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## **Priorities and Priority-Setting in Health Care in the Netherlands**

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Since 1990, the priority-setting has become one of the key issues in making choices in health care. In 1991, the now famous Dunning Report was presented to the Dutch Cabinet. One of its main conclusions was that health services should satisfy four criteria: necessary care, effectiveness, efficiency, and individual responsibility. Priority-setting can be done either by excluding medical treatments from compulsory health insurance coverage and/or by the use of both protocols and guidelines, and the individual selection of patients by health professionals. The discussion on the introduction of in vitro fertilization into the basic health insurance package and the exclusion of dental care for adults have shown that, on the basis of the Dunning criteria, it is not easy to leave complete or parts of services out of the basic health insurance package. The second strategy – the application of the Committee's criteria by the use of protocols, guidelines, and budget restrictions – is even more difficult to realize. More patients assert their right to health care benefits before courts. The courts' decisions have shown that it is difficult for the patient's counsellor to prove that government is responsible for non-delivery due to force majeur. Courts attach much importance to the Dunning criteria; in particular the criterion of necessity.

**Key words:** health planning; health priorities; health services accessibility; health services needs and demand; the Netherlands

On August 30, 1990, the former Dutch Vice-Minister of Welfare, Health, and Cultural Affairs asked Dr. Dunning, Professor of Cardiology at the Academic Medical Center in Amsterdam, to chair the Dutch Committee on Choices in Health Care (subsequently named the Dunning Committee). In the Secretary of State's letter of invitation, he pointed out that the main task of the committee would be to examine how to put limits on new medical technologies, and how to deal with the problems caused by scarcity of care which required setting of priorities, as well as the selection of patients for care. The Dunning Committee presented the report to the Dutch Cabinet in November 1991. One of its main conclusions was that health services within the basic health package should satisfy four criteria: necessary care, effectiveness, efficiency, and individual responsibility. However, the legal rights of the insured in basic health insurance are guaranteed by law. Setting priorities could then mean the explicit or implicit reduction of the rights to health care.

What are the merits and limitations of the Dunning Report in setting priorities in health care in the Netherlands? After having used the criteria for more than five years, what can be said about their implications in this practice? These questions will be discussed hereafter.

Furthermore, the article describes changes in the definitions of entitlement to health care benefits during the past decade. It then addresses the question of the legal foundation for the setting of Dutch health care priorities and the courts' response to the attempts by payers to limit access to care. Finally, it considers the implications of setting the priorities and placing limitations on health care benefits for access to care in another country.

# **Dutch Health System**

Finance System

The present health care system has been disputed for many years and legislative changes have been proposed, particularly the creation of a comprehensive compulsory basic health insurance based on the extension of the existing Exceptional Medical Expenses Act (EMEA).

The Dekker Committee (1) chose the EMEA as the carrier of the health reform as it was already a (limited) national health insurance scheme. All basic benefits were brought under the scope of the EMEA. Parallelly with the transfer of health benefits to the EMEA, other changes previously proposed were successively implemented. Sickness funds were put at risk for the medical expenses of their subscribers. In 1990, the government introduced a slightly modified plan, which became known as the "Simons' plan", named after the former Vice-Minister of Health (2). Despite increasing opposition,

several legal changes were implemented in 1992. Whereas shifting of benefits, such as revalidation, pharmaceutical care, and medical devices, to the EMEA has probably undergone the least fundamental change, it soon became the major stumbling block to further implementation of health care reforms (3). The reform strategy of gradually expanding EMEA coverage, as a means of integrating sickness funds and private health insurance into a single national health insurance scheme, turned out to be an unfortunate choice.

After the failure of the "Simons' plan", the new 1994 Cabinet introduced the idea of three health care compartments. In the first compartment, the entire population is compulsorily insured against chronic health care risks – mainly long-term health services, such as nursing home care on the legal basis of the EMEA. EMEA is no longer the carrier of the health reform but is, as previously, reserved for the chronic health care risks.

In the second compartment, 60% of the population is covered by the compulsory sickness fund insurance (based on the Sickness Fund Act – SFA) and 30% by the voluntary private health insurance. Those with a compulsory insurance on the basis of the SFA can, to a limited extent, choose among different health insurance policies offered by competing sickness funds. Privately insured citizens can insure themselves with competing private health insurers for different health care benefits and services the risks of which are covered by the private insurance principles. A growing part of the privately insured have a guaranteed insurance coverage for a standard package

A growing part of the privately insured have a guaranteed insurance coverage for a standard package of acute care services based on the Health Insurance Accessibility Act (HIAA) (4). Private health insurers have a legal obligation to accept the citizens fulfilling the legal criteria of the Act on the basis of a Standard Benefits Package, which is almost identical to the package of those insured by the sickness funds. Those insured by a private voluntary insurance are entitled to health care services and benefits based on the private health insurance (policies).

The third compartment consists of a private supplementary insurance for extra services and private insurance coverage for those benefits which are left out of the compulsory insurance schemes (EMEA and SFA). In this compartment, a completely private health insurance market includes, for example, dental care for adults and other supplementary (according to the Dunning method, mostly non-essential) health care benefits.

Major changes have been planned and implemented in the first and particularly in the second compartment over the past four years. In the second compartment, the existing compulsory health insurance for comprehensive acute care risks (based on the Sickness Funds Act) and the main health care benefits package of the private health insurance should converge with each other (5). It has been intended that a compulsory health insurance is introduced, containing a package of health care services defined as "necessary and appropriate" (according to the Dunning criteria) and which, above all, is equivalent to the package presently offered to those insured by the sickness funds. Just as with a "new style" private insurance, the package of services offered by the sickness funds would be slimmed down and would contain only "necessary and appropriate" care. The first step in this direction was the removal from the package, as of January 1, 1995, of a number of adult dental care services that had previously been included. Some paramedical services, such as some forms of physiotherapy, were eliminated from the sickness fund package and a part of the pharmaceutical care was excluded in 1996. In addition, the previously existing prescription charge has been replaced by a compulsory individual risk of two hundred guilders (100 ECU) per policy or chief policy holder. The Dutch government's health care policy must be viewed against the background of the broader aims of the Dutch cabinet. The threefold objectives of the present cabinet are to reserve social security for the most needy of its citizens, to achieve cost reductions, and to create a new balance in the responsibilities shared by the citizen, State, business and social partners. It is assumed that market forces will assist in the accomplishment of this last objective.

The health care system of the Netherlands is financed by a mixture of social and private insurance contributions combined with direct payments and government subsidies. Nearly all Dutch citizens have comprehensive health insurance coverage. Four major schemes can be distinguished: 1. an exceptional medical expenses scheme covering the whole population (based on the Exceptional Medical Expenses Act); 2. a compulsory health insurance scheme covering mainly employees with the income below a certain amount and corresponding retirees (about 65% and based on the Sickness Funds Act); 3. voluntary private insurance covering mainly employees earning above a certain income level and corresponding retirees (about 30%); and 4. a compulsory health insurance scheme covering public employees and corresponding retirees (about 5%).

Compared to other European countries, the Netherlands has a large private health insurance sector. Private insurers are free to determine premiums, coverage, and underwriting standards, except for pensioners and high risk groups, who subscribe to a government-instituted private risk pool arrangement (HIAA). The present private health insurance system can mainly be characterized as a

reimbursement model. There is an indirect payment of providers by the reimbursement of patients, without any direct connections between the insurers and the providers. The compulsory health insurance (65%) is provided by sickness funds and private health insurance companies. Compulsory health insurance can be divided into a comprehensive public health insurance for the whole population with a restricted benefit package for a long term hospital and psychiatric care (the so-called first compartment), and a compulsory health insurance with benefits such as general practitioners' care and other short term benefits for those below a certain income level. According to the EMEA, everyone meeting the criteria set in the act is compulsory insured, whether or not they wish to make use of the treatments and services offered, and must pay the relevant premiums. The contribution to the insurance scheme is income related, made by the employees from the wages by the employers. The insurance scheme is implemented by the health insurance funds (sickness funds), private insurers, and the agencies that operate the statutory insurance schemes for civil servants.

According to the Sickness Funds Act, the contribution mainly consists of a percentage of the wage/income of which a large part is paid by the employer. The other part of the premium consists of a flat rate contribution per person. The scheme has been expanded and now covers dependents, retirees from the scheme, and all who receive social security benefits, provided that they earn below a certain income limit.

The compulsory health insurance systems of the Sickness Funds Act and EMEA can legally be characterized as a triangle model based on the relations between third-party payers (sickness funds) – (sickness fund/EMEA) insured – providers. The relation third-party payer – provider is a contractual relation with a direct payment by the third-party payers to providers, based on contracts. Supplementary voluntary insurance is available for the compulsory insured members who can choose between, for example, fully insured dental care for adults or extension of physiotherapeutic treatments.

### Primary Care

The Netherlands has a well developed system of primary care. Primary care is provided by the independent providers and organizations including home care institutions. Non-specialist primary care is in most cases directly accessible. General practitioners are mostly self-employed in independent practice. They fulfill a gatekeeper role and refer patients to specialists and hospital care. They are not involved in hospital treatment.

## Hospital Care

Most hospitals are state-independent institutions owned by private non-profit foundations. The hospital sector is strictly regulated. Hospital rates are derived from the hospital's capital costs and from the annual budget for operating expenses that hospitals have to negotiate with health insurers. Foundation of new hospitals and regualtion of all other major hospital investments are subject to approval by the government.

### **Dunning Report**

In many European countries, governments have tried to contain health care expenditure by supplyside regulation. Indeed, governments did manage to gain substantial control over the total health care expenditure by unilaterally imposing restrictions on the capacity and operating expenses of inpatient care institutions (6).

In its report to the Dutch government (7), the Dunning Committee proposed a number of reasons for considering choice-making necessary: limited financial resources, increase and aging of the population, advances in medical science and medical technology, epidemiological change, and new public health problems such as AIDS. These reasons were very important not only for the Dutch parliamentary debate, but also in convincing other interested parties, in particular policy makers and with minor success - health professionals and citizens, of the need for setting the priorities. The Dunning Report aimed at creating a broad social consensus to solve the problems of scarcity, priority setting, and patient selection. It was very successful in stimulating a discussion on the ethical and social implications of medical treatment. Most attention was given to the proposed system of a funnel with four sieves, in which certain types of care would be retained while others would fall through. The Dunning Committee proposed the so-called "community-oriented approach" for establishing the necessary and unnecessary services. Three groups of services which would be provided were distinguished as follows: 1. services useful to all members of the community, which guarantee a normal functioning in the society (such as nursing homes and care of the mentally handicapped); 2. services useful to all members of the society, but mainly aimed at maintaining or restoring the ability to participate in social activities (emergency medical services, prevention of communicable diseases and facilities for acute psychiatric patients); and 3. services for which the necessity is determined by

the severity of the disease in question and by the number of patients suffering from the disease. The second sieve would select effectiveness on a scale which ranges from confirmed and documented effectiveness, through assumed and poorly-documented, to non-demonstrated effectiveness, and confirmed and documented ineffectiveness. According to the Committee, only care that has been confirmed and documented as effective is a part of the basic package. The third sieve would select on the basis of efficiency, using cost-effectiveness and cost-utility analyses.

The fourth sieve would retain care that may be left to individual responsibility. The Committee believed that one could set limits to solidarity when costs are high and the chances of a good outcome very slight.

The Dunning Committee already provided examples which illustrated the weaknesses of the proposed system. The first example was in vitro fertilization (IVF). According to the Committee, IVF is necessary; the effectiveness (in 1991) was not great in an absolute sense, but reasonable compared to its alternatives; the efficiency depended on the number of centers offering this treatment (four centers were about 20% cheaper than eight centers), and to make it available to everyone, it should be included in the basic package. According to the Committee, one does not have a right to the capacity to have children: "Neither the interests of the community nor the norms and values of society would seem to justify such a compulsory solidarity with the women who want IVF". A second example was dental care for adults. In the Netherlands this can generally be classified as biannual check-ups, extractions, fillings, prevention and dentures. The costs of dental care in the Netherlands in 1990 amounted to approximately 1 billion ECU's (total population: 15 million). According to the Committee, dental care could be considered essential and necessary; it has been shown to be effective and efficient (the efficiency of preventive dental care has also been demonstrated), but good dental care and prevention for the young population would make it possible to leave dental care for the adults to individual responsibility. Again, according to the Committee, costs should not be a barrier. Dental care for adults could therefore be excluded from the basic health insurance.

### **Limits of the Dunning Report**

Setting priorities in health care can be done either by excluding medical treatments from the compulsory health insurance coverage and/or by the use of protocols and guidelines, and individual selection of patients by health professionals (8). An important choice that the Dutch society first had to make was related to the health services and benefits that should be available. This first test of the Committee's ideas was the discussion on what services should be excluded from the compulsory health insurance package. How successful was the Committee in putting its formulated criteria into practice?

A long discussion both inside and outside Parliament was held on the introduction of IVF into the basic health insurance package. Today, more than five years later, IVF is included to a limited extent in the social health insurance package. It is "concentrated" in more than 10 centers and, according to a Court ruling (9), it was (for a short time; ref. 10) even possible to perform IVF-treatments in private clinics.

Dental care for adults was left out of the basic health insurance on January 1, 1995. Soon after this regulation was put into practice, the Dutch Consumers Association asked for an evaluation of the regulation, particularly with regard to the lack of supplementary private insurances. After an evaluation by the Sickness Fund Council and discussion in Parliament, dentures for adults were returned to the basic health insurance in February 1997 (11). The main argument which prompted this decision was that insufficient supplementary insurance policies have been offered by private insurers. In addition. people in need of dentures (1.9 million insured by the sickness fund are supplied with dentures) insufficiently insured themselves privately against the need of a dental prosthesis. This part of adult dental care could thus not be left to the individual responsibility. The Cabinet decided to include dental prosthesis in both the sickness fund and standard (private) package up to a maximum reimbursement of 75% of the total costs. The remaining 25% would be paid by the insured themselves. These examples have shown that it is not easy, on the basis of the Committee's criteria, to leave complete or parts of the services out of the basic health insurance. Could a second strategy be more successful using protocols and guidelines and budget restrictions? Such a policy must however satisfy legal standards and specifications. If the law gives the insured a right to medical treatments, is it then possible to refuse an individual treatment on the basis of a medical protocol or budget restrictions?

#### **Entitlements to Health Care Benefits**

Constitutional Right to Health Care

In the Netherlands, the right to health care is based upon the Article 22 of the Dutch Constitution. It states that "the authorities shall take steps to promote the health of the population". The legal implications of this article are very limited. When this basic social right was introduced to the Dutch Constitution in 1983, the original official interpretation was that is was no more than a symbolic right. It mainly takes the form of a "pure and simple" obligation for public authorities to be concerned with ensuring availability of health care facilities and facilitating access of citizens to health care. However, it does not imply that they should be directly involved in its provision.

The form and content of the right to health care in the Netherlands reflect a series of political and social compromises. Social and health legislation has interpreted the "right to health care" as a right to equal access, to freedom of choice, and as the enactment of the principle of solidarity. However, the "social right" regarding health care in the Constitution offers little, if any, scope for the courts to sanction claims based on more general "legal" social rights (12).

Entitlements Based on Acts and Policies

Before the introduction of the Article 22 into the Dutch Constitution, national legislation on health insurance [since 1964, the Sickness Fund Act (13) and, since 1967, the Exceptional Medical Expenses Act; ref. 14] and international treaties on basic social rights (e.g., the European Social Charter, since 1961; ref. 15) has, for many years, included a right to health care and health benefits for those with (public) health insurance. However these rights have much more content. Social and health legislation has interpreted the right to health care as a right to equal access and freedom of choice, and as the principle of solidarity.

The Dutch health care system has the objective of guaranteeing universal access to a comprehensive range of health care services irrespective of individual income or other circumstances. The Netherlands has adopted a voluntary reimbursement/public contract model of health care (16). *Limits of Coverage* 

In the Netherlands, there has always been a net separation between the functions of financing and provision. The bulk of health care providers are independent practitioners or non-profit institutions. Because of the separation between "insurers" (sickness funds) and providers, the Dutch health care system has always had some form of entitlement-setting mechanism. Patients are entitled to health care services and benefits as defined by the acts and directives based on the acts. Before the emergence of the issue of cost containment in health care more than ten years ago, patients had mainly had access to virtually all care that was medically and technically available. Entitlements to care are now set through a complex process under a strict central control. There is a complex procedure in which the Sickness Fund Council (Ziekenfondsraad), amongst others, advises the Ministry of Health which individual services should be granted and which withheld from the entitlement status. The Ministry makes final decisions here, leaving sickness funds and the executive offices of the EMEA (officially independent from sickness funds and private health insurers) with little autonomy in the matter. These decisions are formalized in the entitlement directives (Verstrekkingenbesluit ziekenfondsverzekering, ref. 17; Besluit zorgaanspraken bijzondere ziektekostenverzekering, ref. 18; Uitvoeringsbesluit particulier verzekerden, ref. 19). These directives describe the guaranteed health services, the providers that are authorized to deliver them, and so on. The legal basis for the directives is the Sickness Fund Act, the EMEA, and the HIAA. Directives can be very general, as in the case of specialist and nursing home care, or they can be too specific, as with outpatient care, prescribed drugs, and medical appliances. Sickness funds cannot pay for the services that are not covered by a directive. On the other hand, patients are entitled to services and benefits mentioned in the directives. Fulfilling their obligations to the patients on the basis of the legal entitlements, sickness funds and the executive offices of the EMEA have to contract with practitioners and providers. The Sickness Fund Act and EMEA also regulate model contracts between representatives of sickness funds and the executive offices of the EMEA on the one hand, and representatives of providers on the other. Payment levels are also negotiated between payers and providers (individual hospitals) and providers' organizations (for professionals), ultimately based on the Health Care Tariffs Act (20). In the Netherlands, central government has, for many years, attempted to contain health expenditure. This attempt is an increasingly important factor in the evolution of entitlement strategies. Central government closely regulates payers and providers, which also places limits on the provision of care. Given that rights to health care are based on entitlements mentioned earlier, it is inevitable that conflicts resulting from the attempts to restrict entitlements end up in the legal arena.

### **Courts' Reactions**

Administrative and Civil Procedures

In the Netherlands, patients can claim their rights to health care benefits and services on the basis of public health insurance acts (Sickness Fund Act and EMEA) and civil law (for the privately insured). Article 107 of the Dutch Constitution draws a clear distinction between civil and criminal law, and between procedures on the one hand and administrative law on the other. According to the Constitution, disputes which do not involve relations specified under the civil law can be adjudged by either of the court systems, but the types of cases which fall under each system are laid down by the Act of Parliament. Since budget restrictions and the Dunning criteria play a more important role, patients are increasingly resorting to courts to assert their rights to benefits (services) which their health "insurers" have not contracted for at all, or the amount contracted for is insufficient, or the quality of delivered care is poor.

## Right to Care

The basic principle of the Dutch health insurance law is that the insured has an entitlement to benefits which have been circumscribed as provisions of insurance. Contractual agreements made between sickness funds and the executive offices of the EMEA on the one hand, and providers on the other, may contain limitations, but not in the sense that they frustrate the realization of entitlements of the insured. The payer is dismissed from his duty to provide benefits and services in cases of force majeur (an exception to the legal duty to provide services). In those cases (legal cases involving inadequate resources), the payer has to prove that the cause of unsupplied, not properly or belatedly supplied services and benefits was out of his control and power. There is a legally accepted force majeur in cases where the government itself – in cases of tight planning of health care facilities, for example – is the cause of non-supply. Insurers are not bound to the impossible.

The *force majeur* argument has been tested in a great number of cases (21). In those cases, the courts' decisions indicated that government could be held responsible. To prove the government's responsibility for, for example, the insufficient provision of health care facilities is not at all difficult considering the carefulness with which planning procedures have to be performed. However, extension of capacity for severely mentally handicapped children and adults was approved by a Royal Decree (another form of administrative appeal) because the Vice-Minister of Health was unable to make his position acceptable. His refusal to extend capacity, contrary to the advice of the Hospital Provision Board and the Provincial Authority, was not based on the criteria of absence of need (22). In another case before the Regional Court of Amsterdam (23), a claim was filed on behalf of the mentally handicapped citizens who could not be placed into recognized (on the basis of EMEA) institutions for this category of handicapped persons. According to court, the Act (Article 10 of the EMEA) did not support the claim.

### Budget Restrictions and Entitlements

On the basis of the Health Care Tariffs Act, the receipts of many health care institutions are bound by budgetary ceilings. Hospitals are given global budgets to operate on. The activities-based part of the budget is determined through negotiation between payers and hospitals. If the results of the negotiations for the budget per year are too tight, the force majeur argument will not stand, because it is only the impossibility to deliver that has caused the problem. This is a circumstance that the sickness fund could handle using its own powers. Restrictions caused by self-binding cannot be objected to by the insured. This is particularly the case when longer waiting periods for patients are medically hazardous.

The Regional Court and the Court of Appeal of Hertogenbosch had to deal with a case of explicit choice-making by a regional hospital. The hospital in question had decided to suspend percutaneous transluminal coronary angioplasty (PTCA) treatments for the remainder of the year since the budget allocated for this particular service for that year had already been used up. A patient who had been placed on the waiting list requested his sickness fund to pay for immediate PTCA. Initially, the Regional Court of Hertogenbosch declared that the sickness fund was liable because it had refused to meet its obligations under the Article 8 of the Sickness Fund Act (24). The sickness fund appealed. The Court of Appeal decided that the sickness fund had an obligation to ensure that the hospital was meeting its duty to provide adequate care to patients (25). It was not required, however, to provide the hospital with the necessary funds, since this might be interpreted as nullifying the legal tariffs set with reference to the budget and finance laws. The sickness fund could instead take legal action to compel the hospital to provide the treatment required by the patient.

In another case, the Regional Court of The Hague (26) had to consider the refusal of the Academic Hospital in Leiden to perform an automatic cardiac defibrillator implant on the grounds that it was under no contractual obligation to provide this service. The Court judged that, even if the hospital were to be considered to have had such a contractual obligation, it would still have the right to delay observing it, if it had a reason to believe that the costs of the operation would not be reimbursed by the health insurer. The implant was not classified as a sickness fund benefit and, in any case, the

Academic Hospital did not have a contract with the patient's health insurer. Therefore the patient's claim was denied.

Necessity

According to the criteria of Dunning, the benefits to be included into the health insurance package should be "necessary and appropriate". The Regional Court of The Hague deliberated on the principle of necessity (27). It found that health insurers were not obliged to finance hospital stays of elderly patients who did not require treatment in hospital, but for whom places were not immediately available in nursing homes.

In another case, a patient was advised by his general practitioner to be treated by an acupuncturist. The sickness fund refused payment because acupuncture is not customary in the circle of GP's. The patient appealed and claimed that acupuncture could be reimbursed on the basis of the Article 9 of the Sickness Fund Act. According to the Court of Appeal of Rotterdam (28), acupuncture treatment was not a provision within the Sickness Fund Act, and reimbursement on the basis of the Article 9 was thus impossible.

### Efficiency and Effectiveness

Another criterion of the Dunning Committee is that care should be "efficient and effective". Only care that has been proven to be effective should be included in the social health insurance benefits package. The Committee had stressed that it is important to consider the effectiveness of a certain treatment in relation to the medical indication and the condition of the patient (29). In this respect, it is important to keep in mind that the starting point of managed competition reforms in the European countries, such as the Netherlands, Germany, Switzerland, and the UK, is fundamentally different (30-32). Health care systems in these countries are strictly regulated at the expense of incentives for efficiency and innovation in order to guarantee universal access. Managed competition is introduced here to enhance efficiency and innovation while preserving equity. The Netherlands was the first among these countries where comprehensive managed competition reforms were proposed and actually began to be implemented by the government.

The Central Appeal Board found that, in the case of acupuncture, the sickness fund was not obliged to reimburse the treatment (33). The Board sympathized with the experience of the claimant that the acupuncture treatment had a beneficial influence on his condition, but it was not up to the Board to decide what was and what was not to be included in the sickness fund insurance. *Individual Responsibility* 

The last criterion of the Dunning Committee is that the care could be left to "individual responsibility". In a case before the Appeal Commission (34), a patient appealed against the decision of the sickness fund to refuse a bald man authorization to be treated under his sickness fund insurance at the Maidenhead Institute in Rotterdam, where he would receive a hair transplant. The Commission rejected the appeal with the argument that the treatment is not part of the medical care to which the insured is entitled. Neither hair transplants nor hair implants are a type of treatment that could be considered customary in the circle of the health professionals. That is the reason why the costs of such a treatment were considered to be the responsibility of the individual.

## **Access to Foreign Care**

Necessity

In the Netherlands, patients have a right to be treated "elsewhere" on the basis of the Sickness Fund Act (Article 9, Paragraph 4) and EMEA (Article 10, Paragraph 2). In cases where it is considered necessary, patients may be treated abroad with the authorization of the sickness fund by which they are insured. According to the Foreign Care Sickness Fund Insurance Regulations (35), the sickness fund has a discretionary power of authorizing or not. Patients can object to a refusal by the sickness fund to be treated abroad and start an administrative or (in cases of emergency) civil procedure before court.

On the basis of the Article 22 of EC Regulation 1408/71, workers and the self-employed who wish to go to another state specifically for a medical care must also obtain prior authorization from the competent health authority in his or her own country.

In a decision on the refusal of a sickness fund to reimburse a patient for a by-pass operation carried out in London, the Central Appeal Board, referring to the Article 9, Paragraph 4 of the Sickness Fund Act, held that urgent treatment could not be refused purely and simply because it was to be provided abroad (36). What is relevant instead is whether the requested medical care is necessary for the patient and whether it can be provided in a Dutch facility. In the case in question, the patient could, in fact, have obtained the required treatment in the Netherlands. The Board found that in this case there was no clinical justification for an operation in London; the sickness fund had been prepared to pay for the operation in Amsterdam and the patient could have been treated within the time period requested.

The Board held that the sickness fund was not obliged under the Article 22, EC Regulation 1408/71, to authorize the treatment. A patient could claim to have a right under this article only if the treatment required could not be provided within a clinically acceptable period of time in the country of residence. In another case, a patient with liver cancer and insured by the sickness fund was sent home by his attending physician because he thought that his chances of recovery were zero. The insured went to Japan for a specific chemotherapy in the Maki hospital in Kumamoto. Neither this treatment nor the medicine employed were used in the Netherlands. The costs of the treatment were very high. The sickness fund indicated that it would not be prepared to reimburse the costs of the treatment. The Regional Court of Alkmaar (Civil Chamber) (37) found that the refusal of the sickness fund to reimburse the high costs of the treatment was reason enough for considering the case at short notice. Furthermore, the illness of the insured required a quick response and a delay in the procedure could be fatal for the patient. The court judged that a legal requirement for the authorization of the treatment abroad was that the provision was recognized under the Sickness Fund Act. In this case, the criterion of being "customary in the circle of the health professionals" was not limited to the Netherlands. Although a limited interpretation is necessary in cases of cross-border care, a refusal on this criterion would be in conflict with the principles of reasonableness and fairness. The argument that the treatment is not used in the Netherlands and therefore not customary in the circle of professionals would lead, according to the Court, to unacceptable consequences. In this case, it has been sufficiently proven that the treatment is customary in Japan and that it has passed the experimental stage. In the opinion of a medical specialist consulted on the matter, this particular case is unprecedented because of the special circumstances. For this reason the Court accepted that the treatment could be regarded as a provision in the meaning of the Sickness Fund Act. The insured could rightfully claim reimbursement of the treatment in Japan.

### Efficiency and Effectiveness

A patient suffering from migraine attacks was treated with positive results using an ozone and neural treatment in Germany. Comparable treatments in the Netherlands did not show any positive effects. The patient claimed reimbursement of the costs of the treatment in Germany on the basis of the Article 9, Paragraph 4 of the Sickness Fund Act and the Article 22 of the EC Regulation 1408/71. The Central Appeal Board, referring to the Article 9, held that this article was only applicable in cases where the employed treatment was a part of the Dutch health insurance benefits package. The Board also concluded that the treatment could not be regarded as a therapeutic treatment sufficiently accepted in medical circles as an efficient therapy. The sickness fund was therefore not obliged to reimburse the costs of the patient on the basis of the Article 22, Paragraphs 1 and 2 of the EC Regulation 1408/71, a decision also reached by the Court of Justice of the European Community. Use of Protocols

Civil and administrative courts recently had to deal with cases involving heart transplant operations. One case involved a privately insured patient and the other, a patient with a public (sickness fund) health insurance. Both patients were refused the authorization of a heart transplant abroad by their insurer, as it turned out, in the same hospital in Aalst in Belgium.

Both patients were refused heart transplants by the transplant center at the Academic Hospital AZR-Dijkzigt in Rotterdam. The decisions were mostly based on the same medical grounds: the patients suffered from vascular diseases and the transplant team saw no possibility of a successful outcome. The Belgian transplant team, in contrast, assessed these operations as having a good chance of success. Both insurers refused to pay for the operations and to authorise the heart transplants in the Aalst hospital.

In the case of the privately insured patient, the Regional Court of Rotterdam (38) decided that there was a difference in opinion between the Dutch and Belgian specialists on the chances of a successful transplant. It held that the patient did not have a fair chance of obtaining an independent second opinion in the Netherlands, because the only two heart transplant centers operating in the country (in Rotterdam and Utrecht) had developed a common protocol. For the reasons of reasonableness and fairness the private insurer could not enforce to the letter the provisions of the insurance policy. The Court concluded that the patient was entitled to reimbursement of the costs of the treatment delivered in the Belgian hospital.

In case of the patient refused by the decision of the sickness fund, the Regional Court of Breda held that the Article 9, Paragraph 4 of the Sickness Fund Act allowed sickness funds to cover the treatment costs of an insured person both outside their health region and abroad (39). The Court believed, however, that the heart transplant team was obliged to follow the national heart transplant protocol. In another, later sentence regarding this case, the Regional Court of Breda found the decision of the sickness fund to reimburse heart transplants admissible only if they met the criteria in the protocol used by the two Dutch heart transplant centers (40). The Court held, that under the

provisions of the Sickness Fund Act, the protocol was an integral part of the specification of the entitlement for the heart transplant benefit.

#### Conclusion

The Report of the Dunning Committee on Choices in Health Care has had an important impact on decisions regarding entitlements to health care benefits in the Netherlands over the past five years. It advised the use of four criteria on which services should be available in the health insurance package and/or by the use of protocols, guidelines and individual selection of patients by health professionals. The examples chosen by the Committee, and followed in practice, have shown that it is not easy to leave complete services or parts of them out of the basic health insurance. A second strategy - the application of the Committee's criteria by the use of protocol guidelines and budget restrictions - is even more difficult to realize. This policy must satisfy legal standards and, if the law gives the insured the right to medical treatments, court decisions play an important role in determining whether the patient has an individual right to health care services or not. These decisions are based on the Constitutional rights and rights formulated in the specific health care legislation. The last category of rights plays an important role in determining whether individual patients could rightfully claim health care benefits or not. The results of the new contracting and budgeting systems in the Dutch social health insurance law are that more patients assert their rights to benefits before court. The definitions of entitlements have been changing over the last decade, particularly the entitlement directives describing the health services which are guaranteed and the kind of providers who are authorized to deliver. However, despite greater contractual freedom, central government has closely regulated the contractual conditions under which providers and payers can negotiate and settle contracts. According to the courts' decisions, it is difficult for the patient to prove that the government is responsible for non-delivery due to force majeur. However, Dutch patients have much more legal avenues to claim health care benefits where providers invoke the force majeur argument because they have negotiated too restrictively on budgets with health insurers. Restrictions caused by selfbinding cannot be objected to by the insured.

Courts attach much importance to the Dunning criteria – in particular the necessity criterion. Moreover, it appears that courts do not interpret the right to health care as guaranteeing access to all services that are medically and technically possible. Dutch citizens have a possibility of using foreign providers. The outcomes of the legal cases suggest that courts consider the restrictions set in the national and European legislation, and the application of the Dunning criteria to be reasonable. However, some cases have shown that the right to reimbursement of foreign care also depends on the type of insurance a patient has, and under which jurisdiction the case falls. Civil courts tend to recognize patients' claims to be valid with reference to general principles of reasonableness and fairness, and administrative courts, on the other hand, are inclined to reject patients' claims on the basis of their reading of rights and health care benefits as contained in public health care legislation. According to administrative courts, medical protocols are also to be considered as falling under the public health insurance schemes. The Dunning criteria seem to be most extensively applied in social health insurance. From a legal point of view, this constitutes, along with other factors, one of the main obstacles for convergence in the second compartment of the Dutch health insurance system. There seems to be many individual possibilities for patients to avoid the strict interpretation and limitation of the Dunning criteria in not authorizing particular medical treatments. Individual arguments could lead to individual contraventions of the rules and criteria.

The observation that courts may play a crucial role in delineating necessary care could be important for other countries. When other coutries also move toward decentralized funding, managed care, or perhaps to some form of managed competition, the need for an adequate definition of entitlement to health care will become even more pronounced. An important lesson from the Dutch health care reform for other countries might be the fact that despite the appealing logic of the managed competition model, its implementation is quite complicated and requires a strong government to set and enforce the rules of competition.

Another lesson from the Dutch reform experience might be that other strategies for cost reduction and preservation of equity are also difficult. For example, the application of the criteria of the Dunning Commission to distinguish among "basic" and "non-basic" health care services is largely stranded. For many medical procedures, the clinical evidence required to operationalize the criteria of necessity and effectiveness turns out to be too thin. Finally, the trouble for high-risk individuals to obtain an affordable supplementary insurance coverage for dental protheses demonstrates that even the relatively straightforward criterion of whether a service is individually affordable is not easy to apply in practice.

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