Contours of the Basic Health Care Benefit Package

Gezondheidsraad **President**
Health Council of the Netherlands

To the Minister of Health, Welfare and Sport

Subject	: presentation of the advisory report on contours of the basic health care benefit package
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Dear Minister,

On 27 February 2001 your predecessor requested advice on the issue of 'contours of the basic health care benefit package'.

I hereby present the advisory report *Contours of the Basic Health Care Benefit Package*, produced by a Health Council committee that I created on 28 February 2001. The Standing Committee on Medicine and the Standing Committee on Medical Ethics and Health Law have reviewed the advisory report. I endorse the Committee's conclusions and recommendations.

You will also find the enclosed background study entitled *Cost Utility Analysis*, which concerns the subsidiary issue of 'applying the efficiency criterion' and was written by a Health Council staff member (Dr JND de Neeling). The conclusions that the Committee draws from what is stated in this study are included in its advisory report.

I have also sent this advisory report and the background study to the State Secretary of Health, Welfare and Sport.

Yours sincerely,

(signed)
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Contours of the Basic Health Care Benefit Package

to:

the Minister of Health, Welfare and Sport

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The Health Council of the Netherlands, established in 1902, is an independent scientific advisory body. Its remit is "to advise the government and Parliament on the current level of knowledge with respect to public health issues..." (Section 21, Health Act).

The Health Council receives most requests for advice from the Ministers of Health, Welfare & Sport, Housing, Spatial Planning & the Environment, Social Affairs & Employment, and Agriculture, Nature & Food Quality. The Council can publish advisory reports on its own initiative. It usually does this in order to ask attention for developments or trends that are thought to be relevant to government policy.

Most Health Council reports are prepared by multidisciplinary committees of Dutch or, sometimes, foreign experts, appointed in a personal capacity. The reports are available to the public.

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Contents

Executive summary

As part of the planned reform of the health insurance system, the Minister of Health, Welfare and Sport has requested the Health Council to 'formulate an opinion with regard to the workable, scientifically based criteria for identifying which care services should be included in a basic package'. The Committee on Contours of the Basic Health Care Benefit Package gives an account of its findings in this advisory report. To begin with, it outlines the interpretation of governmental responsibility for public health and health care customarily adopted in the Netherlands. Then it examines the considerations that can play a role in decisions regarding the scope and composition of a so-called 'basic package'. These include equal access, protection of individuals against themselves, and cost control. Partly on the basis of an international overview of analyses for decision-making on rationing issues, the Committee then specifies the criteria that are relevant when formulating a basic package and investigates the applicability of these criteria.

The Committee's conclusions and recommendations can be summarized in a number of key points.

Distinction between solidarity and compulsory insurance

Criteria for the formulation of the basic package must be derived from the two objectives that such a package seeks to achieve.

First, health care must be readily accessible to all. A 'solidarity' insurance package is funded on the basis of solidarity of rich with poor, young with old, and healthy with

sick. It includes all of the care services for which mutual solidarity can reasonably be invoked. This first objective requires criteria for a 'solidarity' package.

Second, government should protect its citizens against their own ill-advised decisions and those of others. This objective requires criteria for a 'compulsory' package.

Disease burden and cost-effectiveness

For which services are people prepared to exercise solidarity with one another?

Based on an analysis of earlier attempts (at home and abroad) to develop effective criteria in this regard, the Committee considers that, in theory, individual 'disease burden' combined with 'cost-effectiveness' forms a good basis upon which to define a basic package that, in accordance with the principle of solidarity, is accessible to all. Disease burden is defined as 'reduced quality of life or life span as a result of a disease or some other somatic or mental health problem in cases where no health care service would be utilized'. The term cost-effectiveness denotes the relationship between the effectiveness of a care service (i.e., the degree of reduction in disease burden) and the costs (in terms of financial resources, manpower, equipment and time). Thanks in part to the major advances made in scientific research in recent years, 'disease burden' and 'cost-effectiveness' are, in theory, workable criteria that have in the meantime also been applied in a number of situations. However, we currently still lack the data needed in order to apply these criteria to many care services.

Compulsory insurance

For which services are compulsory insurance justifiable? Disease burden and cost-effectiveness are not sufficient conditions for this. Additional reasons are required. One can decide on paternalistic grounds to protect individuals against self-made decisions that may prove to have adverse consequences in the longer term. An example of this would be failure to take out insurance for an expensive service that one would not expect to need. Another motivation for compulsory insurance is to protect individuals against unfavourable decisions made by others – for example, if these other parties fail to insure against prevention and care of infectious diseases. A third reason is to safeguard against the phenomenon of 'free riding'. Sometimes, individuals seek to pass costs on to other insured persons – for example by forgoing insurance in the hope that, in due course, others will shoulder the costs in a spirit of solidarity. A fourth (and final) possible motive is the desire to promote the efficiency of health care as a whole ('macro-efficiency') by introducing compulsory insurance for certain services. An example of this would be the introduction of compulsory insurance for general-practitioner care in order to make proper use of the general practitioner's gate keeping function in relation

to costly secondary-care services. The following criteria for compulsory insurance can be derived from the reasons cited above:

- the costs of treatment, nursing or care (possibly in relation to the insured's income position);
- the extent to which the disease that is to be prevented or treated may afflict other people, or could severely inconvenience them;
- the preventive nature of services;
- the impact that the use of services has on the efficiency of health care as a whole.

Composition of the package

The two sets of criteria may result in a single basic package, but a 'solidarity' and a 'compulsory' basic package need not necessarily coincide. Based on the analytical distinction drawn by the Committee, it is, in principle, feasible to identify a smaller 'compulsory' package within the 'solidarity' package. Other considerations that the Committee is not fully able to assess – such as actuarial feasibility – may have a bearing on the decisions ultimately reached by the government with regard to the choice between one or two packages.

A national assessment framework

In order to apply the criteria to different services, it is necessary to have a 'national assessment framework' that supports rationing decisions. Such a framework is helpful when assessing existing and new services in terms of disease burden and cost-effectiveness, while safeguarding scientific and societal interests. No such assessment framework is currently available, but certain of its elements can be found within several organizations. The national assessment framework will need to accommodate procedures for defining the package, since application of the criteria always requires a qualified approach. Any service or category of services will have various elements that require careful discussion and evaluation. Examples are: the need to differentiate between the concepts of health and disease, and the multidimensional nature of disease burden and reduction in disease burden (effectiveness). Other considerations of a societal, legal or ethical nature also need to be included in the evaluation. Decision-making can only partly be based on scientific principles, since societal beliefs and choices also have a role to play in rationing decisions. This is illustrated by the question of where one should place the lower threshold in relation to disease burden. Moreover, at what point do the costs of a service become unacceptably high compared with its benefits? According to the Committee, the establishment of these limit values or thresholds is a task for government, which then requests the administrators of the national assessment frame-

work to assess services in the light of these limit values for disease burden or efficiency thresholds. The Committee recommends that a national assessment framework should be established, taking advantage of the experiences that have now been gathered in the UK with the National Institute for Clinical Excellence (NICE).

Research recommendations

Further research is needed before the basic package can be formulated entirely in the manner that has been proposed above.

First of all, the criteria for solidarity and compulsory insurance will need to be even more clearly operationalized in relation to a number of points.

Second, more research is required in cases where data on individual disease burden or cost-effectiveness are either missing or incomplete. This is particularly important in the case of services that are associated with a large total disease burden and a correspondingly great demand for care among the population, whereas cost-effectiveness is still insufficient or else unknown.

Third, there is a need for research that contributes to effective decision-making on rationing issues.

Finally, further research is needed into means of promoting efficient practices among care providers.

Chapter 1

Introduction

1.1 The background to this advisory report

On 27 February 2001 the President of the Health Council was formally requested by the then Minister of Health, Welfare and Sport to give advice on the 'Contours of the Basic Health Care Benefit Package' (annex A). In the request for advice, the Minister asked what evidence-based criteria should be adopted for the services that are to be included in a basic package. In this connection, the Minister also requested an opinion on the scope for applying the efficiency criterion in determining the composition of the health insurance benefits package.

The request for advice was prompted by the process of health-care reform that has been under way for several years now (dating back to the 1980s) when a debate arose over the 'limits to health care' and the organization of the care system (GR86, GR89, KNMG86, NRV86, Rut85, SFG87, WVC88, ZFR86, ZFR89). This debate was continued in the years that followed under the banner 'choices in health care' and under the denominator 'modernization of the care system' (Del01, Ger97, GR91a, Har00, KIZ91, KNMG00, Lee91b, Lee97, MCZ94, Mul97, Mul01, Pos97, Ven95, WVC92, Wil93).

In its August 1998 policy programme, the previous cabinet declared itself in favour of framing more far-reaching modifications to the insurance system for the longer term. In the 2001 budget document on health care *(Zorgnota),* this cabinet subsequently declared its wish to lay the foundations for a reform of the insurance system during the remainder of its term (VWS00a). The outline policy document entitled 'A Question of Demand' (*Vraag aan bod*) was published on 6 July 2001, paving the way for reform of

the care system (VWS01a). This document proclaims the advent of a single general health insurance package that sets out to reduce the disparity between privately insured individuals and national health-insurance scheme (*Ziekenfonds*) members. There is also a need during health-care reform to focus more attention on the wishes of patients and clients. According to the aforementioned policy document, the current collectively financed provision of care frequently fails to meet the demand from the insured and is too dependent upon what resources are made available by the government. To enable health-care providers and health insurers to offer managed care, it is proposed that they should be granted more room for manoeuvre within the parameters of the public-sector environment. This will be achieved by introducing more market forces into the various sectors of health care. Furthermore, health insurers (and, indeed, health-care providers) bear financial risks and compete with one another for the favours of the insured public. But, according to the policy document, even a more demand-led system will continue to require effective cost control (see also VWS02a). Two strategies are to be adopted in pursuing this goal:

- reinforcement of the control exercised over health care by the health insurers and
- the introduction of financial incentives for the people insured.

As far as the latter strategy is concerned, the policy document notes that the personal responsibility of the individual citizen also has a role to play when responsibilities are assigned within the reformed insurance system. Consequently, the introduction of a system of compulsory personal contributions is being contemplated within the general insurance package.

There has been a change of government in the Netherlands since the creation of the Committee. An important role is also assigned to the change in the health-care system in the *Strategic Agreement* that has been adopted by the new coalition partners. In this connection, the Ministry of Health's *Policy Agenda 2003* voiced the expectation that a new insurance system will be introduced as of 2005. This will include a single, compulsory insurance provision for all, provided by private operators offering a standard package of necessary care that, as far as coverage is concerned, is virtually equivalent to the present health-insurance fund package (VWS02b). It is evident from this policy document that demand for the definition of a basic or standard package is as topical as ever, and with a further escalation of health-care funding problems in prospect, it will remain so until long after 2005.

1.2 The Committee and its working methods

In response to the request for advice that was mentioned in section 1.1, the President of the Health Council created on 28 March 2001 the Committee on Contours of the Basic Health Care Benefit Package (annex B), henceforth referred to as 'the Committee'. The Committee met in plenary session on seven occasions. With the Committee's approval, separate consideration has been given to the subsidiary question of 'applying the efficiency criterion' in a background study that is being published in conjunction with this advisory report. The conclusions that the Committee draws from this study have been included in this advisory report.

In formulating its opinion, the Committee has not only studied the general scientific literature but also considered reports from various bodies. These include advisory reports from the Council for Public Health and Health Care (RVZ), the Social and Economic Council (SER), the Health Care Insurance Board (CVZ), and the Social and Cultural Planning Office (SCP). In particular, it has given consideration to the advisory report on 'Public Health Care' (*Volksgezondheidszorg)* (also cited in the request for advice) published by the Scientific Council for Government Policy (WRR) in 1997. That advisory report examined various aspects of the question that has been put to the Committee. The Committee also noted the discussions that have taken place in the Netherlands in recent years regarding the proposed restructuring of the insurance system.

The Committee completed work on the draft version of its advisory report in August 2002 and subsequently submitted this for evaluation to the Standing Committee on Medicine and the Standing Committee on Medical Ethics and Health Law. After making further adjustments, prompted in part by comments from both Standing Committees, the Committee then adopted its definitive advisory report.

In the advisory report the Committee first examines the objectives pursued by the authorities (government and Parliament) as part of their responsibility for public health (chapter 2). Then it focuses attention on the role of health care in society, the importance of regulated health insurance, and the developments that could further increase the pressure on the health service (chapter 3). Furthermore, it provides an international overview of analyses concerning decision-making on resource allocation (chapter 4) and, partly in the light of this review, identifies relevant criteria for the formulation of a basic package (chapter 5). Finally, the Committee discusses procedures for defining the package (chapter 6).

Chapter 2

The Dutch Constitution and government objectives

A great deal has already been written about the functioning of the Dutch health care system. The impression given in publications is first that health care is increasingly having to wrestle with shortcomings and second that, by international comparison, the Dutch care system can still stand the test of criticism reasonably well (GR86, Pee02, SCP00, Ven00, Vie97, WHO00). The variation in the reports illustrates the fact that health care is a sophisticated and dynamic service sector that is susceptible to various, relatively autonomous, processes. Supply and demand are constantly increasing, but, judging by waiting lists (Bra01, GR93), they have in recent years become more difficult to reconcile in certain areas. Partly for this reason, ever-increasing attention is being focused on the need to improve the quality of care. Since the 1980s, there have also been growing calls for cost control. Quality of care and cost control are, however, separate objectives that are only to a limited extent mutually compatible (GR89). The Netherlands is not alone in experiencing this particular set of problems. In other Western countries, too, there has been a long-standing debate over quality and efficiency of health care and the question of which forms of health care should be made available through an insured package (DCE97, Ham97, Ham98, Hon95, SCP00).

2.1 Obligations imposed by the Constitution

The first requirement in determining government objectives with regard to public-health policy is to interpret the governmental responsibility that emanates from Article 22 of the Dutch Constitution (*Grondwet*), which states that, ‘The authorities shall take steps to

promote the health of the population'. In general, this responsibility is construed as the duty to monitor the accessibility of care services both from a financial and geographical standpoint, in addition to the adoption of preventive measures (Lee84, Lee95, Rig86, Ros02, RVZ02a, SER00, WRR97). This means that people with a need for care must have access to care services, but that this access does not necessarily have to be unlimited. This fundamental right to health care also implies a responsibility on the part of government to monitor the quality of care (WRR97). After all, if quality is found wanting there will be a risk to public health.

Article 1 of the Constitution, addressing the subject of 'equality', is a further key principal in relation to government action (KIZ91, Rig86, VWS00c). This article states that, 'All persons in the Netherlands shall be treated equally in equal circumstances.' According to this principle of equality*, access to care services must not be dependent upon individual characteristics such as race, sex, ethnic background, genetic make-up, sexual orientation, income position or a person's value to society.

Other fundamental rights that should be mentioned in conclusion are the right to protection of privacy (Article 10 of the Constitution) and the right to inviolability of one's person (Article 11). These fundamental rights guarantee the individual a certain degree of freedom and thus impose limits on the actions of government and society. However, citizens cannot derive any rights that exceed the scope of the fundamental right to health care. Thus, the government cannot be required, on the basis of the Constitution, to allocate scarce services to the individual (Lee84, Rig86).

In its advisory report on *Public Health Care*, the WRR fleshes out the objectives of public health policy in the light of Article 22 of the Constitution, breaking them down into the following categories (WRR97):

1 the promotion of public health, that is the prevention and curing of diseases, and
2 the care and nursing of the sick.

The first objective relates primarily to preventive and curative care services (so-called 'cure' services). In addition, it encompasses health promotion outside the health care sector. The second objective, according to the WRR, concerns the 'care' services. These are services geared towards such activities as nursing, care or pain management.

Examples of this include care of the disabled, nursing-home care and home care. The WRR advocates that the above distinction be drawn with regard to objectives because, in its opinion, different methods are used to evaluate the effectiveness of the services in

* Also known as the postulate of equality, which implies not that people are equal, but that they must be given equal opportunities (Rig86).

question. There are also differences in the opportunities that exist for volume adjustment and the types of decisions that need to be made. The important point here is: To whom does society assign the primary responsibility for different sorts of services? Thus, the prevailing view in the Netherlands (but also in other countries) is that government bears a heavy responsibility for services in the area of preventive care. For example, the control of infectious diseases cannot be handed over to the free market or to individual responsibility.

On the premise that government has a constitutional duty to promote public health (in the collective and individual sense), the SER also summarizes policy objectives in its advisory report entitled 'Towards a Sound System of Medical Insurance' (*Naar een gezond stelsel van ziektekostenverzekeringen*, SER00) as the need to guarantee:

1 quality of care
2 accessibility of care:
   • functional availability (accessibility, geographical distribution of care services)
   • financial accessibility
3 that cost increases are in keeping with other socio-economic policy objectives.

The SER explicitly highlights this last-named objective. This is a broader-based objective than the pursuit of efficiency, which can be interpreted as delivering the most effective care possible with a given amount of resources. The Committee can endorse this view. After all, one cannot infer from Article 22 of the Constitution that government has an obligation to subordinate other forms of State care (e.g., in the area of employment [Article 19 of the Constitution], wealth distribution [Article 20] or education [Article 23]) to the financial needs of the health service or vice versa. As the Health Council stated in its advisory report on 'Limits to Health Care' (*Grenzen van de Zorg*), the extent of the right to health care is, in point of fact, wholly determined by the resources that are available (GR86). These are the resources that society wishes to make available for health care, given the economic circumstances and the resources needed for other prioritised objectives.

In the context of the remaining socio-economic objectives, cost control means that government monitors public spending on health care* along with expenditure in the other sectors. Cost control does not allow health care spending to rise to a level that

* Four-fifths of present-day care is financed collectively via social insurance contributions (Exceptional Medical Expenses Act [AWBZ] and Health Insurance Act [Health Insurance Act]: 75%) and taxes (national and municipal: 5%). The remaining portion (20%) is funded from private insurance schemes. In the proposed new insurance system (a single general health insurance provision), health care is also regarded as part of the collective sector. The premiums are charged to the public purse and the intention is that health-care expenditure should continue to be drawn from the budgetary process in the future and that spending should be controlled (VWS02a).

would have negative repercussions on the economy and on employment, with potentially adverse consequences for (among other things) public health. Under the present system, the government mainly achieves cost control via supply-side steering. Exactly how costs are to be curbed in a new, more demand-led system is a thorny question.* Demand-led care simply appears to be incompatible with controlled health-care expenditure and moderate development of premiums (Bro01, Dan97, GR89, Kam01a, b). According to the policy document *A Question of Demand* and the ensuing measure, government can achieve cost control via the efficient functioning of the system, stronger steering of health care by the health insurers, and the introduction of a system of compulsory personal contributions within the general insurance provision (VWS01a, VWS02a). However, if socio-economic policy so dictates (for example, in the event of a sharp rise in health-care expenditure or an economic recession) it is conceivable that the health-insurance benefits package may need to be restricted or else a solution will have to be sought in an adjustment in the level of personal payments. In either case, the accessibility of health care could be compromised. The issue of 'cost control' has arisen at various points in the wake of this advisory report.

It is evident from the above comments that the Dutch Constitution contains several articles that, either directly or indirectly, have a bearing on public-health policy. The key provision is Article 22, which concerns itself primarily with governmental responsibility for public health. This article can be interpreted as follows. Wherever its other constitutional obligations permit, government should seek to reduce disease burden** both through prevention and by guaranteeing accessibility and quality of care. The Committee understands 'care' to encompass not only the 'traditional' preventive and curative services, but also the care of people whose quality of life has been reduced by disease or disability.

2.2 Limitation of governmental responsibility

Government's views on the role that it has to fulfil within health care have been subject to change over the years (Rig93, Ros02). A sea change in government thinking occurred in response to the advisory report of the Dekker Committee (Pee02, SFG87). The message conveyed in this advisory report was that government should step back and refrain from overregulation. According to the Committee, government should be creating conditions conducive to the proper functioning of health care (through legislation, among

* It also appears that insufficient account is taken of the distinction between demand in the sense of the wishes of patients and demand in the sense of professionally defined needs (CVZ02b, Ros02).

** See section 5.1.1.

other things). Allowing market forces to operate would benefit health care, the Committee maintains. By 'stepping back', the Dekker Committee meant refraining from or else abandoning detailed intervention while maintaining government responsibility for setting the overall course and monitoring progress. This is not, therefore, the same as 'doing nothing'. Indeed, passivity on the part of government could end up adversely affecting quality control and cost control in health care, as scientifically documented experiences have indeed demonstrated in the past (GR89).

Moreover, many determinants of health lie beyond the control of preventive and curative health care. It is therefore best in the public-health domain to closely coordinate prevention policy and intersectoral health policy with government efforts in other policy areas (such as nutrition, environment, housing, occupational health and safety, employment and traffic safety). Governmental responsibility for public health cannot be unlimited. It must also be possible to carry out other essential governmental tasks.

There are limits to governmental responsibility even within the field of health care. Health care develops relatively autonomously. There are various processes in the health-care sector that government has only limited opportunities to steer, an example being fluctuations in supply and demand.* Moreover, government sometimes finds itself pursuing conflicting goals. Accessibility of care and cost control, for example, cannot always be reconciled (GR86, WVC88).

The 1995 policy document *Gezond en wel* ('Healthy Policies') was based on the premise that the central government should confine itself to core tasks. Other interested parties besides government (e.g., health insurers, health-care providers, and patients/consumers) were also held responsible for the delivery of efficient and qualitatively sound care (VWS95a). Under the Quality of Health Facilities Act (WKZ) introduced several years ago, primary responsibility for the quality of health care was explicitly assigned to the health-care providers.

2.3 Reform of the insurance system

In some countries, government ensures the quality and accessibility of health care for the entire population by financing health care from tax revenue. For many years, health care in the Netherlands has largely been paid for through a health insurance system. The principal tool employed by the Dutch government is the regulation of this system. In what is now the distant past, this led to the introduction of the Health Insurance Act, which prescribes compulsory insurance for everyone below a certain income threshold. The premium payable for this insurance is dependent upon income. There is no differentiation in premiums between the sick and the well or between the young and the old. In

* It is thus not possible to remedy the shortage of donor organs in the event of public reluctance to donate.

addition, there is a transfer of funds from the higher income groups to the national health-insurance scheme members, achieved through several special supplements derived from the social insurance contributions for the private health insurance schemes.

2.3.1 *The need for system reform*

Discussions over the design of this 'social' health insurance system have been under way for some time in the Netherlands.* It is claimed that the present 'fragmented' system offers people too little choice, spreads the burdens unevenly, and leads to impenetrable solidarity relationships (Gro02). A reform of the system is being proposed against this background. In the policy document *A Question of Demand,* the then government unveiled a future decentralized steering model. The plan is to replace the dual insurance structure (a mixed system of compulsory health-fund insurance and private insurance) with a single general health insurance provision for all residents of the Netherlands. The new insurance is grounded in public law and is implemented by health-care insurers governed by private law (VWS01a). The government's intention is to create a distance between itself and health-care funding. Health care must be directed in a demand-led manner by competing, risk-bearing insurers, with every resident having access to 'necessary:' care of good quality and with risk solidarity between young and old and between sick and well (VWS01a). And of course, the health-care insurers who are to provide the statutory insurance have a duty of acceptance. The intention is that they should all offer an insured package with the same composition.

In the new system, government wishes to discharge its constitutional duty to provide accessible care of good quality principally through a statutory general health insurance, regulations for the insurers who provide the insurance, and the composition of the insurance package. The request for advice to the Health Council must also be viewed in this light.

2.3.2 *Distinction between solidarity and compulsory insurance*

The request for advice specifies 'criteria for the services that are to be included in a basic package'. The request does not comment on the objectives underlying the creation of a basic package. In the Committee's opinion, this was the first question that required detailed consideration. After all, these objectives play a crucial role in defining the criteria that are developed. The Committee feels that a distinction must be drawn

* For considerations concerning the conventions of the Council of Europe and the International Labour Organization (which establish standards with regard to the organization of social-security systems) and the implications of European Community law for the Dutch care system, see: Gro02, ICER01, RVZ99, RVZ02d, VWS00b.

between the achievement of readily accessible health care on the one hand and protecting people against the adverse effects of their own, and other people's, decisions on the other. The first objective requires a 'solidarity' basic package. That is to say, a basic package that is financed on the basis of solidarity of rich with poor, young with old, and healthy with sick. This basic package includes all of the care services for which mutual solidarity can reasonably be invoked. The second objective requires a 'compulsory' basic package. That is to say, a basic package that contains all care services for which compulsory insurance would need to apply.

As will become evident in the course of this report, these two objectives result in two sets of criteria for the formulation of the basic package, and thus the possibility exists (at least theoretically) that a 'solidarity' and a 'compulsory' basic package may not fully coincide. In the opinion of the Committee, it is feasible that the 'compulsory' basic package may be narrower than the 'solidarity' basic package. If care is taken to ensure that those who opt for the narrower 'compulsory' package nevertheless contribute financially to the costs of the 'solidarity' package (as is the case in the present system with WTZ and MOOZ supplements for the privately insured), then this choice need not necessarily have any repercussions on the solidarity in the new system. However, the Committee is aware that the choice between one or two packages depends not only on the application of criteria for solidarity and compulsory insurance, but also on other considerations that it is unable to assess (including actuarial questions). Consequently, the Committee does not give an opinion on the desirability of differentiation into several packages, and confines itself to an analysis of the criteria for solidarity and compulsory insurance that can be applied when formulating a package.

Chapter 3

Government and society

3.1 Criteria for a solidarity package

Normative principles for the organization of the insurance system can be formulated both in terms of ‘solidarity’ and ‘fairness’ (Ros02). These concepts overlap.

Fairness assumes that people wish to take the interests of others into account and therefore implies a certain degree of solidarity or altruism. Fairness is, however, a more limited concept than solidarity. Fairness implies recognition of the rights of others, whereas solidarity can also engender in someone a feeling of duty to do something for others even though the people concerned do not, strictly speaking, have any rights in this regard. Consequently solidarity places greater demands on a health-insurance system than fairness.

Solidarity can be construed as a sense of fellowship that is aimed at evenly distributing benefits and burdens as well as also implying a willingness to bear the consequences. It goes without saying that people can only demand solidarity from one another for services that warrant such solidarity, mainly if they satisfy criteria established by government on behalf of society. It is therefore unreasonable to demand solidarity for services that are either ineffective or unsafe.

From time immemorial, the emphasis in Dutch health care has been placed on solidarity (Ros02).

3.1.1 *Forms of solidarity*

The Committee on Choices in Health Care (the Dunning Committee) has already given thorough consideration to the different types of solidarity, including 'humanitarian solidarity' or altruism (KIZ91). For health insurance schemes, the most important forms of solidarity (with an eye to the new system) are risk solidarity and income solidarity (KIZ91, Ros02, RVZ00a, SER00, Tra00, WRR97).

In the case of risk solidarity, little or no account is taken of differences in health risk when setting premiums. Ideally, there should be no differentiation in premiums based on risk profile. People who, on account of their health, have little need to avail themselves of care services will then to a significant extent be bearing the burdens of those who have to use these services extensively. There is also a willingness to bear the risks of others where these risks arise from a particular lifestyle (Tra00).

When people contribute according to their ability to pay, we also speak of income solidarity. This may be reflected either in the setting of premiums or in fiscal measures. This income solidarity has hitherto been less prominent in the Netherlands than in other countries of the European Union, where the level of premiums is, to a greater or lesser extent, dependent upon income (Doo98). This applies in our country only to those who fall under compulsory health-fund insurance. In the case of the privately insured (one-third of the population), premiums do not go up when a person's income rises. Risk and income solidarity have always been key principles in relation to social health insurance (health-fund insurance and AWBZ). The Committee presumes that both principles will be retained in the new system (VWS01a).

Sometimes a third form of solidarity, distribution solidarity, is identified. This is based on homogeneity of interests, that is to say willingness to share comparable risks. This form of solidarity is generally applied in private health insurance and standard non-life insurance schemes. This is not actually a genuine solidarity, but rather the promotion of mutual interests in a (self-)selected group. Admission to the insurance is granted under certain conditions (for example, a higher premium for a higher injury or health risk).

The WRR noted in its 1997 advisory report on *Public Health Care* that a marked willingness to show solidarity still prevails in our country. However, the Council feared that if there is any further rise in the individual contribution to that solidarity, willingness to contribute to health care would decline (WRR97). According to the WRR, the definition of the health-insurance benefits package must not extend too far beyond the 'competence' of health care. The remit of the health-care services should continue to be confined to the prevention or cure of disease and the health-related quality of life. A definition is required of the sphere of influence of health care (along with that of other

policy areas) in order to ensure the continued funding of the collective insurance package. This is needed because the broader the package that is accessible to all, the greater the demands that need to be made on solidarity in order to finance this package (WRR97).

Aside from this problem that has been signalled by the WRR, the Committee believes in particular that the more skewed distribution of benefits and burdens within the population may also lead to increasing demands being placed on solidarity in the future. As a result, solidarity may then come under further pressure. Attention has been drawn to this danger of crumbling solidarity in an expert debate on scarcity, division and civic responsibility in health care (RVZ00b). As far as social health insurance is concerned, it appears that solidarity principally boils down to solidarity between the young and the old and between the healthy and the sick. Around four-fifths of health-care costs are currently caused by one-tenth of the insured population. The people in question are primarily the elderly and the infirm. Moreover, several nation-wide surveys in the mid-1980s revealed that a large majority of the Dutch population disagrees with the statement that the elderly should pay out more in health-care costs than young people and that people whose health is impaired should pay more than healthy individuals (Jan85, Ber86). In addition, around three-quarters of the population felt that people on a high income should pay more than people on a low income.

3.1.2 Health and well being

The reason why people wish to show solidarity in the area of health care is that health is not something that can be taken for granted. Health is, however, a somewhat elastic concept. The World Health Organization (WHO) once defined this concept as a ‘state of total physical, mental and social well being, and not merely the absence of disease or infirmity’. This broad definition has frequently been criticized on the grounds that nobody could then describe himself or herself as healthy. Thus, the Health Council has already stated in the past that ‘health care must not pretend to bestow on people an overall well being, when only a fraction of this actually falls within its sphere of influence and competence’ (GR86). The Committee on Choices in Health Care, on the other hand, adopted a rather broad definition of health (partly in order to pinpoint when a need for health care can be said to exist), characterizing it as an individual's capacity to function normally in society (KIZ91).

A clear-cut delineation of well being from the concept of health is justifiable. People can conceive of innumerable situations in life that may affect someone’s well being, but not necessarily their health (for example failed job applications, relationships that break down, or the loss of a loved one). Health is not the same as well being (conceived as wellness in the immaterial sense), freedom (the ability to do what you want), or sociality

(the ability to take part in social intercourse). Health is merely one of the factors that determine well being, freedom and sociality (Har00). The WRR contends that a realistic objective of public-health policy must be based on a definition of health in terms of the 'absence of diseases and other health problems, both of a physical and psychological nature' (WRR97). According to the WRR, the restricted interpretation of the concept of health is not only necessary in order to define the competence of health care (and other policy areas), but, notably, also in order to safeguard the continued funding of the collective insurance package. After all, the broader the package of services that needs to be accessible to all, the greater the demands that will be placed on the solidarity required in order to fund this package.

Instead of a negative definition (the absence of disease or health problems), a positive formulation of health may also be adopted. The concept could then be narrowed down so as to arrive at a biomedical definition: health is species-specific good functioning of body (and mind). The concept can then be applied to all life on Earth, including humans, animals and plants. What 'good functioning' means in relation to an individual member of a species can be approximately deduced from the typical 'design' of that particular species. The advantage of this narrow definition when applied to health care is that it allows a distinction to be drawn between the following two questions. What are the effects of a particular action or a particular service on health? Are those effects desirable or undesirable? When answering the first question it is often necessary to call upon expertise in the field of medical technology, whereas answering the second question is chiefly a matter for the individuals concerned. If no distinction is drawn between these questions, there is a danger that the choice of a certain treatment or care service may be regarded as medical/technological issue. The 'broad' definitions of health are therefore themselves a form of medicalization.

3.1.3 Health care: no ordinary consumer item

As has already been stated, health is only one of the factors that determine well being. The community at large is not, generally speaking, assumed to be primarily responsible for our well being, at least not for the well being of those among us who are able to look after ourselves. People decide for themselves what they wish to make of their lives and try to realize those plans either by producing the necessary means themselves or (in most cases) by acquiring them on the market. This must be done in such a way that the actual social costs of realizing those wants are reflected in the prices. If the market satisfies this condition and if everybody entering the market has an income that satisfies the requirements of fairness, then no one can complain that their plans are not achievable. Government therefore has a twofold task: to see to it that the market functions properly (that contracts are honoured, sufficient information is available about the products on

offer, and no cartels are formed) and to ensure that everyone's income satisfies the requirements of fairness. These requirements can, of course, be interpreted in different ways. There is in the Netherlands a consensus over the need to guarantee everyone a minimum income that enables the person in question to lead his or her 'own' life as a fully-fledged member of society.

It appears to follow from this premise that people also have to try to acquire the means with which to maintain or improve their health only on the market, with the role of government being to ensure that the market also functions properly in this regard (quality control and provision of information). However, objections can be raised to this argument owing to the particular nature of 'health' and 'health care'. First and foremost, the limitations imposed on well being by disease, infirmity or mental disorders are largely not attributable to choices made by the individual in question. Anyone who finds that such 'undeserved' disparities in well being should be eliminated wherever possible would therefore appear to be justified in viewing this as a societal responsibility. Second, health is more fundamental in defining well being than other determinative factors (GR86, Har00, KIZ91, Ros02, Vat01). Health-care services cannot, as a rule, be construed as ordinary 'neutral' consumer items. A marked dependency on the part of the user will often play a role owing to reduced physical or mental functioning. Disease and infirmity are usually associated with pain and suffering, which seriously undermine well being. They usually also form a barrier to the realization of goals that people set in their lives. [1]

3.2 Considerations underlying compulsory insurance

Specific regulation is essential for the health insurance market. A free insurance market may have adverse consequences for consumers of care. In such a situation, they can choose for themselves whether or not to take out (full or partial) insurance against medical expenses. It is then likely that some people will either take out no, or else wholly inadequate, insurance. [2]

Governments can have various motives for requiring people to take out health insurance, including (a) paternalistic reasons (also referred to as the 'merit good' argument), (b) to counteract external effects, and (c) to combat free riding (Ven93, Ven01).

Governments seek to promote expenditure on certain goods or services for paternalistic reasons, since they see that citizens fail to adequately recognize their own interests in the service in question. In the case of health insurance, this may mean that a consumer who feels healthy may underestimate the future risks, or even believe that certain diseases will never affect him. This 'short-sightedness' can lead people to make ill-advised decisions when weighing up certain direct advantages (no premium) and uncer-

tain future disadvantages (medical expenses). The temporary advantage to be gained at present from the absence of a premium may later lead to major costs that may be completely or virtually unaffordable. The latter scenario means that society must pick up the bill. A survey conducted among the Dutch population in the late 1980s revealed that around one-third of the respondents would drop the following from the list of insured services (Nuy92, Ven01): psychiatric hospital care, community mental health care, care of the mentally handicapped, home nursing services, district nursing services, home help services and care of the elderly. These are services that many people presumably think that they will not require in the short term.

The external-effect argument is important in the case of services from which citizens mainly derive benefit (or at least do not suffer any harm from) when others use these services. The aim is to afford protection against other people's unfavourable decisions. The control of infectious diseases and addiction care are services that can be ranked under the external-effect argument (Ven93, Ven01).

A third motivation for compulsory insurance is to combat the phenomenon of 'free riding'. Considerations of solidarity will tend to incline people not to deny necessary care to someone who is seriously ill, regardless of whether that person has taken out insurance against the disease in question. Furthermore, it can be assumed that someone who is ready to contribute to another person's medical expenses would like to see that other person contribute what he can to the costs. Without compulsory health insurance, it is possible that free riding could occur. This occurs when someone does not take out insurance against costs that he would find it difficult or impossible to pay in the hope that others will show sufficiently solidarity to foot the bill for the necessary medical treatment should the need arise (Ven93, Ven01).

3.3 Healthcare under pressure

Various already discernible developments may substantially increase the pressure on healthcare in the future. Trends that impact on supply and demand in the healthcare sector include demographic changes, socio-economic developments, the changing position of the patient as a consumer of care, and technological progress (GR86, GR89, GR90, GR91b, GR95, GR98, Maa89, RIVM97, RIVM02a, c, Ros02, RVZ01b, SCP00, SER99, WRR97).

3.3.1 Greying of the population

The population has been getting older for a number of years and will age still further in the decades to come. According to data from Statistics Netherlands (CBS), the number of those over 65 years of age will increase marginally between 2000 and 2010 from

13.5% to 15% of the total population (CBS00). There will then gradually be a substantial rise, with the 'greying' of the population probably reaching its peak around 2040. Nearly a quarter of the population will then be 65 or older. Thereafter, it is expected that the process will again begin to flatten out. The greying process in most of the other countries of the European Union has already advanced further than here in the Netherlands. In Sweden, around 17% of the population were already over 65 by the mid-1990s. In the United Kingdom, Norway, Belgium, Italy and Greece this figure stood at around 16% (Wis97).

Old age, along with the attendant ailments, happens to everyone sooner or later. Many people have to cope simultaneously with various, usually chronic, diseases in later life (GR90, GR98, GR02, RIVM97). This is a phenomena referred to as multimorbidity or comorbidity. Cardiovascular diseases and cancer remain the major causes of death. A further significant disease of old age is diabetes. So too are diseases of the respiratory tract, urinary tract (incontinence and prostate disease), sensory organs (loss of vision and/or hearing, and balance disorders), the nervous system (neurodegenerative diseases such as Parkinson's disease and dementia) and the musculoskeletal system (joint disease, rheumatism, osteoporosis). All of these conditions severely compromise the independence of affected individuals. The ailments that most hinder the elderly in daily life are principally sensory disturbances (deafness or poor vision), incontinence and difficulty moving or walking (GR90, GR01b, GR02, Ver01).

3.3.2 *Increase in socio-economic health disparities*

The Netherlands, in common with other European countries, is characterized by significant socio-economic disparities in the risk of disease and premature death (Mac97, SEGV01). Several (mainly chronic) diseases and physical limitations are more prevalent in the lower socio-economic population groups and are also associated with a less favourable course. People with lower average incomes also have higher mortality rates for various diseases. This applies in the case of cancer (of the stomach, lung and bladder), cardiovascular diseases (coronary artery disease and stroke), respiratory diseases and traffic accidents, among others. The disparities in the risk of disease and mortality collectively result in a marked variation in healthy life expectancy. On average, people with a high socio-economic status enjoy 12 more years of good health than people with a low socio-economic status (SEGV01, Wat96).

There is a correlation between socio-economic circumstances (such as income, housing, education and employment) and health. Less favourable circumstances can lead to poorer health through behavioural (smoking, excessive alcohol use, poor diet and lack of exercise) or psychosocial factors. Impaired health status in turn impairs opportu-

nities in the spheres of education, employment and social participation. Lower socio-economic status also influences the utilization of healthcare services (Mee96). For example, people with a lower level of education have been found to make less use of specialist care (Jou01, SEGV01).

It is anticipated that socio-economic health disparities, and especially disparities in life expectancy, will become more marked in the future. Mortality figures fall more rapidly in the higher socio-economic groups than in the lower ones, as has already been apparent for several decades in the case of cardiovascular diseases (SEGV01). The sharper falls appear to be based on a decline in unhealthy lifestyles combined with more effective medical care in the higher socio-economic groups. This raises the question as to how far individual responsibility for health plays a role in socio-economic health disparities. However, the fact that systematic disparities in health behaviour exist at a group level between people with higher and lower socio-economic status indicates that this phenomenon is not necessarily a consequence of freedom of choice (SEGV01, Str97).

Healthcare can make only a modest contribution to the reduction of socio-economic health disparities. Control measures will primarily need to be sought in policy areas other than preventive and curative care. It is probable that only a proportion of health disparities are avoidable and can be influenced by government (SEGV01). If there were to be an increase in the socio-economic health disparities in the future (a possibility that the Committee does not rule out), then it would be difficult to establish the extent to which this is due to the new care system that has been introduced. The reform of the system must in any case be aimed at preventing any further exacerbation of the disparities (GR86).

3.3.3 The patient as a consumer

Under the Quality of Health Facilities Act (WKZ), patients have the right to receive, in a timely manner, the care that is medically necessary, safe and efficient. Furthermore, healthcare providers must act carefully and treat the patient with respect. The Medical Treatment Agreement Act (WGBO) also makes certain stipulations and demands that the health-care provider should inform the patient in advance of the necessity and the possibilities for treatment. Is it necessary to set down the patient's rights so explicitly in writing? Is it not self-evident that the interests of the patient will be paramount in (para)medical services? The otherwise valuable efforts of care providers do not always square with that positive assumption. The management and personnel at health-care facilities still sometimes appear not to fully appreciate the fact that the patient is, above

all, also a client (Sch96). It has emerged that one in four Dutch people have complaints about the provision of information or organization in hospitals (Ank95).

It appears in present-day practice that Dutch citizens frequently fail to get the health care that they are entitled to receive, that they need, or that they would prefer. There is consequently a growing debate over the question of whether more demand-steering can be practised in health care and whether more emphasis can be placed on individual responsibility and on the choices that are available to citizens when using care and choosing health insurance (Gro02, Leg02, Ros02, RVZ00a).

The fact that too little attention is sometimes focused on the people for whom health care is intended came to the fore some years ago in the United States. It was then that the Journal of the American Medical Association 'rediscovered' the patient, as evidenced by a new section entitled 'Patient-Physician Relationship' (Gla96). Patient-centred medicine means that the modern patient is fully informed about his state of health, his preferences are taken into account in the choice of treatment, and his criteria carry most be weighted when the quality of care is assessed (Lai96). It is not only the consumer of care who benefits when greater emphasis is placed on the central position of the patient. US physicians are thus also better positioned to safeguard themselves against potential claims for damages, since not being the sole decision-maker also means that you cannot be held solely responsible (Sch96).

The Dutch, too, are showing an ever-increasing interest in health and health care. In 1991 no less than 60% of the Dutch population judged health to be the most important thing in life, whereas in 1966 this view was held by only 35% (SCP92, Ven86). This trend is expected to gain further ground in the future (MGS99, RIVM02a). Informed consumers will probably assume a more critical stance and have different requirements to present-day consumers of care (GR00). This may have implications for the future way in which health-care facilities will have to report on the quality of care that is delivered. The patient-doctor relationship will also change. People have a growing need for information about treatment options, which must be accompanied by comprehensible explanations and advice about the results that can be expected. Sometimes expectations are too high, especially when the wonders of modern medicine appear to open up new possibilities for the patient. In a system that is more geared to demand steering, it will be more difficult for care providers (but also for policy makers) to take a stand against an irrational demand for care due to overestimating new treatment opportunities.

Although the Dutch citizen will probably increasingly assume the role of an informed consumer of healthcare products, there still appears to be a long way to go before the demand steering within healthcare envisaged in the new system can be adequately fleshed out. Proper patient education about healthcare products (whether or not it is provided by the government) is a crucial condition, but it is in no way a sine-

cure. It remains to be seen to what extent each patient can fulfil the role of the aware consumer who is constantly keeping good track of the quality of care (GR00, Ros02).* In particular, individuals who are less well-educated and socio-economically weaker may get left behind in this respect.

According to a recent study on behalf of the Dutch Association of Insurers (VvV), consumers found it important that the problems currently experienced in health care (waiting lists and personnel shortages) should be quickly resolved (VvV02a). Reform of the insurance system was regarded as less of a priority. In addition, 80% of the consumers stated that, in the event of a change in the insurance system, they wanted the opportunity to put together their own health insurance package, with 32% wishing to formulate the entire package themselves and 48% only part of it.

3.3.4 Technological progress

The demand for care in our country has changed dramatically in recent decades. People are showing an ever-increasing interest in their health and their expectations with regard to care services have risen. Alongside this 'technology pull', there is a perceptible 'technology push' that has arisen from advances in medical science and progress in the field of industrial product innovation. Notables among these advances include (Car98, CCO00, GR87, GR89, GR90, GR91b, GR95, IOM96, Mar98, RGO02, RIVM02a, RIVM02c, Ros02, RVZ01b, TNO91, Vel98, Von98, VWS00c):

- Progress in the field of information technology and imaging (three-dimensional imaging, virtual reality techniques, picture archiving, teleradiology and telepathology).
- Increasing adoption of less invasive treatment techniques (less radical forms of treatment and endoscopic surgery).
- An increasing supply of molecular biological products for diagnosis or treatment (such as recombinant-DNA products, monoclonal antibodies and DNA kits).
- Growing interest in early detection of risk factors or diseases (various forms of population screening and, the advent of 'predictive medicine').
- Increasing possibilities in the field of organ function support and replacement (transplantation medicine, artificial organs and tissue engineering).

In the future, various techniques will also more frequently be applied outside the hospital setting. For some time now, a gradual shift has been occurring from clinical to outpa-

* Patients may be satisfied with care of insufficient quality and dissatisfied with care of demonstrably good quality. Different patient groups also evidently view different issues as being of relevance to their quality of care (GR00).

tient, non-residential and home care. Industry is increasingly responding to the demand for home care with devices for monitoring body functions and communication as well as for the administration of medicines and nutrition. Devices are being developed that increase patient self-sufficiency and help to maintain body functions.

Judging from various congresses and publications that have appeared in recent years, progress in medical science and technology is set to continue unabated in the years to come and probably at an even higher tempo than that witnessed over the past few decades (Car98, CCO00, IOM96, Mar98, RIVM02a, RVZ01b). The growing range of graded and ungraded technology and knowledge on offer is likely to put society and care providers to the test with increasing regularity. To judge from the explosive increase that has taken place across the entire spectrum of care technology, there is a risk that the *technology push* will increasingly leave the critical regulator behind. According to some experts, the pace of development is so rapid that it is quite impossible to examine thoroughly all of the relevant aspects (safety, efficacy, effectiveness and efficiency) for every new addition to the package. Against this background, it goes without saying that the quality of care could be put at risk. Common sense and circumspection are therefore to be recommended when introducing a new technology either in the home or hospital setting.

The above comments explain the growing calls in the 1980s for *medical technology assessment* (MTA), and subsequently for the more broad-based health technology assessment (HTA), not only for existing care services but also, in particular, for new services. The Committee on Choices in Health Care was already vigorously advocating the evaluation of new medical technologies in 1991 (KIZ91). This message was reiterated in the 1995 Policy Document *Medical Technology Assessment (MTA) and Efficiency in Health Care* (VWS95).

3.4 Cost control

In its advisory report *Health care in the Netherlands for an ageing population*, the SER evaluated the durability of the care system in the light of the greying of the population. It concluded that the relatively large structural rise in health care expenditure in the present system cannot necessarily be offset (SER99). This growth is mainly caused by sharply increasing expenditure in the higher age groups, which is in part attributable to the high life expectancy of the Dutch population. It is towards the end of life that health-care costs rise enormously.

Analyses revealed that advanced age and debilitating diseases are the principal determinants of the use of care services and costs (Pol98, RIVM02b). Due to the ageing of the population (alongside other causes), it is expected that the real costs will probably

rise by an average of 2.4% per annum in the coming years. The average costs in our health-care system remain relatively low for many years after birth (around EUR 1,000 per inhabitant per year). They then increase somewhat after the age of 50 (to around EUR 2,000 per inhabitant per year), but undergo an explosive rise from the 70th year onwards (Pol98, RIVM02b). In 1994, average health-care expenditure for 70 year-olds stood at around EUR 5,000 per person per year, compared with EUR 10,000 for 80 year-olds, and around EUR 20,000 for 90 year-olds.* Looking at the distribution of costs by diagnostic group for the entire population in 1994, it is apparent that mental disorders necessitated by far the greatest costs, accounting for 23% of total costs, including dementia (5.6%) and mental retardation (8.1%). Next highest were the costs of cardiovascular diseases (11%) and disorders of the digestive system (7.8%), principally attributable to the costs of dental care (EUR 1.1 billion). The costs of cancer were conspicuously low (3.9%), considering the fact that this is second most important cause of death, accounting for 28% of total mortality. Aside from cardiovascular diseases, the majority of spending in health care is evidently associated with non-fatal diseases (Pol98).

A theoretically 'infinite' demand and a limited supply of resources characterize health care. Consequently, there will always be talk of a relative scarcity of resources for health care.

Given the prospect of demand increasing in the future, monitoring of health-care expenditure must continue to be a key government objective if health care is to remain affordable (that is, financially accessible). Examples of measures on the supply side are the official authorization of services (choices at macro-level; see also chapter 6) and financial incentives aimed at the management of health-care facilities or at the care provider. Measures can also be undertaken on the demand side. One approach that has meanwhile been tried fairly frequently at the international level is the use of personal contributions to shift funding towards the consumer. The collectively funded component of health care may then decline. The aim is to curb unnecessary consumption of care and the utilization of care services for relatively innocuous diseases, but to leave the use of care for serious diseases undisturbed.

Health insurers run a relatively large risk of incurring losses precisely because the insured person is financially covered against the consequences of his behaviour. He or she can begin to behave in a more risk-prone manner or take advantage of health care

* In 1999, the last-named group, in particular, experienced a rise in average expenditure totalling approximately EUR 23,000 per year (RIVM02b).

sooner than would have been the case in the absence of insurance. If many people make greater (and, in some cases unnecessary) use of services, the insurer usually has no other option, than to increase the premium. An increase in insurance premiums does not, in general, appear to have any restraining effect on individual consumption of care. The introduction of a personal payment, on the other hand, does have such an effect.

There are various forms of personal payments, including personal contributions, supplemental percentage payments and basic excess. A personal contribution is a fixed sum that the insured person has to pay per unit of provision, regardless of the actual price. For every provision, the consumer pays the personal contribution (e.g. EUR 4.50 per bed day in the hospital) and the health insurer pays the rest. In the case of a supplemental percentage payment, the insured person must pay a fixed percentage of the price (e.g. 10% of the price of the medication). Basic excess means that the insured person himself pays all bills up to a certain amount. If this amount is exceeded, the duty to pay passes to the insurer. In most cases, there will be one basic excess per policy per year.

US research [3] (but also European findings [4] and Dutch analyses [5]) indicated that the adoption of personal payments within the insured package can prove a useful demand-side instrument for curbing over consumption and achieving cost controls in health care. This instrument only becomes truly effective when applied in relation to a substantial portion of the costs per service or group of services. However, its application is then not without risks. The less well off in society may suffer adverse health effects if they are 'forced' to opt to use less of valuable care services. The introduction of substantial personal contributions appears only to be safe in connection with relatively inexpensive forms of care or for higher income groups. Financial incentives on the supply side (e.g., those aimed at the management of health-care facilities or at the care provider) and measures such as supply-side steering are more effective means of cost control than personal contributions by the consumer (Ven85, Ven01).

3.5 Conclusions

Government intervention in the health-care sector will continue to be necessary in the future. There are various reasons for this, including quality control, accessibility of health care, cost control, mounting demographic and technological pressure and the greater value that society attaches to health.

It appears inevitable that Dutch citizens will have to spend an increasing portion of their income on health care in the decades to come. If affordability is compromised, then the accessibility of care may also be placed in jeopardy. Curbing health-care expenditure must therefore remain an important government objective in the future.

Personal payments are, in principle, a useful demand-side instrument for putting a brake on over consumption and achieving cost control. However, the effect only

becomes clear-cut if a substantial portion of the costs per service or group of services is involved. Moreover, their application is then not without risks. The less well off in society may suffer adverse health effects if they are ‘forced’ to opt to less use of valuable care services.

Chapter 4

Earlier analyses and experiences

Various publications have appeared internationally on the subject of priority setting in health care. They describe the strengths and weaknesses of priority setting models and the experiences gathered in the countries concerned (Ham97, Ham98, Hon95, DCE97, KNMG98). A brief discussion appears below.

4.1 The Netherlands

4.1.1 A tradition of advising on the basic package

Our country has a certain history when it comes to giving advice on benefits in the basic package. During the 1980s the former Health Insurance Funds Council (ZFR, now known as the Health Care Insurance Board, CVZ) published two advisory reports on the limits to the growth of the benefits package (ZFR83, ZFR86). Furthermore, in 1986 the Health Council published the advisory report *Limits to Health Care,* which gave consideration to the constitutional duty of government, the equitable distribution of resources in health care, the importance of effectiveness and efficiency, scientific assessment in support of decision-making, and the issue of scarcity and rationing (GR86, Dun86, Rig86, Rig88).

The advisory report *Willingness to change*, published by the Dekker Committee in 1987 (SFG87) is especially noteworthy. This Committee applied two criteria with regard to the inclusion of benefits in the basic package. Risks had to be either unin-

surable or financially unacceptable, and services had to be substitution-sensitive. It proposed introducing a basic package covering 85% of the costs of the services within health care, including the related social services. This package would include preventive care, obstetric care, maternity care, everyday hospital care, care for people in need of long-term assistance (the physically and mentally handicapped) and dental care for people aged 18 years or under. According to the Dekker Committee, the following list of items could remain outside the basic package and chargeable to the patient: medicines prescribed in a non-residential setting; non-residential paramedical care (physiotherapy, speech therapy, exercise therapy); dental care for adults; child health-centre care for children 1 year and over; cosmetic surgery; in-vitro fertilization; termination of pregnancy and sterilization.

In 1991 three advisory reports were duly published: the third ZFR advisory report on limits to the growth of the benefits package, the Committee on Choices in Health Care advisory report and the Health Council advisory report *Medical practice at the crossroads* (GR91a, KIZ91, ZFR91).

In its advisory report, the ZFR emphasized the fact that different indications require different care. Aspects such as necessity and efficiency depend on the range of indications (ZFR91). To completely remove many forms of care from the package would therefore be problematic. After all, the same form of care will have both well-founded and wholly unfounded areas of application. Thus the ZFR opened the debate on the applicability of the statutory definition of the benefits package as an instrument for efficient care.

In the advisory report *Medical practice at the crossroads*, the Health Council answered the question as to why medical practice does not always satisfy the requirement of efficiency. The Council demonstrated the frequently irrational obstacles that lie on the road to efficiency. The medical profession must either choose to impose order in this area itself or else to allow others (government, the insurers or hospital management) to take the initiative. The advisory report emphasized that the effectiveness of a form of care is dependent on how it is delivered by the physician to patients who are eligible to receive it. The primary responsibility for proper use of care therefore lies with the physician. This is also the case because it is difficult for government to achieve coordination of care at the individual level through general measures. The Council pointed out that the lack of data regarding the effectiveness of various forms of care is a major problem when evaluating medical practice and formulating protocols. Many procedures have been introduced in the absence of any evidence of their benefit. Insurers have contributed to this situation because they apply the so-called ‘criterion of established practice’

(see also section 6.2) instead of proven effectiveness when assessing whether or not a procedure is to be reimbursed (GR91a).

4.1.2 *Choices in health care*

Shortly before the emergence of the Health Council advisory report *Medical practice at the crossroads,* the previously cited advisory report of the Committee on Choices in Health Care (otherwise known as the Dunning Committee) was published (KIZ91). In particular, this Committee proposed investment in medical technology assessment, promotion of the use of guidelines and protocols for 'appropriate' care, and the development of criteria for placing patients on waiting lists. The most important section of the advisory report was a priority setting model, consisting of a 'funnel' with four criteria ('sieves'), designed to offer policy makers support in making choices in health care and especially to form the basis for the inclusion of benefits in the basic package. The four criteria are:

1 Necessity of care
2 Effectiveness
3 Efficiency
4 User payment and responsibility

The criteria are also arranged hierarchically. Anything that does not get through a sieve is not deemed to qualify for the basic package. If a particular criterion is not satisfied, then it is not necessary to consider the next one. Thus there is no purpose in looking into the efficacy of an unnecessary (and hence superfluous) care function. Furthermore, if a service is ineffective, it is therefore also not efficient. If effectiveness is unknown, then it is simply not possible to assess efficiency. Besides, a care function can be necessary, effective and efficient, and yet still be chargeable to, and the responsibility of, the insured person (the fourth criterion) – the example cited by the Committee being dental care for adults. One feature of the 'sieves' that has also proved problematic during operationalization is the fact that they are binary in that something either is, or is not, necessary, effective or efficient.

The Dunning Committee adopted this approach at the time in the light of the growing perception that explicit prioritization, and especially the scrapping of certain services, was unavoidable if continued access to 'essential' care was to be guaranteed in the future. This Committee examined the concept of 'necessity' and in doing so made a distinction between the individual, the medical-professional and the community-oriented approach. It took the view that the scope of the basic insurance package, which is largely funded from collective resources, must be determined via the community-oriented approach. According to that approach, necessary care is what enables individuals to

share an existence with other members of society, and to maintain (and, if possible, improve) this co-existence. Individual preferences and needs are not the primary consideration in this situation. The key question is what care is to be deemed necessary from the community's perspective (KIZ91). Based on three basic normative principles (the fundamental equality of people, the fundamental inviolability of human life, and the principle of solidarity) the Committee on Choices in Health Care proceeded to specify, in order of necessity, the following three groups of services that, when viewed from the community perspective, should be regarded as 'necessary care' (KIZ91):

1 Most necessary of all are those services that can benefit every member of society and safeguard an individual's normal functioning as a member of the community or else protect his existence as a member of the community. Here the Committee was thinking in particular of services that relate to people who find it difficult or impossible to care for themselves (nursing-home care, psychogeriatrics, care of the mentally handicapped).
2 Services that are primarily aimed at maintaining or restoring opportunities to participate in society. This applies principally to care services that, if not directly available, could have life-threatening consequences (emergency care, care for premature babies, control of infectious diseases, health care for acute psychiatric patients). In addition, the Committee referred to care services that prevent the occurrence of serious damage to health in the long term. These include care of patients with serious chronic diseases such as cancer, heart disease, sensory disorders, chronic mental illness; and forms of preventive care such as antenatal care, preventive care for children, vaccinations and screening for health risks.
3 In the case of the third and final group of services, the necessity of care should be determined by investigating the severity of the disease and the degree of suffering that it causes patients. In addition to the 'necessity' criterion, the Committee noted that the other criteria already mentioned (effectiveness; efficiency; user payment and responsibility) must also play a role in decisions regarding inclusion in the basic package.

The Committee on Choices in Health Care based its deliberations on the community-oriented approach to health and health care. According to this principle, the first group of services would be more necessary than both the second and third groups, with the second group being, in turn, more necessary than the third (KIZ91, page 21). For the basic insurance, the individual and the professional approaches should only apply within the limits permitted by the community-oriented approach. The individual approach must likewise only be applied within the limits of the professional approach. This is because the professional approach is associated with objective limits that do not feature in the individual approach. This classification into community-oriented, professional and indi-

vidual approaches was applied to decision-making at the macro-level, the meso-level and the micro-level.

The advisory report of the Committee on Choices in Health Care was the most significant attempt made in the 1990s to help government adopt a more rational approach in formulating the basic insurance package and to curb collective expenditure in the care sector. In debating the advisory report, Parliament acknowledged that there are limits to the care that can be reimbursed through basic insurance, but it did not succeed in clearly defining those limits (Kam01c). However, homeopathic and anthroposophic medicines were removed from the health-insurance fund package in 1993 owing to insufficient effectiveness. This was followed in 1994 by the removal of various self-care products after the government decided that people could pay for their own plasters, aspirin and nose drops. Some years later, the attempt to remove the oral contraceptive pill from the package met with social and political opposition, mainly on account of the risk of an increase in teenage pregnancies. It became apparent that streamlining the package (especially on the basis of the 'necessity' criterion) was a tough proposition. The need for a service may, after all, extend beyond the individual concerned. For example, a teenage pregnancy may not only disrupt the development of the girl herself. It could also have adverse consequences for the development of the future child and thereby place a burden of care on society.

In the years that followed the publication of the advisory report of the Committee on Choices in Health Care, the metaphor of the funnel (the four 'sieves') was found to present practical problems. The criteria are not intended to be binary; the ranking (hierarchy) is not always practical (the criteria can, in fact, be used in parallel; effectiveness determines efficiency); and the funnel is less easy to apply in some health care sectors (e.g. the nursing of the sick) than in others. Fresh attempts to apply a set of criteria to the formulation of the package came on the heels of this advisory report.

4.1.3 Cure and care

The advisory report *Distribution through dilution* by the Committee on Criteria for the Choice of Drugs (also known as the 'Van Winzum Committee') was published in 1994 (CCG94). This study argued that drugs should only be included in the package if they satisfy the first three 'Dunning' criteria. It was not necessary to take the criterion 'for user payment and responsibility' into consideration, since this usually related to a social standpoint. In interpreting the 'necessity' criterion, this Committee drew a distinction between two types of care: 1) life-prolonging or life-saving care and 2) care that promotes or restores the possibility of participation in society. Furthermore, for each type of care it applied a ranking according to disease burden, which was based on the severity

and duration of damage to health as well as the risk of damage to health. Thus, for each type of care it defined twelve categories of necessity. The Committee did not, however, succeed in combining the dimensions 'quality of life' and 'life span', nor did it arrive at a ranking that was in every respect logical within the context of the necessity criterion. Its classification model therefore also proved difficult to use for prioritization purposes (CVZ01b).

The aforementioned advisory report on *Public Health Care*, published by the Scientific Council for Government Policy (WRR) in 1997, provided yet another classification system. This Council scrutinized all services, drawing a distinction between preventive, curative and care services* (WRR97).

Responsibility for decision-making in relation to preventive services usually rests with government. According to the WRR, this responsibility can be substantial. Whenever a service does not only benefit the individual but also third parties (as is the case with vaccination programmes), external effects come into play. The governmental responsibility is also substantial because the form of intervention is usually determined at governmental level (e.g., nationwide population screening and measures against smoking).

Two criteria (the irreversibility of the outcome and the acute nature of care) ought to apply to curative care. In fact, the WRR further elaborated the 'Dunning' criterion for necessity to produce a system of prioritization with a hierarchy consisting of five categories:

1 Acute care in patients with life-threatening diseases (examples: heart attack, severe burns, operations for appendicitis, treatment of meningitis, emergency psychiatric care);
2 Acute care in patients with health problems that could lead to loss of essential functions (e.g., post-accident care);
3 Non-acute care in patients with life-threatening diseases (e.g., treatment of cancer or serious respiratory diseases);
4 Non-acute care in patients with diseases that could lead to loss of essential functions. This applies to diseases that, if left untreated, could ultimately lead to irreparable damage to health (treatment of diabetes or glaucoma, etc);
5 Care of the chronically ill in order to prevent or mitigate permanent limitations (services such as hip prostheses, treatment of migraine or joint disease).

According to the WRR advisory report, the majority of (supportive) care services make no contribution to the improvement of public health. They may, however, be of impor-

* non-therapeutic, supportive services e.g. nursing home care and care of the mentally handicapped

tance in relation to the second objective of health care as formulated by this Council, that is, the nursing and care of the sick (see also section 2.1). The target group's dependence on care is said to play a role here, as does the extent of the ensuing need for professional help. Judging from the degree of dependence on professional care, the following prioritization could be applied within the (supportive) care services:

1 Care for people with profound mental and physical disabilities, terminal patients, psychogeriatric patients and psychiatric patients. These are groups of people who are virtually or completely incapable of caring for themselves and for whom a dignified existence is impossible without the deployment of (usually professional) care providers
2 Professional nursing in a home-care setting. This usually involves the nursing and care of people who require home care while recovering from an acute illness or due to dependence on care during a chronic illness;
3 Support with personal care in the event of chronic illness in the home-care setting. Here it is possible that greater use may be made of non-professional help than in the nursing of the previous group;
4 Support with household activities in the home. Here there would be an even stronger possibility of non-professional help being deployed than for the previous category.

The system proposed by the WRR was designed to pave the way for the removal of the least necessary categories of health care from the basic package.

The basic guideline to be applied in preventive health care is optimization of the relationship between costs and effects, as determined at the level of the group in question. It would then be possible to finance the various programmes in reverse order of cost until the available budget is exhausted.

In curative health care, according to the WRR, we should be seeking to equalize the cost-effectiveness ratio across all categories of curative services. Decision-making on whether or not curative services (usually new ones) should be collectively financed ought to be guided by the principle that the same maximum amount must apply in order to realize a single unit of 'health benefit'*. According to the WRR, equalization of the cost-effectiveness ratio would lead to an 'objectification' of decision-making on whether or not curative services should be made available(VWS95b).

Finally, we should for (supportive) care services, in the WRR's opinion, be seeking to equalize quality and looking at the cost/quality ratio; that is, the degree to which investments contribute to an improvement in the quality of care. As far as 'quality' is concerned, importance is attached to such aspects as patient privacy and how the patient

* The WRR argued that a standardized measure (the disability-adjusted life year or DALY) should be adopted for this purpose (for a closer consideration, see Nee03).

is treated. According to the WRR, the development of instruments for measuring quality is still in its infancy, and hence it is not possible to weigh costs and benefits for (supportive) care services in the same systematic manner as is the case with preventive and curative services.

The WRR advisory report represented a further important initiative in the quest to discover a methodology capable of formulating the basic package in a more rational manner. However, the application of the proposed criteria appears not to be without its problems. Thus, it is unclear precisely what is to be understood by 'essential' in the designation of 'essential functions' in groups 2 and 4 of the classification of curative care services. Moreover, the 'other' category (group 5) is extremely broad. Furthermore, the argument that different forms of curative care should be compared 'across categories of care' (the comparison of 'apples and oranges') on the basis of their cost-effectiveness ratio (employing the DALY as a universal outcome measure) is attractive in theory. However, this cannot be properly accomplished for the time being (and possibly never) owing to methodological drawbacks in practice (see also Nee03).

4.1.4 Health technology assessment

Alongside the prioritization analyses (designed to facilitate choices in health care), several of the reports discussed above also highlight the importance of medical technology assessment, or the broader-based activity of health technology assessment. A large and growing number of initiatives have been undertaken in this field in the Netherlands since the 1980s by research groups, professional groups, research institutes and advisory bodies (Ban95, Boe99, Boe02, Bos00, IMTA02, Vel98, VWS97, VWS99). One policy document that also attracted a great deal of interest abroad was *Medical Technology Assessment (MTA) and Efficiency in Health Care*, published in 1995. In this report, the Minister of Health described the progress made with MTA in the Netherlands and the duties and responsibilities of various actors. This policy document was also designed to indicate that the proposed introduction of an 'MTA Act' was no longer necessary in the light of the current plethora of MTA activities.

In the course of efforts to prune the benefits package, the public debate was dominated by the so-called '126 List'. The origins of this list date back to 1989. During that year, both the ZFR and the Health Council were requested by the State Secretary of Health, Welfare and Cultural Affairs (WVC) to take a critical look at the benefits package in connection with the position paper entitled *Limits to Health Care*. In addition, the Health Insurance Funds Council was asked to make an inventory of issues whose cost-effectiveness needed to be reviewed, whereupon the Health Council would be able to issue

more detailed advice on the content of the benefits package.* In anticipation of the ZFR inventory, the Health Council published the advisory report *Medical practice at the crossroads* in 1991 (GR91a). In 1993 the ZFR duly published the advisory report *Cost-effectiveness analysis of existing benefit package services* (ZFR93). This report contained a prioritized list of 126 major and minor services (such as ultrasound treatment for diseases of the musculoskeletal system, intensive care medicine, the use of fluoride in dentistry and pain management in childbirth) that were considered to require further evaluation for the following reasons:

- suspected lack of efficacy,
- inadequate efficiency,
- or because, in the light of the current state of knowledge, there was actually no reason for their use ('inappropriate' use).

The '126 List' was subsequently used in efficiency research (such as the top-down programme that was being undertaken at the time by the Investigative Medicine Committee) and in order to assess the state of knowledge (Boe99, Boe02, Vel98). The Health Council was requested to henceforth take concrete action in the field of medical technology assessment, focusing on, among other things, the '126 List' (see also VWS99).** The Health Council and the ZFR have remained involved in the ongoing process of evaluating existing health insurance benefits (GR96a/b, GR97a, ZFR99).

In 1999 the Minister of Health submitted a final report on the '126 List' to the Lower House. This included the conclusion that one-third of the items had been finalized***, one-third were still in progress and one-third were no longer sufficiently relevant (VWS99). [6]

4.2 Oregon

Towards the end of 1980s, the government of this US state decided to adopt a choice-based model aimed at achieving a more systematic and equitable distribution of resources within the insurance coverage provided by the Medicaid programme****. In 1989 it duly set up the Health Services Commission (comprising five physicians, a

* The request for advice that was submitted to the Health Council reads as follows: 'Given the current state of knowledge, I would ask you to advise me (…) as to which existing procedures should be employed on a restricted basis, or else no longer employed at all.' (See GR91a: Annex A).

** It was to this end that the Central Committee on MTA was created within the Health Council in 1997.

*** The policy document in question noted that 'the ZFR or Health Council has published an advisory report; the outcome of an evaluation has been incorporated in a NHG standard or CBO guideline, or else it has been included in a ZFR *Kompas*'.

**** Government insurance programme for people at or below the poverty line. This applies to people receiving welfare cash assistance, but also to over-65s and disabled people whenever the relevant Medicare programme is inadequate. US states may apply their own criteria for admission to the Medical Assistance Act and the Medicaid programme.

nurse, four consumers of care and a social worker) with the remit of drawing up a prioritized list of services. The intention was first to expand the number of people covered by this social health insurance and second to limit the number of services to items that were generally accepted as being genuinely necessary. This was prompted in part by concern aroused in 1987 over the death of a seven year-old boy with leukaemia, who had been refused a bone-marrow transplantation following a decision earlier that year to remove organ transplantation from Medicaid funding.

In drawing up the list, the Health Services Commission initially based its deliberations solely on cost-effectiveness ratios from health-care interventions, many of which had been determined in a somewhat approximate fashion. These data were obtained not only from the literature but also through expert opinion. The cost-effectiveness data, which, as it later transpired, were usually not based on thorough scientific analysis, resulted in a curious ranking of various health-care interventions. For example, some life-saving services were to be found lower in the ranking list than straightforward procedures. The Committee therefore also decided to examine the values that the population attached to different benefits. To this end, numerous public hearings, local meetings and telephone surveys were conducted. Based on the public values thus identified*, the Committee then identified seventeen categories of care, into which the services/procedures were grouped. Then the cost-effectiveness data for the separate services were assessed using the relevant weighting factor for each category. The 17 categories were finally sub-divided into three main groups of services:

- essential services (categories 1 to 9): care aimed at restoring or promoting health, such as medical care in patients with acute or chronic life-threatening diseases (trauma, insulin-dependent diabetes, cancer), but also maternity care, preventive care for children (vaccinations, screening of hearing and vision) and adults (mammography, blood pressure control, prevention and treatment of tuberculosis), care for terminal patients, and preventive dental care (tooth cleaning, fluoride treatment);
- very important services (categories 10 to 13): care leading to partial or complete recovery plus improvement in quality of life in patients with acute or chronic non-life-threatening diseases (e.g. thyroiditis, caries, hip fracture, diabetes-induced retinal damage, internal knee damage, sinusitis, migraine, psoriasis);
- services considered to be valuable to certain individuals (categories 14 to 17), but with a limited success rate or relatively high costs such as treatments that may possibly speed recovery or be associated with a small improvement in quality of life in patients with non-life-threatening diseases such as pharyngitis, infertility (hormonal

* Considerable value was attached to such issues as prevention, quality of life, cost-effectiveness, independent functioning, fairness, therapeutic efficacy, widespread collective benefit, mental health care, personal choice, solidarity, effects on society, life expectancy and personal responsibility.

therapy, fallopian-tube surgery, in-vitro fertilization), innocuous skin disorders (warts) and similar conditions.

In 1991 the Health Services Commission produced the list of priorities that consisted of around seven hundred condition/treatment pairs. Later that year, the legislature approved a budget for the Medicaid care of the first 587 services on the list. This meant reimbursement of virtually all essential services (98%), many very important services (28%) and some other services (7%). Although the Oregon plan was widely applauded, it also met with criticism from some quarters. For example, it was claimed that the quality of life of disabled people had been undervalued, since the information gleaned from the public had mainly been obtained from non-disabled people. It was also argued that the system effectively rationed health care for the poor, whereas the other inhabitants of Oregon were able to enjoy unrestricted use of care services. Following a limited revision of the list (and approval by the Federal Government under Clinton), the Oregon plan came into force in 1994. In that year 70% of the Medicaid-insured declared themselves satisfied with the accessibility of care, and by 1996 this figure had risen to 88% (Bod97).

The Oregon plan proved successful up to a point. Following its introduction, the number of people able to take advantage of the Medicaid scheme rose by 40%. Consequently, the number of uninsured people fell during the period 1991-1995 from 14% to 12%. This was in contrast to the situation in various other US states, where this percentage rose to around 20%.

In the context of the Oregon initiative, critical comments have been made at international level on the adoption of rationing, the reliability of the methods applied (such as methodologically questionable determinations of cost-effectiveness) and the representativeness of public consultation (Bor93, Edd91, Rut93). For example, it has been argued that steps should be taken to increase efficiency in health care rather than seeking salvation in rationing (Rut93). It has also been pointed out that solidarity and fairness are jeopardized when rationing is only applied to a certain group of the population.

From a methodological point of view, obtaining value judgements from the public is no easy undertaking. The sample consulted must be sufficiently representative of the health-service users as a whole and interviewees should have a good understanding of such issues as health and disease and the costs that are incurred in achieving health gain. Furthermore, the data regarding health gain and costs should be in the public domain and unambiguously interpretable. Such conditions were not fully satisfied in Oregon. Nevertheless, the experiences gathered in this US State teach us that such a sophisticated and time-consuming effort can ultimately count on widespread public support. However, the threshold above which reimbursement is granted as a result of this project is set

at a relatively low level. Such an approach cannot, therefore, be expected to lead to a substantial contraction of the insured package.

4.3 New Zealand

A Core Services Committee (CSC) was set up in this country by the government in 1992 (NAC92). This body rejected the Oregon approach, reasoning that the compilation of a 'simple' list of reimbursable services could not be an appropriate method of prioritization (Ham97, Hon95, NAC93, NAC94). It recommended instead that reimbursement of existing services should continue, but that efforts should be made to achieve better distribution. Thus, regional variations in the delivery of health care for different benefits (such as hip and heart operations) had to be reduced. It is worth noting that the Core Services Committee detected little inclination within health care towards 'defensive medicine', the cautious introduction of new technology and restraint in the use of life-prolonging procedures. Without applying any explicit criteria and having also given consideration to the public debate, the CSC designated the following (among others) as core services: children's health care, mental health care, primary health care, trauma medicine, rehabilitation and care for terminal patients (hospice care). Following further public consultation, the Committee stated that the central question underlying the delivery of health care was 'What is the benefit of a particular service to a particular person at a particular time?' In this connection, prominence was given to the following four criteria:

1 What are the benefits of a service? Does it do the patient good or harm?
2 Does delivery of the service provide value for money? Does it represent the best way of spending the community's money in the given situation?
3 Is the person who can benefit most from the service also the one receiving it (fairness)?
4 Is the delivery in keeping with the community's values and priorities?

In adopting this approach, the Committee also provided guidance on the development of guidelines. In order to formulate guidelines, it organized consensus development conferences on specific diseases and forms of treatment. In addition, it called for the concentration of certain tertiary services (e.g. organ transplantation and intensive care for newborns). Finally, the CSC addressed the problem of waiting lists. The public found it unfair that the approach adopted in practice was usually 'first come, first served'. According to the Committee, it would be better to abolish the waiting lists for non-urgent procedures and replace them with a booking system based on national criteria whereby patients are given a definitive booking for treatment. Priority on the waiting list should be determined only by individual need for care and the probability of treatment

success. Age, income position, cause of disease and pain tolerance were dismissed as less important factors.

4.4 Norway

In 1987 the (first) Lønning Committee established a priority setting model that was further expanded into a Norwegian Parliament policy document in 1994. The Committee identified five categories based on disease severity and treatability:

1 Care of acute, life-threatening diseases (such as trauma medicine, emergency psychiatric care, treatment and control of serious infectious diseases).
2 Services aimed at non-acute diseases in patients that could, without treatment, suffer serious damage to their health (treatment of chronic illness, preventive health care: neonatal and antenatal screening, school health care, genetic counselling, population screening in high-risk groups).
3 Services whose non-implementation does not result in serious damage to health (treatment of patients with mild hypertension, common childhood diseases, varicose veins, uncomplicated herniated disc).
4 Services that are assumed to improve health status and quality of life, but whose benefits are less clear-cut than those derived from measures in the previous three categories (such as routine ultrasound examination during pregnancy, artificial insemination, in-vitro fertilization).
5 A final category *without* priority: services that are unnecessary or whose usefulness has not been adequately documented (e.g. cosmetic surgery without medical justification, 'hi-tech'-medicine of unproven value, routine health checks, population screening in low-risk groups).

The priority setting model was partially operationalized in 1990. A waiting time guarantee was introduced for patients with diseases falling under category 2. This meant that the waiting time for treatment was not permitted to exceed six months.

One positive consequence of the work on the prioritization proposal was that the ensuing public debate led the Norwegian population to recognize that some patients laid more claim to treatment than others did. Furthermore, questions were raised over the practical feasibility of the model, especially as physicians in hospitals showed little willingness to use it consistently. The priority categories were also not clearly formulated, as a result of which major disparities emerged in their interpretation and in the adjudication of the waiting time guarantee. Moreover, a debate had arisen following the introduction of this guarantee over the assignment of measures to category 2. In-vitro fertilization, for example, was transferred from category 4 to category 2. Partly in response to these disappointing experiences, a second 'Lønning Committee' was established in the mid-

1990s with a view to framing proposals for the development of guidelines for different levels in health care.

4.5 Sweden

The Swedish Priorities Commission, established by Parliament in 1992, published a consultation document on the subject of *Priorities in Health Care* in 1993 and a definitive report in 1995. The contents of the report bore the hallmarks of the earlier prioritization efforts in Norway and of experiences gained in other countries. Besides consulting experts, the Commission had also engaged in extensive consultation with the public. It cited the following as the basic principles for prioritization (in order of priority):

1 Human dignity: all human beings are equally valuable, regardless of their personal characteristics and place in society.
2 Need for care and solidarity: resources should be allocated to those whose needs are greatest (e.g. the mentally ill).
3 Efficiency: there must be a reasonable relationship between cost and effect, measured in terms of health gain and improvement of quality of life.

The Commission emphasized the hierarchy of these three points. Human dignity takes precedence over the need for care plus solidarity, with cost-effectiveness being subordinated to both of these principles. The first principle also means that treatment may not be refused on the grounds of advanced age, unhealthy lifestyle or (in the case of premature infants) low birth weight.

On the basis of its three principles, the Commission then defined a system of five priority categories of services to be applied both at the policy making and care giving level:

1 Treatment of acute, life-threatening diseases and diseases that, unless treated, will lead to permanent disability or premature death. The treatment of severe chronic diseases. Palliative terminal care. The care of people with reduced autonomy.
2 Preventive care of proven benefit. Rehabilitation, including the use of required technical aids.
3 Treatment of less severe acute and chronic diseases.
4 Borderline cases.
5 Care for reasons other than disease or injury.

The Swedish approach scarcely led to consistent prioritization in concrete situations, such as the exclusion of certain benefits (though several provinces did abolish reimbursement for infertility treatment). This way of thinking did, however, offer support to

decision-makers in health care, including national and regional policy makers, as well as health-care providers.

4.6 Denmark

In 1997 the Danish Council of Ethics published a critical report entitled *Priority setting in the Health Service*. In this report the Council examined the function and objectives of the national health care system, experiences with priority setting models in Norway, Sweden and the Netherlands (the Committee on Choices in Health Care report), and the utility of decision-making criteria within its own borders (DCE97). The Council highlighted the following key values with regard to the function of the national care system: equality of individuals, solidarity, safety and autonomy. Care activities amount to more than mere treatment of disease. The Council believes that the general objective of the care system must not be confined to a purely scientific definition of what disease is and what it is not. Health care must have the following goals: (a) promotion of health and prevention of disease, and (b) control and alleviation of health-related suffering, aimed at affording everyone the opportunity for personal development, regardless of social background or income position (DCE97). The patient's need for care is regarded as the basic premise for the operation of the national care system. This need is not so much defined on the basis of the health problems experienced by the population, but rather by determining what health care has to offer in terms of treatments with a satisfactory outcome. The need for care can vary from a curative treatment to alleviation of suffering and care, and can be broken down into three dimensions:

1 The severity of a disease
2 Urgency of care
3 Potential health gain.

The Council of Ethics advised against the creation of a Danish priority setting model along the lines of those found in Norway, Sweden and the Netherlands. Experiences in these countries showed that generally formulated models are not readily applicable to the making of choices in everyday care giving. However, the Council did place great emphasis on the importance of medical technology assessment. For the purposes of prioritization at governmental level, it is necessary to observe the following criteria: a) access to care; b) quality of care; c) cost-effectiveness; and d) influence on democracy and the consumer. As far as cost-effectiveness is concerned, efforts should be made to achieve optimum (as opposed to maximum) efficiency, taking into account other considerations that may influence the choice of a particular measure. The question of efficiency must never be decisive in determining which priority setting decisions are made. At the level of clinical care, the need for care as defined by care providers is paramount,

with the determinative factors being disease severity, urgency of care and the prospective health gain. The Council explained why such factors as age, individual responsibility for the origin of the illness and social situation (whether or not an individual has a job) are questionable criteria and therefore do not belong in a priority setting model. In a clinical setting, the possibility cannot be discounted that a factor such as 'age' may be taken into consideration (for example, in connection with organ transplantation) if it is associated with a favourable treatment outcome. According to the Danish Council of Ethics, there may even be grounds for including individual responsibility for health as a general criterion at the clinical level, especially when a patient's lifestyle or habits could militate against a positive treatment outcome.

4.7 The United Kingdom

Health care in the UK is freely available to all. Health services are funded through taxation, but this is not sufficient to satisfy the demand for care (Hon95). Ever since its establishment in 1948, the National Health Service (NHS) has struggled with waiting lists, especially in hospital care. Prioritization does not happen so much at the national level as at the level of the 14 regional health authorities. Factors at play here are the available budget, demographic considerations and the presence of services locally.

In the mid-1990s, the British government formulated a set of general principles for decision-making in health care at national level, concentrating on the fair or equitable distribution of care, the pursuit of efficiency and responsiveness to change (Ham97). Instead of scrapping important services, collective resources were primarily to be used for treatments of proven effectiveness. Central government also championed investment in health technology assessment and in the development of clinical guidelines to support medical practice based on evidence of effectiveness.

A start had already been made in 1992 on the ambitious NHS research and development programme (the so-called 'Peckham programme'). The aims was to conduct a series of R&D projects designed to critically assess the package of healthcare services available in Britain, with the emphasis on effectiveness and efficiency, and to support policy makers in setting priorities at the local level. Within the framework of this national HTA programme, publication began of a series of reports concerning the evidence from new and existing services and epidemiological reviews of health needs. A particularly important development was the establishment in 1992 of the Cochrane Centre in Oxford, where, with the cooperation of the professional groups, all of the relevant randomised controlled trials and related systematic reviews were incorporated in a database. Various professional groups had emphasized their own responsibility for the quality of professional practice. A year later, around 80 experts (clinicians and health-care scientists) from 11 countries founded the international alliance that came to be known as

the Cochrane Collaboration. The Cochrane Centre's database of clinical effectiveness in Oxford provides the information collection point for this network. This centre works in close collaboration with the NHS Reviews and Dissemination Centre in York, which has set up a register for studies and other information with regard to cost-effectiveness. The National Coordinating Centre for Health Technology Assessment was established in Winchester as a spin-off from the NHS HTA programme in 1996. Since its foundation, the NCCHTA has produced a steady stream of publications on the effectiveness and cost-effectiveness of existing care services. A few years later, the National Centre on Horizon Scanning was set up in Birmingham to serve the NHS, with its primary aim being to identify and evaluate relevant new services.*

Around three years ago, as part of the British HTA programme, the National Institute for Clinical Excellence (NICE) was established as a special health authority for England and Wales (Raw99, Tay02). The NICE owed its inception to the explosion of knowledge and technology in recent decades and the rising costs of health care. Some forms of treatment are introduced into everyday practice even though all the relevant aspects have not yet been adequately investigated. In the case of other treatments, uptake is too slow, notwithstanding the fact that sufficient data are already available with regard to their clinical effectiveness or cost-effectiveness (Raw99). NICE has set itself the following tasks:

1 to offer health professionals within the NHS guidance on decision-making in everyday practice, using evidence-based appraisals of the value of existing and new services
2 to achieve a high-quality standard of care within hospitals and non-residential facilities through the regular issuing of guidelines (based on appraisals)
3 to provide support with quality control in the field (development of clinical audit methods).

The appraisals form the majority of NICE activities. An independent, multidisciplinary Appraisal Committee has been set up which gathers the available evidence and also invites the relevant organizations (professional groups, patient groups and industry) to obtain this information (Tay02). The Committee's Standing Members are experts in general practice, general hospital care, specialist medicine, nursing, patient interests, health economics and clinical epidemiology.** They are often supplemented with external

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* This is also the location of the scientific secretariat and database of the European Information Network on New and Changing Health Technologies (EuroScan), an alliance of European HTA organizations established in 1998 that is engaged in HTA for new or 'emerging' care technologies.

** In actual fact, what takes place within this multidisciplinary committee is a decision-making process, as distinct from the preceding HTA procedure (Tay02).

experts, depending on the subject in hand. The appraisal of a service focuses principally on clinical effectiveness and cost-effectiveness. In the former case, depending on the particular circumstances, the Committee determines absolute effectiveness compared with 'no treatment' or relative effectiveness compared with 'standard care'. To determine cost-effectiveness, it examines the direct and indirect costs of a health-care service when compared with equivalent care services (micro-efficiency). If desired, the Appraisal Committee also considers the costs in a broader context, especially with an eye to the implications for the NHS as a whole (macro-efficiency). It remains to be seen what efficiency threshold (maximum acceptable additional costs per QALY) NICE will adopt (Tay02). It is expected that this will be clarified in due course.

In its evidence-based advisory role, NICE assigns services to one of four categories:

a unrestricted use for the appropriate indications;
b restricted use to defined categories of patients;
c restricted use within the context of clinical trials or some other research activity that is in keeping with the intended goal;
d application deferred for the time being.

The guidelines published by NICE are issued via three routes. Sometimes the Institute will issue guidelines entirely independently in response to a specifically formulated need within the NHS. In addition, guidelines may be drawn up on the basis of the systematic reviews that are issued under the national HTA programme. The Institute has resolved that for the first few years it will concentrate on adapting or improving the implementation of existing guidelines already produced by the professional groups (such as by the relevant Royal Colleges).

NICE is aware that thousands of different technologies (medicines, devices, treatments and procedures) are now being used within the NHS, and that it is thus impossible to evaluate the benefit of every item. It has therefore chosen to examine those services that are of greatest relevance to the NHS. Responsibility for the definitive selection of the services to be assessed rests with central government, which also makes use of the priority setting information for health technology assessment from the national HTA programme.

In addition to understanding and appreciation, the manner in which NICE works on behalf of the NHS (coupled with the Institute's important governmental advisory role) has also aroused concern (not least among British healthcare professionals). There is, for example, concern that NICE tends to gloss over the ethical aspects of individual patient interests (Goo00, Tav00). Furthermore, some people fear that costs play a dominant role and that patients are sometimes denied effective treatment (Fle00). Criticism has been levelled at the fact that particularly costly treatments are subjected to scrutiny, thereby

reinforcing the impression that costs play a leading role (Smi99, Smi00). Moreover, some of the more 'everyday' forms of treatment do not now undergo appraisal. Criticism has also been voiced over the fact that information from certain 'authoritative' sources (such as the Drug and Therapeutics Bulletin and the British National Formulary) is either underused or else not used at all. Finally, some observers have bemoaned the fact that NICE has hitherto examined services rather in isolation.* A better point of departure for its assessments would be key conditions or a whole class of drugs (Bur02).

In his inaugural address in 1999, Sir Michael Rawlins (University of Newcastle), the Chair of NICE, responded to criticisms that had already been expressed at that time. He referred to the relatively limited resources that the British government is able to make available to the NHS from the Exchequer on the basis of political decision-making. He also stressed that the political choices that govern the spending of collective resources are determined by the voting behaviour of the electorate. Furthermore, he disputed the allegation that NICE slows down innovation in health care and said that whenever a new, but more costly service emerges that demonstrably represents an advance in health care, NICE will give it due consideration in its advice. New developments cannot simply be pushed aside on account of cost considerations.

4.8 International comparison

In a review article, Ham compared the priority setting models and experiences in five of the countries mentioned above: the US (Oregon), the Netherlands (the model devised by the Committee on Choices in Health Care), New Zealand, Sweden and the United Kingdom (Ham97). He made the following comments:

1 Public interest in the issue of 'choices in health care' is determined in part by media reporting about individual cases, such as the refusal of treatment to severely ill children considered to be 'beyond treatment' or old people.
2 There is a distinction between decision-making at macro, meso, and micro-levels (national, local and doctor-patient level, respectively). There is growing interest at the micro-level in decision-making that is evidence-based and founded on decisions made at the other levels.
3 There is a difference between horizontal priority setting (giving the same assistance to people with the same health problems) and vertical priority setting (giving priority to people most in need of care).
4 Technical approaches may predominate, as was the case in Oregon.

* Apart from that, it did not compare the cost-effectiveness of interventions across categories of services (see section 5.2 and WRR97).

5 Efforts are made to consult the public or to involve them in priority setting by some other means.
6 Various values play a part in priority setting: the value for society as a whole, the value for the individual and the value for the basic package.
7 The scrapping of services from the health-insurance benefits package does not take place without a struggle.
8 The importance of health technology assessment.

Ham stated that work on priority systems is a learning process characterized by gradual improvements. There is no universal methodology. There are similarities in the values and principles on which the priority setting models are based, but there are also marked disparities. Sweden thus attaches greater importance to human dignity and individual rights, whereas in Oregon and the Netherlands the accent is placed on using resources in a way that is beneficial for society. Ham also pointed out that there is a gulf between the criteria formulated at national level and actual implementation in everyday practice. Finally, he stated that the involvement of patients (as opposed to the general population or population groups) has to some extent been disregarded in all of the systems. Specific patient information and education are areas that remain virtually unexplored. The Netherlands probably does, to some extent in this respect, differ from the other countries, he believes, referring to the 1995 Policy Document on *Medical Technology Assessment (MTA) and Efficiency in Health Care*. The then Minister of Health championed the need to inform patients and to involve patient organizations in the development and implementation of clinical guidelines (VWS95b).

4.9 Conclusions

The process of working on priority setting models and pointing out relevant criteria is a learning process that takes different courses in different countries. The 'first-generation' of reports is formed by the models from Norway, Sweden and the Netherlands.* This 'first generation' set itself the goal of formulating a limited list of general criteria that would make it possible to determine whether or not each service belonged in the basic package. This was the so-called 'sieve' method. In practice, the 'sieves' (such as necessity, need for care, efficacy and efficiency) were found not to function properly for reasons that are discussed in the following chapter.

A different approach was adopted during the same period in Oregon. This was based not on a list of criteria, but a list of services, each of them ranked in order of priority. It involved adopting a sort of 'checklist' of possibly relevant, but not interrelated, perspec-

* But, for example, also from Finland, although this was not discussed here (WGP95).

tives. Even the case of the Oregon project was too ambitious. The placing of a service on the fully ordered list frequently appeared to be somewhat arbitrary.

And yet it is the Oregon approach that has been imitated on a modest scale in recent years. Criteria largely have, in this regard, a 'checklist' status. A decision on the prioritization of each service is taken on the basis of the considerations that appear relevant for that particular service. This approach has been adopted in New Zealand, Denmark and the United Kingdom.

Chapter 5

Possible criteria

In this chapter, the Committee tackles the question of which criteria are to be adopted for services in the insurance package in order to justify people demanding solidarity of one another, basing its assessment partly on the priority setting models and criteria outlined in the preceding chapter. Among the topics raised are disease burden, quality of life, efficacy, effectiveness, safety, efficiency, and individual responsibility. Finally, the Committee looks at criteria for 'compulsory insurance'.

5.1 Criteria for a solidarity* package

5.1.1 Disease burden

Ever since the report of the Committee on Choices in Health Care, 'necessity of care' has been one of the central criteria for assessing the inclusion of a care service in the insured package. This criterion has proved difficult to operationalize in the Netherlands and elsewhere (CVZ01a, Hol98, Pol02). Furthermore, the use of this concept has proved problematic owing to terminological inexactitude. Policy makers and politicians also use 'necessary care' as a synonym for the 'basic package', whereas it is, in fact, one of the four criteria intended by that Committee for defining the basic package.** The term 'necessary' also implies that a service that satisfies this criterion does not, in fact, need

* That is to say: accessible to all in accordance with the principle of solidarity.
** See, for example, section 4.2 of the policy document 'A Question of Demand' (VWS01a).

to undergo further assessment. After all, who would wish to deny a sick person necessary care?

The Committee prefers to replace the criterion of 'necessity' with the more easy to operationalize criterion of 'disease burden'. By this it means the individual, illness-related disease burden (or rather, the disease burden endorsed by society for the 'average' individual). The Committee defines that concept as follows: reduced quality of life or life span as a result of a disease or some other somatic or mental health problem in cases where no health care service would be utilized.* The concept of 'disease burden' can be used for the prioritization of both curative and preventive services. In the latter case, it will refer to the anticipated disease burden in the absence of the appropriate preventive intervention.

In principle, an individual's health status determines whether or not a service needs to be utilized. The more serious a disease is, the greater the need for care will usually be. In the case of a disease for which no curative or palliative treatment is available, health care can only consist of nursing and care where the self-sufficiency of the individual in question is found wanting. The need for care, as determined by individual disease burden, therefore plays a major role in relation to the utilization of services. At this point it is necessary to consider the medical indication for which treatment is sought.

The value of a service lies in the extent to which it can bring about a reduction in disease burden. This may mean that health is restored, or that a service prevents or delays the deterioration of a person's health status. In all of these situations, a health gain (that is, a benefit that would not occur in the absence of the service in question) can be said to have occurred. The need for care may relate to medical, paramedical and nursing care.

As far as the potential effect of a service is concerned, no fundamental distinction needs to be made between cure and care activities. Both are aimed at reducing disease burden.** The way in which this gain manifests itself may well vary (see, for example, GR99a on day care in people with profound disabilities). Furthermore, a pure cure or care is often not possible in the health care field (WRR97, RVZ01a). Medical or paramedical care ('cure') cannot usually take place without nursing input ('care'). Conversely, 'care' usually also includes an element of 'cure'. Consider, for example, the care of pressure ulcers, nursing and medical care aimed at preventing pressure sores (a condition that occurs chiefly in elderly, immobile people, those with serious acute diseases and people with certain neurological diseases).*** This area of care, which is reck-

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* See also the definition of the iMTA (in CVZ01b, CVZ02a, Pol02): 'disease burden' is defined as the percentage of remaining health expectancy that a patient could be expected to lose if his or her illness were to remain untreated.

** Even 'mere' care can yield a major health gain. For example, the health status of people who are virtually or completely unable to care for themselves will rapidly deteriorate in the absence of nutrition or administration of fluids.

*** A further example is efficient multidisciplinary treatment of rheumatoid arthritis (Tij02).

oned to account for around EUR 450 million per annum in terms of direct costs, evidently offers room for improvement (GR99c).

Determining disease burden: different dimensions

Two elements are important when measuring disease burden: the loss of life span and the loss of quality of life as a result of the illness, compared with the anticipated life span and quality of life if the illness had not occurred. The average loss of life span can be discovered from epidemiological data. 'Quality of life' is, to a certain extent, synonymous with 'well being' (see also Nee91). [7] The determination of quality of life calls for the evaluation of three relevant dimensions: psychological, physical and social functioning.* In health-economics research on the possibilities of measuring disease burden, this problem is often solved (or, as some critics claim, avoided) by asking a panel of experts to estimate the loss of quality of life.

The past ten years have seen a marked increase in research into quality of life. Various experts (notably health economists) now consider that it is possible to effectively determine the disease burden for various conditions from this type of research by using quantitative methods. At an international level, the World Bank/WHO *Global Burden of Disease Study* has gained particular prominence (Mur96, Mur97). The list of disorders that was originally used in this study mainly consisted of diseases that play a role in third-world countries. The participating Dutch researchers have expanded this list by adding diseases that occur more often in our own country (see RIVM97). This modified list contains 52 diagnostic groups, within which 175 stages of disease are distinguished on the basis of health status, treatment and prognosis (Sto97, Sto00). These diagnostic groups account for 70% of the causes of death, around half of the total disease burden, and 65% of health-care costs in our country. The list also includes valuations aimed at comparing different states of health on the basis of their severity. Thus, substantial progress has already been made in the measurement of disease burden (although many diseases still need to be reviewed). A valuation of health status can be expressed in a so-called quality-of-life weight or disability weight. In health-economics circles, both of these concepts are designated by the term 'utility'. The value of the former weight is allowed to vary from 1 to 0, denoting a good to very poor health status or death, respectively. In the case of the disability weight, this occurs the other way round, with the value chosen ranging from 0 to 1.

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* Health-based (disease-specific and generic) instruments for measuring quality of life do *not* usually involve a person's financial situation, relational circumstances or domestic situation, etc, although these aspects may play a major role in determining well being and can also frequently be influenced by disease (Bon00). Preference is therefore usually given to the term 'health-related quality of life' or 'health status'.

The iMTA model

In a background study accompanying the CVZ advisory report *Scope of the Drug Reimbursement Package*, researchers from the Institute for Medical Technology Assessment (iMTA) have framed a proposal for the measurement and classification of disease burden (CVZ01b; see also: CVZ02a, Pol02). The health loss is measured over the remaining life expectancy. Disease burden is then a relative measure. It is the amount of health loss in relation to the amount of health in the absence of the disease. Health and health loss are both expressed in terms of quality-adjusted life years (QALYs). This approach therefore embraces both life span and quality of life. The researchers show how different disease model bases can measure disease burden. The disease burden can then amount to a maximum of 1 (if all remaining QALYs are lost) and a minimum of 0 (if no QALYs are lost). If, in addition to the indication for which treatment is sought, there is also a question of comorbidity then a complex situation arises, according to iMTA, because the co-existence of several diseases can change the need for treatment of each individual disease. For this reason, the researchers ignore comorbidity as far as possible. They have also established a link between the category of disease burden and the level of efficiency, and classify disease burden into seven categories. Thus, 'category 0' is assigned a quality-of-life weight of 1.00 – 0.95 (limitations minimal or non-existent), while 'category 1' has a weight of 0.94 – 0.80 (mild limitations) and finally, for 'category 6' the weight is 0.04 – 0.00 (unbearable suffering or death). The researchers consider it justifiable to attach more rigorous efficiency requirements to a service that falls into a lower disease-burden category than to a service in a higher category. Based on the literature, they also note the general assumption that the acceptable costs per QALY will increase in proportion to the perceived need for a given service. In the light of data on efficiency and reimbursement decisions within the existing benefits package (such as in renal replacement therapy, lung transplantation and breast cancer screening), they finally deduce efficiency thresholds for each category of disease burden. For category 1 these are set at EUR 4,500 and for category 6 at EUR 45,000 per QALY. The classification proposed here is, in fact, an operationalization of the 'necessity' criterion from the Committee on Choices in Health Care advisory report (KIZ91). Although the CVZ appreciated the iMTA proposal, it nevertheless questioned in its report the scientific, medical and social acceptability of the model and its applicability (CVZ01b). It is, for example, questionable whether uniformly measured, representative quality-of-life weights are available for sufficient diseases.*

* In a follow-up study the iMTA-model has been further tested in relation to diseases that frequently arise in general practice (CVZ02a).

The Committee endorses the CVZ's high regard for the iMTA-model, but adds one rider. The iMTA approach combines two quantities (that are, in fact, incomparable) into a single measure of disease burden. Life span and quality of life are used interchangeably in the QALY. Although this is understandable in the light of the need for standardization, it may conceivably sometimes be better to keep the valuation of life span and quality of life separate.* The classification into seven categories of disease burden is also simply one option. A panel of experts could, for example, also assess disease burden by breaking diseases down into ten, four or even fewer classes of severity. Furthermore, the researchers assign the greatest disease burden a quality of life of 'zero, which is the same value that is applied for unbearable suffering and death. This is surely debatable, since suffering may be worse than no longer being alive.

The iMTA method is at an advanced stage of development, but still requires further validation. Furthermore, relevant data are missing in many areas of care. When measuring valuations, one would ideally need to use a method that involves both patients and healthy people in addition to experts (care providers and scientists). It is important for every valuation that the people involved should have a thorough knowledge of the relevant specific health status.

5.1.2 Cost-effectiveness

Cost-effectiveness is an operationalization of efficiency. This term denotes the degree to which expenditure on a 'health-care technology' is outweighed by its benefits, preferably measured with standardized outcome measures. The term 'micro-efficiency' is also used in this context.** Several subsidiary criteria converge in the criterion of 'efficiency', including efficacy; effectiveness; safety; costs.

Effectiveness

'Effectiveness' denotes the degree to which a procedure has the desired effect in everyday practice (GR91a, EUR97, Pro98, Rig88). 'Efficacy' denotes the effect of a procedure carried out under controlled, optimal circumstances (homogeneous groups of patients, expert researchers, proper facilities), preferably in a randomized study. Compared with the 'ideal' situation of a controlled trial design (efficacy), there are often factors that, in practice, reduce the effect of a procedure. Examples of such 'efficacy

* Thus, the quality of the remaining (albeit short) life for terminally ill patients will be of particular importance.

** When referring primarily to the mechanical processes of health-care delivery, we speak of *organizational* efficiency. When examining the relationship between the total investments and the total benefits at health-care system level, the term 'macro-efficiency' is used (Rut01). The Committee's intention here is to use the concept of micro-efficiency as a criterion for the basic package.

modifiers' are a heterogeneous patient group, limited experience or expertise on the part of the care provider, incomplete compliance on the part of the target population and shortcomings in the organization of the care process.

The main consideration as far as the concept of 'effectiveness' is concerned is the 'goal' of a service. This goal is reduction of disease burden in many variants, including prevention, cure, preservation of health (or alternatively slowing its deterioration), alleviation of suffering (palliative care), or (as is often the case with nursing, and especially with care) helping patients to come to terms with helplessness (see also section 5.1.1). Effectiveness* is therefore not an absolute concept, but should be determined for each form of care. For the time being, this scientific assessment is more feasible for a purely curative form of treatment than for assistance that consists almost exclusively of nursing and care. Thus, for example, the problems that arise during the definition, standardization and measurement of helplessness warrant further scientific consideration. Partly with this in mind, there have been calls for the promotion of health technology assessment (HTA) in the nursing sciences (RGO98, RGO99). 'Health gain' clearly has more aspects than are usually conveyed by the reduction of disease or death. However, the WRR confines this term to the effects of preventive and curative care services and believes that, by definition, care services (nursing and care) do not contribute to the improvement of public health. The benefit derived from this care could therefore not be expressed in terms of 'health gain' (WRR97: page 147). The Committee, on the other hand, finds this a needless distinction (see section 5.1.1).

Safety

A service that is included in the basic package must satisfy safety requirements. This applies to medicines, medical devices, diagnostic or therapeutic procedures, nursing care and preventive care. A service that carries a major risk of complications or serious adverse events should preferably not be included in the basic package. As far as drugs are concerned, DES and thalidomide can be cited as tragic examples in this regard. In the area of medical devices, the problems surrounding a defective heart valve prosthesis aroused attention in the Netherlands some years ago (Gra98, Mol99).

With some diseases, in fact, physicians can be said to have their backs up against the wall. In some cases, services that are introduced into health care are known to carry a risk of serious adverse events. The use of an artificial lung in newborn infants with life-threatening respiratory disorders (extracorporeal membrane oxygenation, ECMO) is an example of this phenomenon (GR97b). Owing to the attendant risk, the value of this

* The degree to which the disease burden is reduced. Disease burden (section 5.1.1) relates to reduced life span and/or quality of life (with the three dimensions of psychological, physical and social functioning).

invasive treatment has repeatedly been the subject of discussion at international level.* People also put up with the serious disadvantages of treatment in connection with several forms of therapy in the field of cancer medicine. Examples here are disfiguring emergency surgical procedures or intensive chemotherapy with unavoidable alopecia and bone marrow depression. Life span is then increased at the cost of quality of life. The risk of adverse events in the long term may justify the inclusion of a care function within the health-insurance benefits package under certain conditions. One such condition may be the establishment of a form of surveillance involving permanent registration of health effects and the performance of any action necessary. [8]

Efficiency: comparison of costs and effects

In the literature, efficiency (also referred to as cost-effectiveness) is understood to mean the benefits of a procedure against its costs in monetary terms, manpower, equipment and time (Hab89, Pro98, Rig88, GR91a, Oos00). In the first instance, it concerns the relationship between the effectiveness of the service, either compared with that of another service or with doing nothing. In most case, therefore, it is a case of determining the added value in relation to the added costs.** What we are actually seeking to establish in asking whether delivery of care is, indeed, efficient is whether the money could not have been better spent on another service either within or outside the health care sector.

There are various methods for comparing costs and effects, including cost-benefit analysis, cost-minimization studies, cost-effectiveness analysis and cost-utility studies. In the first-named type of analysis, both the resources required in order to achieve a certain health outcome and the benefits are expressed in monetary terms. Because it is usually difficult to express all benefits in monetary terms, analyses of this kind are rare. The basic premise underlying cost-minimization analysis, which is more common, is that there is no difference in the effects of the forms of care that are to be compared, and hence only the difference in cost is important. The principal technique used in medical care over the past 15 years has been cost-effectiveness analysis. The resources applied in delivering a service are expressed in monetary terms, but the health effects (such as the number of life-years gained, the number of cases of disease diagnosed or the number of cases averted) are measured in natural units. In order to evaluate different alternatives, one must select directly comparable endpoints. The costs are then related to the effec-

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* Cerebral haemorrhage is the most feared direct complication and the principal cause of death. There is a longer term risk of mental and neurological impairment.

** In everyday parlance, when people say that ‘the efficiency of health care can or must be increased’ they either mean that the same level of quality can be achieved at a lower cost or that the quality of care can be improved for the same amount of money (GR91a).

tiveness of the alternatives. In conclusion, cost-utility analysis is, in fact, a special form of cost-effectiveness analysis. In this method of analysis, which has been widely used over the past 10 years, outcomes are uniformly expressed in terms of the effect on survival and quality of life. The standard measure generally used for this purpose is the QALY or, nowadays, also the disability-adjusted life year (DALY).

When evaluating efficiency, it is necessary to define objectives carefully. The relationship between the level of care attained and the resources applied is expressed in a variety of ways in the literature. Aside from the chosen method of comparing costs and effects, this also depends on what exactly is understood by costs or effects. In efficiency analysis one should, ideally, compare both positive and negative health effects with the costs incurred in each case. Thus, efficiency encompasses both effectiveness and safety. The applicability of the standard measures of effectiveness that are often adopted by economists (such as QALY and DALY) is not universally accepted. This question is still under discussion (Ana97, Ban95, Boe98, DCE97, Edg98, Gui99, NAC93, Nee03). Furthermore, costs are analysed in different ways. Thus, whereas some publications take account of indirect as well as direct costs, others do not. Moreover, not every expert uses the same discount rate, which is a correction factor used to compensate for disparities in the valuation of effects and costs due to the phenomenon known as 'time preference' (where effects and costs can occur at different moments in time).

Efficiency will preferably be expressed either by means of a cost-effectiveness ratio or in a cost-utility ratio. Cost effectiveness analyses (CEAs) and cost utility analyses (CUAs) can identify the most favourable situation for a separate service. However, they do not necessarily make a comparison of different forms of care scientifically acceptable. As far as this particular problem is concerned, the Committee refers readers to the background study accompanying this advisory report (Nee03). The background study also demonstrated the efforts made by health economists over the past decade in confronting the methodological limitations of such analyses. When decisions are made on the inclusion of particular items in the insurance package, it may be demanded in the interests of solidarity that consideration should be given to the 'value' of a care function. This should be done from the perspective of whether the service in question offers value for money when measured by its anticipated effect. In the case of a costly service that offers only minimal effectiveness, there will be a tendency not to allocate space in the basic package. This will automatically apply in the presence of alternatives that are cheaper and more effective or equally costly alternatives that are more effective. The exclusion of a costly service from the package is more problematic when no alternatives exist. This becomes more of an issue the greater the disease burden for the person concerned.

In policy making circles, reference is frequently made to the squandering of resources and over treatment. [9] However, experts from the field indicate that in addition to over treatment, under treatment also occurs. Many people are still not treated in accordance with available protocols, guidelines or standards (Spr98, GR00). Whenever more 'appropriate care' is offered (that is, where need is correctly assessed), both over treatment and under treatment become less of an issue. The health-care costs could then prove to be lower, but they could equally turn out to be higher. In the latter case, improvement in quality does not result in cost control.

5.1.3 *Individual responsibility and health*

The question of individual responsibility for one's own health has frequently received consideration in the literature (Asp98, Bea91, Bea99, CVZ01b, DCE97, Gid98, Hav87, KIZ91, RVZ00a, RVZ02c, Tra00). The citizen does not have unlimited claims on the community; he also has the moral duty to give consideration to others and to avoid unnecessary use of services.

To what extent can unnecessary use be traced back to the responsibility for one's own health? The RVZ follows the example of various authors in drawing a distinction between prospective and retrospective responsibility (RVZ00a, RVZ02c). Responsibility in the prospective sense relates to future behaviour. People can safeguard their health or limit damage to health by themselves taking action with regard to diet, safety and exercise. According to the RVZ, there is nothing wrong with appealing to personal responsibility in this sense, unless individual measures assume a mandatory nature (RVZ00a). Freedom of choice then becomes an issue. There is also such a thing as retrospective responsibility, that is to say individual responsibility for behaviour that has already taken place. The idea behind this concept (also encapsulated in the phrase 'serves them right') is to hold individual citizens responsible for the consequences of 'self-chosen' high-risk health behaviour. Proponents of this approach consider it justified, arguing that numerous diseases are associated with risks that are engendered by an individual's own choices (Asp98, Gid98). After all, they point out, health education campaigns have already repeatedly alerted the citizen to the dangers of smoking, excessive alcohol use, too much fat in the diet and unsafe sex. The scope for shifting responsibility for the health disadvantages of a self-chosen lifestyle to society should therefore be minimized, especially where the services in question are scarce. If this does, in fact, occur, then risk solidarity may be jeopardized as knowledge about the relationship between health behaviour and disease increases. Thus, the question arises as to whether solidarity between smokers and non-smokers is, in fact, still tenable and fair (RVZ00a).

The Committee feels that 'individual responsibility for health' is an appropriate criterion in theory, but that there are still objections to its application. This applies to both

retrospective and prospective individual responsibility. In numerous cases, it is difficult to define precisely what wilfully hazardous behaviour is. To what extent is 'avoidable' behaviour 'culpable'? In the case of smoking and excessive alcohol use, this is already proving problematic. Nor must it be forgotten that these cases often involve an element of addiction. The (physical or psychological) dependence then makes it difficult to stop the risky habit unaided. Defining intentionally hazardous behaviour in relation to sports activities and dietary habits is even more difficult. It is, in any event, still true to say that control of individuals is not only difficult to achieve* but also questionable, owing to the protection that is afforded to personal privacy (Hav87). It would also appear that less healthy lifestyles are not necessarily based on freedom of choice (Hav87, Str97). At group level, there are systematic disparities in health behaviour between people with higher and lower socio-economic status (section 3.3.2).

Reciprocity**

To what extent can citizens also be expected to make an active personal contribution to especially scarce care services, as opposed to simply assuming the passive role of possible future users? Examples of such services are blood transfusion and organ donation. Do not all citizens have the moral duty, out of a feeling of solidarity with the sick, to offer themselves as donors, not least on account of the risk that they themselves may one day have need of blood or an organ? [10]

The reasons why citizens may choose not to do this may either be of an ideological or emotional nature (as is the case when a decision regarding willingness to donate is postponed in order to avoid confronting one's own mortality). But they may also be based on a certain propensity to accord low priority to the risk of a future unfavourable event.

Setting aside the potential advantages, the Committee believes that application of the principle of reciprocity is mainly constrained by objections of principle. After all, the act of explicitly 'honouring' a quid-pro-quo reduces the freedom of choice inherent in the decision on whether or not to donate. However, the pressure engendered by the principle of reciprocity could theoretically also militate against willingness to donate. Furthermore, this could have the effect of jeopardizing the voluntary nature of donation. In conclusion, it should be noted that there are, for the Netherlands, also certain practical objections. What should be done in the case of people who have not recorded their

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* Although the principle of fairness demands that *all* people who voluntarily lead high-risk lives should be treated equally, the problem is that only certain types of high-risk behaviour are visible and recordable (Hav87). Thus smokers are easier to identify than are people who take too little physical exercise.

** According to this principle of 'you get out what you put in', shared responsibility for someone else's health can be equated with responsibility for one's own health.

willingness to donate organs? Are they to be regarded as 'objectors' or as having indicated a potential willingness to donate? According to the Committee, it is, indeed, possible to assert a moral 'claim' to reciprocity, but to use this as a criterion for entitlement to services would be going too far (quite apart from being difficult to achieve in practice).

5.1.4 'For user payment and responsibility'

This fourth 'Dunning' criterion principally revolves around the question (KIZ91) of when the 'user pays' principle can be applied to a service without causing major problems. It can be inferred from section 3.4 (where the Committee examined the issue of 'financial accessibility and personal contributions') that the 'user pays' principle can, at most, be applied to services with relatively minor financial impact. What is important here is the distinction between infrequent and regular use. By making frequent use of a service that is, in itself, inexpensive, a person with a chronic condition may nevertheless run up a large bill. With the possible exception of higher income groups, the Committee believes that full self-payment of effective services must, in principle, remain limited to extremely inexpensive services such as self-care products (e.g. plasters, nose-drops, aspirins). Otherwise, the utilization of effective care may be so seriously affected that adverse health consequences ensue. Restraint is also called for when excluding services from the package, since substitution effects may occur. The consumer will then switch to more expensive, reimbursed forms of care (see CVZ01b). Providing the assessment of need is correct (e.g., if it is laid down in guidelines or protocols), then the latter scenario should not occur in practice. If this situation does, indeed, arise then the care provider strays into the realm of inefficient care.

5.2 Applicability

Consensus is beginning to emerge in the scientific literature over the criteria that need to be applied when formulating a basic package (based on the principle of solidarity). This applies to two of the criteria discussed above, namely, disease burden and cost-effectiveness As far as the second of these criteria is concerned, the Committee noted that, in practice, priority should be given to the evaluation of effectiveness. After all, if a service is virtually or completely ineffective, it cannot be cost-effective either. In theory, the two criteria mentioned above each form a sound basis (in their respective contexts) for the definition of a 'solidarity' package. Solidarity can only reasonably be invoked in cases where there is a considerable disease burden and the service in question offers a cost-effective method of reducing that burden. According to the Committee, the other criteria discussed in the previous sections are not applicable. For example, the criterion of 'individual responsibility for health' cannot be used, since it is both difficult to define and to

monitor. The criterion 'for user payment and responsibility' offers only limited applicability, largely owing to potentially adverse health effects.

The scope for using the 'disease burden' and 'cost-effectiveness' criteria when making actual policy decisions regarding the insurance benefit package depends on:

- practicability: is there a valid method for measuring the criterion in question?
- availability of data: are there sufficient reliable data to determine such factors as the disease burden, the costs or the effectiveness?
- availability of decision rules: what thresholds or limit values are used in applying the criteria?
- availability of appropriate (national) procedures: when choices are made in health care, which interested parties are involved in checking whether the services conform to the criteria?

Even after policy makers have chosen the criteria to be adopted, the Committee points out that choices in health care can only be partly based on scientific principles. Societal beliefs and choices also have a crucial role to play. Where, for example, should one place the lower threshold in relation to disease burden? Moreover, at what point do the costs of a service become unacceptably high compared with its effectiveness?

Major advances have been made in recent years with regard to the applicability of the criteria of 'disease burden' and 'cost-effectiveness'. Slowly but surely, these criteria are becoming easier to operationalize, though distinctions are still sometimes blurred. Moreover, far more data are available nowadays with regard to disease burden and cost-effectiveness than was the case 10 or 15 years ago. Nevertheless, it is not yet possible at present to assess the entire spectrum of health-care benefits that should, theoretically, qualify for inclusion in the basic package for compatibility with these criteria. For many services, the requisite data are still unavailable. In these areas, continuing scientific research must provide a solution.

Partly because reliable cost-effectiveness data are unavailable for many services (GR91a, GR01a, Nee03, Rut01, Rut02), we often look in the first instance in practice at effectiveness* (or the 'numerator' in the cost-versus-benefit equation). An ineffective service is, by definition, not cost-effective (see, for example: Bou00, GR99b). The 'cost-effectiveness' criterion will be a particularly useful decision-making tool for identifying the most favourable situation when use of a service is compared either with similar services or with doing nothing. For the time being, comparisons of the cost-effectiveness of

* According to the CVZ: 'In practice, the question of efficiency is unimportant in the absence of effectiveness (and likewise in the case of major disparities in effectiveness). Disparities in efficiency play a more important role in relation to effects that are more or less equal.' (CVZ01a, page 24).

interventions across different categories of services (WRR97 proposal) are precarious and scientifically questionable (see also Nee03). Largely because of the multidimensionality of the 'disease burden' criterion, there is then a risk that apples will be compared with oranges (for example, heart transplantation and in-vitro fertilization) in supporting package prioritization.

For the criteria of 'disease burden' and 'cost-effectiveness', the application of a threshold (to be established by the Minister) for each class of disease or type of benefit appears unavoidable. In principle, whatever falls below the line will then not be eligible for the basic package. It is justifiable to progressively lower the threshold for cost-effectiveness as the disease burden becomes higher. Members of the general population usually place a higher value on a particular health gain that is achieved in someone who is severely ill than on the same health gain when it is achieved in a relatively healthy person (Dan93, Men99, Nor99, Sas01). This may, in part, explain the major disparities in cost-effectiveness ratios between various preventive and curative care services (see Ten95).* The Committee is aware that the extent to which the criteria of 'disease burden' and 'cost-effectiveness' are quantifiable may be limited by problems of a conceptual nature (see Nee03). These problems increase progressively as larger categories of diseases or services are considered. Evidently, therefore, it is more important to establish a threshold for every class of disease or type of benefit. Then one would need to critically examine every disease or benefit within a decision-making structure (see chapter 6) in order to ascertain whether it should rightly be included or excluded. It would need to be possible to deviate from the threshold if there were grounds for doing so (no 'mechanical' application). Thus, in some cases, the main function of the threshold is to increase the burden of proof for inclusion of a service.

5.3 Criteria for a compulsory package

Section 3.2 reviewed the factors that government would be able to consider in requiring people to take out insurance against medical expenses. Aside from disease burden and cost-effectiveness, the following factors also play a role: paternalistic grounds, the control of external effects and the prevention of 'free riding'. The underlying reasons may result in a different answer being given to the question of which groups of people should be required to insure against which medical expenses. Paternalistic reasons

* The surgical removal of malignant brain tumours scores poorly in league tables that compare the efficiency of a range of interventions: the CU (cost utility) ratio is in the region of EUR 100,000 to 150,000 per QALY gained (May91). On account of the substantial individual disease burden involved, nobody advocates stopping these procedures.

and the risk of free riding play a lesser role in the case of people with a high income, since if they fall ill they will first need to draw on their income or capital.

For the services traditionally offered under the Exceptional Medical Expenses Act (AWBZ) (such as care of the mentally handicapped, nursing-home care, long-term hospital care and certain forms of preventive care), the aforementioned motives have been key reasons for operating a system of compulsory insurance for the entire population (Ven01). For these services, there is too great a risk that people will not voluntarily take out sufficient insurance cover. This is often the case with forms of care whose costs are so high that they are not even easily affordable for affluent people (e.g. long-term institutional care). Also possibly involved are services such as infectious-disease control or addiction support, whereby the disadvantages of external effects for society as a whole are so great that compulsory insurance is appropriate.

From the cost standpoint, compulsory insurance for the less expensive services (such as general-practitioner care and 'straightforward' specialist medical assistance) is, in principle, only required for the lower income groups. Although GP care is relatively inexpensive, it is nevertheless advisable that this service should be included in the compulsory insurance provision for everyone, the aim being to promote the efficiency of health care as a whole ('macro-efficiency'). The general practitioner acts as the 'gatekeeper' for access to the health-care system (especially in connection with referral to secondary-care services) and also forms the 'linchpin' of the primary-care system (see also Ble94, Fri97, MCZ94, MGS99). Government might view this as a reason to adopt an efficiency motive at system level: to support citizens in connection with consumption of care and to protect them against unnecessary consumption.

The Committee believes that the following criteria should be employed in formulating a 'compulsory' package:

- the costs of treatment, nursing or care (possibly in relation to the insured's income position);
- the extent to which the disease that is to be prevented or treated could give rise to a disease burden and prove problematic for others;
- the preventive nature of services;
- effects on the macro-efficiency of health care.

5.4 Applicability

The applicability of these criteria is also dependent upon practicability (method of measurement), the availability of data and decision rules, and the availability of nationwide procedures. The situation can be characterized as follows:

- The criterion 'level of treatment costs' is, in theory, readily measurable. In addition, it is necessary to weigh the anticipated costs of treatment and the financial situation of those involved. More specific decision rules are needed as far as the imposition of compulsory insurance on people with higher incomes is concerned.
- The 'extent to which the disease that is to be prevented or treated could give rise to a disease burden and prove problematic for others' also appears to be a criterion that can readily be operationalized. It is relatively easy to determine whether there is a substantial risk of others suffering damage to health or major inconvenience. This risk exists, for example, in the presence of infectious diseases, addiction to drugs, or serious psychiatric disorders, but also in connection with various other care-related issues. Health problems in pregnant women or mothers can result in damage to the child's health. Ante- and post-natal care is aimed at preventing or treating problems of this nature. Relationship or parenting problems can prove damaging to the health of the children growing up in such an environment. These are some of the problems towards which community mental health care is geared.
- The 'preventive nature of services' is, in theory, a criterion that can readily be operationalized, providing it is limited to services that are explicitly aimed at primary or secondary prevention.
- The criterion 'effects on the macro-efficiency of health care' is, in general, difficult to operationalize. In the Committee's view, this criterion is for the time being only applicable to general-practitioner care, by virtue of the gate keeping role that has been assigned to the GP in connection with referral to secondary-care services.

As far as the various aforementioned examples of care that may fall into the compulsory-insurance category are concerned (see also section 3.2), available data with regard to estimated disease burden and costs of care are, in general, of a reasonable or good standard. Finally, the application of decision rules is dependent upon the thresholds or limit values that are adopted. [11]

5.5 Contours of the package

In the case of an insurance package that is based on a solidarity principle, the services are accessible to all and the premiums are payable by all income groups. It does not nec-

essarily follow, however, that the conclusion of that insurance must also be compulsory (aside from the mandatory payment of a solidarity contribution). The government must have well-founded reasons for this, such as those discussed in section 5.3. Whether the application of the two sets of criteria, which relate to solidarity and compulsory insurance, respectively, must indeed lead to variation in the composition of the package will depend on how the criteria are applied and on other considerations, some of them of an actuarial nature. This falls outside the scope of the present advisory report. Theoretically, the difference in the two sets of criteria could give rise to the following two packages: a basic package that is accessible to all and, 'inside it', a smaller package that is compulsory for all.* The Committee does not wish to pass judgement on the desirability of two packages and will here confine itself to making a few comments on the pros and cons of a distinction between a solidarity and a compulsory package. [12]

One advantage of the distinction is the greater choice that would exist for the citizen (see also section 3.3.3 and VvV02a) and the potentially greater scope for market forces within the system. Although a broad basic package is financially accessible to all, there is no unnecessary pressure on the higher income groups to take out insurance (the privately insured nowadays form a substantial proportion of the total insured population). In addition, the existence of two packages reduces the importance of the supplementary insurance. At present, chronically ill and older national health-insurance scheme members suffer disadvantages in this respect if they wish to change from one health-insurance fund to another. Disadvantages of having two packages are: somewhat less transparency in the system, the risk of antiselection** and extra actuarial 'instrumentation'.

The advantages of having a single package are: the obviously large measure of transparency (all insurers offer the same package, though the premiums may well differ, partly by dint of more efficient purchasing of care), less incentive to engage in antiselection and the possibility of fewer actuarial formalities. The main disadvantage is that the citizen cannot choose between different-sized packages. Even those who are currently privately insured must take the complete package.

Thus even though a 'solidarity' and a 'compulsory' basic package do not necessarily need to coincide, the Committee is also aware that considerations that it is not fully able to assess (such as actuarial feasibility) may have a bearing on the decisions ultimately

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* It is conceivable, for example, that a service such as in-vitro fertilization may fall under the principle of solidarity and thus form part of the broader basic package, but not of the compulsory package.

** Opportunistic behaviour whereby citizens only opt for the most comprehensive insurance coverage in a year when they expect to make extensive use of health care. It should also be possible to combat this practice by committing people to this choice for a longer period (several years).

reached by the government with regard to the composition of the package. It would also be possible to achieve the two objectives of package differentiation (the combination of financial accessibility and prevention of unnecessary pressure to take out insurance) through a single basic package with voluntary, income-dependent basic excess.

When opting for one or two packages, it is, of course, also important that there should be sufficient forms of care for which only the principle of solidarity can apply, but without there being grounds for compulsory insurance. In other words, is the size of the 'difference package' sufficiently relevant? Or does voluntary, income-dependent basic excess in itself satisfy the rationale underlying the distinction between solidarity and compulsory insurance? The Committee does not feel that it is responsible for answering that question.

Regardless of the actuarial computation, it does believe, however, that the analytical distinction between solidarity and compulsory insurance is fundamental to the design of the future insurance package.

The Committee presumes that the package will, in the first instance, consist of relatively large categories of care. This is unavoidable, since too much detail detracts from clarity. However, the criteria that it advocates are not readily applicable to large categories of care. A considerable variation in disease burden and cost-effectiveness will be encountered within each of these categories. Evidently, therefore, the benefit package entitlements need to be defined in such a way that the only benefits reimbursed for each indication within these broad-based categories of care will be those that have been assessed for compatibility with the criteria of 'disease burden' and 'cost-effectiveness'.* As far as the criteria for compulsory insurance are concerned, the use of the criterion 'level of treatment costs, etc.' requires more detailed actuarial computation (taking account of such factors as the insured's income position).

As discussed, application of the criteria named by the Committee, combined with other considerations, may result either in a single basic package or two packages based on the principle of solidarity. In conclusion, it goes without saying that voluntarily supplementary health-insurance packages are available. It should be possible for these to include (safe) services that fall outside the basic package and to offer care in situations where disease burden and/or cost-effectiveness are either minimal or else disputed.

* This (nationwide) assessment would need to be based on prudently applied thresholds established for these criteria by the Minister (no 'mechanical' application: see section 5.2).

5.6 Conclusions

Since the Dunning Committee's advisory report on *Choices in Health Care* from 1991 and the WRR advisory report on *Public Health Care* from 1997 (discussed in the previous chapter), advances have been made with regard to the conceptual framework, the practicability and the applicability of different criteria. Consensus is beginning to emerge in the scientific literature over the criteria that need to be applied when formulating a basic package (based on the principle of solidarity). These criteria are disease burden and cost-effectiveness. For the time being, applicability is limited, partly because the criteria cannot as yet always be clearly operationalized. Furthermore, the requisite data are still unavailable for many services. Continuing scientific research must provide a solution in these areas.

In order to assess services in the light of the criteria, transparent procedures involving experts, patients and healthy members of the population will be required for each disease, benefit or group of benefits. For every criterion (for each disease, benefit or group of benefits), it appears advisable to adopt a threshold, to be determined by the Minister. In principle, whatever falls below the line will then not be eligible for the basic package.

Apart from solidarity criteria, there are also criteria for compulsory insurance. Whether these two sets of criteria are to result in a distinction being drawn between two packages based on the principle of solidarity (a basic package that is accessible to all and a smaller package that is compulsory for all) will depend on the actual application of the criteria and on other considerations, some of them of an actuarial nature. This is not a matter on which the Committee feels a duty to give an opinion.

Chapter 6

Procedures for defining the package

6.1 The need for procedures

The question is: what methodology must government follow when setting priorities at the macro-level? The establishment of a system of scientifically based criteria is a first step. A second is the formulation of careful procedures whereby interested parties can agree about the (weighted) application of criteria.

Careful procedures are necessary in the first place because the application of the solidarity-oriented criteria (disease burden, effectiveness and cost-effectiveness) always demands a qualified approach. [13] For every service (or category of services), different elements arise that require discussion within a system of consultation: the definition of health and disease, the multidimensional nature of disease burden, disease burden reduction (effectiveness) and efficiency, heterogeneity and disparities in the quality of available data, and finally, any other considerations. A qualified approach can, for example, mean that when the only service available for a severe health problem is one that offers moderate cost-effectiveness, the care function in question is nevertheless included in the package. Reduction of disease burden (effectiveness) will then be more important than efficiency (see section 5.2). Government can also accord extra priority to certain ethical, legal, or social aspects. Examples here are the relatively scarce, costly or quality-sensitive services (such as tertiary care functions, which are now regulated under Section 2 of the Specific Medical Services Act [WBMV]) or services in the sphere of public preven-

tive care. In the latter case, a relatively urgent nationwide supply may be desirable (e.g. the National Immunization Programme).

Second, careful procedures are required because policy decisions regarding the insurance benefit package can only be based in part on scientific principles. Societal beliefs and choices also have a major role to play. Based on scientific assessments of health, diseases can be ranked according to their individual disease burden. The question then remains as to what lower limit needs to be applied for disease burden in order to decide whether or not a related, effective service qualifies for inclusion in the insurance package. But likewise, what threshold should be applied in the case of effectiveness (i.e. reduction of disease burden)? There is no sense in including a service in the basic package that, despite a large individual disease burden, does little or nothing to reduce this burden. When weighing up efficiency, one can ask the question as to when the costs of a service are unacceptably high compared with its benefits. The application of an efficiency threshold has the advantage that the 'cost-effectiveness' criterion includes both the potential reduction in disease burden (effectiveness) and the cost factor. All this means that government, having consulted the public at large, will have to establish thresholds for the criteria 'disease burden' and 'cost-effectiveness' (or efficiency). Naturally, we must beware of applying this principle too strictly (see section 5.2). Within a decision-making procedure (section 6.3), it will always be necessary to critically assess whether a disease (or service) that ranks above or below the threshold should rightly be included or excluded. A different authoritative opinion may emerge, with justification, than would have been reached had the threshold been 'mechanically' applied.

6.2 Efficiency thresholds and cost control

It is feasible that efficiency thresholds may vary from one care sector to another. There may be social or economic reasons for imposing stricter requirements with regard to cost-effectiveness in one care sector than in another. There will, for example, be a greater onus on preventive and curative services to prove their worth than on (supportive) care services (such as nursing-home care and care of the mentally handicapped) that a 'civilized' society will always wish to extend to people who find it difficult or impossible to look after themselves.

Theoretically infinite demand and a limited supply of resources characterize health care. Consequently, there will always be talk of a relative scarcity of resources for health care (see also Ros02). Where demand is enduring, and especially where it rises, priority setting at the macro-level becomes necessary in order to keep collective funding within acceptable limits. If the costs of care at macro-level and the resultant individual insurance premiums become too high, then the financial accessibility of health care may be jeopardized and solidarity eroded. People who have little need to avail themselves of

health care services may then become less willing to bear part of the burdens of those who need to make extensive use of these services. Monitoring of health-care expenditure must therefore remain an important government objective in the future. The level of this expenditure will depend on what society is willing to spend on health care under the economic circumstances that prevail at the time. Government, in its capacity as the people's representative, would need to investigate from time to time what level of health-care expenditure society finds desirable. This could be reflected in the level of the efficiency thresholds that are applied.

In spite of the efforts made and results achieved in our country in the sphere of HTA (or MTA) and in the development of guidelines, the collectively insured package still includes various ineffective and inefficient forms of care (Ven95, ZFR93, Rut01, Rut02).* According to the Health Insurance Act (ZFW), it is still the case that 'treatments that are customary in medical professional circles qualify for reimbursement'.** In its 1991 advisory report *Medical practice at the crossroads*, the Health Council recommended that this criterion of established practice should be abandoned and that proven effectiveness should be adopted as the standard for assessing whether a procedure qualifies for reimbursement (GR91a). This recommendation remains equally valid to this day (Rut02). Moreover, the Committee does not rule out the possibility that health-care costs will rise to such an extent in the future (due to the greying of the population, new medical possibilities or the value that is attached to health) that the insured package will need to be restricted. In addition to care that is virtually or completely ineffective, it is then possible that effective*** care may also have to be excluded from collective funding. Only in rare cases will it be justifiable to completely remove effective health care services from the collectively financed package. It will be necessary to identify ranges of indications where a service is less beneficial when measured in terms of reduction in disease burden or cost-effectiveness.

6.3 A national assessment framework

Before a new system is introduced, government should develop a policy that supports decision making in health care at the national level. Within this policy, existing and new

* Topics addressed by the Health Council in this connection have included 'Effectiveness of physical therapy' and 'The efficiency of long-term psychotherapy' (GR99b, GR01a).

** In 1997 the Minister of Health added the proviso: 'and which are scientifically acceptable'.

*** It is undisputed that there can be no question of inclusion in the collective package in the absence of 'effectiveness'. Assessment of whether or not a service is 'effective' (i.e. whether it reduces the disease burden) is still somewhat problematic, because 'disease burden' is a multidimensional variable. That is, a service can be effective in one dimension, ineffective in another and harmful in a third. A service that is effective in only one dimension (e.g. psychological functioning) and not overwhelmingly harmful in another (e.g. physical functioning) is, in theory, an 'effective' service.

services are assessed in terms of disease burden and (cost-)effectiveness, while safeguarding scientific and societal interests. One should always follow a transparent procedure here that is geared to the particular disease, benefit or group of benefits. The Committee does not comment on whether the implementation of such procedures needs to be entrusted to a single institute or to a formalized association comprising various organizations. The approach adopted by the British NICE and the experiences (negative as well as positive) garnered by this institute to date may possibly offer pointers as far as the establishment of a proper structure in our own country is concerned (Rut02). The structure envisaged by the Committee would need to accommodate the provision of authoritative advice to the government. The ultimate decision regarding inclusion of benefits in the basic package is a matter for government. A national assessment framework that provides government with well-founded advisory reports only makes sense if these reports are given due weight in the decision-making process.

At this moment, the Netherlands lacks an organization that would be able to carry out the procedures in question. Given the complexity of the subject matter and the scope of the task, it is currently rather unlikely that the Ministry of Health* or one of its existing advisory bodies can assume full responsibility for this task. Nor can the institutions that are engaged in the development of professional guidelines in the Netherlands necessarily discharge this (independent) public duty. Although they may well possess the relevant expertise and professional networks, they currently operate in most cases under the umbrella of professional bodies. It remains to be seen how the requisite national assessment framework can best be realized. In the first instance, the Committee considers it advisable to continue building on the experience and expertise of the advisory bodies that have already been supporting decision making on the content of the collectively insured package for many years as part of their statutory responsibilities.

The entitlements of Dutch citizens to health care under the collective insurance scheme (basic package) will need to be established nationwide, under the authority of the Minister of Health. It seems unavoidable that the collectively funded package will not only be defined generally in terms of services (global entitlements), but also, for a growing number of these services, in terms of indications. These are itemized entitlements to reimbursement of those services, and they are already in place for such items as in-vitro fertilization, cholesterol-lowering medicines and population screening for breast cancer. This means that reference is made in the definition of ‘the package’ to a body of binding, itemized entitlements (specific terms of insurance), in which the indications for the

* Now that the Ministry of Health is undergoing deregulation, it seems obvious to place the execution of the procedures in question in the hands of an external, independent organization.

delivery of health-care services (or parts thereof) are broadly outlined. The Minister of Health lays down these specific terms. But who formulates them? The assessments of disease burden and efficiency (multidimensional variables) on which this process is based can be perceived and weighted in different ways. To determine how this is to be accomplished, relevant stakeholders (as yet unspecified, but to include experts [care providers, scientists], patients, consumers and insurers) must be involved in the procedures for each situation (disease, benefit or group of benefits). Experts play a key role here, since they must furnish a proper scientific basis upon which to establish the specific terms of insurance. A multidisciplinary approach will then often be required. Such an approach involves scientific input from a (para)medical, clinico-epidemiological, health-economics and (if necessary) a social, ethical and legal perspective. The specific terms of insurance will need to be the result of a well-defined methodology, whereby all parties are brought into play at an appropriate moment and efforts are made to achieve transparency of choices and argumentation.

In order to prevent all relevant perspectives and elaborate assessments from becoming unmanageably complex, it seems advisable to aim for homogeneity with regard to types of problems and assessments. It is therefore best to develop the specific terms of insurance within well-defined areas of health care, such as the (para)medical disciplines.

In the first instance, those framing the specific terms of insurance could themselves determine which efficiency measures are practicable in their particular field. Possible examples include costs per life-year gained, costs per disease-free life-year and costs per QALY (the objections to this particular measure diminish as the health problems and services in question become less diverse). It is then up to the Minister to determine what limit values need to be observed for those measures. This might lead to a situation in which different efficiency limits would be adopted for different areas. It is also up to the Minister to adjust those limit values if this is desirable from a political or macro-economic standpoint.* This approach has the advantage that the various responsibilities are properly segregated. As far as content is concerned, responsibility rests with those 'in the field' (the scientific community, professional groups and society at large), while the politicians have the task of setting limits (efficiency thresholds).

6.4 Relationship to professional guidelines

What is the relationship between the benefit package entitlements described by the national assessment framework and the guidelines, standards and protocols established

* Disparities in threshold levels that are difficult to justify can give rise to an unacceptable degree of arbitrariness. Borderline cases will occur whereby a service can be assigned to two sub-areas, one of which means that it would be included in the package while the other entails exclusion. This is all the more reason not to apply thresholds 'mechanically' (section 5.2).

by the medical and (para)medical professional groups (in the interests of promoting quality of care)?

Professional evidence-based guidelines will, in general, be more detailed than the intrinsic 'benefit package entitlements' that are formulated through the national assessment framework. Efforts must, indeed, be made to establish a strong link when formulating those benefit package entitlements by intensively canvassing professional opinion, and professional guidelines can be viewed as more detailed elaborations of the benefit package entitlements. However, a one-to-one relationship will probably not always be achievable. For example, the professional group that draws up the guidelines may not be in agreement with the disease-burden or efficiency thresholds that are adopted in the national assessment framework. However, the care providers and their patients will then need to take account of the fact that the benefits in question do not fall within the basic package and do not qualify for reimbursement from the collective insurance scheme.

The formulation and periodic updating of guidelines, standards or protocols by the (para)medical professional groups has escalated dramatically over the past ten years (Boe02, IMTA02, GR00). This is a good thing, because quality of care and cost control can only be partly influenced by government through the limits of the insurance package. There are numerous procedures in health care that do not lend themselves to general government intervention, but that do lie within the ambit of professional autonomy and quality control (GR91a). Assessments regarding the purpose of a given treatment are made every day in consulting rooms and the effectiveness and efficiency to be achieved in a care service are largely associated with the context in which the care provider chooses to utilize it. Anything that cannot be controlled via the limits of the package is therefore better stimulated via selective and systematic promotion of efficiency in practice (see also CVZ01a).

The Committee is here referring in particular to the development and application of so-called second- and third-generation guidelines, standards and protocols.* The principal yardstick applied here is the potential reduction in disease burden (or effectiveness).** The Health Council advisory report *From implementation to learning (*published in 2000), provides an analysis of the experiences gathered in this area, with the implementation issue being viewed primarily in the light of the objective 'optimization of patient care' (GR00). The Dutch experiences appear to compare favourably with those from abroad.***

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* First-generation guidelines, standards or protocols are also described as 'opinion-based', while second- and third-generation material is said to be 'evidence-based'.

** In the case of third-generation guidelines, etc, cost components and patient values are also explicitly examined.

*** Research conducted among general practitioners in the 1990s by the Centre for Quality of Care Research (WOK) showed that 72% of them complied with NHG standards (Spi99, GR00).

In addition, the Committee refers to the use and further investigation of incentives for efficient practices by care providers, as has already been advocated in earlier advisory reports to the government (KIZ91, MCZ94, SFG87, GR91a).

6.5 Further research

Further (quantitative and non-quantitative) research is needed in order to promote the procedures to be followed when making policy decisions regarding the insurance benefit package.

First of all, the criteria for solidarity and compulsory insurance will need to be even more clearly operationalized in relation to a number of points.

Second, further research is required in cases where data on individual disease burden or cost-effectiveness are either missing or incomplete. This is particularly important in the case of services that are associated with a large (total) disease burden and a correspondingly great demand for care among the population, whereas cost-effectiveness is still insufficient or else unknown.

Third, methodological research is needed with a view to developing effective decision making procedures in which limit values or thresholds are applied. Non-quantitative methodological research is also required. This means research into the possibilities that exist for reasoned decision-making with regard to application of the criteria.

Finally, further research is needed into incentives of promoting efficient practices among care providers.

Notes

1 The community considers that it has a responsibility (through government) to guarantee everyone a minimum income. Must something similar also apply for matters that affect the citizen's health? Health is no less important than income as a prerequisite for an individual's way of life and participation in society (SEGV01). There is, however, a distinction. No one can ever claim a right to health, since no guarantee can be given that someone will not fall ill. However, it does seem possible to infer a certain right to health care as a *claim* on the community. This right cannot be absolute, but, as was discussed earlier, depends on how responsibilities (and the ensuing duties) are apportioned in the sphere of public health and on the available resources (see also Lee91a, Lee95). No guarantee of health can be inferred here either.*

Government and society should, in principle, do everything possible to eliminate health problems, since health is such a fundamental good that a person's opportunities in life in areas other than health are, in fact, to a considerable extent determined by health. However, doing everything possible is easier said than done. This is dependent upon various peripheral factors, and account must be taken of the fact that the government-espoused objectives of quality, promotion of citizens' rights, accessibility of health care and cost control are not entirely mutually reconcilable. Although they are worth pursuing, these various goals are, in fact, incompatible when taken to extremes. Undesirable effects are inevitable if all of the goals are pursued at once. For example, improvement of quality is not necessarily compatible with the curbing of costs. Equality and efficiency are also difficult to combine. The principle of equality dictates that everything possible should be done to reduce the disparities in the health of the population (in so far as these can be influenced): accordingly, resources should be distributed according to need for care and not primarily according to levels of efficiency. If this latter yardstick is paramount, then only the most efficient forms of care should be utilized. The Health Council discussed the equitable distribution of resources in health care in 1986 in its advisory report entitled 'Limits to Health Care' and argued that efforts should be focused on optimizing (as opposed to maximizing) efficiency in relation to each goal (GR86, Rig86). Recently formulated theories with regard to *fairness in the allocation of resources* suggest that health care is still a somewhat problematic area. Theories of fairness always consist of two elements. The first element is the identification of the good that is to be allocated (the *distribuendum*). The basic *distribuendum* may be a good that cannot be directly distributed, such as well being or health. Whatever can, in fact, be directly distributed (income or health care) must then be distributed in such a way as to bring about the desired distribution of the basic *distribuendum*. The second element is the principle of the desired distribution. If, for example, the basic distribuendum is well being (welfarism), then the principle may prescribe that it should be distributed in such a way that overall well being is maximized (utilitarianism), or equally distributed (egalitarianism), or so that the least well-off benefit most (the 'maximin criterion').

In the wake of the criticism levelled by Rawls, Dworkin and Sen, welfarist theories are now rarely defended in the literature (Dwo00, Raw82, Sen85, Sen92). Since that time, priority has been given to respect for the other person as an autonomous being. This implies that people are themselves primarily responsible for realizing their own well being given the talents and means at their disposal. Shortcomings in this regard should not necessarily be compensated for, since that principle may reward 'free riding' (see also section 5.3).

The most widely supported theory of fairness is currently so-called liberal egalitarianism. According to that theory, the fundamental distribuendum to be equally distributed is 'real freedom', which is under-

* The Committee on Choices in Health Care also stated: 'Health care is no guarantee of good health, but access to necessary care is, indeed, a precondition for minimizing the disadvantages and hazards of disease and impairment' (KIZ91).

stood to mean the total package of talents, resources and opportunities that enables a person to carry out his own autonomous decisions. Health is regarded as an essential component of that package (Dan85).
Here is, however, also a growing and perceptible dissatisfaction over these *monistic* theories (i.e. theories that identify a single fundamental distribuendum and propose a single principle for distributing it). *Pluralistic* theories accept several distributive principles (such as equality, need, fairness in the sense of a prohibition of *free riding*, merit), each with their own sphere of application. However, while some pluralists (Wal83) seek the principle in the sphere of application, others (Mil99) seek the sphere of application in the principle. In the former case, it is essential first of all to determine precisely what is included in the sphere of health care (accommodation and housing would, for example, be excluded), whereas in the latter case all that matters is the degree of urgency. Whether items of equal urgency are brought under the same distribution system or under different systems is a purely pragmatic question.

The theoretical debate alluded to above is of relevance to various controversial questions relating to the basic package. Thus the concept 'quality of life', which is used in determining QALYs (quality-adjusted life years) and other similar measures (see section 5.1.2), is welfarist. The fairness argument* is directly relevant to the debate over the significance of personal responsibility in health care and the question as to whether it is fundamentally important to establish whether or not a service genuinely falls into the category of health care cannot be avoided. The Committee nevertheless believes that there would be little point in it adopting particular standpoints in this theoretical debate. In the first place it must be stated that all theories (with the exception of certain variants of libertarianism that find scant support in the Netherlands since, providing that coercion and deception are avoided, one form of distribution is just as good as another) converge as far as their conclusions regarding health care are concerned. That is, essential care should be accessible to everyone, regardless of his or her purchasing power. However, the theories do not get us much further as far as the central question of what essential care should include is concerned. This observation brings the Committee to the second point. A number of persistent problems recur in all theories. For example, there is the question of whether we wish to spend our resources on achieving a minor health gain in connection with a major disease burden or a major health gain in connection with a minor disease burden, or alternatively, what trade-off needs to be made between the two relevant criteria? Third, because the different theories generate different solutions to some problems, there is little to be gained so long as the conflict between the theories remains unresolved. However, the conclusive argument is as follows. Assuming that a given theory (e.g. liberal egalitarianism) gives rise to a particular principle (such as a strong emphasis on individual responsibility for health). Then, according to prevailing opinion, it is not true to say that the principle derives its credibility entirely from the theory. On the contrary, the acceptability of the theory is at least equally dependent upon the plausibility of the principle. The inescapable conclusion, therefore, is that top-down reasoning (i.e. from theory to principle) should be rejected. We should instead begin directly at the 'intermediate level' (the level of relevant general viewpoints and considerations). This is also generally accepted practice in bioethics (Bea94).

2 Furthermore, certain risks usually prove to be uninsurable in a market of this kind (e.g. the so-called 'burning houses'). This can occur in the case of medical expenses that are extremely likely to be incurred by everyone, or for certain groups of people. Thus many benefits that fall under the AWBZ (Exceptional Medical Expenses Act) (such as long-term hospital care, nursing-home care and care of the mentally handicapped) are probably virtually or completely uninsurable in a free market. This is

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* This means that a person is obliged to adhere to the rules of an equitable 'institution' whose advantages he has voluntarily accepted for himself (see Raw89).

due to the high degree of predictability of anticipated medical expenses and the extremely high costs per event. In conclusion, it should be noted that a free insurance market might have major implications for consumers of care. The setting of premiums can then be expected not to be based so much on the principle of solidarity, but rather to incline strongly towards the so-called equivalency principle. This means that insurers strive to achieve equivalency between the underwritten risk and the premium. The practice of premium differentiation will result in the premiums for some diseases or disease combinations (comorbidity) becoming virtually unpayable.
These problems are becoming still more difficult as a result of the rapid increase in genetic knowledge. In a free insurance market, the insurer would be able to make taking out an insurance agreement conditional upon access being granted to this knowledge. This could once again lead to major premium differentiation, possibly resulting in certain risks becoming uninsurable. However, if the person concerned is granted the right to withhold that knowledge for the above reasons and due to considerations of privacy, then the very foundation of the insurance as risk cover is undermined. An insurance against fire damage would not be possible if all of the people insured were to know from the outset whether or not they will suffer fire damage.
The regulation of the conduct of insurers has already been scrutinized in reports by other advisory bodies and will not receive any further consideration in this report.

3 Empirical research was conducted in the United States in the 1970s and 1980s into the positive and negative effects of personal payments. A particularly well known example was the large-scale Health Insurance Experiment started by the Rand Corporation in the mid-1970s (Man87, New74, New81, New87, Ven83, Wel87). Around 7,700 people under 62 years of age in six US states took part in this experiment. The project ran for 3-5 years and cost nearly $80 million. The insurance coverage encompassed virtually every form of medical care with the exception of non-preventive orthodontics, cosmetic surgery and psychiatric outpatient care involving more than 52 consultations per year. To measure the effects of personal payments, lots were drawn to determine which participants would qualify for policies with and without supplemental payments. The participants were assigned to a total of 15 insurance schemes with varying levels of supplemental payments. The personal payment amounted to 0, 25, 50 or 95% for all insured services, with an upper limit of 5, 10 and 15% of family income up to a maximum of $1,000 per family per year. If they wished, the individuals concerned could forgo further participation in the experiment at any time and revert to their former insurance. However, it was more attractive to remain in the study on account of the financial bonus that participants stood to receive when it finished. Data were gathered at various times during the study with regard to the participants' state of health, their use of services and their level of satisfaction. For example, comprehensive physical examinations were conducted at the start and end of the experiment and participants were required to complete annual health questionnaires.
Publications about the Rand experiment revealed that the personal payments yielded savings, whereas the participants did not, in general, appear to suffer any *serious* damage to their health (Bro83, New81). Reduced use of services was recorded in all branches of health care (Lei85a, b, Loh86, Ogr85, Sha86, Val85): hospital admission, outpatient visits, first-aid care, medication use, preventive care for children and community mental health care. Furthermore, no undesirable substitution effects were recorded. For example, supplemental payments that applied only to outpatient care were not offset by patients being admitted to hospital more often. The results of the Rand experiment clearly highlighted social disparities in disease and health, as well as the income dependency of the effects of supplemental payments on the utilization of care services (Loh86, Ogr85, Sha86). In general, the less well off participants were found to avail themselves of care less frequently than people with higher incomes, in spite of the fact that they were, on average, already in poorer health than the higher-earning group at the start of the experiment. The reduced use of care also applied to acute diseases and preventive care. In the group with the lowest incomes, the recipients of ‘free care’ displayed significantly lower blood pressure read-

ings than the participants who were making supplemental payments (Kee85).
From a health-economics standpoint, the Rand study shows that family spending on health care appears to rise in inverse proportion to personal payments. Average expenditure in the absence of personal payments is 46% higher than that recorded in participants making a 95% supplemental payment. It also emerges that *price-sensitivity* (the relationship between the relative change in demand in response to price, also known as *price elasticity;* this ranges from –1 for price-sensitive products to 0 for price-insensitive products or care services) differs for non-residential care against hospital care (Bri01, Zwe00).*
The following are among the conclusions drawn from the findings of the Rand experiment (Ven93, VVW92).
Personal payments notably lead to a reduction in the number of disease episodes for which medical assistance is sought, but hardly to fewer consultations and procedures per treated episode. In particular, medical care is less frequently sought for less serious symptoms. Finally, the reduced use of care as a result of personal payments does not, in general, have any adverse health effects, but this appears not to apply in the case of people with a low(er) socio-economic status.
Other studies in addition to the Rand experiment have been conducted in the US. A study involving around 4,500 US senior citizens showed that health-care expenditure rose in a quantitative and qualitative sense in people with lower personal payments (Car92, Jeg99). Not only was more care provided, but that care was also more expensive.

4 An overview concerning the use of personal payments in 19 West European countries revealed that in virtually every country there is a supplemental payment for some or all medicines (Sal97). Furthermore, around half of the countries have personal payments for primary care and hospital care. In Belgium and France, for example, personal contributions (usually amounting to around 40%) are required for virtually all benefits (Jeg99, Bri01, VWS01b). To ensure that care remains affordable and to avoid putting individual health at risk, the Belgian government has imposed an income-dependent maximum ceiling of 3 to 4% of an individual's income on personal payments. The less well-off are also granted a substantial reduction (50% or more) in their compulsory personal payment. No ceiling is imposed for personal payments in France. However, the majority of people have their personal payments reinsured. Research in both countries into the effects of personal payments reveals a variable picture. Patient visits to GPs in Belgium fell by 1.4% following a 10% increase in the supplemental payment. In France, higher personal payments did not result in a marked fall in the consumption of non-residential care, with the exception of the number of home visits by GPs (Chi98). The explanation may lie in the fact that France allows reinsurance of supplemental payments whereas this practice is prohibited in Belgium (Bri01).

5 In the 1980s the Dutch government conducted a two-pronged experiment with personal payments for medication and referral to specialists. Both measures were soon abolished again owing to opposition from health-care professionals and failure to achieve the desired effects.
Several years ago, researchers studied the effects of the General Personal Contribution (AEB) Scheme, which was introduced in early 1997 and repealed two years later (Del99). The AEB initiative required national health-insurance scheme members to pay a personal contribution of 20% of the costs of certain items such as specialist assistance, medicines and physiotherapy, as well as a personal payment of

* In the case of a supplemental payment of between 0 and 25%, elasticity in both cases amounts to –0.17, but above 25%, elasticity is –0.14 for hospital care and –0.31 for non-residential care. This means, for example, that an increase in the personal payment from 25 to 35% would reduce the consumption of hospital care by 1.4% and that of non-residential care by 3.1%.

EUR 3.60 per day for admission to hospital. This was all subject to a ceiling of EUR 90 (benefit claimants and senior citizens: EUR 45) per principal insured person per year. GP services were not included in the scheme. The researchers found that the measure had only minimal effects. This was, to some extent, to be expected, since the personal payments and the adopted ceilings were, after all, relatively limited. However, the measure provoked anxiety in some insured people. Among this section of the population, the fear of reduced access to necessary care resulted in a reduced use of medicines. In addition, the less well off were found to be more inhibited in their use of medicines than people with higher incomes. A surprising finding of the evaluation study was the fact that national health-insurance scheme members had begun to make greater use of physiotherapy services since the introduction of the measure. The researchers concluded that personal contributions as low as those adopted in the AEB scheme (which also only applied to 'follow-up consumption' and not to directly accessible care) have so little effect that the costs of implementing such a measure exceed the benefits (Del99).
Furthermore, Dutch experts have conducted a systematic analysis of the observed effects of personal payments in the period from 1983 to 1995, based on 35 foreign publications (Sta99). The specific aim of the study was to establish what form of personal payment is most effective if the desired effect is a reduction in *moral hazard* (the phenomenon whereby consumption increases in the presence of insurance cover). The analysis showed that many factors influence the direction or magnitude of a perceived 'personal-payment effect' (notably the level of the personal payments, but also the type of care services involved). The researchers noted that a personal payment for non-clinical care tended to result in a greater reduction than a supplemental payment for clinical care. Expenditure on non-clinical mental health care and non-clinical dental care were found to be especially sensitive to supplemental payments. The most effective combination identified by the analysis, as far as reducing moral hazard is concerned, was a compulsory supplemental payment of 50% combined with a family income-dependent ceiling of 5%, without the possibility of supplemental insurance. In both high and low income groups, this form of supplemental payment led to a fall of around 25% in total health-care expenditure, while no generally identifiable detrimental health effects were observed. In another Dutch-based analysis, based on the Statistics Netherlands (CBS) Health Interview Surveys (1990-1994), researchers have made micro-econometric estimates of the effects of personal payments on medical expenses (Vli99). A comparison was made here of the use of care (general practitioner, specialist, hospital, medicines, dentist and physiotherapist) by groups of people with and without personal payments. To estimate the effect of a supplemental percentage payment, the consumption of care by national health-insurance scheme members was compared with that of people insured under public law (who make a percentage supplemental contribution subject to an income-dependent upper limit). Following correction for disparities in background characteristics such as health and income level, no statistically significant difference in consumption was identified for the forms of care examined. To estimate the effect of basic excess, the researchers studied the consumption of care of privately insured people with varying levels of basic excess. Except in the areas of dental care and hospital care, they discovered a modest negative effect for the types of care examined (the price elasticities varied between –0.062 and –0.021). The researchers determined that the effect of basic excess on total costs is significantly negative, but relatively small in that an increase of 10% leads to a 0.35% reduction in medical expenses (Vli99).
Finally, in 2001, based on the CBS Health Interview Surveys (1989-1994), a second analysis (with a different study design) was made of the relationship between personal payments and consumption for the aforementioned six forms of care (Ras01). The analysis shows that price has a modest (but significant) negative effect in the case of the majority of services (the exceptions being hospitals and specialists). In the case of medicines and hospitals, there is a significant correlation between the type of insurance and consumption in that a national health-insurance scheme member consumes more than another insured person who is identical in respect of all other characteristics.

6 The policy document cites the various follow-up reports by the former ZFR*, noting that work on the 1993 list took no less than seven years to complete. This long period was attributed largely to the length of the list, the complexity of the issues involved and the long lead time required for (patient-based) research. The Minister found that the results compared favourably with the '126 List' and declared that, partly as a result of the ZFR follow-up reports, a process had been set in motion within the medical and paramedical professional groups aimed at achieving rational and economical delivery of health care. She referred to the development of standards, protocols and guidelines that, after close consultation between the relevant parties, have culminated in definitions of 'appropriate use' of care. Finally, the Minister emphasized the fact that, alongside the development and drafting of guidelines, explicit consideration must be given to the *implementation* of research findings and guidelines, a process that should ultimately lead to significant changes in everyday practice (VWS99). The Health Council published the advisory report *From implementation to learning* on this topic (GR00).

7 Broadly speaking, two distinct positions can be identified among the philosophical and ethical theories that have been formulated on these concepts.
The classic economic interpretation, whereby a person's well being is equated with the fulfilment of his personal preferences, has, generally speaking, been abandoned. Problems encountered with this approach include preferences that are founded on erroneous information and 'adaptive' preferences (the 'sour grapes' syndrome). According to a modified form of the classic interpretation, someone's well being can be equated with the fulfilment of the preferences that he/she would have if he/she were absolutely rational and fully informed about the relevant facts ('laundered preferences'). Because this is a condition that cannot, in fact, ever be fulfilled, however, this interpretation of 'well being' is difficult to operationalize.
The alternative, and possibly equivalent, approach attempts to formulate a list of essential components of the 'good life'. Martha Nussbaum, for example, in her 'Thick vague theory of the good' presents a list of ten 'basic human functional capabilities', such as 'being able to use the five senses, being able to imagine, to think, and to reason' and 'being able to laugh, to play, to enjoy recreational activities' (Nus92). Her list is controversial. Can something be removed or should something be added? As she herself concedes, each of the elements is vague. Moreover, it is difficult to assess the relative merits of all of these items. This does not mean, however, that a comparative assessment of well being cannot be explicitly justified. It simply means that that justification cannot take a *top-down* form, starting from a pre-established list of relevant dimensions and a scoring register.
It would be preferable to adopt a *bottom-up* approach to such a justification, by asking a panel of experts (and, if necessary, laypersons) to give their assessments of the disease burden arising from a particular disease or impairment (together with explicit supporting data, where possible). This also has a major bearing on the transparency of the decision-making. It is scarcely acceptable for a patient with a disease that does not qualify for reimbursement to be given no other explanation than the fact that a panel of experts did not deem his condition to be sufficiently serious.

8 Extra attention has been focused in recent years on the issue of avoidable disease and mortality in hospital care (Gia01, IOM99, Hay01, Gra98, Mol99, Sox00, Vin01). Researching medical shortcomings is no simple matter. Quite apart from the problem of definitions, the task of demonstrating causality or

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* In its 1999 report 'Gewikt en gewogen' ('Weighed and Weighted'), the ZFR names 31 promising initiatives seeking to improve efficiency within social health insurance (ZFR99). Among the initiatives spawned by the '31 List' were advice issued by the RGO on the prioritization of efficiency research (RGO99, RGO01) and the programming of such research (e.g., the work currently being undertaken by the Netherlands Organization for Health Research and Development (ZonMW)).

errors poses complex methodological problems. For example, the clinical outcome that can be achieved in a given patient is to a great extent determined by his/her initial health state and by prognostic factors. Vulnerable patients usually stand less chance of achieving a favourable treatment outcome than more healthy patients. It can therefore be misleading to assess outcomes without first correcting the position at the outset. After all, the outcome is then more indicative of the patient's initial state of health than of the care that has been provided (Dav96, Tre99). Depending on what definition is adopted, mistakes (whether major or minor, avoidable or unavoidable) can be made in everyday practice. Doctors are not infallible (Gia01, Hor01). This does not alter the fact that serious errors can be identified and prevented through the adoption of a systematic approach, for example through targeted quality control of the care process and evaluation of the care that is provided by means of outcome indicators (Hem94, Mol99, Rou96, Tre99).

9 Efficiency is a widely used term, especially in policy making circles. Policy makers view the improvement of efficiency as an important lever for curbing macro-costs in health care. In the 1990s there was a growing realization that improvement of efficiency is not only a useful tool in relation to medical treatment, but that it can also prove particularly fruitful with regard to the organization of care (GR89, GR91a, MCZ94, MGS99, SFG87, Spr98, Rut01). The Committee shared this opinion. It also noted that, compared with other European countries, the government in our country actually made an early start (in the 1980s) on the task of promoting efficiency research (Ban95, Boe99, Boe02, VWS95b). It is partly with this in mind that the medical and paramedical professions are making increasing efforts to draw up and update *evidence-based* protocols, guidelines or standards, geared toward the efficient delivery of health care (GR00). Nevertheless, such tools are still not available for many services. From this standpoint, there is still a long way to go. Although we have in our country now gathered around 15 years experience with efficiency research (a key form of HTA activity), it is not clear to what extent the resultant changes in medical and paramedical treatments have led to substantive control over the macro-costs in health care.

10 The Committee on Choices in Health Care has already noted that blood and organs are donated in our country without any reward, and in a spirit of humanitarian solidarity (KIZ91). It acknowledged the fact that a moral appeal can rightly be made for reciprocity, but a majority of its members believed that the quid pro quo must be voluntary. The Committee declared that neither coercion nor pressure is called for, let alone making blood transfusion or organ donation dependent upon a similar quid pro quo. Our Committee endorsed this view, but was eager to point out that the increasing scarcity of certain services is imposing pressures on the opinion-forming process. For example, the dearth of donor organs in European countries (this applies especially to kidneys, livers, lungs and hearts) has recently prompted German authors to call for the principle of reciprocity to be applied in the Eurotransplant organ allocation system (Gub00). They propose that an individual's *willingness to donate* should be recorded and taken into account at a later stage when allocating any donor organ that may become available at the time that the person concerned himself has need of an organ. Willingness to donate could then be used as an extra allocation criterion alongside such considerations as blood group, tissue characteristics (HLA factors), distance from the transplantation centre and waiting time. Those who have not in the past registered as donors are then placed somewhat later in the queue than those who have done so. The study's authors claim that this demand-side health-care incentive could alleviate the growing shortage of organ donors. The debate over this proposal has yet to crystallize (Daa00, Sel00, Til00).

11 It appears appropriate to take an extra critical look at efficiency in relation to care services in the sphere of primary and secondary prevention, since these are services that are offered to usually healthy, symptom-free individuals. The disadvantages may outweigh the advantages. For the individuals concerned,

the preventive measures can prove stressful and may entail risks that outweigh any health gain. In population screening (a form of secondary prevention), for example, a moderate-quality screening test that carries a considerable risk of false-positive results can give rise to unnecessary, large-scale anxiety or to fear in the individuals concerned.
There is also a risk that large numbers of people will be subjected to follow-up testing and sometimes even invasive procedures. In the case of vaccination (a form of primary prevention), there is sometimes a risk (it is in most cases, fortunately, extremely remote) of serious adverse events. Moreover, there is a feeling that preventive services can usually yield a far greater efficiency gain than curative measures. The axiom 'prevention is better than a cure' also appears to apply here in an economic sense. It is better to spend a limited amount now than a large amount later. However, the potential efficiency gain is highly dependent on the method of discounting that is used. The objection has been raised that applying the same discount rate to effects and costs would lead to a systematic and wrongful under valuation of the efficiency of preventive interventions. The extent to which effects and costs should be subject to different discounts remains a topic of discussion in the literature (Nee03).

12 The second Kok government rejected the creation of different packages in the policy document *A Question of Demand* (VWS01a).* Two arguments are advanced for dismissing this option. The first is that such a distinction would undermine solidarity. This would, however, only be correct if the broadest package were not to be subject to a duty of acceptance and if the setting of the premium for that package were to be left entirely to the marketplace. We do, of course, need to avoid a situation in which people with lower incomes opt for the narrower package for financial reasons, in spite of the fact that the broadest package is financed in accordance with the principle of solidarity. This problem can be overcome through careful application of the criteria for compulsory insurance (giving due consideration to the income of the person concerned). The second argument advanced by the Kok government was that an increase in the number of choices available to the public does not promote the transparency of the system. This is, in itself, both correct and relevant, but the Committee believes that if the choice is between only two (rather than a large number of) packages, then this transparency does not need to be jeopardized.** The Committee noted that the present system of health insurance is already implicitly based on a distinction between motives for solidarity and motives for a compulsory health insurance provision (paternalistic grounds, also called the 'merit good' argument, control of external effects, combating 'free riding'; see section 5.3). The application of criteria in respect of free riding has led regulators to make the health fund insurance compulsory for the lower income groups, but not for the highest earners. As far as the highest income groups are concerned, there are evidently reasons for compulsory solidarity. Under the Access to Health Care Insurance Act (WTZ), high-risk privately insured people – including those aged 65 and over – enjoy statutorily guaranteed access to the WTZ package (comparable to the health-insurance fund package). Private health insurers are subject to a statutory duty of acceptance under the WTZ and a statutorily established maximum WTZ premium. This is set far below the cost price. The losses are offset via compulsory statutory solidarity levies (the so-called WTZ levy) that are to be paid by the remainder of the privately insured population. High-risk privately insured individuals are *not* obliged to take out the WTZ policy. For reasons of solidarity, however, they enjoy statutorily guaranteed access to the subsidized WTZ policy.

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* According to a legal study carried out on behalf of the Association of Insurers (VvV02b), the Social and Economic Council (SER) advisory report is more compatible with European law than the proposal advanced in the policy document *A Question of Demand* (VWS01a).

** According to the Committee, this problem will only truly arise if citizens are able, as proposed by the SER (SER00), to opt for several variants that lie in between the two packages.

13 This applies, among others, to the measures of health that have been devised for mortality and morbidity, the QALY and the DALY, which are applied above all in determining effectiveness and cost-effectiveness: To what extent is disease burden reduced and at what costs? For various reasons (both conceptual and scientific), these measures of health are not completely perfect and therefore require prudent use. For the time being, it will sometimes be necessary to revert to more direct, clinical measures of disease burden. Indeed, the situation is only relatively straightforward with regard to mortality (or life span), where it is possible to look at the number of life-years gained or lost. For morbidity, it is more difficult to give generally applicable, 'standard' clinical measures of disease burden. It will then be necessary to choose suitable measures for the disease in question (e.g., length of hospital stay or disease-free period).

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A Request for advice

B The Committee

Annexes

Annex **A**

Request for advice

On 27 February 2001, the President of the Council received a letter from the Minister of Health, Welfare and Sport (reference PTZ/2153079), from which the following extract is taken:

The August 1998 cabinet policy programme provides for a review of whether, in the longer term, it is desirable in the light of the greying of the population and other developments to make more far-reaching adjustments to the insurance system, giving consideration to systems and developments in other EU countries. In the 2001 budget document on health care (*Zorgnota*), I subsequently stated that the cabinet was proposing to lay the foundations for a reform of the insurance system over the next two years.

It is my intention to bring about more demand steering in health care, to increase the emphasis on client-centeredness, and to extend the freedom of choice for care-users by varying the range of services on offer.

I am currently preparing a letter for presentation to the cabinet with regard to the future organization and funding of health care. It is my aim to ensure that Parliament is duly informed on this issue before the summer of 2001. In this letter I shall be referring to various reports and advisory reports, some of which have already been published. Recent reports include Public Health Care (1997) by the WRR, Europe and Health Care (1999) by the RVZ, Division of Roles (2000) by the RVZ, Care and Cure (2001) by the RVZ, Health Care in the Netherlands for an Ageing Population (1999) by the SER, Towards a Sound System of Medical Insurance (2000) by the SER, the Netherlands in Europe (2000) by the SC, and The Basic Package: Content and Borders (2001) by the CVZ.

The debate over the future of the Dutch health-care system can be expected to address the following three main issues:

- the insurance system (statutory reframing)
- the content and scope of the insurance package
- the steering model.

I would like to draw your attention to the second point. Here the debate will address the question of what precisely needs to be insured. What forms of care should a basic package include? Further to the WRR advisory report on Public Health Care (1997), I would therefore welcome your views on the workable, scientifically based criteria that need to be applied in order to identify which care services are to be included in a basic package. As far as policy is concerned, the question is not so much "what could potentially be removed from the package?" but rather: "which services will definitely need to remain part of the insurance package in the future?" In this connection, I would also like to hear your opinion regarding the possibility of using the efficiency criterion to determine the composition of a basic package.

The Minister of Health, Welfare and Sport

(signed) Dr E Borst-Eilers

Annex **B**

The Committee

- JP Mackenbach, MD, PhD, C*hairman*
  Professor of Social Health Care; Erasmus University, Rotterdam
- M Boers, MD, PhD
  Professor of Clinical Epidemiology, rheumatologist; Free University, Amsterdam
- I de Beaufort, PhD
  Professor of Medical Ethics; Erasmus University, Rotterdam
- E Briët, MD, PhD
  Professor of Internal Medicine, member of Board of Directors; University Medical Centre, Amsterdam
- HJM Cools, MD, PhD
  Professor of Nursing-Home Medicine; University of Leiden
- R van Dyck, MD, PhD
  Professor of Psychiatry; Free University, Amsterdam
- GA den Hartogh, PhD
  Professor of Philosophy; University of Amsterdam
- ALM Lagro-Janssen, MD, PhD
  Professor of Family Medicine/Women's Studies; Catholic University of Nijmegen
- J Ormel, PhD
  Professor of Social Psychiatry; University Hospital of Groningen
- E van der Veen, MSc
  Chairman of the Board of Directors; AGIS Group, Utrecht

- AHJ Veneman, MD
  Corporate health adviser; AKZO-Nobel, Arnhem
- WPMM van de Ven, PhD
  Professor of Social Health Insurance; Erasmus University, Rotterdam
- SP Verloove-Vanhorick, MD, PhD
  Professor of Preventive and Curative Health Care for Children; University of Leiden
- EA Bolhuis, MSc, *adviser*
  Director, MEVA Directorate; Ministry of Health, Welfare and Sport, The Hague
- GGJ Klein Ikkink, MSc, *adviser*
  Director, Projectbureau Toekomst Zorgstelsel, MEVA Directorate; Ministry of Health, Welfare and Sport, The Hague
- A Boer, MD, PhD, *adviser*
  Deputy Director, Health Care; Health Care Insurance Board (CVZ), Amstelveen
- GHM ten Velden, MD, PhD, s*ecretary*
  Health Council of the Netherlands, The Hague