by both the government and the Sick Fund Council. In 1988 a revolving National Fund for Investigational Medicine (*Fonds Ontwikkelingsgeneeskunde*) was created by the Minister of Health, the Minister of Science and Education, and the Sick Fund Council at the level of Df136 million. A standing committee was given the task of selecting research proposals submitted by the hospitals (in cooperation with NWO) based on scientific excellence. Projects may evaluate new or established medical

technologies, looking prospectively at efficacy, cost-effectiveness, social, ethical, and legal implications, in view of the policy decisions to be taken (admission to the benefit package, reimbursement, redefining the established indications, regulation under Article 18, etc). The Standing Committee on Investigational Medicine (*Cornmissie Ontwikkelingsgeneeskunde*) is made up of experts in medicine, health economics, medical ethics, health law, and health administration; and representatives of the ministries, the sick funds, and the Health Council.

Projects are funded for three years, after which a report is submitted to the standing committee. Most assessments take the form of prospective, randomized trials, with an added component for cost-effectiveness analysis. Since 1989 more than 80 research projects have been funded for a total of Dfl 150 million. In 1993 the first projects were completed and will soon lead, it is hoped, to policy decisions on those subjects.

Until 1993 the procedure of funding proposals was essentially a "bottom-up" procedure: projects for research were chosen by the hospitals themselves. In 1993 the Standing Committee initiated a "top-down" procedure alongside the existing arrangement. Research groups are invited to submit proposals for projects selected by the Committee itself so that areas in which technology assessment has been rather weak can be studied (e.g., in mental health care, clinical geriatrics, and small-ticket routine diagnostic procedures).

Looking back at the start of medical technology assessment activities in the Netherlands, they can be considered to have been reasonably successful. However, procedures are not finally established. Some important problems remain and will have to be overcome in the near future, including:

- a need for priority-setting in technology assessment;
- a need for more international dissemination of technology assessment information and cooperation with agencies abroad, to avoid duplication;

- a need for better follow-up of technology assessment studies to ensure that the results are taken up in clinical practice; and
- a need to integrate the technology assessment approach into the thinking of the medical professional at large.

New Policies for Medical Technology Assessment

Medical technology assessment has become an important health policy issue in the Netherlands in the 1990s. The government has made the assessment of new medical technologies a key component of its policy to promote the appropriate use of medical care and to deal with problems of shortage, rationing, and waiting lists. In 1989 a committee was appointed with the task of analyzing the problems of "choices in health care." This committee looked into the different aspects of making choices on the macro-, meso- and micro-level of health care and presented a strategy to admit medical technologies to the benefit package. On the one hand, "traditional" criteria such as efficacy and effectiveness were included. On the other hand, questions like "Is a specific type of care/technology essential to let a person continue a normal role in society?" and "Can people pay for this type of care out of their own pocket?" were considered. To be able to make such choices the committee has recommended that assessment of medical technologies be carried out on a wider scale. The government has stated that this approach will be included in the coming health care reforms.

In a recent report by the Health Council (21), titled *Medical Practice at the Crossroads*, the Council observed that inappropriate use of both established and new medical procedures and technologies is widespread. The report documents examples from almost all medical specialties, focusing not so much on the efficacy and effectiveness of medical technologies themselves, but rather on how doctors use the procedures.

The main conclusion of this report is that large and unexplained variations in medical practice point to the inefficient use of resources, which can no longer be ignored. The report urges the medical profession to start their own process of critical self-evaluation (or others will do it for them). The report recommends that accountability for medical practice based on systematic evaluation should become routine for doctors. This accountability can be enhanced by setting up independent quality assurance committees with the professional organizations. The change of attitude needed in the medical profession should start from the basic medical curriculum, according to the report. Finally, the report recommends that formal assessment should be the criterion for admitting new procedures to established medical practice, and also that long-accepted procedures should be re-evaluated, preferably by the medical profession itself.

This report has influenced the current discussion on evaluation of medical practice and the assessment of medical technology within the professional bodies in the Netherlands. In 1993 the Sick Funds Council initiated a long-term project to critically evaluate the entire benefit package in terms of cost-effectiveness and appropriate use. Through a Delphi-type study (using a large panel of experts) a first selection of 126 items where doubt has been expressed on cost-effectiveness or appropriate use has been made. This list will be subjected to further critical evaluation on the basis of priorities.

Organizations Involved in Medical Technology Assessment

The Central Government

The Ministries of Health and of Education and Science are involved in health care technology assessment as cofunders of the Investigational Medicine scheme. Technology assessment is also carried out by other organizations at their request. The Ministry of Economic Affairs has a policy for promoting the development of medical technology through funding the national industry.

Technology assessment (with emphasis on technical performance and good manufacturing procedures) is an important item on the agenda.

The Health Council (Gezondheidsraad)

The Council advises the government on the scientific state of the art of medicine and health care. To this end it brings together groups of experts on specific subjects at the request of the Minister of Health or the Minister of Environmental Protection. Technology assessment has traditionally been part of the activities of the Council; many reports on specific technologies have been published (e.g., transplantation; diagnostic technologies such as CT scanners, MRI scanners, and PET scanners; neonatal intensive care; genetic screening and counseling; cardiac surgery). Committees are made up of physicians, economists, social scientists, experts in management, lawyers, and ethicists. The Council has a strong focus on identifying new technologies before they come into widespread use. The Council also recommends new emphasis for the Investigational Medicine Fund.

Sick Funds Council (Ziekenfondsraad)

This Council became involved in health care technology assessment in the early 1980s. It has funded most of the early studies (heart and liver transplantation, IVF, breast cancer screening) and it plays an important role in the Investigational Medicine Fund. In 1993 the Sick Fund Council started a project to review and redefine the criteria for "appropriate use" of a wide range of established technologies.

National Council for Health Care (Rationale Raad voor de Volksgezondheid)

The National Council comprises representatives of health care providers, insurance agencies, and consumer organizations. It advises the government and the health care community on general policy issues. Some studies have been done on medical technology in which the importance of technology assessment is stressed.

National Institute for Health and Environmental Hygiene (RIVM)

This organization carries out clinical trials of vaccines. It monitors the adverse effects of vaccines and of toxic substances, and also looks into the safety aspects of certain medical devices.

Netherlands Organization for Applied Scientific Research (TNO)

TNO studies medical devices (e.g., filters, laminar flow units), focusing on safety and technical effectiveness. It also supports studies of medical technologies and procedures (e.g., thrombolytic therapy for blood vessel recanalization, extra- and intracranial bypass operations, and mammography). TNO has progressively become involved in technology assessment in a broader sense, taking a lead role in assessing technology for home care. In 1993, TNO formally established a medical technology assessment program.

Steering Committee on Future Health Scenarios (STG)

STG is an independent advisory group to the Dutch government, installed in 1983 to carry out scenario studies as an aid to long-term health policy. It published a study on *Anticipating and Assessing Health Care Technology* in 1987 (3), and has published scenario-studies on accidents, aging and care for the elderly, drugs, and demographic development and health. In 1993, government discontinued funding of the STG because of budget cuts. The work of the STG may continue, using other (presumably private) funds.

National Organization for Quality Assurance in Hospitals (CBO)

CBO examines quality and medical effectiveness at the hospital level, and promotes quality awareness by organizing consensus conferences on specific technologies for practicing clinicians.

Council for Health Research (Raad voor Gezondheidsonderzoek; RGO)

The RGO was created in 1987 to advise the government on the coordination of biomedical research in the Netherlands. In 1988 a report was published on the importance and coordination of technology assessment in biomedical research. The Council makes suggestions for new areas of technology assessment.

University Institutes for Technology Assessment

Several universities in the Netherlands are developing programs in health care technology assessment. The Institute for Medical Technology Assessment of the University of Rotterdam (IMTA) is very active in the field of economic evaluation and cost-effectiveness (e.g., in the field of transplantation and bypass surgery). It provides technical support to many hospitals carrying out research for the Investigational Medicine Fund. The Institute of Health Care Economics of the University of Limburg is also involved in cost-effectiveness studies and clinical trials of vaccines and drugs. The Institute for Medical Sociology of the University of Groningen has carried out technology assessments focusing on quality of life and social and ethical aspects of technologies. Other university institutes continue to develop interest in technology assessment.

Case studies

TREATMENTS FOR CORONARY ARTERY DISEASE

Coronary Artery Bypass Grafting (CABG)

The first attempts at CABG in the Netherlands were made in the late 1960s, in the university clinics in Groningen and Amsterdam. At that time coronary artery disease (CAD) had become the leading cause of death in the Dutch population. However, government policy focused on prevention rather than surgical intervention. In 1968 the Minister of Health asked the Health Council to report on options for preventing and treating CAD. The Council appointed a large committee which reported in 1971. One recommendation was to immediately increase the capacity for open-heart surgery to 1,300 procedures per year, since CABG had become an established intervention. The government ignored this recommendation, however, and continued to focus on prevention.

In 1972 the Nieveen Committee repeated its plea to increase the surgical capacity of the heart centers, and to bring the capacity to 3,000 operations by 1980 and increase the number of centers from seven to 11. Although this proposal was discussed in Parliament, no steps were taken to implement it. One reason was that the Minister of Finance found this masterplan too expensive (the estimate being around Df125 million). He presented a counterreport estimating the need at a maximum of 1,200 operations per year, performed in five centers. The Health Council Committee reacted furiously to this, saying that the Minister of Finance had overstepped his competence and was not qualified in any way to assess the need for medical treatment.

The real problem was that open-heart surgery

took place almost exclusively in the University Hospitals, which came under the budget of the Minister of Education and Science, who paid practically all the cost: research, medical education, equipment, and a large part of the health care provided. The social and private insurance agencies paid only for the hospital stay and not for the medical procedures. If open-heart surgery in these hospitals was to be increased, the financial burden for this would fall on other parts of government, including the Minister of Finance.

By 1974 the whole situation had come to a dead end. At that time, the Dutch Heart Patient Association staged a massive demonstration and even occupied the Parliament building. The Parliament, shocked by the violent actions of the patient organization, blamed the Minister of Health for the slowness of his decisionmaking. The Minister quickly reached an agreement with the insurance agencies over a reimbursement fee for CABG that would cover the cost at the University Hospitals, and announced that he would begin to increase the capacity for CABG in the University Hospitals, but not create new centers. The Heart Patient Association, not satisfied, organized an airlift in 1976. Patients on the waiting list were sent for surgery to the United States, London, and Switzerland, with the cooperation of the insurance agencies and the heart centers.

In 1976 the Minister of Health visited the United States and was alarmed at the growth in the number of CABGS. He observed that U.S. health authorities admitted that the increase might be due to an unjustified broadening of the indications for the procedure. Returning home, the Minister stated to the press that the estimate of 4,500 open-heart procedures might be too high, and that it was not necessary to increase the number of centers.

TABLE 6-7: Development of Open Heart Operations (OHO), CABG, and PTCA, 1975–1992

Data	1975	1980	1985	1990	1992
Population (millions)	13.7	14.1	14.5	14,9	15,1
Number OHO's	1,698	4,630	8,532	11,503	12,905
OHO (per million population)	124	328	588	772	854
OHO centers	9	12	13	14	15
Pop. per center (millions)	1.5	1.2	1.1	1,0	1,0
Case-load per center	189	386	656	822	860
Number CABG	663	2,926	6,789	9,202	10,325
CABG as % OHO	39	63	79	80	80
Pop. per center (millions)	1,5	1.2	1,1	1,0	1,0
Case-load per center	74	244	522	657	688
Number PTCA		36	2,556	8,205	10,521
PTCA (per million population)		3	176	550	697
PTCA centers		2	10	12	14
Pop. per center (millions)		7	1.4	1.2	1.1
Case-load per center		18	255	683	751

SOURCE M Bos, 1994, from reports of the Health Council, 1974-1993

In 1976 the permanent advisory committee on heart surgery (based at the Health Council) began work. They organized a consensus meeting, where a prominent role was played by eight “foreign experts” (mainly from the United States). The outcome of this meeting was a revised estimate of the future need for heart surgery (mainly based on U.S. data, since epidemiological data for the Netherlands were lacking). The new estimate was 5,500 to 6,500 open heart procedures per year (4,500 to 5,000 CABG, 1,000 to 1,500 operations on valves and congenital defects). The government had no option but to expand the number of heart centers. The decision was made to start two new centers in general hospitals, with a target of 1,000 procedures each per year.

In the early 1980s the number of open-heart operations expanded rapidly because of the new centers, and the number of operations performed abroad decreased (table 6-7). In 1984 the Health Council published a new report on the long-term development of cardiac surgery. It estimated that the number of cardiac operations would grow to 12,500 in 1992. The impact of percutaneous transluminal coronary angioplasty (PTCA) was not

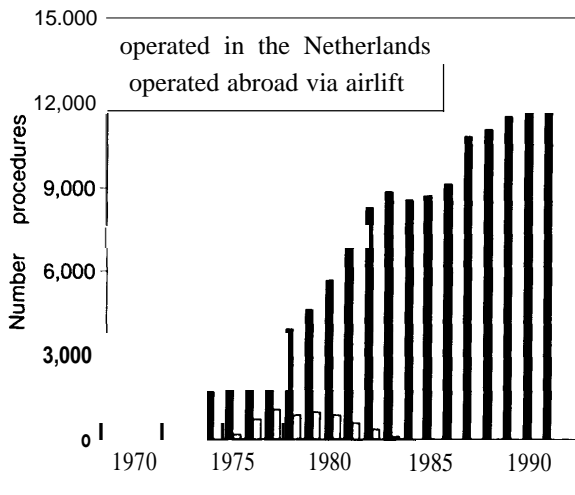
calculated, but the Council expected a substitution effect of 15 percent on the rate of CABG.

By 1984 waiting lists began to grow again. The Minister of Health hesitated to permit further expansion of cardiac surgery because of financial constraints within the health care system. Also, there was some doubt over the appropriateness of growing referrals for CABG (in view of the fact that PTCA was also expanding rapidly). Finally, the Minister of Health gave in to the growing pressure and approved two more centers. Since 1988 the growth rate of the number of heart operations has slowed, reaching 12,900 in 1992 (figure 6-1).

Government Policies Concerning CABG

In the 1980s the government was keen on regulating not only the number of surgical centers, but also the volume of procedures (in particular, the number of CABG) through the use of Article 18. However, it was argued that with the introduction of the budget system this type of control was outdated. It was felt that the volume of cardiac operations should be agreed on in the negotiations between hospitals and financing agencies. In 1989 the Minister of Health stopped regulating the

FIGURE 6-1: Open-heart Procedures: Adult and Pediatric, in the Netherlands and Abroad



SOURCE M Bos, 1994, from reports of the Health Council 1970-1993

number of procedures, leaving this to the insurance agencies. Budget control was effective, but there is still a steady (but modest) increase in the number of CABGs.

Assessment of CABG

Full-scale assessment of CABG was never undertaken in the Netherlands, although it was recommended by the Health Council very early. The medical profession relied mostly on the data available from the United States and was unwilling to start a study in the Netherlands. A limited cost-effectiveness study was performed in the surgical center in Maastricht. Recently, the Dutch centers are cooperating in an international multicenter assessment study, organized by the IMTA in Rotterdam and the RAND Corp., focusing on appropriateness of use. This study is also collecting information on the effectiveness of PTCA versus CABG.

Percutaneous Transluminal Coronary Angioplasty (PTCA)

The first cardiologist to use PTCA in the Netherlands, in 1980, was Ernst (trained by Gruntzig). Others were quick to follow, and within two years

all heart surgery centers were using the technique. By 1984 PTCA was considered to be established for the revascularization of (uncomplicated) single-vessel occlusions. When the Health Council reported on PTCA in its 1984 study of heart surgery, the committee (consisting of surgeons and cardiologists) was unanimous in its opinion that around 15 percent of all CABG procedures could be substituted by PTCA. However, as a growing number of cardiologists were trained in performing therapeutic interventions, they attempted more difficult coronary lesions. Also, more and more patients were treated with PTCA who were not yet candidates for CABG, but whose symptoms (anginal pain) were not successfully relieved with medicines. As a result, in the middle 1980s the number of both CABG and PTCA procedures increased rapidly, without any real coordination between cardiologists and surgeons. However, since there were long waiting lists for cardiac surgery in the Dutch heart centers at the time, the surgeons were probably relieved that the cardiologists were taking some of the workload.

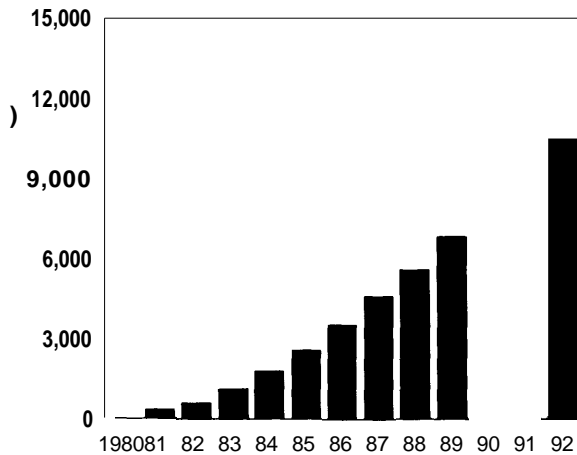
In 1987 the Minister of Health began to regulate heart surgery as well as PTCA under Article 18 of the Hospital Provisions Act. On the basis of the Health Council report (18) it was assumed that a maximum of 25 percent of all CABG could be substituted by PTCA. Following this reasoning, the growth of CABG was restricted while PTCA was allowed to expand.

The policy failed because both the surgeons and the cardiologists expanded the indications and exceeded the limits set by the Article 18 regulation. Although PTCA has replaced CABG for uncomplicated single-vessel disease, surgeons are now performing CABG in older patients (up to 85 years), and cardiologists are treating multivessel disease and patients who are not yet CABG candidates. As a result the numbers of CABG and PTCA procedures are both approaching 10,000 per year in the 1990s (see table 6-7 and figure 6-2).

Factors in the Diffusion of PTCA

The policy of the Minister of Health was to expand the number of PTCAS, to facilitate the substitu-

FIGURE 6-2: Diffusion of PTCA in the Netherlands 1980-92



SOURCE M Bos 1994 from reports of the Health Council, 1980-1992

tion of CABG by PTCA. To this end, the heart centers were given an extra budget for PTCA, while the number of CABG procedures was restricted. The health insurance agencies, which every year prospectively negotiate the number of CABG and PTCA procedures with the heart centers as part of the next year budget, also favored the expansion of PTCA. Finally, the media and the consumer organizations supported the development of PTCA as a patient-friendly procedure. Consequently, patient demand for PTCA has become stronger. When some hospitals tried to limit the number of PTCAS in 1990 because of a tight budget, the court ruled that patients were entitled to this procedure when there was a proper indication. The hospitals had no choice but to provide PTCA, and the insurance agencies had to pay for it.

Evaluation of PTCA has not played any part in its diffusion. In its 1984 report the Health Council recommended an evaluation of the proper indications for PTCA and the possible rate of substitution of CABG with PTCA. The Minister of Health asked the Cardiologists Association to set up the evaluation. However, such a study could not be organized during the 1980s. Because of strong competition between surgical and cardiology

specialties in the field of therapeutic intervention, surgeons refused to cooperate with cardiologists to join in a prospective study. Dutch centers are currently participating in two assessment studies.

Concerns with CABG and PTCA

Both CABG and PTCA are fully accepted in the Netherlands. The rates for CABG and PTCA are the highest in Europe (but less than in the United States). However, neither procedure has been influenced by evaluation. Since there is still considerable overlap in indications for the procedures (especially for multivessel disease), evaluation is needed to ensure appropriate use. Also, patient demand and consumer pressure may have led to some inappropriate use. The Dutch health authorities have stated that they will make further expansion of the number of procedures dependent on the outcome of the ongoing assessment studies.

MEDICAL IMAGING (CT AND MRI)

Computed Tomography (CT)

The case of the CT scanner demonstrates how the international network of medical professionals functions (8). Dutch radiologists learned about CT scanning at the yearly Radiological Society of North America (RSNA) Congress in the early 1970s. Some of the leading radiologists voiced strong opinions that the Netherlands should take part in the clinical development of CT scanning from the very beginning, and they were successful. In 1975 the Minister of Education and Science (who was then responsible for the University Hospitals) gave permission for the first brain scanner to be installed in Amsterdam University Hospital, with the proviso that the scanner be used for research purposes only. Shortly afterward, a second scanner was installed in a neurological clinic in Wassenaar. Before long other hospitals requested the support of the government to buy CT scanners.

The Minister of Health then asked the Health Council to report on the state of the art of CT scanning. Specifically, the Council was asked to consider the evidence of clinical benefit of CT and the necessity of regulating the diffusion process

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through article 18 regulation. The radiological community stated that this report was unnecessary because there was enough evidence already of the efficacy of CT scanners. They increased their pressure on all parties and were supported by the national industry (Philips Medical Systems). They argued that CT should not be withheld from eligible patients.

The Health Council published its first report after six months (14). The main conclusions were:

1. CT scanners should be regulated under Article 18 (because of the high cost, speed of technological developments, and special expertise needed);
2. CT scanning is of great potential value to neuroradiology (brain/CNS);
3. the value of CT scanners for other parts of the body is not yet defined; and
4. CT scanners should, for the time being, be restricted to teaching hospitals.

Although the Minister of Health had asked the hospitals not to buy CT scanners while the Health Council was preparing its report and until a decision was made about further diffusion, eight hospitals were operating scanners by 1977. In the same year the Health Council published its second report, calculating the future need for CT scanners in the Netherlands at 20 to 30 brain scanners and seven to eight whole-body scanners (one CT scanner per 300,000 to 500,000 inhabitants). The Council made a strong plea for the hospitals to join in a study of costs and effects of CT scanners, and warned that rapid improvements in CT technology caused scanners to be obsolete in just two or three years, making careful diffusion even more important. However, in the following years the Ministry of Health failed to implement a regulation for CT scanners, and no evaluation was conducted.

In 1979 the Central Board for Hospital Provisions (CvZ) published a plan for the diffusion of CT scanners, under which each health region would have at least one scanner (this meant 27 scanners for patient care) and another 10 should be available for research and teaching. In the same

year the Health Council published a third report saying that the lack of radiologists and technicians trained in CT scanning made too rapid an introduction hazardous. Nevertheless, in the next years 15 CT scanners were installed, without any planning or coordination. Some general hospitals evidently bought scanners because they anticipated future government regulation.

The Health Council published its final report in 1981, concluding that from a medical point of view there was no good reason to restrict the use of CT scanners. The need for CT scanners was set at one per 300,000 inhabitants (50 for the whole country). In the same year the Ministry of Health published a temporary decree to regulate CT scanners, to the effect that no more scanners could be installed by general hospitals until a definite plan for diffusion was published. By that time 24 general hospitals were operating CT scanners, while the seven University Hospitals had 13 scanners at their disposal.

In the next few years, only the University Hospitals (which were exempt from the regulation) were able to acquire more scanners. Finally, in 1984 (eight years after the first Health Council report), the Minister of Health promulgated a regulation, but it did not follow the Health Council's recommendations. The Ministry restricted scanner use to 130,000 scans per year until 1990 (at 4,000 scans per year per scanner this meant 33 CT scanners for the whole country, or one CT scanner per 450,000 inhabitants). In fact there were 45 CT scanners in operation at that time, producing some 160,000 scans per year; all of them were given permission to stay in operation but only until they had to be replaced. This policy had the effect that until 1987 the number of CT scanners remained at 46. This caused a lot of opposition from the radiologists, who held that introducing CT scanners in middle-size or even small peripheral hospitals added quality and could be done without extra budgetary resources (because of substitution). They were ardently supported in this by Philips Medical Systems (whose home market for CT scanners had almost collapsed). In 1989 the Minister of Health gave in and article 18 regulation for

TABLE 6-8: The Use of CT Scanners in the Netherlands

Data	1981	1984	1990	1992
Number of CT's	37	45	66	110
CT's per million population	2.6	3.1	4.5	7.3
Number of scans per year	95,000	160,000	290,000	330,000
Average number of scans per CT scanners per year	2,550	3,550	4,400	3,000
Inhabitants per CT scanners	381,000	322,000	224,000	136,000
Number of CT scans	1989	1990	1991	1992
Scans per 1,000 hospital admissions	35.7	61.0	68.1	84.8

SOURCE Health Council, *Advisory Report on Nuclear Magnetic Resonance Imaging Spectroscopy* (The Hague, 1984), National Raadvoor de Volksgezondheid (National Board of Health), *Advisory Report on MRI* (Zoetermeer, 1993)

CT scanners was abolished. Hospitals now had to negotiate with the regional insurance agencies to obtain reimbursement for CT scanning within the existing budgets. This policy has resulted in an enormous increase in the sale of scanners (see table 6-8).

Assessment of CT Scanning

In spite of the 1977 recommendation by the Health Council to start a program of evaluation and assessment of CT scanners in the Netherlands before the technology spread to the general hospitals, such a study was never performed. No initiative was taken by the Minister of Health, but there also was no real willingness on the part of radiologists, who maintained that the technology had become completely established by 1980. The only attempt to evaluate the role of CT scanners in hospital care in the Netherlands was by a young radiologist, who in his 1988 Ph.D. thesis looked into the effect of CT scanners on average inpatient stay and on the total number of radiological procedures (4). In hospitals with CT scanners at their disposal, the number of conventional radiological procedures declined, while in hospitals without CT, the number of radiological procedures increased. Therefore, CT appears to have had a partial substitution effect. However, the thesis did not determine whether the introduction of CT scanners had significantly improved the quality or reduced the cost of the diagnostic process.

Reimbursement for CT Scanning

The initial reimbursement fee (tariff) for hospital services was fixed at Df1400. However, when the number of scans began to increase rapidly and CT replaced conventional radiological procedures, the fee was lowered to Df1290. The radiologist can charge an additional fee of Df1100 (for brain CT) to Df1350 (for high-definition body CT).

Policies Toward CT Scanners

Government policy during the period of introduction of CT scanners in the Netherlands was focused on limiting the purchase of equipment. CT scanners were seen as a high-cost technology that added cost rather than quality. This was at a time when the health authorities were preoccupied with increasing health care costs and with instituting cost-containment measures. Article 18 regulation indeed resulted in keeping the number of CT scanners stable for several years. However, the government did not account for future increases in the use of CT scanners, and fixed the number of scans allowed at too low a level. Fierce resistance from the hospitals and the radiologists led to the regulation's abandonment.

Magnetic Resonance Imaging (MRI)

Development of MRI in the Netherlands started before most Dutch doctors had even heard of it (8,25). The Philips Co. had begun experimenting in 1973 with the MR principle in its Physics Labo-

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ratory, following the first studies in 1972-73 by Lauterbur. By 1980 a prototype was ready and producing images of the human body. The Philips Co. was aware of the fact that this new technology could only be introduced into clinical practice with the help of doctors, especially radiologists. Because doctors knew nothing about the technology, and because the machines were too expensive for hospitals to acquire, Philips installed a prototype in its factory in Best. Starting in May 1981 this machine was made available without cost to radiologists from four University Hospitals, who could bring their patients there for MR examination. In this way the radiologists became familiar with the technology (and spread the word to their colleagues), and Philips was able to improve its machine through their clinical experience.

A second prototype was installed in the University Hospital in Leiden in 1982 as a test site for inpatient MR studies. In 1983 the other University Hospitals approached the Minister of Education and Science (then solely responsible for these hospitals) to get permission to invest in MR technology. He contacted the Ministry of Health in order to develop a careful policy for the introduction of MRI (the failure to regulate CT scanners was still fresh). The Health Council was asked to report on the state of the art of MRI and the Minister of Education informed the university hospitals that he would take no further steps before a detailed diffusion plan was on the table. The boards of directors of the hospitals were asked to provide the necessary coordination. However, their answer was that they were unable to come to consensus (because of competition among them over the new technology). The University Hospital in Leiden was allowed to continue its experimental MR studies (paid for by the Philips Co., which had received a subsidy for the development of national industry from the Ministry of Economic Affairs).

In January 1984 the Health Council presented its report on MRI (17). This new technology was considered to be a very promising diagnostic

modality; however, the exact application in medicine was not yet defined. The Health Council proposed that three hospitals cooperate in an assessment. By mid-1984 the Minister of Education (supported by the Minister of Health) announced his policy: four University Hospitals (including the test site in Leiden) could operate MRI, under the following conditions: 1) the four hospitals would cooperate in a national assessment of MRI, and 2) the cost of MRI equipment and scans would not be borne by the Minister of Education, but would have to be covered from the health care budget. (To prevent general hospitals from acquiring MRI scanners, the Minister of Health introduced a temporary regulation under the new Hospital Budget Law.)

Early in 1985 an agreement was reached with the sick funds and private insurance companies that they would pay half the operating cost of MRI in the four selected hospitals. The other half was considered to be a research cost to be borne by the Minister of Education. (This was a breakthrough in the attitude of the insurers, since before this they considered all new technologies as "research," not payable through the health care budget. Two hospitals chose Philips scanners (for which the Ministry of Economic Affairs paid them a bonus) and one selected an American Technicare scanner; by 1987 all scanners were in operation.

At the end of December 1987 the MRI introduction period and policy was evaluated by an independent analyst at the request of the government. In addition to the evaluation, the analyst proposed that 14 MR scanners be in place in 1991 (one per million population). Following this report, a group of radiologists (supported by Philips) promoted a plan for a nationwide diffusion of MRI (in which Philips was to have a monopoly position) through a nonprofit organization run by themselves. The government quickly rejected this idea as too commercial (and in conflict with European Community free market principles).

TABLE 6-9: The Number of MR Scanners Installed Per Year and in Total, 1982/1993

Year	New MRI's per year	Cumulative number	Remarks
1982	1	1	First test-sale In Leiden
1983	0	1	
1984	0	1	Health Council report 3 MRIs
1985	2	3	4 hospitals selected, regulation
1986	2	5	Start assessment study
1987	0	5	Government policy on MRI evaluated
1988	0	5	Assessment study completed
1989	2	7	8 new MRIs approved
1990	7	14	Regulation abolished
1991	6	20	—
1992	7	27	National Board of Health report
1993	9	36a	80-90 MRI's needed in 2000

*Including 3 replacements—33 in operation

SOURCE National Raad voor de Volksgezondheid (National Board of Health), Advisory Report on MRI (Zoetermeer, 1993)

By 1989 the assessment in the four University Hospitals was completed. On the basis of the positive outcome, the government gave permission for six more scanners (four in university hospitals and two in national oncology centers). Extra money was provided to these hospitals to finance the scanners. However, a growing number of regional general hospitals also requested permission to operate MRI. In 1991 the Minister of Health decided to end restrictions on the diffusion of MRI, and freeing hospitals to acquire scanners provided they could cover the cost from the existing budget. The reason behind this decision was that so-called “low-budget” MR scanners (0.5 Tesla) had come on the market and were replacing (in part) conventional x-ray and CT scanners. From 1990 to 1993 another 26 scanners were installed and 14 hospitals decided to make use of a mobile MRI system (leased by a for-profit company) (see tables 6-9 and 6-10). In 1993 the future need for MRI (to the year 2000) was calculated by the National Health Care Board at 80 to 90 scanners (32).

Reimbursement for MRI

Hospitals must negotiate the reimbursement for MR scans (based on substitution within the budget) with the insurance agencies. In the beginning there was no special reimbursement fee for MRI, but radiologists and hospitals charged the same

amount as for CT scanning. When the fee for CT was lowered, a separate MRI fee of Dfl865 was agreed on by the insurance agencies (Dfl750 for the hospital services and Dfl115 for the specialist fee).

Assessment of MRI

Because of the unfortunate experience with the introduction of CT scanning, the health authorities in the Netherlands emphasized from the start that MRI should be evaluated. Formal assessment was to be a precondition for further diffusion. The first assessment by the four University Hospitals was very limited in scope (not a true technology assessment), focused mainly on the efficacy of MRI, the established and emerging indications, and possible substitution for other diagnostic procedures. Later assessments (32) have looked into the cost-effectiveness and appropriate use of MRI.

The Role of Philips

The introduction of MRI in the Netherlands was influenced by the interests of Philips Medical Electronics, by far the largest medical equipment company in the Netherlands. Philips has contributed to the early introduction and diffusion of new diagnostic technologies, including digital x-ray, CT scanning, MRI, and angiography. The company has usually invested in test sites in major hospi-

TABLE 6-10: The Use of MRI in the Netherlands

Data	1987	1990	1993
Number of MRI in operation	5	14	33
MRI per million population	0.3	0.9	2.2
Number of scans per year	7,000	14,000	40,000
Average number of scans per MRI per year	1,400	1,000	1,200
Inhabitants per MRI (millions)	2.8	1.1	0.5

SOURCE Nationale Raad voor de Volksgezondheid (National Board of Health), *Advisory Report on MRI* (Zoetermeer, 1993)

tals. Although the home market is rather small compared to worldwide sales (85 percent of imaging equipment is exported), Philips needs high-quality academic and regional hospitals in the vicinity of its research laboratories as partners in technical development. This was particularly true in the case of MRI (Philips needed to have MRI machines installed in a clinical setting for further development). Ordinarily, protection of the national industry is not practiced in the Netherlands to such an extent as in other European countries, but in the case of MRI, Philips was supported by a large grant from the Ministry of Economic Affairs. Other MRI companies have objected to the virtual monopoly of Philips in the early MRI sales in the Netherlands.

Policies Toward MRI

The Ministers of Health and of Education and Science were determined to avoid the type of situation that arose over the introduction and diffusion of CT, (34) when too strict regulation created a stalemate. With MRI, the introduction and first phase of diffusion went satisfactorily. The decisionmaking process took less time than with CT and there was constructive cooperation with the medical community. By 1990 the government as well as the radiologists considered MRI to be a standard diagnostic procedure, so strict regulation was not necessary.

Concerns About CT and MRI

In general, the use of radiological diagnostic procedures in the Netherlands is modest compared to other countries (27,35). Both the government and the hospitals have taken initiatives to limit and,

where possible, push back the number of unnecessary x-ray procedures (e.g., routine pre-operative x-rays), both to save money and to diminish radiation exposure of the population (35). The introduction of new diagnostic procedures, however, presents at least two problems. If the new technology has an “add-on” effect and does not substitute for existing procedures, it will add costs to the health care sector. If it makes use of ionizing radiation, it will result in a higher exposure rate to the population, which may be a risk to health.

CT scanning contributes relatively highly to radiation exposure. The recent increase in the number of CTs in the Netherlands (which has been only partial substitution) may thus have had a negative effect. MRI on the other hand, does not use x-ray. Thus it may be advantageous to let MRI substitute for a large part of all examinations currently performed with x-ray (conventional x-ray, angiography, CT, e(c)). From the quality point of view this poses no real problem, since MRI has shown to provide, in many cases, superior information. Such a policy, however, would mean that the number of conventional radiological devices (including CT) would have to be reduced. In 1992 only 25 percent of the 30,000 MR scans in the Netherlands substituted for other radiological procedures. It has been calculated that the substitution effect could be at least 50 percent. This would mean that in the coming years 50 CT installations (or 150,000 scans per year) would have to be replaced by MRI. Since most of the CT scanners in the Netherlands have been acquired in recent years, one may doubt whether hospitals and health care financiers will agree to such a policy.

Another concern with MRI is the low caseload in most hospitals (in 1993, an average of 1,200

scans). The cost of an MR scan has been calculated to be competitive with CT assuming a case-load of 2,500 to 3,000 scans per year. This should correct itself if the substitution of MRI for other radiological procedures continues to increase.

LAPAROSCOPIC SURGERY

The first laparoscopic surgical treatment introduced in the Netherlands was probably laparoscopic appendectomy, which has been performed by the surgeon de Kok since 1971. Although the new technique was successful (de Kok has performed more than 1,500), it never became popular with other Dutch surgeons. Only recently, since the successful introduction of laparoscopic cholecystectomy in 1990, has laparoscopic appendectomy become somewhat more popular.

The story is similar for laparoscopic surgery in gynecology. In 1979 Ijzermans (in Eindhoven) treated endometriosis and removed ovarian cysts through the laparoscope. For 10 years he was almost alone in this field. Colleagues began to show interest only after the publicity for laparoscopic cholecystectomy. In 1989 Ijzermans organized a symposium on the subject, and about eight hospitals are now treating endometriosis laparoscopically. Laparoscopic removal of ovarian cysts has met with little enthusiasm, however, perhaps because the procedure is technically difficult and because there seems to be consensus in the Netherlands that removal of early ovarian cysts is unnecessary.

Another development of minimally invasive surgery in urology is percutaneous nephrolithotomy (PCN), or the laparoscopic removal of kidney stones, which was introduced around 1980 (26). By 1985 all university urology departments and the majority of peripheral centers had adopted the technique. However, in 1984 shock-wave lithotripsy was introduced, and, after a difficult start, expanded rapidly. The diffusion of PCN slowed down. Today, because of the relatively low price of lithotripsy equipment and the availability of more than 10 machines in the Netherlands, most urologists prefer ESWL over PCN for treating

smaller stones (up to two cm diameter). PCN is performed for larger stones. Conventional open surgery has become obsolete.

In 1990 laparoscopic cholecystectomy was introduced in Eindhoven by van Erp, who had been trained by Dubois in France. Two other surgeons soon followed. But other surgeons were not very interested in the new method, perhaps because it takes longer than conventional surgery. However, after van Erp appeared on television, patients started to demand the new procedure. By May 1991 about 60 hospitals were doing this procedure routinely, but mostly in small numbers. Reasons for the slow diffusion include the limited supply of operating laparoscope and the budgetary constraints in most hospitals. In spite of these problems the technology continues to diffuse rapidly.

Reliable evidence of efficacy and effectiveness of laparoscopic procedures was lacking at the time of its introduction in the Netherlands, and this situation has not really changed. Some controlled trials have begun (funded by the Investigational Medicine Programme run by the Sick Fund Council) to assess cholecystectomy, treatment of bladder tumors, and appendectomy.

Factors in the Diffusion Process

The introduction and development of laparoscopic techniques in the Netherlands, as elsewhere, has been very much the work of a few innovative surgeons. They saw the positive side of these techniques (less trauma to the patient, shorter hospitalization, quick rehabilitation), although they may have been technically more difficult, time-consuming, and costly in the beginning. In most cases it took several years before fellow surgeons ventured to follow their example, forced into action by public demand (informed by the lay media) for the new procedures. In general, however, the diffusion of laparoscopic surgery in the Netherlands has been slow (at least in comparison to that in the United States, Germany, and France, for example), with the exception of laparoscopic cholecystectomy and percutaneous nephrolithotomy (2).

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Some other factors that have slowed down the diffusion are:

1. budgetary pressures on hospitals, which make them reluctant to undertake new, capital-intensive procedures or treatments that require extra time or personnel;
2. financial incentives for hospitals, which make shorter stays unattractive;
3. lack of reimbursement of a new procedure (seen as "experimental");
4. lack of training in minimally invasive techniques to bring skill to acceptable levels; and
5. conservatism among many surgeons.

On the other hand, there are also factors at work that facilitated the diffusion of laparoscopic surgery:

1. media reporting, raising patient demand and physician interest;
2. commercial pressure and information (equipment manufacturers);
3. convincing evidence on effectiveness for some new procedures, in some cases acquired through controlled trials in the Netherlands; and
4. the availability of appropriate training with respected physicians.

Policies Toward Laparoscopic Surgery

There has been striking lack of interest and action among policy makers at all levels with regard to laparoscopic surgery. This noninvolvement has led to the absence of any regulation and has certainly not been an impeding factor. Interest from the insurance agencies might have been expected, since most laparoscopic procedures are claimed to be more patient-friendly and cost-saving in the end. However, no attempt has been made to facilitate the diffusion of new techniques by financial incentives or arrangements. On the contrary, most of the existing budgetary and reimbursement procedures work against their adoption

Concerns with the Technology

Policymakers have recently begun to appreciate the far-reaching implications of laparoscopic surgery. While patients may profit from procedures that cause less trauma and disability, the potential for overuse of these procedures is great because of commercial promotion by the industry and consequent patient demand, even in the absence of evidence of effectiveness. The new procedures also have important implications for physicians. The new techniques have begun to change patterns of practice where treatment is now provided by specialists who were traditionally diagnosticians. Also, most practicing surgeons have had no formal training in using these techniques. Finally, hospital administrators are concerned since laparoscopic surgery (minimally invasive surgery in general) is changing the organizational structure of the hospital through more outpatient treatments, day surgery, shorter hospital stays, and new equipment used outside the operating theatre. Eventually more than half of all surgical interventions may be done with minimally invasive techniques.

TREATMENTS FOR END-STAGE RENAL DISEASE (ESRD)

When Kolff developed his artificial kidney in the Netherlands during the late 1940s he found little recognition for the innovation in his own country. Unable to get funds for further research and development he left the country in 1950 for the United States where he devoted himself to the perfection of the artificial kidney and other bioengineering projects. Soon after, dialysis for acute kidney failure became a standard treatment around the world.

In 1963 chronic intermittent hemodialysis, made possible by Scribner's new shunt system, was introduced in the Netherlands in the university hospitals of Leiden, Utrecht, Amsterdam, and Nijmegen. Selection of patients was very strict, as the treatment was not covered by insurance and hospitals had to pay for it out of their own funds

TABLE 6-11: Renal Replacement Therapy (RRT) in the Netherlands (1970–92)

Number of patients	1970	1975	1980	1985	1990	1991	1992
On dialysis	400	1,050	1,468	2,386	3,042	3,203	3,318
With functioning graft	—	—	891	1,665	2,725	2,890	3,131
Total number of RRT	—	—	2,359	4,051	5,767	6,093	6,449
Total per million population	—	—	166	279	387	409	430
New patients on dialysis per year	—	—	523	672	965	1,041	1,088
New patients per million population	—	—	37	46	65	70	.72

SOURCE M Bos 1994 from Renine Foundation Statistical Reviews

Dutch nephrologist then formed a pressure group to persuade the government and the insurance agencies that dialysis could no longer be seen as experimental. Finally, in 1967 dialysis became a reimbursed part of the social insurance benefit package. The Dutch Kidney Foundation grew in 1968 out of this pressure group of nephrologist, joined by the dialysis patients. This organization has been powerful and effective in the diffusion of renal replacement therapy, promoting dialysis and transplantation and supporting the hospitals with funds for research and patient care facilities.

The first kidney transplant in the Netherlands took place in 1966 in the University Hospital in Leiden, using an identical twin donor. The first transplants with a cadaveric organ followed in 1967, in Leiden and Amsterdam simultaneously (using two kidneys from the same donor). At Leiden University the immunologist van Rood had perfected typing and matching human tissues on the basis of human leukocyte antigens (HLA) and made the system usable for routine clinical transplantation. He later advocated matching cadaveric donor kidneys to recipients on a European scale, from which sprang (in 1967) the Eurotransplant organization, the first exchange program of its kind in the world. Today, Eurotransplant is responsible for the matching and exchange (through its central office in Leiden) of all cadaveric donor organs in the Netherlands, Belgium, Luxembourg, Germany, and Austria, resulting in more than 5,300 transplants a year (9).

Other factors have also influenced the development of kidney transplantation in the Netherlands.

In 1976 several private organizations (Eurotransplant, the Kidney Foundation and the Red Cross) joined forces to promote organ procurement, introducing a national donor card system. A Task Force was founded in 1980 with the goal of stimulating public support for organ donation through information and media campaigns. The number of donated organs increased significantly after the first transplant coordinator was appointed at the University Hospital in Groningen in 1979. There are now 11 regional transplant coordinators. The insurance agencies have agreed to reimburse the cost of organ removal to the donor hospitals, thus breaking down one of the important barriers that prevented hospitals from cooperating with the transplant centers.

Tables 6-11 and 6-12 show the diffusion of dialysis treatment and kidney transplantation in the Netherlands. Table 6-13 presents some basic data on the current status of ESRD patients and services.

Policy Actions Concerning Dialysis and Transplantation

During the early years of renal replacement therapy the Dutch government and the health authorities played a very modest role. Almost all actions to promote dialysis and kidney transplantation were taken by individuals and nonprofit organizations, such as the Dutch Association of Dialysis Doctors (DGN), the Dutch Kidney Foundation, Eurotransplant, and the Renal Patients Association (LVD). They not only made possible the first

TABLE 6-12: Kidney Transplants (1970–92)

Kidney transplants	1970	1975	1980	1985	1990	1991	1992
Patients on waiting list	275	480	464	977	1,343	1,412	1,434
Number of transplants	54	193	239	332	442	474	527
With cadaveric donor	50	191	236	289	406	431	445
With living donor	4	2	3	43	36	43	82
Transplants per million population	—	13.7	16.8	22.8	29.8	31.8	35.1

SOURCE M Bos, 1994 from Eurotransplant Foundation Annual Reviews

facilities for treatment, but also financed dialysis centers, facilities for home dialysis, specialist training for nephrologists, and education of the public through mass campaigns. Eurotransplant has built an extremely effective national and international network for matching donor organs with recipients. The Kidney Foundation finances almost 75 percent of all scientific research on kidney disease in Dutch institutions.

Despite a need for legislation recognized in 1968, the government has failed to get a bill on organ transplantation through Parliament (a draft was presented in 1991). In practice, a system for organ donation based on “opting-in” (explicit consent) has been adopted, whereby permission for removal of organs is given either by the deceased (carrying a donor card) or by the next-of-kin. The recent Bill on Organ Removal is also based on the opting-in principle, although the Council of Europe advocated an opting-out system based on presumed consent in 1978 and most European states have adopted this type of law.

Since renal replacement therapy is expensive, health authorities have sought to control its diffusion. Since 1979, Article 18 of the Hospital Provisions Law has required hospitals to get authorization from the Minister of Health to provide dialysis and kidney transplantation. The policy pursued by the Minister is to concentrate all transplants in a limited number of centers in order to assure a high level of quality—only eight university hospitals have been licensed so far (with an average case-load of 60 transplants per year). Dialysis facilities are present in 55 institutions (hospitals and free-standing dialysis units) with an average of 13 dialysis units and 63 patients

each. In the early years the government promoted hemodialysis at home (being less costly and allowing the patient more freedom). However, since 1985 the emphasis has shifted to continuous ambulatory peritoneal dialysis (CAPD) which now accounts for 28 percent of all dialysis.

The Role of Technology Assessment

In 1972 and 1978 the Dutch Health Council published reports on dialysis and kidney transplantation that were influential in instituting regular financing for these therapies. A 1986 report looked into the cost-effectiveness of different renal treatment modalities and also presented a mathematical model to predict inflow and outflow of patients in renal replacement therapy. This report was the basis for a Planning Document published by the Minister of Health in 1987. The latest report by the Health Council, published in 1992, studied the effect of recent developments in renal therapy on the use of different treatment alternatives. A National Registry for Renal Replacement Therapy, founded in 1986, collects and analyses complete statistical data on dialysis and transplantation (33).

Concerns with the Technologies

The main concern today is with the shortage of donor organs for transplantation. The gap between the number waiting for transplants and the number of transplants is widening. Although there are enough potential cadaveric donors to fulfill the need, only a fraction are actually procured because many brain-dead patients are not recognized as

TABLE 6-13: Dialysis and Transplant Data on Jan. 1, 1993

Patients on dialysis	3,473
on hospital dialysis	2,410 (69%)
on home dialysis	104 (3%)
on CAPD	959 (28%)
Number of dialysis centers	53
Number of people per dialysis center	0.3
Number of dialysis units	680
Number of transplant centers	8
Number of people per transplant center (millions)	1.8

SOURCE Renine Foundation, *Annual Statistical Review 1993* (Rotterdam Foundation for the Registration of Renal Replacement Therapy, 1993)

potential donors and because many families (up to 40 percent) refuse permission for removal. Pending legislation and educational campaigns may improve this situation.

Erythropoietin (EPO)

EPO was introduced to the Netherlands about 1990, following FDA licensing in the United States. The introduction was negotiated between the Association of Dialysis Doctors and the Sick Fund Council, resulting in prompt coverage by social health insurance. The cost is included in the overall dialysis fee (Df100 per dialysis treatment) and is included in the hospital budget (prospective calculation) but with the possibility of a correction afterwards. In the Netherlands, 60 to 65 percent of all dialysis patients get EPO (higher use by patients on hemodialysis than on CAPD). Use is limited to patients with nephrogenic anemia (because of chronic dialysis) and transplanted kidney patients with deteriorating kidney function.

There was no formal assessment of EPO preceding its introduction. The results of U.S. clinical trials have been accepted as conclusive. Discussions were held between the Sick Funds Council and a Dutch technology assessment center concerning the possibility of carrying out a prospective cost-effectiveness analysis, but the coverage decision was made while these discussions were still ongoing. (Nonetheless, one has

been completed (28).) A clinical trial is under way to establish the optimum dosage of EPO.

NEONATAL INTENSIVE CARE

Between 1900 and 1940 infant mortality declined in the Netherlands by half because of better hygiene and nutrition, but there was little improvement in perinatal mortality during the first month of life. In the late 1940s, pediatricians became involved with obstetric care resulting in the creation of a specialized neonatal ward, situated between the obstetrics and pediatrics departments. In 1968, the University Hospital in Leiden was the first to start such an "intensive care" facility. After 1970 neonatal intensive care improved again through the introduction of controlled ventilation, making it possible to save extremely premature babies.

The development of modem, sophisticated neonatal care around 1970 led to the establishment of regional neonatal intensive care units (NICUS) in the seven University Hospitals and some pediatric hospitals. By 1978 there were 31 fully equipped intensive care beds available. However, the very success of neonatal care created its own problem: because more and more peripheral hospitals referred their premature babies to the university centers, there soon was a serious shortage of NICU facilities. In 1974 the Dutch Pediatric Association formed a committee to report on the need for NICUS and their optimal organizational structure. The Committee's recommendations (in 1975 and 1978) led to some improvement in the quality of the care and better regional referral arrangements, but could not resolve the capacity problems. The continuing shortage in the university centers led to the establishment of many small facilities in regional hospitals, a development which was not supported by the university neonatologists who believed that it compromised the quality of care.

In 1979 when the situation had really become critical, the Minister of Health asked the Health Council to assess the scientific development of neonatal intensive care and report on the future need for facilities. In its report (16) the Health Council recommended the following:

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TABLE 6-14: Development of NICUs in the Netherlands, 1978-92

	1978	1981	1987	1989	1991	1992
Approved ICU centers	7	7	8	10	10	10
Number of IC beds	31	32	47	88	98	144 ^a
Centers without approval	8	8	14	24	20	12
Number of IC beds	17	17	17	—	—	—

^aThis number includes both intensive and high care beds, according to a new definition used by the Health Council

SOURCE Health Council, *Report on Neonatal Intensive Care*, publication 1982/20 (The Hague, 1982), Ministry of Health, *Planning Document Neonatal Intensive Care* (The Hague, 1993)

1. neonatal intensive care should be restricted to 10 fully equipped supraregional centers,
2. the future need (1985-90) for neonatal intensive care in the Netherlands was calculated to be 140 beds and 228 high-care/medium-care beds,
3. the minimum size for a center should be 10 intensive care, 12 high-care and 10 medium-care beds, and
4. neonatal intensive care should be concentrated in these 10 centers by means of legal regulation, by applying article 18 of the Hospital Facilities Act.

In 1983 article 18 regulation came into force but the Ministry of Health did not publish a planning document until 1987 (*Planningsbesluit Neonatologie*) in which the 10 centers were actually named. Between 1986 and 1991 the Minister of Health made development of these NICUS one of his priorities, approving new facilities and increasing the budgets of the centers. During these years the capacity of the NICU centers had almost doubled (tables 6-14 and 6-15) but it was clear that the shortage was not resolved. The Minister again asked the Health Council (in 1989) to report on the future of intensive care. Their 1991 report contained a survey of NICU facilities in the Netherlands, which showed that the demand for care was growing (in part because of an increase in the multiple birth rate since the 1970s) (7). It also contained an assessment of NICU effectiveness (in improving survival and preventing handicaps). The need for NICUS was estimated to be 165 to 202 beds in the 1990 to 1995 period, to be located in the existing 10 centers. The Minister of Health

acted quickly: in January 1993 a new Planning Document was published that set the future need for NICU at 168 beds. Peripheral hospitals that provide NICUS on a small scale but have not been authorized under article 18 will have to terminate this care (though some are allowed to continue until the capacity in the 10 centers is fully realized).

Factors in the Diffusion of NICUS

The development and diffusion of NICUS has been influenced to a large extent by the concern of university pediatricians and neonatologists with the quality of perinatal care. They took the initiative in the early 1970s to set up regional NICU centers and make arrangements for referral. They promoted the concentration of neonatal care in a limited number of centers.

The idea of concentration was adopted by the central health authorities, who used existing legal instruments to bring it about in the face of significant opposition from the peripheral hospitals with small NICUS (one to four beds). Between 1987 and 1993, the Minister has made the development of NICU centers one of his priorities in intramural care and pumped extra money into centers. In doing so, he was supported by the Minister of Education and Science, who shares responsibility for the university hospitals and provided financial support to build extra NICUS. The efficiency of NICU centers has increased since 1987, when a computer network was installed that enables referring hospitals to judge the availability of NICU capacity in the individual centers at any time.

TABLE 6-15: Use of NICU Facilities in the Netherlands, 1990

Number of patients treated in approved centers	2,372
non-approved centers	667
abroad	20
Total	3,059
Number of patients who died in ICU (%)	418 (17.61X0)
Total number of IC-days	49,168
Average stay in NICU (days)	16.1
Percent of all live-born children treated in NICUS	1.62

SOURCE Health Council, *Report on Neonatal Intensive Care*, publication 1982/20 (The Hague, 1982), Ministry of Health, *Planning Document Neonatal Intensive Care* (The Hague, 1993).

The Role of Technology Assessment

Technology Assessment has played an important role in the development of NICUS. The two reports issued by the Health Council were the basis for the policy pursued by the Minister of Health (16,22). Another influential report was the POPS study (project on preterm and small-for-gestational-age infants) conducted by a group of pediatricians from Leiden University Hospital (1983 to 1987). They followed 1,338 children with a birth-weight below 1,500 g for a minimum of three years. Survival, risk of perinatal mortality, quality of life, and risk of handicaps were assessed and compared with historical controls (born 1979 to 1983). The initial results show a significant increase in survival without a rise in the handicap rate (36). As yet no cost-effectiveness study of NICU. has been conducted in the Netherlands.

Extracorporeal Membrane Oxygenation (ECMO)

In 1990 ECMO was introduced in the Netherlands in the neonatal clinic of the Nijmegen University Hospital, after several years of animal experimentation (10). Although the first treatments were successful, there was doubt over ECMO long-term results (11). The Health Council, in its 1990 annual report (20) found that although immediate results were favorable (more than 80 per-

cent survival), ECMO had significant complications, and about 10 percent of the survivors showed mental and physical disability. Experience with ECMO in older infants was also very limited. The Council voiced the opinion that ECMO should be considered as "experimental therapy" and recommended its use only in cases of neonatal respiratory failure in selected NICUS. The Council strongly recommended a prospective technology assessment.

These recommendations were followed by the Ministry of Health and the university hospitals. In 1991, four centers applied for funding of an ECMO technology assessment project from the Investigational Medicine Fund. Subsequently two centers (Rotterdam and Nijmegen) were selected. Preliminary results of their study (non randomized, with conventionally treated historical controls) have been reported. They found significantly better survival for neonates with serious respiratory distress and no difference in short-term morbidity in ECMO-treated babies at a cost of Df153,500 per baby.

In 1993, the Minister of Health restricted the use of ECMO by applying Article 18 regulation (already in force for NICUS) (29). For the duration of the technology assessment study, the use of ECMO is restricted to the two centers involved in the clinical trial. Expansion to other centers depends on the outcome of the assessment. The preliminary estimate of need from the Dutch ECMO trial is a minimum of 24 patients per year, which may increase to 45 to 50 patients per year, based on the U.S. and U.K. experiences.

SCREENING FOR BREAST CANCER

Breast cancer accounts for one quarter of all cancer deaths in Dutch women. Breast cancer incidence increased from 50 per 100,000 in 1960 to 96 per 100,000 in 1989 (although much of this increase is probably an artifact of screening). As early as 1974 some hospitals introduced screening mammography for breast cancer (in place of self-examination). organized in cooperation with regional cancer centers. Experience with this method was described in a 1974 report by the

Health Council (13). In 1977 the Minister of Health asked the Health Council to look into possibilities for a national screening program for breast cancer. The Council reported in 1981 and again in 1984, describing the experiences with breast cancer screening in Nijmegen, Utrecht, and Leiden (15). These hospitals used different age criteria (over 35 years, over 50 years) and different screening intervals (one, two, or three years). The Health Council concluded that there was insufficient epidemiological data available to decide what was the most relevant age group and time interval. Also, there was uncertainty as to the logistical and financial consequences of nationwide screening. At that time there was little experience with screening studies in general in the Netherlands. The Council recommended that a cost-effectiveness study of the possible alternatives be conducted.

In 1986 representatives of the Ministry of Health and the Cancer centers visited Sweden to study the ongoing screening program there (1). Also in 1986, the European Community convened an international working party on early detection of breast cancer to discuss issues such as the relevant age groups (consensus reached on 50 years old and over), the best screening interval (consensus reached on two years), and who should do the screening (professional radiologists or radiography technician—no consensus reached).

The Health Council published its final report in 1987 (19), recommending mammography screening for women 50 to 70 years old, at an interval of two years, by radiologists. The organization would be the responsibility of the regional cancer centers. Before screening started, education would be organized for general practitioners (GPs) and the public. An essential issue was continuous quality assurance of the screening program, to be carried out by an independent body. In 1987 the National Health Care Board (NRV) made recommendations on logistical aspects of the screening program.

The Sick Fund Council took responsibility for introducing nationwide screening in 1987. The program was to be paid for out of the Exceptional Medical Expenses Fund, a national insurance pro-

gram. The Sick Fund Council asked the Institute for Medical Technology Assessment (IMTA) of the Erasmus University in Rotterdam to study the costs and effects of breast cancer screening (23). In its first report (23) IMTA calculated the cost of preventing one case of death from breast cancer by screening as Dfl 100,000; the cost per life-year saved was put at Dfl 19,700. It was also calculated that half the cost of the screening program could be earned back by saving on extra diagnostic and therapeutic procedures (as a result of early detection of cancer). IMTA calculated it would take seven years to introduce an effective nationwide screening program (completed in 1995).

Guidelines for mammography screening were introduced by the National Organization for Quality Assurance (CBO) in 1988 as the result of a consensus conference. Finally, the Sick Fund Council appointed a National Coordination Committee in June 1988, after which the screening program started.

Factors in the Diffusion

It was of some importance that several Dutch University Hospitals already had some experience with mammography in the early 1970s. But models for a nationwide screening program were taken from the Scandinavian countries, since there was very little experience with mass screening in the Netherlands. Although the central government was interested in starting a mass screening program, it was the social insurance programs (represented by the Sick Fund Council) that took decisive action. The cost-effectiveness study by IMTA was very influential.

Current Status of the Screening Program

In 1989 the first phase of the screening program began. The organization was carried out by the nine Basic Health Services, in cooperation with the Regional Cancer Centers. Each regional screening program will be evaluated before it starts, including logistics, costs, and assessment aspects. Furthermore, in each region a screening information system has been set up, with the rele-

vant population data. By 1993 the screening programs were operating in five regions; by the end of 1994 all regions will have begun.

IMTA published a first evaluation of the screening program for breast cancer in June 1992 (24). The following indicators of effectiveness have been developed to assess the Dutch screening program:

- a high response in the relevant age-group (more than 70 percent of women 50 to 70 years old),
- a high predictive value of a positive screening result (more than 40 percent confirmed),
- detection rate of at least 6.0 per 1,000 women screened,
- high specificity of mammography (greater than 99.1 percent),
- earlier tumor stage treatable with surgery, and
- possibilities for breast-sparing treatment.

In 1992 the first two screening regions were evaluated, with the following results:

9 a response in the first round of 79 percent,

- predictive value of screening test of 57 percent,
- detection-rate of 6.6 breast cancer cases per 1,000 women screened,
- detection in early tumor stage (most tumors half the size of those found without screening), and
- most tumors were operable (38 percent had radical surgery, 51 percent had breast-sparing operation, 11 percent had lumpectomy).

In conclusion, it can be said that the first screening programs did well, when effectiveness is considered. However, these results are not yet proof of the value of mass screening.

It was also found that the screening programs had some adverse effects, that were not anticipated (5). The following problems were observed:

- an extra psychological burden on women, a relatively long period of uncertainty,
- increasing waiting time for the results of mammography, and
- an increase of diagnostic procedures and consultations with specialists.

CHAPTER SUMMARY

The Dutch health care system developed to its current form after the second World War. The main characteristics are: a mixed system of social and private insurance, almost complete coverage of health risks by insurance, and a high quality of care to which all citizens have equal access. Control and regulation of health care technology by the central government is an important feature of the system. Assessment of health care technology is becoming more important in decisionmaking.

Ways To Control Health Care Technology

In the Dutch health care system, control of health technology is effected in three major ways:

1. Before 1983 (introduction of the global hospital budget), health technology was controlled almost exclusively by the central health author-

ity. Regulation was mostly through direct legislation, requiring approval or certification by the Minister of Health. In some cases the authority to control health care services was handed down to the regional health authority, but general guidelines for planning by the provinces were laid down by the government. In other cases (as with drugs, vaccines, and blood) control was referred entirely to an independent body.

2. The second instrument of control over health technology, which has increased in importance since 1984, is the admission of new technologies to the social insurance benefit, which is the responsibility of the Sick Fund Council. By admitting or excluding specific technologies from the benefit package, the Sick Fund Council controls the reimbursement of health services.

3. The adoption of a global budgeting system for hospitals and other health care institutions in 1983 introduced a powerful instrument of control over health care technology. Annual budgets are prospectively negotiated between health care providers and regional insurance agents, and approved by the Central Tariffs Board. Budget arrangements include the expected volume of specific health technologies. In this way caps can be put on, for example, cardiac surgery, radiation therapy, or the number of CT procedures.

The Success of the Control Mechanisms

Control of health care technology by direct legislation has been most successful in the field of drugs and biologics. The strict legal system of pre-market approval by independent boards has proven to be effective, rapid, and flexible. Quality standards are very high and adverse effects are monitored closely. Least successful has been regulation of the introduction of medical devices. Although relevant legislation is on the books, there is no effective system of approval for the admission of new medical devices.

Regulation of health care technology by the central government has been most successful in the field of “high-tech” services using Article 18 legislation. Early experiences (in the 1970s), for example, with the introduction of CT and cardiac surgery, were not very successful because the procedure was too slow and bureaucratic, and often diffusion was well under way before control became effective. Later on, when the government used Article 18 regulation in a more global sense (regulating only the number of hospitals using the technology and not the number of machines and the volume of procedures), this method of planning became more effective. The main purpose of using Article 18 regulation today is to concentrate certain technologies in a limited number of centers. The relative success of Article 18 regulation (when compared to CON type regulation in other countries) is dependent mainly on two factors. First, hospitals that break the rules and provide

services without approval are confronted with severe sanctions. Second, the planning document that is the basis for approving specific types of services is usually very explicit as to the number of centers, quality standards, and other requirements.

Control of technology through defining the benefit package has proved to be very effective in a number of cases (e.g., IVF, bone marrow transplantation, heart and liver transplantation). The Sick Fund Council has widened its span of control and has become involved in technology assessment through this mechanism. Introduction of the hospital budget system has had an enormous effect on the introduction and use of health care technology in general: autonomous growth has been curbed to a large extent and cost containment on the macro-level became feasible.

The relative success of regulating and planning health care technology in the Dutch system relates to the fact that the three instruments described above are used in conjunction so that the effect is reinforced. For instance, the budget system may be a powerful instrument to control hospital spending, but it is not a very good instrument in itself for planning specific services. In combination with Article 18 regulation however, the budget system is very effective in controlling the diffusion of expensive health services.

Apart from these regulating mechanisms, health care technology assessment has become an increasingly successful tool to control the introduction and diffusion of health care technology. It has been demonstrated in recent years that formal assessment has made it possible to influence the diffusion and use of a number of new medical technologies. The use of prospective, randomized clinical trials and cost-effectiveness studies has been an important aspect of these endeavors. The structure for a more systematic technology assessment approach is now being developed, especially through the Investigational Medicine Fund. Both the government and the insurance agencies are taking part in this program. However, participation from the medical profession is still limited. In the coming years, policy

should be directed at involving clinicians to a greater extent by integrating technology assessment methods, information, and results into daily medical thinking and practice (by education on different levels). Also, there is a need for priority-setting in assessments and for cooperation in international efforts.

Changing Policies for Controlling Health Technology

The health care reforms that have been introduced recently in the Netherlands will have some effect on the way health services and technologies are planned and controlled. In general, the role of the central government will become less pronounced. The Minister of Health will have global control through formulating general guidelines and quality criteria (through the new Health Care Quality Act), but planning will depend on the results of negotiations between health care providers and financiers. Also, the medical professions are expected to exercise more self-regulation.

The central government will continue the planning of specific "high-tech" medical services through Article 18 but the focus will be on controlling the introduction and the first phase of diffusion. Once new technologies become generally accepted, the central government is less active in regulating them and more interested in promoting their appropriate use. Technology assessment and control of the benefit package are becoming more important instruments in this respect.

However, the Dutch health care system is going through a process of major reforms, which will affect all participants. In the new situation, possibilities and responsibilities for assessment health care technology will probably have to be redefined.

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