

# **Appropriateness and Efficiency**

**Bonn 2001**



**ADVISORY COUNCIL  
for the Concerted Action  
in Health Care**

**Appropriateness and Efficiency**

**Volume I**

**The Formulation of Aims, Prevention, User Orientation and Participation**

**Volume II**

**Improving Quality in Medicine and Nursing**

Report 2000/2001

Summary



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## Preface

1. In May 1999 the Federal Ministry of Health commissioned the Advisory Council for Coordinated Action in Health Care with the preparation of a special report for improving management in the health care system. The report was to focus on quality assurance and new forms of health care finance, the role of health care targets, prevention, the competence of the insured and the role of primary care. In February 2000, based on the re-definition of the tasks of the Advisory Council that went into effect in January 2000 (German Social Code, Book V, §142), the Minister of Health freed the Advisory Council from the tasks and deadlines as specified in May 1999. Furthermore, the Minister left it to the discretion of the Council to integrate elements of the original special report into the regular report dealing with issues of unnecessary care, shortages in the health care system, inappropriate care and with opportunities for improving the utilization of existing facilities as a means for ensuring the appropriateness of care as called for by §142 of the German Social Code, Book V.
2. As called for by law, the Council integrated elements of its original special report on the formulation of health care objectives, prevention, user focus and user participation as well as on improving quality in medicine and nursing into the new report. Following a practice introduced in 1996 and 1997, these reports were published in two separate volumes. The Council will present a third volume in the Spring of 2001. All three volumes will be published under the general heading “Appropriateness and Efficiency”.
3. In the first volume, subtitled “The Formulation of Goals, Prevention, User Orientation and Participation”, the Council presents in Chapter 1 its position on the need for a stronger goal-orientation in the German health care system. The Council calls for a political and public discourse in Germany on the explicit goals of health policy that goes beyond the cost-containment debate of the past 25 years (an issue that was also dealt with in the Council’s Special Report published in 1997). In the Council’s view, such discourse is a central prerequisite for measuring the success of health policy instruments and evaluating health care delivery in general. The creation of an awareness for health objectives can also help coordinate the actions of stakeholders and individual actors in the health care system with the common values and processes of the health care system.

Chapter 1 also deals with the integration of improved health monitoring in the health care system and its contribution to increasing transparency and to the rational discussion of controversial health policy issues.

The Council also evaluates data on health status and on international comparisons of health care expenditures in this chapter. As revealed in the recently published report of the World

Health Organization “World Health Report 2000”, which created some controversy in Germany, the analysis of the Council concludes that Germany has only a mediocre ranking among industrialized countries with respect to life expectancy and life years lost, despite clear improvements in the past. Furthermore, Germany’s ranking is worsened by the comparatively high level of health care expenditures. The Council views this as an indicator for considerable structural deficits in the allocation of health care resources in Germany and therefore calls for continued improvements in the quality of health care delivery and prevention.

In the discussion of objective and subjective health indicators as well as in the formulation and implementation of health targets the Council places special emphasis on the integration of stakeholders and the preferences of the general public in the formulation of health policy objectives. The chapter also deals with the functions of health policy objectives in the context of European experience.

In the analysis of the effects on health status that can be ascribed to health care in the strict sense, the Council points at the end of Chapter 1 to the endogenous determinants of the health care system as well as to the role of exogenous factors in other policy areas.

4. Chapter 2 deals with the optimization of the health care system through health promotion and prevention. The Council calls emphatically for more prevention as a valuable and necessary investment in the future. In addition to the examples of dental health and vaccinations for children, the Council notes that prevention also has considerable potential in the health care of the elderly; a potential that can be quickly mobilized but which has been neglected in the past.

Based on the analysis of the endogenous and exogenous determinants of health status presented in Chapter 1, the Council points out that the effect health care in the strict sense on indicators such as life years lost is only 10-40 percent. The Council therefore calls for a new focus of prevention that is based on an intersectoral approach which goes beyond the health care system and includes educational policy, wealth policy and incomes policy as well as labor, transportation and environmental policies.

In light of the amended version of § 20 of the German Social Code, Book V for the re-introduction of prevention in the Social Health Insurance (SHI) system and the high expectations associated with this change, the Council analyzes quality assurance and quality management in health promotion and prevention with particular reference to the legal mandate of the Social Health Insurance Funds to reduce socially determined differences in health status.

In a separate section, the Council elucidates approaches to improving prevention in the treatment of patients and existing quality deficits and hurdles to progress in this area, in particular in the primary care sector. The Council views the role of the general practitioner as particularly important for the appropriate development of preventive measures. However, there are considerable deficits in the promotion of practical measures and research as well as in the undergraduate education, residency and continuing education of doctors.

5. For the first time, the Council has dedicated a separate chapter to the users/clients of the system. This group includes the general populace, the insured and patients, all of whom play different roles with respect to the health care system. With their knowledge, predilections and user behavior these groups represent a central but largely ignored determinant of processes in the health care system and their outcomes.

The Council considers the improvement of the competence of users/clients through increased information and transparency as an important health policy objective. The required scope and quality of the information as well as ensuring adequate access to the information are currently being debated and should be subject to more general debate.

The Council calls for the increased participation of users on the basis of expanded rights to information, participation in hearings and active participation in the decision-making bodies of the health care system. The Council proposes a more detailed analysis of the means for allowing the direct participation of users in decision making processes.

6. Volume II is entitled "Quality Development in Medicine and Nursing". In the first chapter, the Council expresses its belief that the undergraduate education, residency and continuing education of doctors as well as the education and training of the paramedical professions are essential elements of the "quality culture" in the health care system. In particular, the Council advocates the introduction of re-certification procedures for medical specialists in Germany on the basis of practices in other countries.
7. The second chapter of Volume II provides an overview of the concepts, methods and instruments of quality assurance and quality management. The Council views quality management procedures as a "secondary technology" that, like the primary technologies of diagnosis and therapy, must be subject to an assessment of its desired and undesired effects as well as of its costs prior to and during implementation (evaluation). In this context, the Council discusses the chances and limits of evidence-based medicine in the "gray areas" of medical decisions.

The Council provides a detailed review of the development, implementation, quality and evaluation of evidence-based guidelines. These are playing an increasingly important role in

the German health care system as well as worldwide. In the view of the Council, evidence-based medicine has considerable potential for the development and management of the health care system. However, its effects hinge on the quality of the guidelines.

8. In the Chapter 3 of Volume II, the Council describes its position on issues of quality management in the provision of health care by general practitioners and medical specialists. The Council emphasizes the need for targeted, user-oriented and problem-focused quality-based measures that are selected and applied on the basis of the framework in which care is provided. The Council also stresses the need for quality management approaches that transcend professional, institutional and sectoral boundaries.

Furthermore, the Council provides a detailed analysis of those aspects of the patient-doctor relationship which are often neglected but important from the quality management perspective.

A considerable part of this chapter is dedicated to issues of quality management in nursing. These issues are particularly relevant due to public discussions of quality deficits in this sector.

In light of the Council's demand in Chapter 3 of Volume I for a reinforcement of user competence based on increased information and transparency, the Council calls on policy makers to publicize the results of external quality assurance measures (e.g. obligatory performance reports). The Council also proposes linking such requirements to the pending legislation for the improvement of data transparency in the Social Health Insurance system. This would provide important incentives for focusing public debate on quality and for quality-oriented competition in the health care system.

9. The final chapter of Volume II deals with the new hospital reimbursement system which is based on diagnosis related groups (DRGs). The Council discusses the potential of the new reimbursement system as a means for improving efficiency, but also points to possible false incentives, especially with respect to the threat of quality reductions due to cost pressures. Therefore, the Council calls emphatically for a binding, transparent and user-friendly quality culture in German hospitals.

Based on trends in other countries, the Council points out that the new reimbursement system can be expected to lead a reduction in hospital length of stay. This will increase the burden on post-hospital care, both in the inpatient sector (e.g. nursing homes) and in the ambulatory sector (private practices and home care). These facilities must be developed to ensure a smooth transition from one sector to the next and to maintain and improve the quality of

care. The repercussions of the new system of hospital reimbursement on post-hospital care are not yet fully appreciated in Germany.

The Council also discusses basic problems and specific problems associated with the decision to apply the Australian system for DRG classification and provides a theoretical analysis of the incentives associated with the new reimbursement system and its implementation.

10. In the course of preparing and compiling the first two volumes, the Council conducted numerous discussions and received valuable assistance from many individuals. The German Ministry for Health was always an important source of expert information. In particular, the Council would like to thank Dr. Reinhard Busse, M.D., Escuela Nacional de Sanidad, Madrid, Dr. Norbert Donner-Banzhoff, M.D., Marburg University Hospital, Dr. Annette Güntert, M.D. and Martina Busch, German Medical Association, Dr. Elke Jakubowski, M.D., M.S.P., World Health Organization, Copenhagen, Dr. Thomas Lichte, M.D., Medical Association of Lower Saxony, Prof. Dr. Thomas Löscher, M.D., Ludwig-Maximilians University, Munich, Prof. Dr. Dr. Günter Ollenschläger, M.D., German Agency for Quality in Medicine, Cologne, Prof. Dr. Hagen Sandholzer, M.D., Leipzig University Hospital, Dr. Angelika Schreiber, M.D.D., M.S.P., Berlin, Prof. Dr. Dr. Alf Trojan, M.D., University Hospital Eppendorf, Hamburg, Dr. Christian Festersen M.D., Association of German General Practitioners – House Doctors Association.

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The Council is responsible for any mistakes and flaws in the report.

Bonn, December 2000

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# **Volume I: The Formulation of Aims, Prevention, User Orientation and Participation**

## **1. Increasing the Focus on Health Care Objectives**

### **1.1 The need for increased focus on health care objectives**

1. The German health care system suffers from a lack of orientation with respect to explicit health care objectives. As a result, health policy discussions tend to emphasize expenditure issues. This narrow focus on the resources that flow into the health care system is also reflected by the fact that an indicator of input – the concept of stable health insurance contribution rates – was written into social security law as a basic principle of health care policy. As a result of this narrow perspective, most health care reforms are reduced to pure cost-containment exercises.

The focus on expenditures could and should be met with a broad public discussion of goals that questions the desired indicators of outcomes and the goals of the health care system. Since health care policy shies away from the explicit definition of priorities and main areas of action – which, under conditions of scarcity, always implies a ranking of priorities according to their importance – it usually exhausts itself in the continuation of the existing and sometimes outdated, i.e. inefficient and ineffective, structures. The corporatist structure of the German health care system, which undoubtedly has advantages over the alternative modes of co-ordination based on free markets or on government control and administration, favors the status quo and thus the inertia of existing structures. A critical deficiency of an approach that focuses solely on expenditures is that it does not allow for an analysis of the efficiency and effectiveness of health care.

2. The Council hopes in particular that a focused discussion of health policy objectives that is given the same importance as the analysis of health care expenditures – the necessity of which remains undisputed – will fulfil the following functions:

- increase the awareness of objectives,
- derive concrete objectives for health care delivery,
- identify explicit areas of action and priorities for defined time periods,
- provide guidance for health policy measures and programs,
- create a basis for assessing the success of measures,
- initiate learning effects for future health care policy,

- improve health monitoring,
- provide a rational basis for health care policy controversies,
- increase transparency in the health care system.

3. A detailed analysis of health policy objectives entails the development of an approach for the formulation of concrete, indication-based goals for the provision of health care. However, the rational derivation of health care objectives requires well-founded epidemiological studies, health economics studies and intensive research of health care delivery. In comparison to other countries, Germany has considerable deficits in this area. In its earlier reports (Special Report 1995, par. 327-342; Special Report 1997, par. 196-216) the Council therefore recommended the cooperation of health insurance funds and researchers for the analysis of specific clinical research issues. The Council wished to ensure the participation of health insurers in the choice of topics, in project decisions and above all in the funding of research that is of particular interest to the health insurers. The Council therefore welcomes the agreement between the responsible federal ministries and the national associations of the health insurance funds concerning the first projects for health care research. However, in view of the immense tasks remaining in health care research, the agreed volume of funding is much too low: The most pressing tasks in this area will require much more financial effort. The Council's analysis of excessive, inadequate and inappropriate care document the obvious lack of valid data.

4. Essential for the formulation of objectives is that all those who must implement the accompanying measures on a day-to-day basis are in a position to make the necessary changes to their activities; i.e. they must be provided with the necessary information, participate in the decision-making process, receive requisite training and when necessary, have incentives and financial discretion to modify their behavior. This is an extremely complex undertaking, especially for broad national objectives. A solution to such problems could be to concentrate on a few important objectives that are urgent and associated with considerable benefits and then gradually introduce further objectives.

5. Whether objectives must be quantitative and measurable depends on their function. If the focus is on the political awareness of problems, then the type of definition and the quantification and measurability of objectives must be assessed differently than when specific changes in health care delivery or the prevention of defined risks and diseases are targeted. However, the focus on a few, precisely defined objectives will also fragment public opinion. It will be necessary to find the proper balance between general, "inspirational" and concrete objectives in the sense of planning goals, as well as between short-term and long-term objectives and the "optimistic" or negative contents of goals. It would be helpful to increase the exchange of ideas and experience with respect to these numerous political and methodological issues across Europe

and with countries that have experience in the formulation and implementation of health objectives.

Such an exchange should include benchmarking or best practice approaches, which could motivate other countries, regions or municipalities.

The World Health Organization (WHO) and the European Union (EU) as well as other interested national governments in Europe should promote networks and working groups. Some groups should have a political focus and some should deal with managerial and technical issues.

**6.** The lack of an orientation towards goals or outcomes is reflected in health monitoring. Compared to the many monetary and physical inputs in the provision of health care, official statistics still neglect measures of outcome. The increased focus on objectives gives rise to additional demand for data. Official statistics can and must be based on the needs of health policy. Furthermore, valid data on indicators of outcomes can provide a basis for benchmarking between countries, regions, gender, age groups and social classes. The benchmarking of outcome indicators is particularly useful in the more detailed research of hypotheses on the efficiency and effectiveness of the provision of health care for specific diseases. However, due to the complex nature of health care and the exogenous inputs that determine health outcomes – e.g. transportation, education and working and living conditions – it is often not possible to reach clear deterministic conclusions, but only to identify tendencies in the health care system.

## **1.2 Objective and subjective health indicators as models**

**7.** An international comparison of health care spending in 1997 revealed that Germany has the third highest pro capita expenditures on health in the OECD countries following the USA and Switzerland (Table 1). In terms of the “health care spending ratio”, i.e. the share of total health care spending in gross national product, Germany is in second place behind the USA. In an international benchmarking of indices of life expectancy and life years lost for 14 countries at comparable stages of economic development, however, Germany is ranked below average. In view of the differences in health status and in the condition of the health care systems in these countries at the end of WWII, the absolute level of these indicators is not as useful as the level of their growth rates. With respect to the rate of change in remaining life expectancy (Figure 1) and in life years lost over the periods 1960 – 1996 and 1962 – 1992, Germany is above the average of the 14 countries but not among the first three.

**8.** Life expectancy and life years lost are valid and relevant indicators of outcomes but reflect only a limited number of health care policy goals. For example, they do not reflect distribution

issues (differences in access to health care and in the results of health care) nor the many aspects associated with the quality of life. In its *World Health Report 2000*, the World Health Organization (WHO) chose a relatively comprehensive approach to the evaluation of the current status of the health care systems of its member countries. Although the WHO approach has some serious drawbacks with respect to its substance and methodology, the study's conclusions with respect to the chosen indices and performance of the German health care system are similar to those of a simpler comparison based on the outcome indicators of life expectancy and life years lost. To put it mildly, the results provide absolutely no support for the popular belief in Germany that Germany has "the best health care system in the world". It is interesting to note, however, that the German health care system has a better ranking with respect to the attainment of objectives than with respect to overall performance, which includes resource utilization as a basis for assessment.

9. Regardless of the many substantive and methodological inadequacies of international comparisons of health care systems, the results indicate that Germany is slightly better than average with respect to the attainment of health care objectives. However, it consumes an inordinate amount of resources to reach these goals. At a theoretical level, this indicates that there must be a considerable potential for rationalization. In this context, the legal mandate of the Council to identify unnecessary, inadequate and inappropriate care gains more relevance for health policy making. The likely increase in the liberalization of the European health care markets is likely to increase competitive pressure on health care providers both with respect to quality and efficiency. However, this process of liberalization will not require a harmonization of the health care systems of the member states and, in fact, is unlikely to make such harmonization expedient.

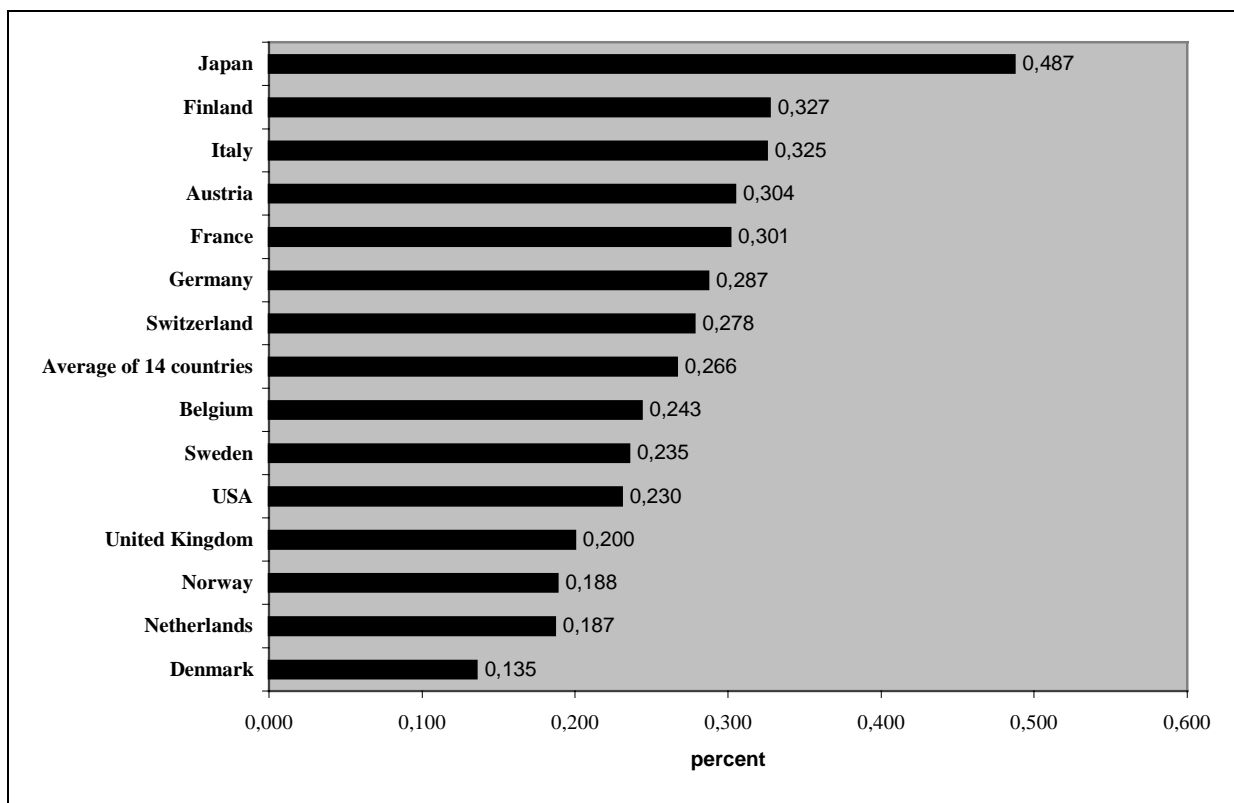
**Table 1: The development of per capita expenditures on health in different countries <sup>a)</sup>**

<b>Country \ Year</b>	<b>1960</b>	<b>1970</b>	<b>1980</b>	<b>1990</b>	<b>1991</b>	<b>1995</b>	<b>1996</b>	<b>1997</b>
<b>Australia</b>	94	207	663	1320	1403	1778	1874	1909
<b>Austria</b>	64	159	663	1205	1270	1675	1773	1905
<b>Belgium</b>	53	130	578	1247	1381	1698	1725	1768
<b>Canada</b>	109	262	716	1695	1833	2106	2109	2171
<b>Denmark</b>	67	216	832	1424	1486	1855	1973	2042
<b>Finland</b>	54	163	510	1292	1412	1414	1486	1525
<b>France</b>	72	206	701	1539	1656	1984	2005	2047
<b>Germany</b>	90	224	824	1602	1600	2178	2288	2364
<b>Great Britain</b>	74	144	444	964	1013	1281	1396	1415
<b>Greece</b>	21	100	345	702	772	1054	1113	1196
<b>Iceland</b>	50	137	577	1374	1453	1826	1918	1981
<b>Ireland</b>	35	98	455	759	856	1246	1189	1293
<b>Italy</b>	49	154	579	1321	1449	1534	1615	1613
<b>Japan</b>	26	131	524	1082	1165	1637	1713	1760
<b>Luxembourg</b>		147	605	1495	1575	2120	2147	2303
<b>Netherlands</b>	67	202	679	1326	1417	1777	1832	1933
<b>New Zealand</b>	90	174	458	937	1015	1244	1267	1357
<b>Norway</b>	46	131	632	1365	1513	1860	2010	2017
<b>Portugal</b>		43	260	614	731	1046	1086	1148
<b>Spain</b>	14	82	325	815	900	1063	1122	1183
<b>Sweden</b>	89	270	850	1492	1458	1623	1701	1762
<b>Switzerland</b>	87	252	801	1760	1958	2464	2549	2667
<b>Turkey</b>		23	75	171	185	188	227	259
<b>USA</b>	149	357	1086	2798	3035	3776	3926	4095
<b>Average</b>	67	167	591	1262	1356	1684	1752	1821

a) Expressed in purchasing power parities in US\$.

Source: OECD (1999a), Advisory Council for the Concerted Action in Health Care

**Figure 1: Average growth rates of life expectancy of females between 1960 and 1996 in 14 OECD countries**



Source: OECD (1999a), Advisory Council for the Concerted Action in Health Care

**10.** One characteristic of the German health care system that is often subject to criticism is the lacking integration of patients and the insured in the *prima vista* paternalistic definition of health care objectives. For this reason, a number of recent studies examine the public preferences with respect to the health care system on the basis of representative surveys. Most of these studies conclude that the general public is very satisfied with respect to the central elements of the German health care system, e.g. general risk sharing and a comprehensive benefits catalogue, and desire only incremental changes. The questions on which the surveys are based, however, usually do not refer to the opportunity costs of measures and/or inaction and allow no conclusions with respect to the actual need for reform.

The high level of satisfaction with the German health care system revealed by these surveys must also be seen in the context of general satisfaction with respect to other areas of life and the results of similar surveys in other countries. Compared to the satisfaction of the German population in other areas, satisfaction with the health care system is only average, and compared to the results of surveys in other countries, only slightly above average.

### **1.3 Health targets and participation**

**11.** Tested participation models and a knowledge of which models are appropriate for the actual integration of patients and the insured in the formulation of health policy objectives at each level of decision making are lacking. The participation of users in the formulation of health policy objectives should therefore be understood as a process in the course of which the concept of participation and its various facets are defined only on a preliminary basis so that the self-image of the users of the health care system is allowed to change over time. The constellation of interests among the actors in the health care system is likely to change through such participation (not only with respect to the formulation of health objectives) and lead to an increase in the potential for conflict as well as to a redefinition of the roles of the different actors.

The Council proposes that users be granted participatory rights in all decisions dealing with the definition and implementation of health objectives. This includes political committees at national, state and regional level and in health care associations and other institutions. The various approaches for the representation of user interests in the health care system with the aim of ensuring equal representation should be analyzed and developed on a systematic basis.

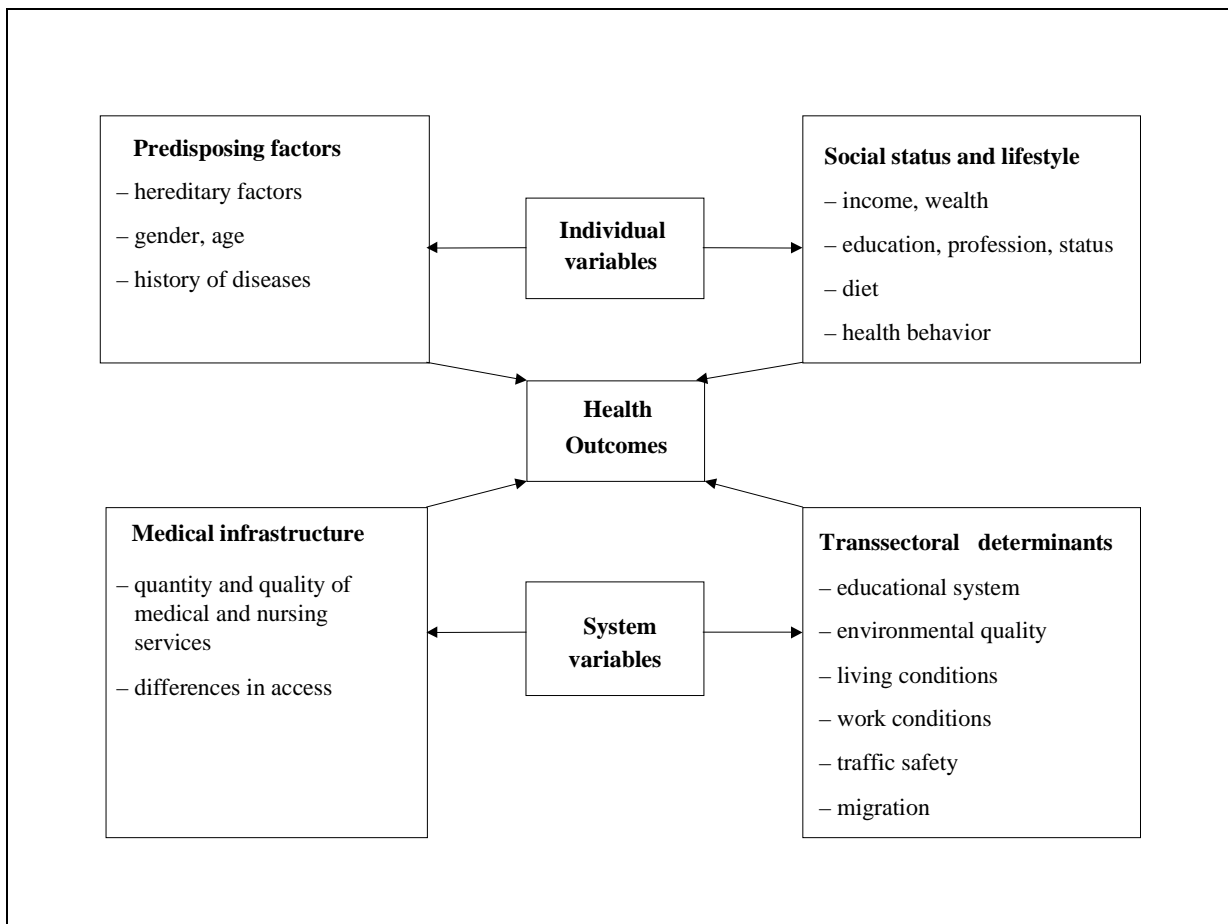
Furthermore, the Council recommends that the participation models be chosen for each type of committee and health objective on a flexible basis. For disease related health objectives, for example, it may be appropriate for self-help groups to represent user interests. The same basic approach may be used for health conferences at regional level. Some municipalities may have established systems of “informed citizens”. The members of these groups can be nominated to represent the interests of the affected population even they are not directly affected. At state and national levels, user interests are probably better represented by delegates of the insured and not by patient groups. In addition, surveys of the insured can be conducted at state and national level as a means for setting priorities that are more attuned to the preferences of the general public.

### **1.4 Endogenous and exogenous determinants of health outcomes**

**12.** A central problem in the evaluation of the performance of a health care system on the basis of outcome indicators is the empirically proven fact that health outcomes are affected by numerous factors that lie beyond the health care system and are thus beyond the scope of decision makers (Figure 2). These exogenous or transsectoral determinants of health outcomes reside, for example, in the labor market, in the distribution of income and wealth, in the educational and transportation systems, in the quality of the environment, in the working and living conditions as well as in the life style of the population. According to the results of numerous national and international studies, the health care system in the strict sense explains only 10 to 40 percent of the

changes in life expectancy and mortality. This implies that cooperative efforts that transcend strict policy boundaries and ministerial responsibilities, for example, through the establishment of interministerial committees, are needed to ensure the efficiency and effectiveness of measures aimed at affecting health outcomes.

**Figure 2: Determinants of health outcomes**



*Source:* Advisory Council for the Concerted Action in Health Care

## **2. Improving the System Through Health Promotion and Prevention**

### **2.1 Definitions, concepts and framework conditions**

**13.** The terms health protection, prevention and health promotion are applied with different meanings and an often unclear differentiation of concepts, programs and activities for preventing the genesis and occurrence of diseases. Following most scientific definitions, the Council generally understands prevention as measures aimed at avoiding the worsening of a condition. Restoration and rehabilitation are aimed at improving a condition. Primary prevention is thus intended to reduce the causes of certain diseases or sickness in general. The objective of primary prevention is to reduce the probability of occurrence and achieve lower incidence rates. Secondary prevention, on the other hand, is related to the detection of clearly defined clinically relevant early stages of diseases and the medical interventions for their successful treatment. More recently, secondary prevention has been also understood as the prevention of the renewed occurrence of a disease event (e.g. the avoidance of a second myocardial infarct following survival of a first infarct). The term tertiary prevention can mean the effective prevention or deferment of the worsening of a manifest disease (tertiary prevention in the broad sense) as well as the prevention or alleviation of long-term disability and loss in social functions (tertiary prevention in the narrow sense).

**14.** Strategies for reaching these objectives may be limited in some areas to influencing actual or possible risk factors (e.g. biological, physical or chemical risks, distress, physical and mental exhaustion, poor nutrition, smoking habits, lack of exercise, social isolation). In most cases, however, the increase in resources that have a positive effect on the health (e.g. self-awareness, information, education, income, adequate participation, support through social networks, relaxation) of the affected individuals or target groups; either by augmenting physical and psychological abilities to cope with disease, by increasing individual opportunities to overcome behavior that is detrimental to health or by developing and promoting the release of individual competence to modify factors that have a direct effect on health or favor behavior that is detrimental to health. This aspect – the strengthening or augmenting of resources – corresponds to the health promotion approach. The aspect “health promotion” as an increase of resources is not restricted to prevention but may be used functionally in all areas of health care.

**15.** The promotion of individual competence corresponds in part to the broader “salutogenesis” concept of Antonovsky (1987), who also postulates a so-called “sense for coherence”. The Council believes that this model is promising on a theoretical level, but not robust enough for use in practice. Even at the theoretical level, however, an appropriately updated “pathogenetic” model and a “salutogenetic” model are not mutually exclusive.

**16.** The prevention of today's major chronic-degenerative diseases must aim at the reduction and avoidance of health risks as well as at the improvement of the means to cope with these diseases. In the development of prevention strategies, programs and measures, it is necessary to pose both questions: Which risks can be reduced with respect to the avoidance of disease and where are more resources needed? As the Council pointed out in earlier reports (1995, 1996 and 1998), prevention plays a central and increasingly important role for the improvement of general health status. The focus on prevention is also in the spirit of German law on social health insurance, which places the same priority on the improvement of health as on the maintenance and restoration of health in §1 of the German Social Code, Book V.

**17.** Despite past and expected advances in medicine, chronic diseases – which are now the predominant factors of morbidity and mortality in industrialized countries – are in most cases incurable in the sense that the provision of medical treatment does not lead to the restoration of patients' original health status. However, the occurrence and course of chronic disease depend to a large extent on individual behavior, false incentives and on risk factors in the social and physical environment. Even in a wealthy country such as Germany, risk factors and resources that are favorable to health are not distributed evenly throughout the population. Health risks and health expectations usually show an inverse relation to social strata (see Special Report 1996, par. 111 and Figure 13). This issue is tackled for the first time through the amended § 20 of the German Social Code, Book V (1999).

**18.** Investments in disease prevention can not only increase health benefits by extending life expectancy and improving the quality of life but also lead to savings in the health care system. Theoretically (without discounting and full cost accounting), long-term prevention would reduce the current spending on health in Germany by 25 to 30 percent. However, an adequate assessment of economic efficiency is lacking for many population-based measures, in part because no studies have been conducted, in part because of the difficulties in the measurement of (intangible) costs and benefits. In addition, the methods for measurement often do not reflect the complexity of multiple causality of one or more related diseases and the multiple effects of preventive measures.

**19.** Cost benefit analyses, however, can and should provide only one of many decision making criteria. Social policy criteria (e.g. the reduction of social differences in health opportunities) as well as priorities developed in the social discourse of health objectives should play an equal role (see Chapter I-1). The broad public discussion in Great Britain on the health program "*Saving Lives: Our Healthier Nation*" demonstrates the many different ideas and projects that can be mobilized by such a public dialogue of health policy.

**20.** For the scientific input in the public debate of health care priorities (and thus of a priority ranking) with respect to prevention, the Council recommends that the same criteria be used as for the definition of appropriate care. In other words, in relation to the population as a whole or defined population groups, the targeted health problem must be

- relatively common (incidence and prevalence),
- clinically relevant (severity of disease),
- economically relevant (direct and indirect costs),
- prevention should be effective, have no unjustifiable undesired side-effects, be accessible to professional implementation and
- have an acceptable cost-effectiveness ratio.

**21.** These criteria are already applicable to a number of well-established prevention programs, such as iodine prophylaxis, and document the success of the criteria as well as the need for their broader application. However, the Council is aware that feasible models for important prevention projects as well as the attainment of unequivocal results on the effects of preventive measures in these areas are often impeded by the complexities associated with disease etiology, medical interventions and their effects. Such problems of method must not result in resignation or lead to health policies that favor disease or prevention strategies that are better suited to modeling exercises and easier to quantify.

**22.** Numerous institutions, associations and other organizations at all levels in Germany, many of which are little known to the general public, are involved in prevention and health promotion (see Figure 3). The spectrum reaches from self-help groups concerned with the prevention of specific diseases in defined target groups (e.g. AIDS groups) or tertiary prevention (e.g. asthma schooling), doctors' private practices, pharmacies, special services offered by hospitals, schools, public health offices (monitoring), private actors (e.g. employers who are required to provide worker protection), to ministries and their subsidiary institutions (the prevention of epidemic diseases, food hygiene, educational campaigns). In general, current public debate stresses measures targeting individuals and not those which are aimed at the context in which disease occurs. The existing potential of these individuals, groups and institutions could be built on by establishing prevention measures in the appropriate institutions (e.g. smoking cessation programs for patients with high-risk diseases directly in hospitals) and through improved coordination, which is presently lacking in many areas. There are many gaps in the established prevention programs and measures in Germany and at the same time many areas in which they overlap. A survey of the prevention measures available in a given region is often lacking, although desirable.

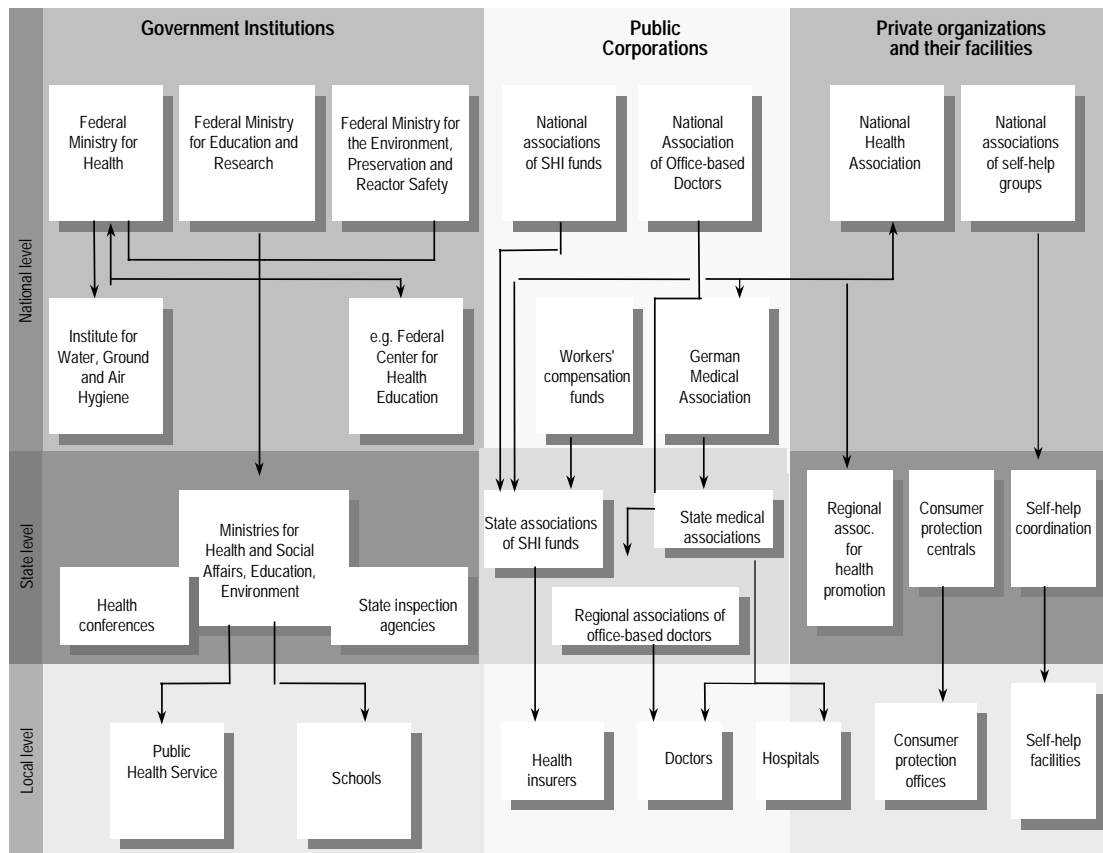
The Council recommends that the topic of prevention be included in regional and interregional health reports. The Council also advocates the establishment of coalitions based on topics and target groups and, when necessary, inter-institutional coalitions that include all levels of the hierarchy in the health care system.

**23.** In the view of the Council, all traditional approaches to the organization of prevention measures ( e.g. social and behavioral prevention, individual and contextual prevention, specific and general prevention, medical and non-medical prevention, health protection and health safety), are inappropriate for a clear delineation of preventive measures in practical applications.

**24.** A useful approach for the organization of preventive measures is one that is based on target groups. Target groups may be defined according to geographic areas (e.g. the inhabitants of an administrative district or region), according to social characteristics (e.g. individuals living under similar social conditions or with similar life styles), according to age (e.g. the elderly; see par. 32-34), according to shared risk factors, risk levels or according to setting. The consistent organization of prevention on the basis of target groups leads to a stronger focus on the objective and subjective health risks and resources, the conditions for healthy life styles and to a clear basis for the planning of access to health care and of health care interventions.

Measures based on settings are also supported by the World Health Organization. A “setting” may be a school, the workplace, the family, a leisure center such as a sports club or a neighborhood or community. A characteristic of the setting approach is that it can reach different target groups in a given setting (e.g. in schools such measures reach pupils, teachers, parents and personnel) and may employ a combination of mutually reinforcing measures based on the setting approach and on individual measures. The Council recommends that preventive measures be increasingly based on the setting approach (especially in schools and the workplace).

**Figure 3: Institutions and facilities for prevention and health promotion at national, state and local level**



Source: Based on U. Walter and F.W. Schwartz (1998), p. 201

**25.** Prevention is an interdisciplinary political task that goes far beyond the established approaches and institutions for the protection of health care. The primary starting points for the prevention of disease are beyond the boundaries of conventional health care policy. Most improvements in the health status of the population depend on social factors, knowledge, education and hygiene. They are related to factors such as the level of wealth, the distribution of income, the availability of work, working conditions, leisure activities, transportation and the physical and technological environment. Thus, mortality and morbidity are variables that are also subject to social determinants. The role of Germany's social health insurance system in prevention policies can therefore not be established on the basis of scientific analysis alone but must be determined largely as the result of a political process.

**26.** With the amended version of § 20 of the German Social Code, Book V, lawmakers have initiated a new start in prevention policy that the Council endorses. Health insurance funds are

now required to include in their statutes primary prevention services that improve general health status and contribute to the reduction of social inequalities in health. Together with employers and workers' compensation funds, social health insurance funds may also implement health promotion measures at the workplace. Furthermore, they are supposed to define joint priorities and criteria for primary prevention services that apply to the whole SHI system, especially with respect to needs, target groups, modes of access, content and methods (§ 20, par. 1, German Social Code, Book V). Both tasks are to be financed in the year 2000 at a level of up to DM 5 per insured person. This sum, which the Council views as too low, will be adjusted annually on the basis of the rate of change in the average income of the social pension fund during the previous calendar year (§ 20, par. 3, German Social Code, Book V). Finally, the Social Health Insurance funds are also required to support self-help groups, whose contribution to tertiary prevention and thus to a form of health promotion that is based on the competence of individuals who are directly affected by disease is undisputed, with DM 1 per insured person and year (§ 20, par. 3, German Social Code, Book V).

The national associations of the social health insurance funds passed “joint priorities and criteria for primary prevention services that apply to the whole SHI system” in June 2000. The Council embraces the expressed readiness of the health insurance funds to promote primary prevention not only on the basis of an individual approach but also within the framework of a settings approach across all health insurance funds, even though this will occur initially only on a trial basis. This applies equally to the documentation and evaluation requirements and to the naming of an external commission of experts including representatives of the Council and the Federal Center for Health Education with the task of ensuring quality, transparency, and the appropriate development of guidelines. However, the Council notes a lack of adequate concepts for the specific implementation of measures for the “reduction of social differences in health opportunities” that is required by the law. The advisory commission will have to modify the guidelines and procedures to meet this requirement.

**27.** The Council expressly warns against believing that these issues have been solved by delegating some prevention tasks to the social health insurance system, which have only limited financial means for this purpose. The Council calls emphatically for the inclusion of prevention areas, forms of prevention and actors in the necessary public debate on health objectives as a way to increase public awareness of the limited importance of curative medicine for health and of the potential and responsibilities in the area of prevention.

## 2.2 The potential of prevention

**28.** The Council has analyzed the challenges of prevention in specific age groups (see also Special Report 1995) to provide examples of the type of problems that must be dealt with. For this purpose, the Council chose selected topics of health prevention for children and the elderly.

**29.** The Council sees growing risks to the health of children, including the increasing reluctance (of parents and guardians) to vaccinate children. Vaccination rates for major infectious diseases that can be prevented through vaccination are clearly below the rates considered necessary. The vaccination rate of children in socially deprived families is still considerably lower than that of other children. The Council therefore recommends – in addition to the established means of providing information and education – that additional active means and methods for motivating the increased participation in vaccination be analyzed and implemented.

**30.** Hearing impairments in children, 85 percent of which are congenital, can be identified using modern detection methods at an earlier stage and with increased certainty than is the under the established program (pediatric exams according to § 26 German Social Code, Book V). The Council recommends a review of the new screening methods in the context of the medical examinations of the newborn. The decision for the use of these new methods should depend ultimately on the additional health benefits that result from earlier, more focused treatment and support for parents and children.

**31.** The introduction of a legal basis for “group prophylactic measures” (§ 21, Social Code, Book V, 1989) was a milestone for prevention in the dental care of youth in Germany. The measure was based on the realization that the reduction in caries in other industrialized countries was due less to dental treatment than to the increased use of fluoride toothpaste in the 1970s, to the fluoridation of salt and water and to population based prophylactic measures. Since 1993, special programs have been available for children with an especially high risk for caries. In January 2000, the population based prophylactic measures were extended to “high risk groups over the age of 12” (§ 21, German Social Code, Book V).

The state (*Länder*) working groups founded by the social health insurance funds, the Public Health Service and Association of Dentists implement a colorful variety of measures for "diet counseling, enamel hardening and oral hygiene".

Despite the slow and only partial introduction and implementation of the measures required by law (Annual Report 1992, par. 207), towards the end of the 1990s there was a marked decrease of caries prevalence among 12-year olds in Germany to 1.7 decayed, missing or filled teeth.

As the prevalence of caries decreases it becomes clear that caries is concentrated in a relatively small target group in each age bracket. Improvements in dental health have also seemed to benefit disadvantaged schoolchildren. Nonetheless, a 1997 survey revealed clear social differences in the oral health of 12-year olds. However, it is not necessary to identify each group of children who are at risk for caries and subject them to special care. It would be more appropriate to compile a profile of caries prevalence of the schools in all cities and towns and to focus specific measures (e.g. two applications per year of fluoride lacquer, which reduces caries incidence by 30 %) on the most "needy" schools.

Overall, the measures for the promotion of oral health appear to have been very successful during the 1990s. However, there are no satisfactory studies that show the extent to which various factors (e.g. group prophylaxis, individual prophylaxis, sealing of fissures, fluoridated table salt) are responsible for the decrease in caries prevalence. The Council therefore recommends that adequate studies be conducted for this purpose.

Although the measures are supposed to be implemented uniformly, annual spending on group prophylaxis ranges between DM 3 and DM 11 per child across the states. The Council recommends that the states or the state working groups analyze the reasons for these differences and, when appropriate, strive to achieve uniform group prophylactic measures throughout the country.

At international level, there are demands for integrating the promotion of oral health with general health promotion, because the indirect causes of oral diseases are poor oral hygiene, poor eating habits, smoking and stress. These factors are also at the root of diseases of the heart and circulatory system, diabetes and cancer. Health promotion should therefore modify all living habits and conditions that promote widespread chronic diseases. Advanced pedagogical approaches to health education in the schools are aimed at teaching children a playful approach to hygiene. In addition to health education, however, the "environmental factors" must be adjusted to short and long term objectives: promoting the use of fluoridated salt, fluoridated toothpaste, the use of proper techniques for brushing children's teeth, the promotion of health foods and more controls on the advertisement and distribution of tobacco products and sweets.

**32.** The great potential for preventive medicine with respect to the elderly is usually underestimated. The Council pointed to this issue in its 1996 Special Report and in particular to the tasks of the sickness funds as specified by § 20 of the German Social Code, Book V, as well as to the tasks of doctors in private practice and those of hospitals (in the sense of clinical preventive medicine). The Council notes that almost all significant diseases in the elderly have a large potential for effective preventive measures: diseases of the heart and circulatory system, diabetes mellitus type II, respiratory disease, osteoporosis and falls, infectious diseases, incontinence and

some mental disorders. A promising approach for the realization of this potential could be based on life-style changes, in particular with respect to physical activity, diet and the living environment, as well as on a modern functional combination of primary care with elements of clinical preventive medicine.

**33.** Measures and strategies for the realization of this potential should not be based solely on the prevention of disease but also on the aging process itself, with its functional impairments, the impending or actual loss of physical or mental fitness and the resulting problems of social integration.

The societal and professional objective should be to enable "successful aging". Primary, secondary and tertiary prevention should emphasize health promotion, remove hindrances to successful aging whenever possible and reinforce those conditions that promote health. Since there are also social inequalities in the health opportunities of the elderly, the identification and design of access routes and interventions, especially for vulnerable target groups, deserve special attention.

Existing access to patients via primary care doctors, standardized self assessment, routine data of the social security system and user-oriented information should be analyzed with respect to this aspect and, when necessary, coordinated or reinforced.

**34.** When planning measures it is important to take into account that the health benefits of common forms of information, education and behavioral modification have been established primarily for the middle class, which is subject to fewer health risks.

The Council sees a need for the research and development of methods and measures that have an effect on such life-style changes under everyday conditions. Proceeding from successful models, it is necessary to evaluate the settings and affiliations of the elderly that can be used for initiating and promoting such developments. Particular attention must be paid to the different forms of communication and different life styles based on education, professional experience and social status as well as to the a priori frequency of symptoms and diseases, the stages of diseases and complications.

### **2.3 Prevention and health promotion in health care**

**35.** The Council also sees considerable need for more prevention and health promotion activity in the established health care institutions. In this report, the Council analyses health care provision by primary doctors and hospitals to exemplify these needs.

Even though clinical prevention should have a relatively important role in the care provided by primary doctors, there is a lack of consistent preventive concepts and strategies for using the given opportunities for long-term professional assistance.

**36.** In the future, however, the quality of care provided by primary physicians will be measured to a large extent on the basis of preventive services. For example, further research and development is needed that focuses on effective forms of counseling and communication by primary doctors, apply to each patient, contain participative elements and take into account sexual differences in health risks and the ability to cope with them.

The distribution of appropriate educational and evidence-based information material should also be promoted in medical consultations by primary doctors (see Chapter II-3). Furthermore, preventive medicine should be included in the patient documentation prepared by primary doctors as a basis for evaluating the effectiveness of preventive measures, especially in the long term.

Geriatric assessment can contribute to the establishment of preventive services. A preventive program for the elderly that is adapted to the primary care setting with flanking assessment measures could be an important step towards enhancing the quality of prevention in the private practice setting. The suitability of existing programs in this area as standard benefits of the social health insurance funds should be evaluated.

Programs based on invitation as well as visits by health care professionals, especially in patients' homes, should be considered for those preventive measures that have been shown to be effective.

**37.** The implementation of preventive measures requires positive incentives for the provision of preventive services. The Council welcomes the regulations that exempt preventive services included in the standard catalogue of SHI benefits from budget restrictions. In the future, (standardized) preventive counseling and preventive services requiring special professional qualification should be reimbursed appropriately. Such issues should be reflected in the reform of the fee schedule for primary care doctors and specialists.

**38.** New paths must be taken in the undergraduate education, residency and continuing education of doctors to inform practitioners of the principles, approaches to and methods of patient-oriented and evidence-based clinical preventive medicine that targets problems and risk groups. New approaches are needed to implement preventive services in combination with quality assurance measures. Furthermore, the support of health insurers, faculties of medicine and medical professional societies for a modern, practical and scientific development of preventive methods and measures must be reinforced.

**39.** A network of "health promotion hospitals" has evolved in Germany on the initiative of an international project sponsored by the World Health Organization (WHO). These activities are based on the assumption that the development of organizations towards better quality is closely related to health promotion. Health promotion is seen in part as a universal concept for the improvement of all aspects of quality in the health care system (in medical, nursing, organizational, administrative and economic terms). In part it is interpreted as a complement of or extension to health care that is based on a stronger focus on psychological and social aspects, including the provision of additional services. The programs are based on the results of research on personal ability to cope with sickness and disease, the role of social support, the requirements for the best communication and interaction between patient and doctors and nurses as well as on experience with the concept of the "learning organization". However, a rigorous comparative analysis of the results is still lacking.

Hospital employees are exposed to many risks in the course of their professional activity. The Council therefore sees a need for the appropriate development of health promotion in hospitals that is supported by evaluation measures and based on established concepts of health promotion in the workplace. Since the interaction with patients and their situation is a central aspect of these projects, such measures would benefit both hospital employees and patients. Evaluation programs should focus on these issues, as well as on employee motivation, satisfaction, job fluctuation and the focus on patients.

The Council views the introduction of systematic health promotion strategies in the hospital setting as an important measure for patients as well as for hospital employees.

#### **2.4 Quality assurance and quality management in health promotion and preventive medicine**

**40.** Quality assurance and quality management in health promotion and preventive medicine begin with the definition of targets, target groups, means of access and methods for interventions and evaluation. A central condition for the evaluation of quality is the precise, theoretical definition of the target on which the choice of measure, target group, means of access to the target group and the necessity for the involvement of participating professionals is based. Particular attention should be paid to the quality of the initial phase of planning and the development of evaluation criteria, because these factors are decisive for the quality of the implemented measures and their results.

**41.** The foremost objective of health promotion and prevention is the long-term improvement of the health status of the target population. In many cases, the intended health benefits can not be

measured over periods of only two to five years. It is therefore necessary to identify intermediate outcome parameters that can be used as a reliable estimate of the further health status of the target group. It is also necessary to take any possible disturbances into consideration.

**42.** The measures should focus as much as possible on specific target groups. Knowledge of the expectations, needs, habits and context of the target group is needed to address and motivate the targeted individuals, for the educational and organizational design of measures and to ensure the long-term stability of their effects.

The appropriate settings and sites must be determined for interventions and adequate identification strategies and paths of access chosen.

**43.** Target groups that are defined solely on the basis of setting are often too diffuse for a targeted intervention. As a result additional instruments are needed to identify the target group more precisely. Self-assessment questionnaires, telephone interviews, assessment (e.g. by health counselors, doctors or nurses) and the routine data of the health insurance funds are well-suited for this purpose.

**44.** The large number of possible measures for preventive medicine and health promotion and the resource scarcity make it necessary to choose measure on the basis of defined priorities (see par. 20).

**45.** Recommendations for prevention and health promotion that are based on evidence-based studies are available only for “clinical prevention”. The Council warns that the application of criteria founded on evidence-based medicine to primary prevention and health promotion can favor measures that have been more thoroughly analyzed because they are not very complex. The evaluation of existing studies according to the best available evidence does not mean, however, that a procedure for which there is only limited evidence or evidence that is not methodologically sound should not be subject to further consideration. Rather, it is necessary to bear in mind the existing weaknesses and gaps in knowledge. In cases of uncertainty, it is therefore very important to conduct repeated outcomes-oriented evaluations of innovative measures and programs as well as a continuous outcomes-oriented quality management.

Since there are only few empirical studies for many of the central concepts of health promotion (e.g. for the concept of salutogenesis), outcomes-oriented and operational objectives are needed for these approaches.

**46.** The improvement of the health status of the target group is the most important benefit to consider in the choice outcome parameters. Secondary parameters, which are important and, in some cases, indispensable include: the development of competence, the creation of prevention

“structures”, the influence of the social and psychological environment, costs and marketing effects (see Table 2).

**47.** Objectives, means of access, the types of measures, responsibilities, roles and schedules should be determined jointly with representatives of the target group. The whole process should be thoroughly documented, at least with respect to the central parameters, in order to facilitate comparisons, enhance transparency and allow for modifications in the definition of the target group. When defining the means of access for preventive medicine and the types of measures to be taken it would be useful if individual programs were linked to the objectives of overarching systems, e.g. national objectives (Chapter I-1).

**48.** The Council believes that quality assessment and quality management in preventive medicine and health promotion will have to deal with the difficult challenge of developing methods, instruments and procedures that bring the quality of measures more in line with evidence-based medicine without fettering the creative development of the necessary population and setting based interventions.

**Table 2: Benefit dimensions and goals of prevention and health promotion for non-communicable diseases**

<b>Dimension</b>	<b>Goal</b>
<b>I: Health</b>	<p>Long-term parameter: reduction of the incidence of avoidable cases of sickness or death, e.g. mortality, morbidity, handicaps, impairment</p> <p>Assessment of subjective health, quality of life, functionality, e.g. SF 36, instrumental activities of daily life</p> <p>Intermediate physiological and functional parameters, e.g. blood pressure, heart frequency, blood values, body-mass index, skin tests, functionality</p> <p>Intermediate behavioral parameters, e.g. diet, physical activity, spinal health behavior, stress response, addictive behavior</p>
<b>II: Competence/ empowerment</b>	<p>Acquisition and maintenance of social support</p> <p>Knowledge</p> <p>Attitude</p> <p>Perceived and actual control</p> <p>Self-value and self-awareness</p> <p>Self-efficacy</p> <p>Informed and lasting behavioral changes</p> <p>Participation, e.g. in controlling one's environment</p>
<b>III: Physical and social environment</b>	<p>Setting, e.g. workplace organization, living conditions, school</p> <p>Physical environment, e.g. living conditions, noise, exposure to pollutants</p> <p>Social network, social support</p> <p>Politics, e.g. public awareness</p> <p>Legal foundations</p>
<b>IV: Costs</b>	<p>Program costs, costs of participation</p> <p>Return on investment (e.g. through reductions in sick leave, pharmaceutical consumption or hospitalization)</p>
<b>V: Access</b>	<p>Acceptance in specific target groups</p> <p>Effectiveness of specific means of access (accessibility)</p>
<b>VI: Capacity building</b>	<p>Competence building of professionals and institutions</p> <p>Institutionalization of interventions</p> <p>Resource utilization, e.g. cooperation, collaboration with central actors, networks</p> <p>Diffusion of programs</p>
<b>VII: Service/ Marketing</b>	<p>Satisfaction of the target group</p> <p>Reputation</p>

Source: Based on U. Walter et al. (2000)

### **3. Optimizing User Behavior through Competence and Participation**

#### **3.1 The users**

**49.** The users of the health care system can be classified according to the chosen perspective. “Citizens”, “insured” and “patients” represent a differentiation according to interest group, the concepts “customer” and “consumer” focus more on the economic aspects of health care.

#### **3.2 Means for increasing competence and participation**

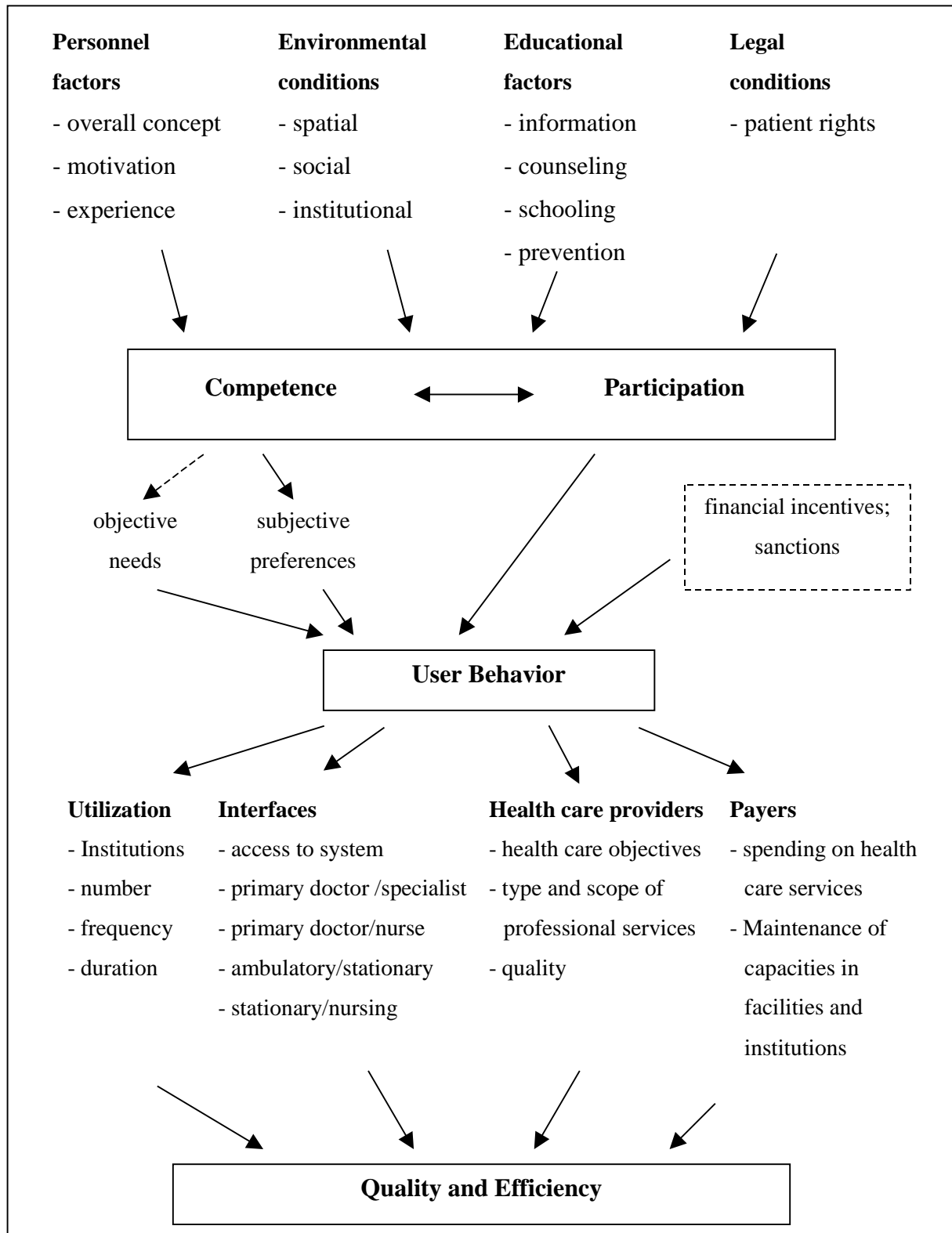
**50.** The Council views competence and participation as the key qualities of the user. These factors have a significant effect on the quality of health care processes and outcomes as well as on the efficiency of the whole health care system. This means that existing competencies must be better utilized and user behavior improved by increasing user competence and participation.

**51.** The role of the patient is in a state of flux. While patients were once primarily those who wanted to or had to rely on the aid and counsel of others, in the future they will assume a role as an independent "third power" in the health care system. This will have a growing effect on the objectives, processes and structures of the health care system. In the future, the health care system will be judged increasingly on the extent to which it allows for the active participation of citizens, the insured and patients. In the past, enough lip service has been paid to the issue of strengthening the role of the consumer in the health care system but only few measures have been taken.

**52.** The user can not be viewed solely as a consumer that makes autonomous decisions and choices. The more the situation of the user is characterized by disease or disability, the more the ability to make rational decisions is impaired by factors such as uncertainty, fear and the desire and need for assistance and care.

**53.** Measures to increase user competence must start with the environmental conditions such as social and institutional support (e.g. self-help groups) as well as with educational issues and the legal framework (see Figure 4).

**Figure 4: Relationship between competence, participation, user behavior, quality and efficiency of health care delivery**



Source: Advisory Council for the Concerted Action in Health Care

**54.** A central condition for participation and user competence at all levels of the health care system is the exchange of information. At present, the exchange of information is deficient with respect to medicine and the health care system on the whole as well as with respect to the relationship between users and health care providers (especially between patients and doctors). This is the case despite the doctors' legal obligation to inform patients. Communication is often shaped by the traditional pattern of the paternalistic doctor-patient relationship. However, a prerequisite for more patient autonomy and joint decision by doctors and patients is information that is well-founded and informative: information that details the pros and cons of medical procedures and also describes health care processes and alternatives, thus providing the user with a basis for making informed decisions. Furthermore, this information is necessary to increase patient autonomy and joint decisions by doctors and patients.

**55.** In view of the given deficiencies the Council recommends:

- The obligatory participation of patients in all medical decisions that affect them. This must include clarification of the advantages and disadvantages of planned health interventions as well as their actual benefits and possible alternatives. This enables patients who are capable or who request such information to decide for or against the planned medical interventions.
- That all documentation which is designed to remain in the possession of the user, such as vaccination passes, maternity passes, documents, information leaflets, screening IDs etc. is written in terms that are readily understood by laypersons. This applies to all health care professionals (doctors, nurses and SHI funds).
- The development and perfection of existing approaches of the SHI funds to the provision of information, education, counseling, and schooling to the insured. The SHI funds should use all forms of modern communication and distribute information for defined target groups. The focus on target groups in this context means that information packages should be designed to reach groups of users according to cultural and socioeconomic backgrounds, language, age and sex. The same requirements should apply to the health information services provided by consumer organizations (see § 65 of the German Social Code, Book V) and equivalent facilities (e.g. hotlines).

**56.** Educational approaches (§ 43 German Social Code, Book V) for all chronic diseases should be implemented to reduce the burden on the health care system and improve health care outcomes. The programs should enable patients to assume more responsibility in the management of their care, provide training for family members and form an integral part of the health care process.

**57.** In addition to improvements in the dissemination of information, the Council views the expansion and redefinition of user participation as the second essential element for enhancing user

behavior. Improving user participation is a continuous process. It requires the practical application of participative measures beyond theoretical debate. The Council sees a clear need for the development and implementation of models for procedural participation, i.e. the right to a hearing and expression of opinion, and in models for participation in hearing procedures themselves. Pilot projects should be promoted for these purposes and subject to careful evaluation. Many issues related to the legal requirements, responsibilities and assignment of tasks under forms of participation that are based on participants' right to vote in decision-making process need to be examined.

For the debate on participation, the Council recommends the evaluation of participation models and their results in countries where they have already been implemented.

**58.** The new provisions in social health insurance law for the introduction of so-called integrated (managed) care and the use of pilot projects – in particular for projects for specific diseases or target groups – offer chances for achieving the direct participation of users. In light of the fact that this process could lead to considerable changes in the regional provision of health care and regional health care infrastructures, the Council recommends that these new legal opportunities should be used particularly at regional and local levels.

**59.** Government and para-government institutions should show more willingness to allow users a right to direct participation. This includes the participation of those who are affected by decisions in important decision-making organs such as the Federal Standing Committee of Doctors and SHI Funds or other suitable bodies of the social security system (e.g. quality assurance or the compilation of lists of medical aids and appliances), including the Medical Review Boards (e.g. in the determination of the need for nursing care).

**60.** The participation of users has also been barely developed in other health care institutions (hospitals, nursing homes etc.). The Council recommends drawing on the experience of residents' councils in homes for the elderly and nursing homes as well as on the experience of patient representatives in hospitals to design an infrastructure for the participation and involvement of laypersons in health care facilities.

**61.** The expected outcomes and opportunities related to an increase in competence and improved participation would affect the whole health care system. Some of the outcomes could be:

- The system will become more transparent.
- There will be opportunities for opening the system and health care services to a public discussion of goals and measures that goes beyond the traditional expert debate.

- The growing health awareness of the population will increase self-responsibility, improve health behavior and result in more appropriate user behavior.
- There could be a shift of health care services (whether intended or not) into the area of self-care (e.g. family care of the disabled, self treatment of minor sicknesses).
- The need for health care reform will become evident at an early stage and reforms can develop from the "bottom up", thus proceeding more from a patient perspective than has been the case in the past.
- The quality of structures, processes and outcomes will be stimulated and improved in the direction of health care objectives that have been co-determined by users.
- The focus of health care providers on users will create a need for a more pronounced individualization of treatment and thus create opportunities for the more flexible use of medical alternatives that focuses on the priorities of patients. This can lead ultimately to improvements in the quality and cost-effectiveness of care.
- Patient participation or the delegation of medical decisions to patients will bring with it a need for the critical reflection of health care providers with respect to medical treatment concepts. Health care providers must have up-to-date information on health care problems at all times.
- Patients will be better protected from malpractice that results from inefficiencies in the health care system (e.g. excess treatment resulting from competition or inadequate care due to budgets).

### **3.3 Patient rights**

**62.** In order to make the complex legal situation more accessible to patients, the Council recommends that provisions on patient rights, which are presently scattered throughout different legal texts, be brought together in a single law on patient rights. This law should also observe the requirements of European Union law. Furthermore, the law should deal with those problems for which solutions are needed, such as patients' wills and dispositions.

Liability law should also be summarized and further developed. This should include an analysis of the applicability in Germany of "no-fault" insurance – i.e. damage-based insurance with absolute liability as it is being used in the Scandinavian countries.



## **Volume II: Improving Quality in Medicine and Nursing**

### **1. Improving Human Resources Through Education, Training and Continuing Education**

**63.** The quality of education, training and continuing education in the health care professions has a considerable effect on the quality of health care processes and outcomes. The Council therefore believes that the qualitative development of personnel resources should be given high priority.

The health care system will change considerably in the future, e.g. due to revolutionary innovations, the rapid expansion of knowledge, changing settings, transformed health care infrastructures, changes in the role of the patient and new participatory forms of decision making. This will require new qualifications for health care professionals.

**64.** The medical and nursing professionals will make decisions and have to justify them within a broader framework that is determined by a new set of ethical, economic and individual values. New approaches to the provision of health care such as "integrated care" require that health care providers become involved in organizational tasks that go beyond purely medical issues, e.g. health care resources, economic resources and the health care infrastructure at regional level as well as integrative quality management programs.

**65.** In the Council's view, the trend should be towards more flexibility in the education and training of health care professionals with an increased focus on basic skills and the continuity of further education. This will allow doctors and nurses to meet the changing requirements of the health care system.

In addition to the cultivation of new knowledge and skills, there is a need for a continued professionalization process that begins during the formal education of health care professionals. Consequently, the conveyance of knowledge will play an increasing role in standardized means for maintaining and upgrading professional qualifications.

The promotion of the constant development of professional qualifications is a task shared by all health care professions, professional organizations and the facilities in which health care professionals are employed. The promotion of alternative means for training and continuing education and the creation of new professional opportunities will be particularly important in the non-academic health care professions.

## **1.1 Undergraduate medical education, residency and continuing education**

### *Undergraduate medical education*

**66.** The Council welcomes the current reform activities at medical schools and the provisions for trial projects that were introduced at the beginning of 1999. The Council supports the speedy passage and implementation of the amendments to medical licensure laws.

**67.** In this context, the Council recommends that new developments in the health care system be reflected in the qualification profile of doctors, e.g.

- an increasing awareness of prevention and health promotion,
- the increasing participation of citizens in the health care system,
- new expectations with respect to quality and cooperation,
- new professional opportunities for doctors.

An indispensable part of any reform of medical education will be to rid the curriculum of contents that are not high priorities with respect to the goals of the medical school system or are better imparted during residency.

The reform of medical education has to do with more than just a reduction in the length of medical school education or dealing with problems of university capacities. At issue is the credibility of medicine's principles as an instance of utmost social value. Medicine must not be understood solely in terms of its theoretical possibilities, but in terms of its social obligations. This change in perspective will allow us to shape a new role for the doctor that meets future needs and provides a basis defining the educational requirements.

**68.** Many aspects of medical education need reform. It should focus on a model of the student that allows students more autonomy. Furthermore, it should demand a readiness to learn the traditions of medical science and decision making yet at the same time cultivate a capacity for critical reflection of these traditions in the context of social change and expectations.

The acquisition of competence in the sense of decision-making skills, manual skills and personal skills, including the ability to work in a team, should be given the same priority as the conveyance of theoretical knowledge.

There must be a shift in the contents of medical education in which the purely scientific knowledge of details about diseases is supplemented by information about society and the population, such as medical ethics, management, population-based medicine and basic public medicine.

Furthermore, greater emphasis must be placed on psychological and communication issues as well as on quality assurance factors.

**69.** The Council therefore supports the recommendations of the German Science Council (1999) that call for the extension of general medical education at all medical schools into the ambulatory setting. The Science Council holds that research is necessary only at selected medical schools. This Council, on the other hand, believes that General Medicine should be better institutionalized through the establishment of regular faculty positions.

**70.** From the educational perspective it makes sense and could save resources if students were trained not only on the basis of model cases. Under systematic tutoring and supervision, students should be allowed to gain more first-hand experience in dealing with concrete problems in the provision of care.

The results of course evaluations should be taken into account for the distribution of state funding.

### ***Residency***

**71.** The Council calls on the doctors organizations for self-governance to focus on the following issues in the planned reform of medical education: patient safety, present and future health care needs, the conditions for cost-effective and cooperative care and the requirements for the continuous refinement of professional skills.

**72.** The reduction of training catalogues to a realistic and appropriate level is indispensable. This will require a differentiation between obligatory and elective courses. The contents of the obligatory courses and the electives should be of consistently high quality.

**73.** The contents and range of courses in the training of specialists should better reflect the actual focus of care in hospitals and in the ambulatory sector, e.g. by requiring training in internal medicine for anesthesiology, neurology, dermatology or obligatory courses in psychiatry for general practitioners in training.

In addition, medical specialists should be able to prove that they have a basic knowledge of evidence-based medicine and the guidelines based on this information (e.g. by performing a critical review of literature and a balanced appraisal of benefits, risks and costs).

**74.** Specialists' ability to cooperate and to coordinate their services should be promoted through the provision of information on other health care professionals and working visits in the prac-

tices of those professionals with whom they cooperate on a regular basis. Their knowledge of quality assurance measures should not be restricted to particular medical specialties but also cover other professions and institutions.

**75.** The increasing importance of prevention and health promotion and the present lack of qualifications in these areas should be contended with by including preventive health counseling in the curricula of all medical specialties. Furthermore, preventive medicine could be established as a separate medical specialty.

**76.** The Council welcomes the continuation of the program for the promotion of continuing education in general medicine. There is an urgent need for a suitable framework as well as for sufficient training capacity and funding in order to fully implement the program as planned.

Primary care doctors should receive some training in accredited health care facilities outside of the acute-care sector, e.g. in hospices. However, primary care doctors must still have adequate training in acute care hospitals.

**77.** The inclusion of residency programs in the curriculum of primary care doctors is indispensable for all assistant doctors who wish to work as general practitioners (see the Special Report 1995).

**78.** The Council recommends the establishment of more opportunities for residency in the ambulatory sector, especially for specialists who intend to establish a private practice.

The introduction of combined residency systems should apply not only to general practitioners but to other medical specialties as well. This would provide a basis for residency in the ambulatory sector and for rotation between hospitals as a means for fulfilling certification requirements. Participation in a combined residency system should be taken into account in the certification of training facilities.

As has been demonstrated in Great Britain, the effects of increased rotation on hospital procedures can be moderated through courses that familiarize new residents with the most common indications and emergencies as well as with the organization of the responsible teams.

The certification of training personnel and training facilities should be possible within the framework of a combined residency system or on the basis of contractual agreements in the hospital and ambulatory sectors. However, they should be linked to quality requirements, such as proof that internal rotation plans have been implemented successfully and internal continuing education courses have been conducted on a regular basis.

**79.** In the interest of patient safety, the guidance and supervision of residents and in particular of doctors in practical training (*Arzt im Praktikum*) should be improved and measures taken to ensure that legal requirements on working hours are fulfilled. Professional guidance should be enhanced by increasing the number of certified professional counselors and improving the documentation of training by using "log books".

**80.** The Council holds it for absolutely necessary that the additional time and personnel requirements of training facilities are reflected in the financial agreements with social and private health insurers. (see Special Report 1995).

**81.** The educational councils of the medical associations should be made up of a sufficient number of ombudsmen who can provide more information and support to training facilities and personnel than has been the case in the past. The planned evaluation of training facilities and personnel should be linked to certification or re-certification procedures.

Increased efforts should be undertaken to include in residency programs the subject matter needed by primary care doctors and specialists and to ensure that doctors master these skills. Visits in private homes and nursing facilities or differential diagnostic and therapeutic decisions for a required minimum number of patients should be explained, discussed with a supervisor and included in the specialist examinations.

The medical chambers are called on to be more diligent in their tasks related to the quality of residency programs. This applies both to the certification of training personnel as well as to the control of residency credentials and the performance of specialist examinations according to standardized quality criteria in each state. The state agencies should follow closely whether the medical chambers fulfil their tasks with respect to specialist training more conscientiously than in the past.

### ***Continuing medical education***

**82.** The Council welcomes the reinforced efforts in the medical community for improving the quality and relevance of continuing medical education. However, it is essential that further efforts be undertaken to improve continuing medical education in order to meet the changing needs in the health care system and the different qualification requirements of doctors.

Intense effort is needed to improve continuing education programs, for example through more stringent and more explicit accreditation criteria, the intensified promotion of appropriate multipliers and the diffusion of information and guidelines for the design of high-quality courses.

Furthermore, continuing education should be as non-partisan as possible and free of industrial interests. In accordance with international publishing standards, the particular interests of the sponsors of continuing education programs should be revealed in the printed media as well as in the courses.

In particular, it is necessary to increase the use of systematic continuing education series (e.g. in professional journals). These should focus on specific health care issues in different areas of the health care system (e.g. primary care and specialist care) and also provide a multidisciplinary approach to problems. In addition, these measures should focus on the most common quality problems in the provision of health care, e.g. improving care at the interface between different types of health care providers, the most common emergencies, reasons for seeking treatment and avoidable life-threatening conditions. In 1998, the Council recommended that the regional doctors associations utilize existing legal opportunities for requiring the participation of office-based doctors in the associations' continuing education programs (Annual Report, par. 106).

Furthermore, it is necessary to find ways for reducing the hindrances (such as the threat of legal action by manufacturers) to the doctors associations' measures for providing information on more rational prescribing practices.

**83.** Continuing education for preventive and geriatric medicine as well as training in rhetoric and communication need to be supported more by the professional associations.

Continuing education should go beyond clinical issues and include topics that are considered as continued professional development in other countries, such as quality assurance, health economics, team work, work organization and the use of information technology.

As a means for furthering qualified self-education, more information and courses on accessing qualified sources of information and on the critical evaluation of scientific literature should be provided. Professional journals should focus more on improving the educational quality of articles, their practical relevance and their informational content to ensure that they meet international standards.

**84.** The utilization of accredited continuing education programs should be increased through the use of incentives as well as through the introduction of qualification standards for all members of regional medical chambers. Factors that could function as good incentives are the ease of access, relevance for medical practice, non-partisanship (e.g. freedom from the influence of industry), quality and low cost. In addition to certification, the courses could include memory aids for use in everyday practice, written patient information on the topics treated in the courses, the display of continuing education certificates in doctors' offices or on the internet and the publication of certified doctors by the medical chambers. Furthermore, the structural effects of the

planned Diagnosis Related Groups system in the hospital sector should be reflected in the continuing education curriculum (see Chapter II-4).

To ensure the quality and relevance of continuing education it is necessary to introduce procedures for the accreditation of continuing education courses and media.

**85.** The Council recommends introduction of procedures for the re-certification of doctors based on the Anglo-Saxon model. The re-certification of medical specialists should occur at frequent and regular intervals. It should depend in part on an internationally accepted credit point system for the regular participation in continuing education programs. In addition, re-certification should rely on examinations conducted at intervals of two or more years. The Council is aware that accreditation in a medical specialty is of central importance in the medical profession and that the introduction of mandatory re-certification could limit a doctor's professional opportunities and potential income. However, it is the task of the responsible institutions to find appropriate solutions.

It is evident that re-certification procedures for general practitioners as well as for pediatricians and specialists in internal medicine who serve as primary care doctors must have a different emphasis than the re-certification of doctors who provide only specialist care or those who are university professors. A similar solution is needed for doctors who have no medical specialty.

## **1.2 Human resources and the education, training and continuing education of professional nurses**

**86.** Approximately 1.2 million people were employed in the health care system and related social services in 1998 (see Table 3). The number of employed in the hospital sector has remained fairly constant in the recent past despite the intensification of care. This also applies to the number of students and trainees in this area and is related primarily to the decrease in the number of hospital beds. The number of persons employed in the care of the elderly, on the other hand, has increased. In 1999, 228,000 persons were employed in the inpatient care of the elderly, which represents a 25 percent increase in comparison to 1996. The number of employees in the ambulatory nursing sector increased at a comparable rate.

Overall, the nursing sector is described as a growing branch for the future. However, the increase in the need for nursing services has not yet had the expected effects on the labor market.

**Table 3: Employees in the nursing professions and related social services according to profession**

Work area	Trained professionals and trainees	Trained professionals
Nurses, pediatric nurses and maternity nurses	785,000 (64.4%)	719,000 (63.4%)
Assistant nurses	124,000 (10.2%)	121,000 (10.8%)
Geriatric nurses and assistant geriatric nurses	268,000 (22%)	246,000 (21.9%)
Special education nurses	33,000 (2.7%)	30,000 (2.7%)
Family nurses and community nurses	9,000 (0.7%)	8,000 (0.7%)
Total	1,219,000 (100%)	1,124,000 (99.5%)

Source: German Ministry for Health (1999); German Statistics Office (1998)

**87.** There is a professionalization trend in nursing and the related social professions that can be viewed as an improvement in human resource development. More than two thirds of all nursing professionals and workers in related social services have completed three years of formal training. An above average number of nurse trainees have completed secondary school and nursing careers are still in high demand. In both the hospital sector and in homes for the elderly there is a marked increase in the qualifications of nurse administrators.

In addition, the promotion of nursing science as a university discipline has made considerable progress over the past ten years through the establishment of 50 different courses of study in Germany. In 1999, the first two doctoral theses on nursing were accepted by German medical schools.

**88.** There are also trends towards deprofessionalization in nursing and the related social services that weaken the human resource base in these professions. The number of qualified employees in geriatric nursing decreased between 1996 and 1999. The number of unqualified employees in ambulatory and inpatient geriatric care facilities increased six-fold over this period. Since introduction of the law on long-term care insurance, educational programs have been established that provide only partial qualification. The result has been a "crowding out" of fully qualified nurses. Such developments contradict the increasing demands placed on the nursing profession that arise from demographic trends, shifts in the disease spectrum, the changing legal framework and advances in technology and science.

**89.** The central problems in the educational system for nurses and related social services remain the lack of flexibility of the educational infrastructure, the unique situation of nursing education in the context of the vocational education system, outdated course content, a shortage of qualified teaching personnel and the distinction between the systems for the education of nurses and social service personnel.

The finance of education and training for nursing professionals is also subject to controversy. The intention of social health insurance funds to cease their funding in this area would have negative effects on personnel recruitment for schools and training facilities.

**Table 4: Professional qualifications of health care personnel in ambulatory and inpatient facilities for the elderly in 1999**

<b>Qualification</b>	<b>Share of health care personnel in ambulatory facilities (%)</b>	<b>Share of health care personnel in inpatient facilities (%)</b>
Geriatric nurse	29.5	36.5
Nurse	41.1	34.3
Assistant geriatric nurse	8.7	9.6
Other professional qualification	15.6	9.2
No special qualification	6.6	6.4
Commercial training	3.6	3.8

*Source:* marmas bonn (2000a)

**90.** To develop human resources in the nursing profession and in the related social professions the Council makes the following recommendations:

- Efforts to overcome the divisions between the health and social professions must continue. It is already apparent that nurses and geriatric nurses have many tasks in common and that there is a growing tendency in the labor market to treat these professions as interchangeable. This strategy would also increase the mobility of health care professionals in Europe. To this end the basic education of nurses and geriatric nurses should be combined. Furthermore, possibilities for integrating this curriculum in the tertiary educational system should be assessed. This would increase the flexibility with respect to qualification levels, increase

career opportunities in each area and thus make these professions more attractive. Integration would also normalize the finance of education and training in nursing.

- The course contents should be modernized and adjusted to reflect the demands of daily practice. The basic curriculum for professional nurses and geriatric nurses should be reviewed in regard to the new demands on these professions in terms of rehabilitation, prevention, the counseling of patients' families and new developments in medical technology and telematics. Furthermore, the reform of nursing education should help promote the transition of the profession from a manual-technical orientation to care concepts based on the focus on individual patients.
- University level education and training should be promoted. This would include the consistent promotion of students, the targeted development of nursing curricula at vocational colleges and universities and the creation of the infrastructure needed for the continued development in the nursing sciences, including national and international cooperation in research.
- A nurse monitoring system should be developed for the assessment of nurses on the basis of professional qualifications and job position. In addition "nurse indices" should be developed to measure future needs for qualified and specialized nurses. This would include the evidence-based planning of the capacity of schooling and training facilities in order to avoid shortages of qualified personnel in the future.

## **2. Concepts of Quality and Quality Management**

### **2.1 Quality assurance and quality management: concepts, goals and benefits**

**91.** The Council employs a definition of the "quality of health care services" that highlights the importance of ascribable and desired health outcomes. A systematic generalization of this concept of quality, which includes the quality of health care services, the quality of health care providers and the quality of health care facilities, would also include the quality of the structure of the health care system and control processes in the health care system.

The quality of health care depends on a number of factors. It is necessary to differentiate between those factors that are subject to the influence of the health care system and those factors that are beyond the scope of the health care system. It is also necessary to distinguish between the quality effects of structures or control processes at macro level or mesa level and the scope of influence of control measures at the micro level; i.e. at the level of individual health care facilities, health care providers and individual services or procedures. The existing methods of quality assurance and quality management are aimed at the micro-level. Quality assurance programs can not be expected to correct the deficiencies in the structures and control processes at macro level.

**92.** In German legal texts and in the system of self-governance, the term "quality assurance" is used for all measures and objectives that have to do primarily or explicitly with issues of quality. The concept of "quality management" is understood in this context as one possible method for the implementation of quality assurance measures. Standardization agreements at international level, on the other hand, see quality assurance as a possible method for implementing the more general concept of "quality management". The Council holds a combination of both approaches as necessary and sees no insoluble differences between the two.

**93.** Methods for quality assurance or quality management are concerned with the ways in which existing facilities, procedures, measures and services can be improved to benefit patients and with the avoidance of potentially damaging effects. The Council considers it prudent to term such measures as "secondary technologies" that are used to perfect the so-called "primary technologies" of diagnosis, therapy, rehabilitation and counseling. These "secondary technologies" serve to support health care professionals, health care facilities and patients in the attainment of the desired health and treatment objectives.

In light of the considerable effort and high costs associated with quality assurance measures, however, it is important that these measures are subject to critical review. Like all other procedures or technologies in the health care system, quality assurance measures must be reviewed with respect to their effects and costs prior to and during implementation.

The primary issue in such pre-evaluation and re-evaluation is whether the benefits justify the costs and how quality assurance measures can be targeted to help improve the outcomes of health care services.

**94.** The Council views the following quality criteria as important in the planning and implementation of quality assurance programs:

- Agreement on the goals of quality assurance measures is imperative. Possible objectives of a quality assurance approach that is focused on outcomes have been presented in earlier reports of the Council. These include the prevention of avoidable fatalities, the prevention, cure and alleviation of diseases and their symptoms, the restoration of physical and psychological functions as well as the confidence that appropriate care will not be available when it is needed (Special Report 1995, par. 58).
- Quality assurance must contribute primarily to patients' health and protect patients from avoidable harm associated with health care services. Quality management in the health care system focuses on a patient and outcomes orientation. The ideal of the responsible and informed patient, whose dignity and autonomy is respected, must be upheld.
- Quality assurance measures must focus on health care priorities. They should be limited to common and serious health problems, the core services of the different health care providers and to high-risk interventions.
- All parties who are affected by quality assurance measures in the various sectors of the health care system should be granted appropriate rights to participation in agreements on quality assurance goals and priorities.
- Quality assurance should be designed to find the acceptance of health care providers, patients and third-party payers. The motivation and acceptance of participants is an essential condition for guaranteeing the lasting success of quality assurance measures. The acceptance of the actors in the health care system depends in part on their participation in the design of quality assurance measures and whether the measures taken are effective. Interests of patients and health care providers should be allowed appropriate consideration.
- The methods chosen for quality assurance should be appropriate and reflect the current state of knowledge. The implementation of quality assurance measures should be embedded in a process that covers all phases of the quality improvement cycle.
- The quality of medical care should be made more transparent and the information needs of patients respected.

- The additional benefits resulting from quality assurance must be made evident. The risks of quality assurance as well as its monetary and intangible costs should proportionate to the additional benefits to which it gives rise. The evaluation of quality assurance measures should occur before, during and after implementation and be based on appropriate monitoring methods.

**95.** Above all, the improvement of the position of the users of the health care system requires comprehensive, comprehensible and easily accessible information on quality targets and quality outcomes. This is a basic condition for the cultivation of a quality-oriented information culture in the health care system and should be accorded high priority.

## **2.2 Quality assurance methods and quality management methods**

**96.** Once a quality problem has been identified and concrete targets have been agreed upon, there are many quality assurance methods for reaching these objectives. In general, most methods of quality assurance or quality management can be used to deal with very diverse quality problems. Table 5 provides an overview of traditional and more modern quality assurance methods and classifies them according to the different phases of the quality improvement cycle on the basis of their conceptual focus. Quality assurance measures can then be distinguished according to whether they focus on a specific phase of the quality assurance cycle or on all phases of the quality assurance cycle.

An unambiguous classification of measures is not always possible. Ultimately, the focus of a given quality assurance measure on a particular phase and in a particular intensity and level of formalization depends on the actual application. The scope and limits of selected quality assurance measures, as well as their acceptance and the efforts and costs associated with them are discussed in the following.

**Table 5: Focus of quality assurance methods during the quality improvement cycle**

Phase of the quality improvement cycle	Examples of quality assurance tools
1. Whole quality cycle	<p>Quality circles, continuous quality improvement</p> <p>Quality management, total quality management, organizational learning, risk management</p>
2. Identification of the quality of care and analysis of quality problems	<p>Tools for self-assessment and external assessment, e.g. check lists, doctors' reports, complaint system, performance reports</p> <p>Hygiene controls, safety controls, quality controls, "ring experiments"</p> <p>Documentation of primary and secondary data on quality improvement, e.g. problem-oriented patient files, documentation of the undesirable side effects of pharmaceuticals, registries, data collection based on quality criteria (e.g. external comparisons) patient IDs and patient "passports"</p> <p>Analysis of quality issues in health care, e.g. monitoring studies, patient interviews, employee surveys</p>
3. Measures of quality	<p>Health care objectives, quality indicators, tracers, guidelines, standards of care, laws, directives, framework agreements</p> <p>Comparison with other facilities, regions or best-practice models (benchmarking)</p>
4. Feedback methods	<p>Feedback on internal data and quality results, e.g. during team meetings</p> <p>Feedback on external comparisons, e.g. levels of pharmaceutical prescriptions</p> <p>Methods for the communication, visualization and publication of information on the existing quality of care</p> <p>Retrospective peer review, usually without recommendations for improvement, e.g. autopsies, medical audits, evaluation of appropriateness, utilization review</p> <p>Prospective peer review, e.g. second opinions, prior authorization</p> <p>Technical or computer-supported early warning systems and achievement reports</p>
5. Identification of solutions	<p>Description of existing quality of care (usually without feedback), e.g. continuing education, suggestions system, quality handbooks, regulations</p> <p>Decision-making support and/or coordination of processes, e.g. evidence-based clinical practice, guidelines, nursing standards, health technology assessment</p> <p>Internal peer review, usually with specific recommendations, e.g. calls by the chief physician and assistant chief physician, consultation, interdisciplinary visits (clinical pharmacological visits etc.), case conferences</p> <p>External peer review, usually with specific recommendations, e.g. visits in doctors' practices ("outreach visits"), consultation, audits</p> <p>Analysis of factors that promote or hinder the success of quality assurance projects</p>

Phase of the quality improvement cycle	Examples of quality assurance tools
6. Dissemination of solutions	Internal and external continuing education, local opinion leaders Written information (professional journals, e-mail, internet etc.), visual media (films, posters etc.) Information for patients or the general public on evidence and the supply and quality of health care services, e.g. performance reports and quality reports
7. Implementation of solutions	Supervision of health care services, training procedures, interactive multimedia and serial education Clinical pathways, flow charts, computer-supported decision-making aids, expert systems Reminders Material and abstract incentives, legal obligations, contracts, sanctions Patient information, patient versions of guidelines, shared decision making
8. Evaluation of quality assurance projects	Methods of self-assessment and external assessment; team discussions Evaluation of the benefits, risks, costs and processes of quality assurance measures under ideal conditions and actual conditions
9. Description of the quality assurance measures and their results	Self-assessment or external assessment of the quality management system, health care processes and structures, patient satisfaction and health outcomes, e.g. certification according to DIN, EN, ISO etc., quality awards (e.g. European Quality Award etc.) Publication of information on the results of quality assurance programs (aimed at target groups)

*Source:* Advisory Council for the Concerted Action in Health Care

**97.** There are indications, mostly in the international literature, that under certain conditions single quality assurance methods such as targeted feedback, quality circles, peer review and to a certain extent audits and guidelines can improve the quality of health care processes and outcomes.

However, since there is little evidence on the effectiveness of quality assurance measures in the context of the German health care system, the Council refrains here from the recommendation of particular methods on the basis of their effectiveness. Indeed, the Council considers it necessary to subject existing and planned quality assurance processes to an intensive pre-evaluation and re-evaluation with respect to their benefits for patients and their costs. Much more emphasis should be placed on the "quality assurance of quality assurance" in Germany than has been the case in the past. The Council points to the need for the development of appropriate research on quality and health care in Germany.

**98.** Furthermore, the Council views the following principles as essential for the success of quality assurance measures:

- The organization and substance of quality assurance measures should be adapted to each quality problem, the health care setting and the quality objectives.
- Experience with and studies of quality assurance programs show that improvements in the quality of processes and outcomes are attainable when all phases of the quality improvement cycle are taken into consideration.
- Since most quality assurance methods are designed to focus on single phases of the quality improvement cycle, it is usually necessary to combine different measures in order to ensure that the cycle is complete.
- Experience with and studies of quality assurance programs also show that the goal setting, feedback and implementation phases are often neglected even though they are crucial for the positive effects of quality assurance measures on the health status of patients. It is therefore essential that extra attention be paid to these phases of quality assurance projects.
- Increased emphasis should be placed on factors that may promote or hinder the effectiveness of quality assurance measures during the planning, implementation and evaluation phases.

**99.** A number of procedures have been shown to be beneficial for the successful implementation of quality assurance measures, including:

- The integration of all participants beginning at the design phase of a quality assurance project,
- the personal involvement of participants and decision makers,
- clear and comprehensible information and effective forms of communication,
- financial and intangible incentives,
- forums and methods for the continuous review of the quality assurance process,
- forums and methods for the continuous feedback of outcomes and experience.

The following barriers often impede quality assurance measures:

- Inadequate access to information,
- a lack of basic knowledge and skills or a lack of confidence in the ability to change one's professional behavior,

- lack of time, resource and motivation for learning new skills,
- heavy work load,
- increased financial pressures,
- doubts in the effectiveness and necessity of a quality assurance measure,
- communication problems and conflicts between professions and levels in an organization's hierarchy,
- resistance to a perceived threat to professional autonomy.

An analysis of motivating and promoting factors as well as possible barriers should precede the implementation of all quality assurance measures. The integration of all persons involved in the quality assurance project is of particular importance.

**100.** More attention should be paid to the integration of patients in the evaluation of quality and, if appropriate, in the implementation of quality assurance measures (e.g. additional patient information). In this context, the Council refers to the issue of the public transparency of quality data discussed in Chapter II-3.6.

### **2.3 Evidence-based medicine - potential and limits: The "gray area" of medical decisions**

**101.** Research has revealed a lack of acceptance for scientific evidence among health care providers and inadequate implementation of evidence-based results in routine care. Furthermore, it is virtually impossible for individual health care professionals to maintain an up-to-date overview of all medical information. The Council therefore sees an urgent need for a modern system of information management that is critical, efficient and user-oriented as a means for improving the decisions of doctors and patients.

**102.** The teaching of the basic theoretical and methodological skills (i.e. clinical-epidemiological knowledge) as well as the technical and practical skills needed for the successful implementation of evidence-based medicine should begin at an early stage of medical education. This is the only way to ensure that all doctors have enough routine in quality assurance when they begin practicing medicine that they will be able to integrate evidence-based medicine in their clinical activities. Germany must follow the lead of other countries by establishing curricula in medical schools, training facilities and continuing education programs and by fostering research opportunities as well as the informational, organizational and decision-making techniques that contribute to the diffusion and development of applied clinical epidemiology.

**103.** In the Council's view, most of the criticism and objections to evidence-based medicine are based on a basic misunderstanding of the objectives and methods of this approach. This applies to the reduction of evidence-based medicine to "scientifically established medicine" or to a "science of evidence classes" as well as to the critique that it is a form of scientism in the sense of ascribing to scientific knowledge the claim to absolute truth. These views do not do justice to the primary goals of evidence-based medicine: to combine the best available evidence with the clinical experience of doctors and the preferences of patients. It is precisely the application of evidence-based medicine that has shown that medical decisions based solely on scientific knowledge are inadequate for dealing with the complex requirements of patient-oriented health care.

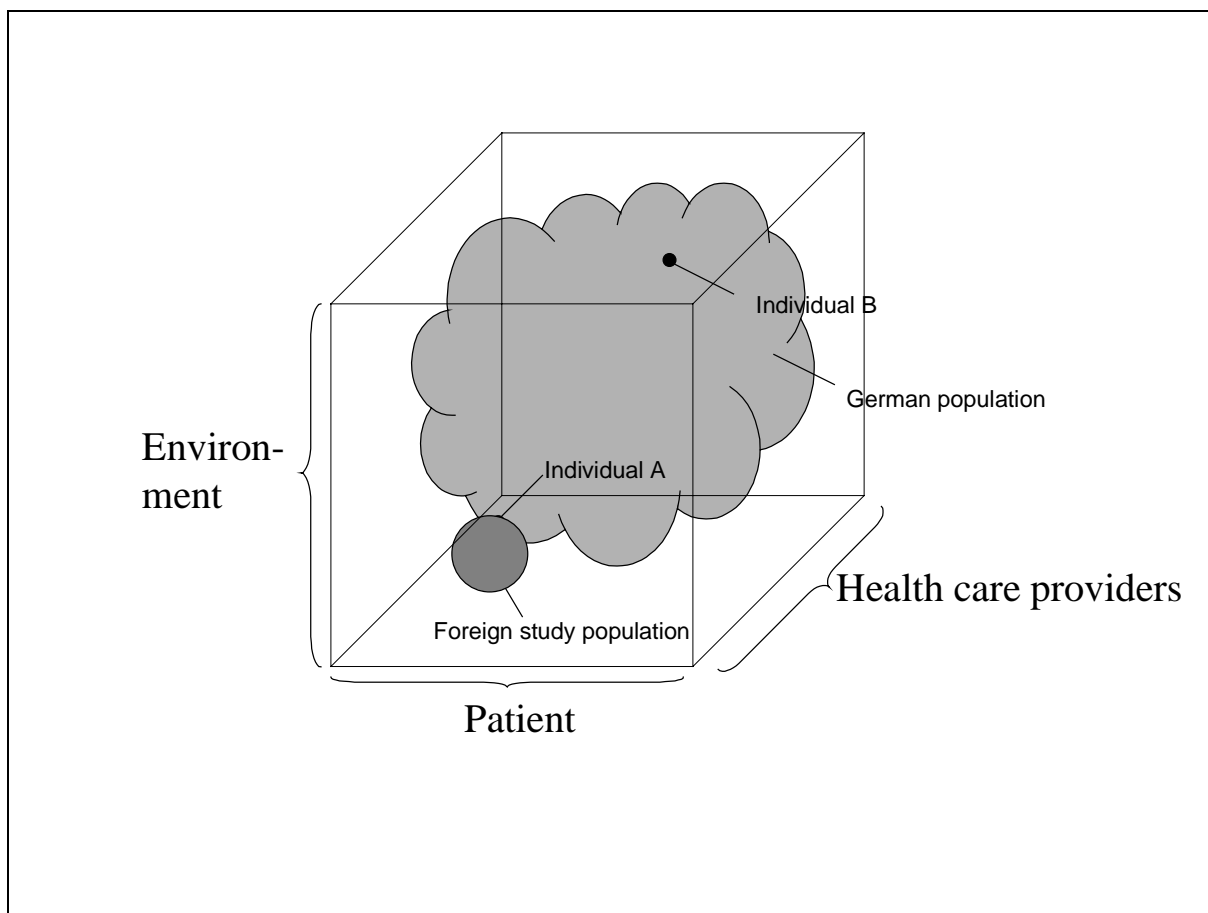
**104.** The term "gray area" is usually applied to those areas of medical activity in which the best available evidence on diagnosis and treatment are incomplete or contradictory. Gray areas also exist at the system level where health care providers and decision makers must confront ethical, legal, political and economic problems that can not be solved by recourse to convincing scientific and medical evidence alone. These problems include issues such as the allocation of scarce resources, balancing individual with public interests and demands for a humane and equitable health care system.

Gray areas are inherent to medicine. Like scientific knowledge, their contents and boundaries are in a constant state of flux. In this respect, they are an expression of the dynamic processes that characterize the relationship between medicine and the imponderabilities of its subject matter, which may be changed or limited but never eliminated. The effectiveness of medicine, and in particular of evidence-based medicine, depends to a significant extent on the way in which the uncertainties of the gray areas are handled. In the gray areas of medicine, neither a therapeutic minimalism based on methodological purism nor an attitude of therapeutic arbitrariness ("anything goes") is called for.

The tools of evidence-based medicine can be used to expose and objectify gaps in knowledge or contradictory evidence in the gray areas of medicine. In the course of the procedures recommended by evidence-based medicine, clinically relevant, methodologically sound and operational scientific evidence may be found in areas that were hitherto viewed as gray areas. However, it is also conceivable that accepted clinical routines may prove to be in the gray area of inadequate or contradictory evidence. It is clear that the definition of a "gray area" depends on the current state of scientific knowledge as well as on the personal knowledge and interpretation of the medical practitioner. Only systematic reference to the best available evidence on the basis of the procedures recommended by evidence-based medicine can either confirm or refute the existence and scope of potential gray areas.

**105.** Gray areas in the practice of medicine are not characterized alone by a lack of evidence that is sound or based on experience. Clinically relevant research results that are based on a sound methodology and which are operational contain gray areas that arise when the results of research on patients are reapplied to patients beyond the study population or when the averages calculated for groups are applied to individual patients (i.e. the problem of domain effectiveness, see Figure 5).

**Figure 5: Domain model of the applicability of study results on patient populations and individuals**



*Source:* Advisory Council for the Concerted Action in Health Care

The methods and models developed in evidence-based medicine for testing the transferability of results can not completely eliminate these Grey areas. One reason for this is that the procedure used in evidence-based medicine is based in part on clinical intuition and thus leaves much room for interpretation. Another reason is that the procedures recommended by evidence-based medi-

cine are based on specific conditions that are not always met in practice and must therefore be subject to critical analysis. The complexity of the formal measures recommended by evidence-based medicine as well as the effort associated with them, both of which place limits on their implementation in a clinical setting, must also be subject to critical analysis.

**106.** Despite these reservations, testing transferability according to the criteria of evidence-based medicine represents an advance over the intuitive and implicit procedures presently used in the provision of health care. It is an attempt to explain, objectify and quantify the expected benefits of treatment for each patient by combining the doctor's clinical judgment and patient preferences in an explicit, transparent and systematic procedure. It should not be forgotten that the transfer and extrapolation problems arise whenever one's own experience with patients or the experience of others is transferred to new patients; i.e. this point of criticism applies to a basic problem of medical knowledge. Evidence-based medicine helps to make this problem explicit and accessible to critical reflection.

**107.** Since there is a tendency in both the practice and theory of medicine to avoid the topic of "gray areas" or uncertainty, there is a need for a new systematic and open treatment of the limits and sources of error of medical knowledge and activity. What is needed are research programs and educational curricula at medical schools that combine the methods of clinical epidemiology with those of clinical decision making.

In the Council's view, the treatment of the gray areas in medicine requires the long-term re-orientation of research activities towards practical, elementary and accepted medical practices that have either not been evaluated or inadequately assessed. This includes complex treatment regimes with long-term effects and the whole field of "caring medicine", with its advisory, supportive and informative character that makes it an essential element of daily medical practice.

## **2.4 Evidence-based guidelines**

**108.** There is enough scientific knowledge available at present to ensure that guidelines could provide a contribution to the improvement of the quality and efficiency of health care in many areas of diagnosis and therapy if they are developed, distributed and implemented properly.

However, it is difficult to predict whether the intended medical and economic effects of guidelines will be achieved in actual practice. It is even more difficult to estimate the overall effects of existing guidelines. For these reasons, guidelines should first undergo pre-evaluation in the context of pilot projects or demonstration projects to analyze the course, extent and type of effects that result from the application of guidelines before they are introduced universally. Fur-

thermore, the use of guidelines in routine care must be documented and evaluated continuously in order to identify unplanned effects and long-term effects and respond to them when necessary. The Council recommends the evaluation of guidelines in different stages of their application; an approach that has proved itself over many years in the testing of pharmaceuticals.

Like other decision-making tools and process management methods in medicine, guidelines are "technologies" and must undergo a health technology assessment before they are implemented on a general scale.

**109.** Experience with the use of guidelines under routine conditions have shown that their full potential is often not realized because of deficiencies or omissions in their planning, development, dissemination and implementation or because of the lack of foresight with respect to potential hurdles and resistance to their application. Failure and disappointment are thus usually not due to guidelines as a tool of quality assurance as such but to their improper development and implementation.

**110.** Many studies have shown that the majority of guidelines in Germany and other countries do not fulfill the required quality criteria for the development of multidisciplinary, evidence-based guidelines based on transparent documentation. In addition, there are deficiencies with respect to the inclusion of patient preferences and to adequate strategies for the dissemination, implementation and evaluation of the guidelines. In light of these problems, programs have been developed in Germany for the targeted promotion of guideline quality on the basis of international models. Examples of these efforts include the guidelines program of the Association of the Scientific Medical Societies and the German Society for General Medicine as well as the guideline clearinghouse of the Agency for Quality in Medicine.

**111.** The Council views the current activities for the promotion of guideline quality as very important and gives them its emphatic support. However, the Council also sees the following problems in current guideline programs:

- Many professionals who develop guidelines use an overly narrow concept of "multidisciplinary" that is restricted to interdisciplinarity in the medical profession. Multidisciplinary in the development of guidelines extends far beyond cooperation among the medical specialties and includes the participation of other health care professionals and interest groups. Patient associations and self-help groups must also be included, as they express the interests of those affected by guidelines and are typically underrepresented in the normal procedures for the definition of medical standards and guidelines.
- Past programs for the promotion of guideline quality often focus primarily on unanswered questions in the development of guidelines and neglect the importance of the proper dis-

semination, implementation, evaluation and revision of guidelines. Since deficiencies or omissions in the areas of planning, development, implementation and evaluation can threaten whole guideline projects, the Council regards the focus on the methodological quality of guidelines as too narrow.

**112.** The use of guidelines in routine care only has a realistic chance of success if the following requirements are observed in the planning, prioritization, development, implementation and evaluation of guideline projects:

- limiting the development of evidence-based guidelines to a few areas of care that are viewed as priorities in terms of their epidemiological, clinical and economic relevance, for which there are indications that the current provision of health care is either inadequate, incorrect or excessive and which, if eradicated, could have significant effect on morbidity and mortality;
- the application of transparent, systematic and data-based procedures for determining guideline priorities;
- following a systematic, evidence-based strategy for the development of guidelines;
- the representation of all relevant actors in guideline committees;
- the use of transparent and formal consensus building procedures for the formulation and endorsement of guidelines;
- the validation of guidelines by external experts;
- the pre-evaluation of guidelines in pilot projects and demonstration projects;
- the modification of guidelines by users to reflect local conditions;
- effective, multi-dimensional measures for the dissemination and implementation of guidelines among defined target groups;
- the integration of guidelines in existing and emerging quality management programs;
- the integration of guidelines in the education, training and continuing education of doctors and other health care professionals;
- the continuous control and evaluation of the success of guidelines under routine conditions on the basis of a few central parameters;
- the regular re-evaluation and revision of guidelines.

**113.** Even the most meticulously planned and implemented guideline programs may not succeed if lawmakers, the self-governance bodies and the designers and users of guidelines do not

develop the structural conditions that would remove existing systemic, user-based and political barriers. The success of guidelines depends in particular on:

- a political consensus of all stakeholders on the joint development of guidelines for integrated disease management that transcends professional, institutional and sectoral boundaries;
- the coordination and harmonization of the activities for the development of guidelines of individual groups and organizations (professional associations, medical societies and third-party payers)
- the preparation of the necessary financial and human resources for the proper planning and implementation of theoretically sound, practical guideline programs;
- the promotion of behavior that follows the recommendations of guidelines by removing false incentives and implementing fee schedules that are based on guidelines.

**114.** The Council recommends that the medical societies focus in the future more on the development of evidence-based and multidisciplinary guidelines that are based on consensual processes ("S3 Guidelines" according to the classification of the Association of Scientific Medical Societies). Due to the considerable effort associated with the development of such guidelines, it is necessary to increase cooperation among the medical societies as well as between the medical societies and other stakeholders and organizations in the health care system (e.g. the self-governance organs, professional associations and patient groups) and to focus on a few important health care problems.

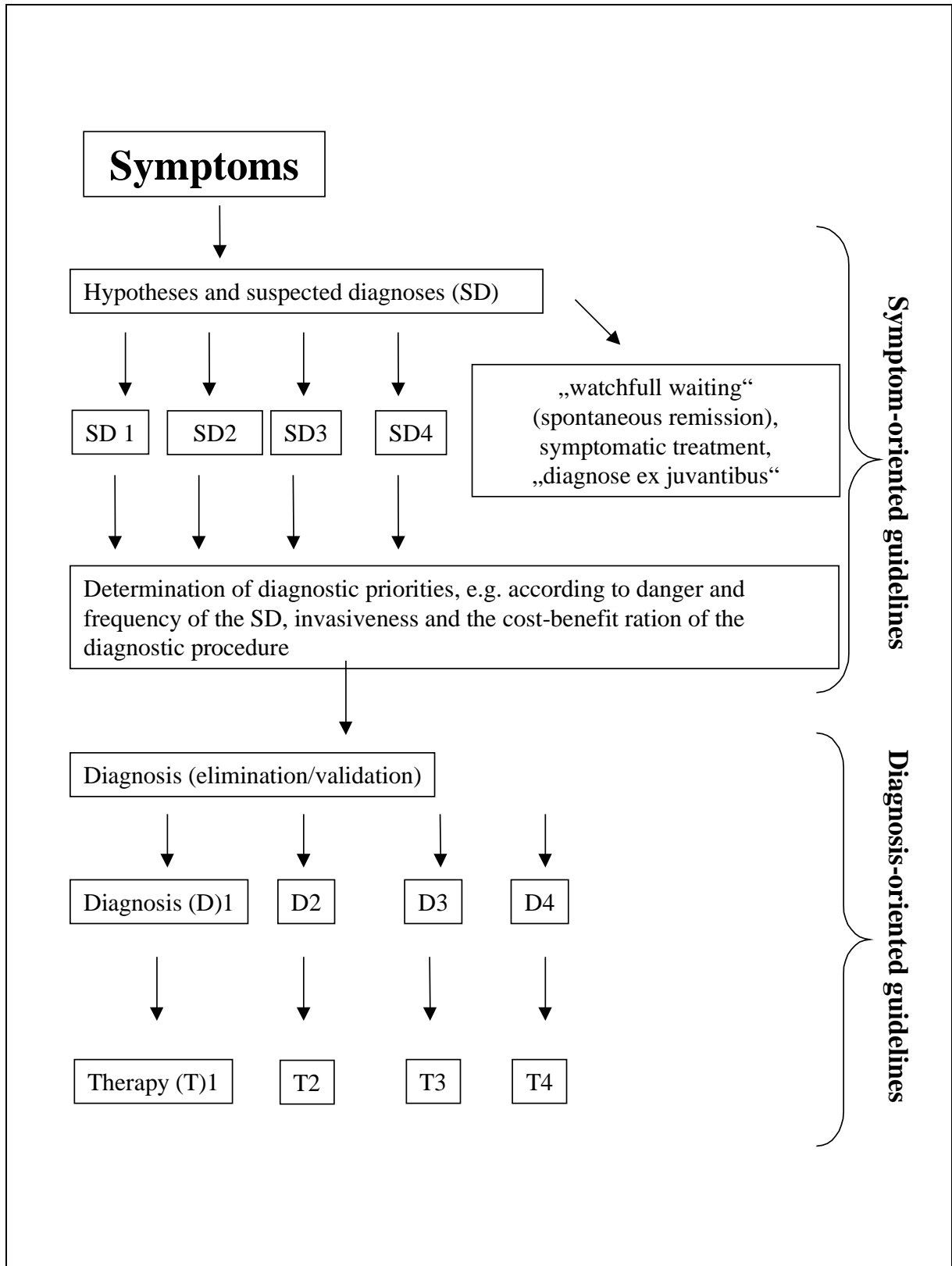
**115.** Symptom-oriented guidelines and diagnosis-oriented guidelines are not competing but complementary forms for the classification of guidelines on the basis of their content. A guideline concept that combines both perspectives is the natural result of medical activity and also establishes the basis for linking primary care guidelines with guidelines for special care (Figure 6). The Council recommends that different work groups (e.g. of separate professional societies) develop corresponding symptom-based and diagnosis-based guidelines in coordinated, modular guideline programs.

**116.** One problem that remains to be solved has to do with the finance of the costly development of evidence-based guidelines by non-partisan ("ethics") groups. Adequate funding plans must be developed in order to supply sufficient resources and to prevent the dominance of particular interests.

**117.** The Coordinating Committee should based its decisions on the criteria for rational and efficient health care as called for by the quality assurance provisions of social health insurance

law on evidence-based, multidisciplinary guidelines that have undergone formal consensus-building procedures.

**Figure 6: The role of symptom-based and diagnosis-based guidelines in the provision of medical treatment**



Source: Advisory Council for the Concerted Action in Health Care

### **3. Quality Assurance and Quality Management in Health Care**

#### **3.1 Quality assurance and quality management in the provision of specialist care in the ambulatory and inpatient sectors**

**118.** There are indications of excess care and quality problems in a relevant proportion of the care provided by medical specialists in the ambulatory and hospital settings in Germany. Quality assurance measures are therefore of primary importance in the delivery of specialist care. This applies in particular to those specialties in which procedures are invasive, technically complex or associated with the risk of serious or life-threatening complications.

**119.** There is at present a lack of comprehensive and continuously updated information on quality assurance measures in the area of special medical care. The legal obligations of decision-makers at national and state level to notify the Association for the Promotion of Quality Assurance of quality assurance agreements is inadequate, in particular because it lacks sanctions.

Furthermore, only a few of the documented quality assurance measures have evaluative elements. Thus, the majority of the quality assurance measures that have been introduced in the daily routine in Germany or are in development have not been tested with respect to their effectiveness and efficiency. Quality assurance measures and quality management, however, are secondary technologies and like other decision-making aids and organizational procedures in medicine must also be subject to health technology assessment prior to and during their general implementation. In addition to this warranted criticism of the insufficient evaluation of quality assurance measures, it should not be forgotten that the medical and economic evaluation of quality assurance measures is associated with considerable methodological and logistical problems, some of which have yet to be solved. However, the Council does not believe that these problems speak against the need for the evaluation of quality assurance measures.

**120.** Past problems in the implementation of quality assurance measures can be traced mainly to the following problems:

- The measures are incomplete and incorporate only individual phases of the problem-oriented quality cycle.
- Data on the long-term outcomes of diagnostic and therapeutic activities is lacking.
- Problems of motivation and a lack of incentives hinder the development and implementation of quality assurance measures.
- Quality assurance measures stop at institutional and professional boundaries.

**121.** Another problem with respect to external quality controls in the hospital sector (e.g. the quality assurance measures associated with the use of flat-rate payments based on diagnosis and/or procedure) is that they react very slowly to possible quality problems. In some cases, it may take years before the discovery of irregular data leads to the implementation of targeted measures.

**122.** The Council believes that the planned introduction of a hospital reimbursement system based solely on prospective flat-rate payments will increase the need for thorough quality assurance measures in order to prevent potential threats to the quality of care due to the underprovision of services in hospitals (see Chapter II-4).

**123.** A problem common to both the ambulatory and hospital sectors is the lack of positive incentives for the establishment and implementation of quality measures. In some cases, most doctors involved with the actual application of quality assurance measures have the impression that they consist primarily of more work, control and sanctions. In contrast to other sectors of the economy for which the modern concepts of quality assurance were developed, there are no incentives in the health care system to stimulate competition among health care providers that is based on the factor of quality.

**124.** The Council therefore recommends the following:

- Traditional quality assurance measures in the medical specialties that have proven effective should be refined and developed. The Council views with concern the continuing decrease in the use of clinical section, an established quality assurance tool in clinical diagnosis and therapy. It should be evaluated whether the further reduction in the number of autopsies and the associated negative effects on quality assurance in the hospital sector can be brought in check by a law on autopsies that would eliminate legal uncertainties.
- Incentives should be established for the notification of quality assurance measures to the Association for the Promotion of Quality Assurance in Medicine.
- New quality assurance approaches should not be accepted uncritically but evaluated with respect to their effectiveness, feasibility and costs. In addition, established quality assurance measures that have been introduced on a routine basis must be subject to re-evaluation and constant control.
- External and internal quality assurance measures should be combined. The day-to-day control of processes to affect quality can be maintained only by a functioning system of internal quality assurance with short reaction times. For this reason, external quality comparisons should emphasize not only data collection and evaluation but feedback and dialogue with

health care providers. The project offices should be equipped with the required personnel and material resources in order to collect data and assume an advisory role for the hospitals.

- One approach to the promotion of quality-oriented competition among health care providers is to create more transparency for the insured, doctors and health insurers with respect to the range of services, performance and quality management of a hospital or doctor's practice. The Council believes that uniform and standardized certification procedures are a good instrument for creating more transparency with respect to the provision of health care and enhancing quality-oriented competition in the health care system. Standardized, obligatory "report cards" are also needed. Such report cards should contain the following:
  - Information on the staff and equipment of facilities (including the departments, specialties and the qualification of employees),
  - information on the number of patients (including the case mix),
  - diagnosis statistics based on the International Classification of Diseases (number of diagnoses per year),
  - data on the number of procedures (especially for complex and invasive diagnostic and therapeutic procedures),
  - for university hospitals, information on research activities (external funding, publications and citations) and
  - information on outcomes (success rates and complication rates for invasive procedures, hospital mortality, nosocomial infections).

In order to provide an unbiased comparison of different facilities that regards differences in case mix and prevents risk selection, certification procedures and report cards must be adjusted to reflect different risk structures. Report cards should be available (e.g. via the internet) to the general public (e.g. patients and their families) and should be written in language that is easy to understand.

**125.** The Council regards doctors' routine in the performance of technically complex and risky interventions as a meaningful indicator of a doctor's performance. Therefore, the Council recommends requiring all facilities and health care providers to document procedures for which there is empirical evidence that the quality of a procedure is dependent on the number of times it is performed. For such procedures, the Council believes that it is worth evaluating whether remuneration could be made contingent on doctors' routine (measured as a minimum number of procedures per year). At the same time, however, quality assurance measures must control the

number of diagnoses to ensure that procedures are not performed merely to reach the minimum requirements.

**126.** The serious cases of false diagnoses and unnecessary surgery that were made public in the course of the "Essen breast cancer scandal" made it clear that there is a definite need for increased external and internal quality assurance of mammography, explorative surgery and treatment, and of the analysis of cell samples. The Council therefore welcomes the initiatives and pilot projects aimed at improving the quality of mammography, the surgical removal of detected lesions and the analysis of tissue samples and the attempts to bring them up to international standards. The promotion of the quality of breast cancer diagnostics must not be aimed solely at early detection programs but extend to curative diagnosis.

**127.** The Council calls attention to the fact that the costs associated with the establishment and implementation of quality assurance measures must be considered in relation to the proven and objectifiable benefits to patients and employees. However, evidence of objectifiable benefits alone is not sufficient for requiring general reimbursement by third-party payers of quality assurance measures that fulfill this criterion. This would remove all incentives for health care providers to ensure the efficient implementation of quality assurance measures. An adequate and promising approach for the finance of quality assurance measures by third-party payers could be the use of bonus payments and reduced payments based on proof of implemented quality assurance measures (see Special Report 1997). Such an approach should be considered during the development of fee schedules that are oriented towards performance, quality and outcomes.

### **3.2 Quality assurance and quality management in general practice**

**128.** The application of quality assurance and quality management in general practice must meet special requirements that result largely from the high degree of complexity of the health problems confronting doctors. Comorbidity is common among patients seeking care in the primary care sector and primary care doctors are confronted more often than specialists with symptoms for which there is no specific diagnosis.

**129.** An unavoidable yet frequent mistake in the establishment of quality assurance in primary care is that new measures are overly complex. This often results in demotivation and disappointment among the participants. New quality assurance measures should therefore be introduced in the form of clearly defined compact projects. As evidenced by primary care programs in the Netherlands, Great Britain and Ireland, counsel and support are useful aids. Such measures could include facilitators or supervisors who provide support to teams in their practices.

**130.** A consistent patient-orientation of all quality assurance efforts is also a requirement in the primary care sector. In addition to consistent objectives, instruments for the evaluation of the quality of care by patients must be developed for use in this sector.

**131.** The successful implementation of measures for quality improvement requires appropriate incentives systems. These should emphasize participation in the exchange of information among health care professionals and mutual support.

**132.** Quality circles are particularly suited to the primary care sector as a means for promoting quality. They provide an opportunity for making explicit the implicit treatment and problem-solving strategies in family practice. The knowledge gained by these means can contribute significantly to the development and revision of guidelines and may be used for the exploratory and analytical generation of research hypotheses. In particular, problem-oriented and case-oriented methods should be promoted in quality circles.

The Council recommends improving the quality of quality circles by placing more emphasis on external evidence and on the evaluation of health care provision in the participating facilities. This also applies to the establishment of quality circles in the context of "practice networks" and managed care structures. Many practice networks have established interdisciplinary quality circles. Since the need for cooperation and a clear definition of interfaces will be greater than ever, quality circles will have a number of tasks. These extend from the adaptation of national recommendations to local requirements to medical controlling based on quality indicators.

**133.** Modern total quality management and continuous quality improvement are hardly compatible with the traditional practice management that focuses on doctors. The systematic promotion of quality with the goal of continuous quality improvement and comprehensive quality management is a task of managers and executives. Doctors in private practice must assume personal responsibility for the attainment of defined quality goals. Quality promotion in primary care is a living process at grass-roots level and depends on the motivation of primary doctors and their practice teams.

**134.** Present documentation practices in the primary care sector are unsatisfactory. In contrast to the standardized admission forms for the documentation of new patients in hospitals and the documentation requirements for many diagnostic and therapeutic procedures, there are no binding rules on the form and content of information in the primary care sector except for the existing legal guidelines. Documentation is restricted largely to data needed for accounting and invoicing. This data usually lacks information on the relationship between health problems and the medical measures taken to solve them and does not allow for the analysis of treatment pathways and the health care process as a whole. The Council therefore recommends the introduction of

documentation measures that are designed specifically for primary care doctors. These should document the course of a disease as well as the course of treatment and serve as a basis for internal audits and controlling measures.

**135.** Guidelines for primary doctor care must be related to the symptoms presented by patients (e.g. "back pain") and can not usually assume a confirmed diagnosis (e.g. "disc prolapse"). This is the only effective way to support timely decisions, which are often decisive for the further course of treatment, in the provision of care to patients with diffuse health problems. In order to deal with adequately with specific conditions in primary care, especially those determined by epidemiological factors, guidelines must be developed for use only in the provision of primary care or existing guidelines adapted to meet these needs.

**136.** To improve the applicability of the results of clinical studies in the primary care sector and thus increase the quality of doctors' care, the Council recommends the promotion of studies that compare the results of quality assurance projects and quality evaluations that have been initiated by health care professionals in actual practice (bottom-up approach) with measures that have been developed by external instances (top-down approach). More studies must be conducted under actual conditions in the primary care sector that deal with the problems and quality improvement measures that are typical of this sector. To this end, structural, financial and cooperative measures are needed to promote research in the primary care sector.

### **3.3 The patient-doctor relationship as a quality characteristic of health care**

**137.** In view of the many studies and observations indicating that patient interpretations, expectations, desires and goals as well as other psychosocial factors in the exchange of information and interpretations between patients and doctors have a decisive effect on the course of a disease, more attention should be paid to personal interaction as a quality criterion of medical interventions.

The Council points out that this interaction is equally important in other health care professions and should also be monitored in these areas.

Medical education, training and continuing education should create a broad awareness for the effects of a doctor's behavior towards patients on the course of disease and on the utilization of the health care system.

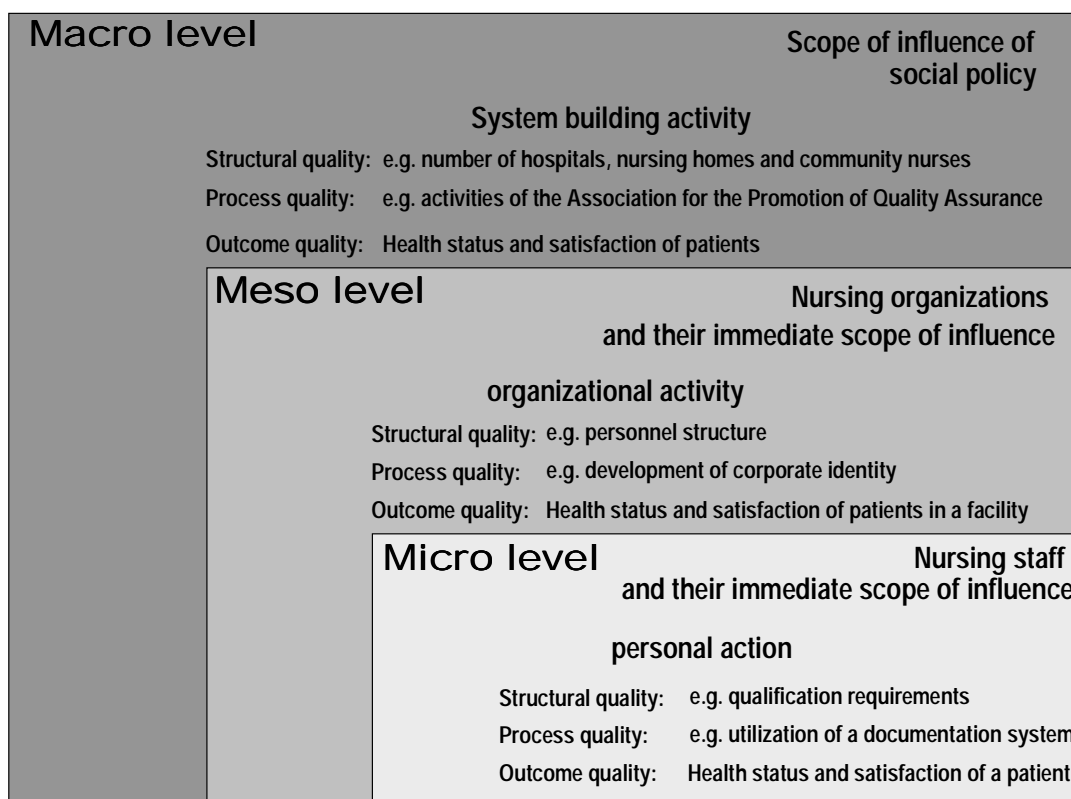
### **3.4 Quality assurance and quality management in nursing**

**138.** Quality improvement requires that a certain stage of development has been reached in a profession. The nursing profession is in transition from the traditional role of the nurse as an assistant to the role of the nurse as a modern health care professional. In this context, the Council recommends the promotion of the nursing sciences in Germany, e.g. through the development of nursing curricula and the increased promotion of research (see Section II-1.2).

**139.** There is a clear imbalance in nursing between the extent of discussion about quality assurance and its actual implementation. Studies on the implementation of quality assurance measures in nursing reveal that uncertainty and skepticism with respect to quality assurance measures place considerable limits on their effectiveness. In contrast to the USA and the United Kingdom, quality management is not yet an integral part of the work culture and professional activity. There are practically no professional regulations for nursing to ensure that special nursing tasks are performed at the necessary level and subject to quality assurance measures. The Council therefore recommends that professional quality control regulations be developed and implemented for specific nursing tasks and work processes.

Figure 7 combines the different levels of activity in nursing with quality assurance measures at the levels of the health care system, health care processes and outcomes.

**Figure 7: Dimensions of quality assurance in nursing**



Source: based on M. Ewers (1998)

**140.** Professional nursing is embedded in a health care process, in particular in the hospital setting, that involves many different health care professions. Inherent to this process is a mutual inter-professional control process in the sense of quality assurance (see Section II-3.5). This applies in particular to the common activities of the different professions that require mutual control. In Germany, however, a quality assurance discussion involving all health care professions which combines the relevant methods and the various strategic perspectives has yet to be developed. This situation is evidenced in nursing by the fact that the quality assurance discussion focuses only on the nursing context and involves only nursing personnel, while excluding, for example, doctors. The Council therefore recommends that the intersectoral and inter-professional quality discussion called for by social health insurance law be put into practice. The same applies to the reform of quality assurance in long-term care under the law on social long-term care insurance.

**141.** At present, not enough attention is paid to the individual dimension of nursing quality (patient satisfaction). The Council therefore recommends that quality assurance measures that pri-

ority be given to the focus on users of the health care system. This includes the continued shift in focus from functional nursing to primary nursing as well as the universal and effective provision of binding and targeted guidance to family caregivers. The experience and opinions of patients and their families should play a decisive role in a functioning quality management system. The establishment of internet platforms for the exchange of information (e.g. negative and positive feedback) can also help improve the quality of nursing and its focus on users (see Chapter I-3, Section II-3.6).

**142.** Although there is a consensus that quality and quality awareness in health care facilities must be enhanced, quality assurance in nursing is characterized primarily by a wide range of external measures; i.e. it results mainly from legal pressures and may be counterproductive in different institutions. Quality assurance and quality improvement, however, are intrinsic tasks of health care facilities and the nursing profession. External controls can only assist these processes. Ultimately, the nursing staff in health care facilities is responsible for ensuring the best possible quality of care.

**143.** Clinical sections for monitoring nursing damages (e.g. bed sores) and unannounced control visits are effective external measures for identifying deficiencies in nursing quality. When using these methods, it must be remembered that quality development can not be imposed on a facility by an outside party. Given this reservation, the Council recommends implementation of the above mentioned quality assurance measures.

**144.** The Council believes that more emphasis should be placed on outcomes quality in certification procedures. Certificates should be granted by independent commissions according to clear criteria that are transparent for all users.

### **3.5 Inter-sectoral, inter-institutional and inter-professional approaches**

**145.** When possible, the outcome and quality objectives of quality assurance measures and quality management should correspond to general objectives related to health status and the provision of health care. Furthermore, they should focus primarily on patient-oriented outcome quality.

It follows from the principle of outcome-oriented quality promotion that quality assurance must be organized, whenever necessary, across professions and institutions. This requires coordination at association level. For example, quality circles should be implemented across sectoral boundaries and be based on a multidisciplinary approach (see Section II-2.2, II-3.1, II-3.2).

Future documentation and information technology systems should be compatible with approaches and measures that transcend the boundaries between professions, institutions, health care sectors and third-party payers. Issues of quality-oriented documentation and data analysis should be considered right from the start of planning.

**146.** The development of inter-institutional measures for specific indications or health care services is also recommended. Such measures do not focus on the quality of outcome of a particular health care service but on the quality of the process between health care providers and patients over the whole treatment pathway. Such indications can be derived from or developed on the basis of treatment guidelines (see Section II-2.4). Adequate treatment guidelines should be combined with guidelines for cooperation and the integration of quality assurance measures across institutional boundaries.

**147.** To develop existing quality assurance approaches consistently on the basis of (long term) health outcomes, measures for defined health care priorities must be planned and evaluated with respect to their effectiveness and costs. These measures must be designed to allow for the monitoring, evaluation and management of processes between institutions at different levels of health care.

**148.** New forms for the provision of health care (i.e. pilot projects and integrated care structures in accordance with social health insurance law) that are supposed to improve the quality of care should only be authorized if they include the introduction of quality management based on outcomes parameters as well as an independent external evaluation. Although this could raise hurdles to innovation, it also improves the chances of success for innovative forms of care.

**149.** Quality assurance measures should be based on the broadest possible political consensus between the participating professions, patient representatives, umbrella associations and institutions and politicians. It must be ensured that the committees are able to function and work productively.

**150.** Patient and consumer representatives should be included in all committees (see Chapter II-3) that make decisions on the objectives, concepts and implementation of quality assurance measures, e.g. in the course of planning quality assurance measures for the prospective diagnosis-based system of payment in the hospital sector (see Chapter II-4).

### **3.6 The results of quality assurance and quality management as user information and as a contribution to the promotion of a quality culture**

**151.** Patients and the insured have a right to be informed of the quality of health care services. As informed and quality-conscious users they can contribute to the improvement of quality (see Chapter II-3).

**152.** In this context, the Council welcomes the fact that the health monitoring of the federal government and some state governments will focus more on the quality of care. The Council approves of the publication of information on the quality of care as part of hospital report cards, certification procedures and other external comparisons of data in accordance with social health insurance law (see Figure II-3.1) as well as in the planned quality assurance of the prospective diagnosis-based system of hospital finance (see Chapter II-4).

**153.** The publication of data on quality has enhanced quality assurance measures and resulted in demonstrable success in the improvement of the quality of care, especially in hospitals and in cooperative efforts among health care providers. The chance to advertise quality awards (e.g. certification and quality prizes) should not be restricted to the final outcomes but also to the criteria and evaluation results. In combination with formal and standardized quality assurance methods and projects, such as those documented by the Association for Quality in Medicine, the Council believes that the threat of data manipulation can be minimized. Such measures should not only report on negative factors but also on positive aspects of care and health care outcomes as well as on the targets that have been attained. This would provide incentives for competition based on positive aspects of quality.

Furthermore, the Council believes that health care providers must be allowed to use only valid data. Non-compliance with this requirement represents a deception of users and is to be considered as unfair competition.

**154.** The Council also recommends that the insured have access to published information when their consent is required for participation in those integrated care structures called for by social health insurance legislation that are intended explicitly to improve quality and therefore involve quality management measures (see Section II 3.5). In the interest of the increased focus of competition on quality it would be desirable that private and social health insurers are more open about the quality of their own services in so far as these are related to particular health care programs and services.

**155.** Depending on the "transparency culture" of users, the public, health care providers, payers and policy makers, the acceptance and benefits of quality data, quality measures and quality improvement efforts may be promoted or hindered. It is necessary to promote a transparency

culture that fits the needs of patients/users, health care providers, third-party payers and policy makers.

During the preparation of a "Law for improving data transparency in the Social Health Insurance system", the Council recommends that lawmakers consider how the needs of users (patients) and doctors (as "agents" of patients) can be better integrated.

The objective is to foster a quality-oriented culture that strengthens the willingness and ability of all actors to recognize and identify quality deficiencies, to learn from them and to undertake targeted actions to change them.

## **4. Development of the Prospective Finance System for Hospitals**

### **4.1 The current situation**

**156.** The Health Care Reform Act 2000 that went into effect on January 1, 2000 calls for the introduction of a comprehensive, performance-based prospective payment system for hospitals based on diagnosis related groups (DRGs) beginning on January 1, 2003. This system will replace the current system for funding the operational costs of hospitals, which since 1995 has been based on per-case payments (*Fallpauschalen*) and payments per procedure (*Sonderentgelte*) in combination with per diem rates that are negotiated individually for each hospital.

### **4.2 Prospective payment: Efficiency potential and false incentives**

**157.** The basic decision of lawmakers for a patient classification system in which the remuneration of hospital performance on the basis of indices such as inpatient days or individual procedures is the exception instead of the rule is viewed by the Council as a positive development in principle. With some exceptions<sup>1</sup>, treatment cases are better suited to the identification or classification of hospital services than the number of hospital days or the individual procedures performed. The Council believes that the new system has a considerable potential for improving the transparency of hospital services and costs, which, in turn, is a key prerequisite for measures aimed at increasing efficiency in the provision of health care.

**158.** On the other hand, if one considers the many false incentives related to prospective payment, the Council believes that mechanisms do exist to offset these false incentives. Right from the introduction of the new system, there is therefore a need for auxiliary measures of adequate quality management as well as for concepts and measures to ensure the delivery of adequate health care following hospital treatment (follow-up care, rehabilitation, nursing).

Strategies for dealing with these issues comprise the following:

1. Measures to ensure that reimbursement codes for case groups are based on medical criteria that are homogeneous with respect to costs;
2. Integrated coding controls to limit up-coding and expansion of indications (“DRG-creep”);

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<sup>1</sup> E.g. when treatment is very heterogeneous with respect to medical effort and costs even though the diagnosis is the same, such as in geriatric and psychiatric care; in the care of patients with very costly accompanying diseases such as hemophiliacs or dialysis patients; cases in which an organ donation is taken from a living donor; cases in which the hospital length of stay is atypical but justified.

3. Intra- and intersectoral quality assurance measures and payment mechanisms to limit cost shifting into other sectors (see Section II-3.3.2);
4. Tools for planning the number of cases as a means to limit potential increases in the number of cases and expansion of indications;
5. Four strategies are relevant for avoiding the negative effects of cost pressures on quality:
  - Quality assurance and quality management measures (chapters II-2 and II-3);
  - Improving the transparency of performance, quality and costs on the basis of data collected in the course of patient classification;
  - Increasing user competence through more transparency with respect to quality and reinforced patient rights (Chapter I-3);
  - Using quality indicators as an element in the determination of reimbursement rates.

### **4.3 The decision for the Australian classification system**

**159.** The German Hospital Federation, the national associations of the social health insurance funds and the Association of Private Health Insurance Companies (the contracting parties) decided in favor of the Australian system of patient classification, the AR (Australian Refined) - DRGs. The AR-DRG system fulfils the criterion of medical homogeneity much better than other DRG systems. One drawback of the AR-DRG system, however, is that the classification algorithm applies only to the basic case groups, which is too general for quality assurance purposes, or to individual procedures without the corresponding case group, in which case the level of aggregation is not enough for quality assurance. The potential of the AR-DRG system to support quality assurance measures thus depends to a great extent on the development of adequate instruments for the analysis of DRG data; a task that requires great effort. Evidence on the cost homogeneity of the AR-DRGs are not available at present, since no studies of cost variance were conducted for the Australian data. However, the system allows for costly individual procedures that are not grouped separately. The AR-DRG system also allows special rates for cases that exceed the average length of stay within limits that are to be defined by the contracting parties. The comparability of German case groups based on the AR-DRG system with case groups in other countries, however, will be limited.

**160.** Nationally defined characteristics such as the rules for case groups could be integrated in mandatory task lists that would be required of all companies that provide DRG software. The

control of such requirements could proceed on the basis of an inspection procedure for software that is conducted by a certification board. Such an approach would have two advantages: 1. It would give rise to competition among software designers and thus create incentives for innovations in the DRG user software. 2. By limiting the general requirements of the contracting parties to a minimum, this approach could prevent possible conflicts with anti-trust legislation. The Council therefore recommends the establishment of a certification board for grouper software that follows the Australian model.

**161.** The introduction of a patient classification system for virtually all hospital cases will create costs in the hospital sector for the adaptation and continuous upkeep of the system, its implementation in hospitals, the calculation of cost weights and the continuous implementation of quality assurance measures. Experience with DRG systems in other countries reveal that even after implementation of the DRGs, the administrative costs in the hospital sector remain higher than those in a system based on per diem payments. Additional costs will also be incurred in the provision of post-hospital care.

#### **4.4 The future of payment based on case groups**

**162.** Given the legal principle requiring the stability of social health insurance contribution rates, the potential cost saving effects of flat-rate payments were decisive for lawmakers' decision to reform the system of hospital remuneration. Flat rate payments are generally assumed to save costs by creating economic incentives to decrease the length of hospital stay. On the basis of the regulations for determining the reimbursement levels of the existing per-case payments and payments per procedure, the provisions of the Hospital Finance Law call for a procedure for the calculation of payment levels that is largely centralized. Actual payment for each case group at the level of the individual hospital will be determined by a combination of national cost weights, national and regional point values and add-on payments and discounts. The latter will be subject to national regulations and are intended to reflect financial conditions that are not present in all hospitals.

**163.** The contracting parties decided for good reason to use German data for the calculation of national cost weights. If the calculation of national cost weights is based on a sample of hospitals, it is also important to note that, strictly speaking, the criterion of representivity should apply not only to hospitals but also to each case group.

**164.** The calculation of cost weights on the basis of German cost data is likely to be very time consuming. The organizational adjustment required of each hospital for introduction of the new system will also be time consuming (e.g. the transition to unit-of-output costing). Introduction of

the AR-DRG system in Germany on January 1, 2003 requires that all preliminary work be completed by the Fall of 2002, when the negotiations between hospitals and insurance funds for 2003 begin. This time limit seems too short, in particular in light of the need for flanking quality assurance measures and for concepts and measures for the management of post-hospital care. Furthermore, the desired effects of the DRG system will be due mostly to the payments for each case group, and these must first be calculated.

**165.** In addition to removing the system of hospital reimbursement based on individually negotiable price elements, the lawmakers' aim is to prevent the return of the inefficient system of full cost coverage in the hospital sector. In light of the given contractual structures in the hospital sector, the threat that individually negotiable prices for case groups could lead to a return to full cost coverage is definitely given. Under social health insurance law, the (state) associations of the health insurance funds jointly conclude service contracts with individual hospitals. The legal obligation of health insurers to act jointly and uniformly reduces the economic incentive as well as the ability of each health insurer to work effectively towards cost effective solutions.

**166.** Despite the corporatist structure of the health care system, the determination of prices at an average level (i.e. at the cost level of case groups in a sample of hospitals) is a tool that will put pressure on hospitals with above average costs.

From a macroeconomic perspective, a system based on average costs is preferable to one based on full cost coverage. However, the application of average costs

- is no guarantee that the minimum price level is much lower;
- leaves no possibilities for health insurers and the insured to benefit from the profits in hospitals with below average costs. However, drawing off all potential profits should be avoided in any case, since it would remove the economic incentive for hospitals to function more efficiently;
- means that there is no "automatic" calculation of regional cost structures.

**167.** The Health Care Reform Act of 2000 does not specify how the method for determining payment for case groups is to be linked to the principle of stable contribution rates and the budget limits on hospital spending. A system based on retrospective floating point values such as that used for the reimbursement of office-based doctors is inappropriate, since the necessary accounting base is lacking and this system doesn't adequately reflect the role of each hospital at local level. Even the milder version, with prospective floating point values, is not as promising as a "cost-point value system" in which the point value is adjusted at regular intervals on the basis of changes in average costs. The Council recommends an adjustment of point values to

changes in costs at intervals of at least three years in order to allow hospitals enough time to adapt and to provide them with an economic incentive to increase the efficiency of their services. The use of existing methods for planning and controlling the number of hospital cases could be used as a support measure. However, the planning of the number of hospital cases should be based less on historical utilization data than on prospective epidemiological data.

**168.** The focus of the new system of hospital reimbursement on cost savings and the principle of stable contribution rates is dangerous. The costs of hospital care are not the only problem. Rather, the benefits of increased efficiency in the provision of hospital services is also at issue: i.e. the quality of care is an important part of the financial problem. Under the given conditions, uniform prices will put pressure on costs without creating incentives to limit potential negative effects on quality. At presents, the existence of hospitals depends less on quality than on costs. This has less to do with the availability of quality assurance measures (chapters II-2 and II-3) than with the lack of economic incentives for health care providers to use, refine and pay for them.

The legal obligation of those responsible to ensure that the new system complies with the quality assurance provisions of social health insurance law (§§ 135-137, German Social Code, Book V) will probably offset this tendency only partially. The Council therefore reiterates its recommendation to utilize the legal possibilities for quality-based add-on payments and discounts. Measures for improving the transparency of quality and for the publication of comparative quality reports are also promising, because they can stimulate hospital competition for patients (e.g. hospital comparisons; Section II-3.6). Evaluations of hospital performance based on data collected in the course of case documentation will create new opportunities. Public reactions could create additional incentives for health insurers to support or subsidize quality assurance measures in the hospital sector and, if necessary, to cancel contracts with selected hospitals.

**169.** On the basis of social policy considerations, health insurers are limited in their capacity to meet the different preferences of the insured with respect to the quality of care and the level of the contribution rate. The insured may also be interested in quality parameters that go beyond strictly medical factors. It should be the task of health insurers to find out what these are in order to provide services that meet the preferences of the insured. Pilot projects and contracts for integrated care offer social health insurance funds with a legal basis for initiating competition based on the quality of services of hospitals or hospital departments.

**170.** Due to the existing framework (corporatistic service contracts, hospital location) it is advisable to use the very powerful tool of uniform prices carefully during the transitional period. That this measure could create the same inefficient conditions as full cost coverage for some hospitals must be accepted during the transitional phase in order to protect patients from the

effects of cost saving on the quality of care. It could even be viewed as an accomplishment if the new system succeeds only in diminishing existing tendencies towards full cost coverage.

A sustainable compromise between avoiding the negative effects on quality of the cost pressure of flat-rate payments and the re-introduction of full cost coverage could be provided by national regulations that list the types of costs that may be covered by add-on payments and reduced payments. All measures must observe the special role of university hospitals. The list could include the average costs per type of cost (e.g. training costs per student or emergency costs per emergency case). It would also be interesting to provide information on the average costs for the nation as a whole and in the region of a particular hospital. If a hospital can not demonstrate extra costs for a parameter in the list, then it would not be eligible to receive the corresponding add-on payment. Lastly, it would be possible to limit the volume of add-on payments and discounts per hospital. Other arguments for such a compromise are:

- The introduction of the inpatient case as the unit of output in the German hospital sector is very ambitious both with respect to its planned universality as well as in terms of the time schedule.
- There is no other country (except the USA) in which a DRG system covering all the costs of hospital services has been introduced on the basis of flat-rate payments that apply nationwide. In Australia, DRG-oriented flat-rate payments are used only to cover the operating costs of hospitals. In France, uniform prices are used only for information purposes.
- The transparency of health care service in the hospital sector will increase considerably. More refined comparisons of hospital services will increase competition among hospitals.
- The introduction of unit-of-output costing in hospitals to meet the requirements of the new system is an important precondition for the creation of an entrepreneurial culture in hospitals.

**171.** Finally, the Council reiterates its central demand in the context of the planned DRG system. Based on the experience in other countries, it's likely that the expected decrease in hospital length of stay will place additional demands on ambulatory and stationary facilities as well as on doctors and nurses providing post-hospital care. In order to avoid negative effects on patients the development of these facilities must be synchronized, well-coordinated and observe quality considerations.

## **5. Annex**

### **5.1 Commission of a Special Report**

The German Minister for Health commissions the Advisory Council with the compilation of a special report on the following questions:

What opportunities can the Advisory Council identify for improving the delivery of health care services, especially with respect to issues of quality assurance and new forms of reimbursement, when it is assumed that the basic structure for the finance of the Social Health Insurance system remains unchanged?

In answering this question, the report shall discuss:

- the role of health care targets,
- the role of quality-oriented and performance-oriented incentives and payment structures,
- the role of increased prevention and health promotions as well as of the enhanced competency of patients and the insured,
- the role of the primary care doctor in regard to the improved coordination of the processes of health care delivery, especially in regard to ambulatory care, hospital care, rehabilitation and nursing.

The Council is requested to submit the report by mid-2000.

During the time it takes to complete the Special Report, the Advisory Council is released from its obligation to submit an annual report (in accordance with Decree of November 12, 1992, last amended on January 2, 1997, par. 2, clause 1).

Bonn, May 20, 1999

The Federal Minister for Health

Andrea Fischer

**5.2 Legal basis of the Advisory Council for the Concerted Action in Health Care**  
(as of January 1, 2000)

German Social Code, Book V

Chapter 5

Concerted Action in Health Care

§ 142

Supporting Concerted Action; Advisory Council

(1) The Minister for Health shall provide and explain the data needed for the work of the Concerted Action using the Federal Government's Annual Economic Report.

(2) The Minister for Health shall appoint an Advisory Council to support the Concerted Action in Health Care in fulfilling its tasks. The Advisory Council shall also be responsible for the compilation of reports on trends in the Social Health Insurance system. The report shall identify and analyze areas in which the provision of health care is excessive, inadequate or inappropriate in respect to adequate care. The Federal Ministry for Health can identify more specific subject matter of the report. The Advisory Council shall prepare the reports in intervals of two years and submit them to the Federal Ministry for Health on April 15th of each year, beginning in the year 2001. The Federal Ministry for Health shall distribute the report immediately to the legislative bodies of the federal government and state its position on the report within an appropriate time frame.

### **5.3 Inclusion of parts of the special report in the legal mandate for a regular report**

On the basis of the amended version of § 142 German Social Code, Book V, from December 15, 1999, the Council is required to submit a report to the Ministry for Health every two years, with the first report due on April 15, 2001. The report shall identify and analyze areas in which the provision of health care is excessive, inadequate or inappropriate and identify and analyze means for increasing efficiency in the health care system.

In my letter of May 20, 1999 to the chairman of the Advisory Council, I requested that the Council prepare a special report on the improvement of the management of health care provision, with special focus on improving quality assurance and on new forms of reimbursement. The report is to focus on the role of health targets, quality-oriented and performance-oriented forms of reimbursement, the reinforcement of prevention and health promotion, the competence of the insured and patients and the role of primary care doctors, especially in the delivery of ambulatory, inpatient and rehabilitative health care services as well as in the provision of long-term care. This report was to be submitted by mid-2000.

Due to the new regulations in § 142, German Social Code, Book V, the resulting very short time period for the submission of the first regular report on appropriate care, and in view of the importance of this report, which I am to pass on to the German Bundestag, I release the Council from the content and deadline of my order of May 20, 1999.

Following discussion with the chairman of the Advisory Council, I assume that those parts of the special report that have already been completed by the Council can be easily integrated in the regular report called for by § 142, German Social Code, Book V, which is due in April 2001. I therefore request the Council to examine the extent to which the completed parts of the Special Report 2000 can be subsumed in the report now called for by law, including the specific questions posed in my commission of a report of May 20, 1999.

Bonn, February 8, 2000

The Federal Minister for Health

Andrea Fischer

#### **5.4 Members of the Advisory Council for the Concerted Action in Health Care**

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