

# **Appropriateness and Efficiency**

**Bonn 2001**



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

**Appropriateness and Efficiency**

**Volume III**

Overuse, underuse and misuse

Report 2000/2001

Executive Summary



# Table of Contents

<b>Preface</b>	<b>11</b>
<b>1. Introduction and Overview</b>	<b>13</b>
<b>2. Observations on the Legal Tasks of the Council</b>	<b>22</b>
<b>3. Need, Appropriate Care, Overuse, Underuse and Misuse</b>	<b>24</b>
3.1 Background	24
3.2 Introduction	24
3.3 Observations on the German Social Health Insurance System	26
3.4 The application to population based issues	31
3.5 The level of supply	33
<b>4. Survey Objectives and Methods</b>	<b>35</b>
4.1 Background and goals of the survey	35
4.2 Participants, survey design and evaluation of survey results	35
4.3 Rating categories of the Council	37
<b>5. Summary of the Survey Results</b>	<b>40</b>
5.1 The response rate	40
5.2 The survey of medical societies	40
5.3 Survey of patient groups	41
5.4 Survey of state governments, doctors' associations and health insurance associations	45
5.5 Recommendations for future surveys of the health care system	47

<b>6.</b>	<b>Indicators of Differences between the Eastern German States and the Western German States</b>	<b>50</b>
6.1	Health status	50
6.2	The health care situation	52
6.3	Summary and recommendations	54
<b>7.</b>	<b>The Care of Patients with Chronic Diseases</b>	<b>55</b>
7.1	Introduction	55
7.2	The epidemiology and costs of chronic diseases	56
7.3	Requirements for the care of the chronically ill	57
7.4	Overuse, underuse and misuse	60
7.5	Lessons from ten years of diabetes care in Germany	70
7.6	The care of the terminally ill	74
7.7	Summary and recommendations	75
<b>8.</b>	<b>Ischemic Heart Disease, Including Heart Attack</b>	<b>78</b>
8.1	The burden of disease	78
8.2	The views of the interviewed groups	78
8.3	The Council's viewpoint	81
8.4	Summary and recommendations	86
<b>9.</b>	<b>Cerebrovascular Diseases and Stroke</b>	<b>90</b>
9.1	The burden of disease	90
9.2	The views of the interviewed groups	90
9.3	The Council's viewpoint	93
9.4	Summary and recommendations	97

<b>10.</b>	<b>Chronic Obstructive Lung Disease</b>	<b>99</b>
10.1	The burden of disease	99
10.2	The views of the interviewed groups	101
10.3	Summary and recommendations	104
10.3.1	The structure of care	104
10.3.2	Asthma	105
10.3.3	COPD	108
<b>11.</b>	<b>Back Pain</b>	<b>109</b>
11.1	The burden of disease	109
11.2	The views of the interviewed groups	110
11.3	The Council's viewpoint	114
11.4	Prevention and workplace health promotion	117
11.5	Summary and recommendations	122
<b>12.</b>	<b>Oncological Diseases</b>	<b>125</b>
12.1	Lung cancer	125
12.1.1	The burden of disease	125
12.1.2	The views of the interviewed groups	126
12.1.3	The Council's viewpoint	129
12.1.4	Summary and recommendations	134
12.2	Breast cancer	138
12.2.1	The burden of disease	138
12.2.2	The views of the interviewed groups	139
12.2.3	The Council's viewpoint	142
12.2.4	Summary and recommendations	149
12.3	General aspects of the care of cancer patients	150
12.3.1	The burden of disease	151
12.3.2	The views of the interviewed groups	152
12.3.3	Summary and recommendations	155

<b>13.</b>	<b>Depressive Disorders</b>	<b>158</b>
13.1	The burden of disease	158
13.2	The views of the interviewed groups	158
13.3	The Council's viewpoint	162
13.3.1	General issues in the care of psychiatric patients	162
13.3.2	The diagnosis and treatment of depressive disorders in family practice	164
13.3.3	Depression in the elderly	166
<b>14.</b>	<b>Oral, Dental and Orthodontic Health</b>	<b>170</b>
14.1	The views of the interviewed groups	170
14.2	Overuse, underuse and misuse in general dentistry	171
14.2.1	Current problems in dentistry	171
14.2.2	Current activities for the improvement of quality	174
14.2.3	Future approaches for improving quality	175
14.2.4	Measures for improving the framework	176
14.2.5	Economic effects	179
14.3	Overuse, underuse and misuse in orthodontics	179
14.4	Summary and recommendations	180
<b>15.</b>	<b>Appendix</b>	<b>183</b>
15.1	Legal basis of the Advisory Council for the Concerted Action in Health Care (as of January 1, 2000)	183
15.2	Surveyed organizations	184
15.3	Text of the survey	217
15.4	Summary of the Council's most urgent recommendations (A) for reducing overuse, underuse and misuse in the health care system	223
15.5	Members of the Advisory Council for Concerted Action in Health Care	230

## List of Tables

<i>Table 1:</i>	System for the classification of problems and solutions	17
<i>Table 2:</i>	The new rules of health care in the 21 <sup>st</sup> century	21
<i>Table 3:</i>	The definition of overuse, underuse and misuse	31
<i>Table 4:</i>	The need for intervention, development and investigation	39
<i>Table 5:</i>	The number of responses	40
<i>Table 6:</i>	Average life expectancy at birth in the eastern and western states	51
<i>Table 7:</i>	Health insurance status of the population	53
<i>Table 8:</i>	Models, concepts and measures of health	63
<i>Table 9:</i>	Objectives of the St. Vincent Declaration of 1989	70
<i>Table 10:</i>	Organizations that provided information on overuse, underuse and misuse in the area of ischemic heart disease	79
<i>Table 11:</i>	Facts on cardiology in Germany (1999)	82
<i>Table 12:</i>	Trends in the number of invasive cardiologists, cardio-surgical facilities and the number of cardiological interventions (1990 - 1999)	83
<i>Table 13:</i>	Organizations that provided information on overuse, underuse and misuse in the area of cerebrovascular diseases and stroke	91
<i>Table 14:</i>	Data sources on stroke in Germany	94
<i>Table 15:</i>	Organizations that provided information on overuse, underuse and misuse in the area of chronic obstructive pulmonary disease	102
<i>Table 16:</i>	A selection of important risk factors for the development of chronic back pain	109
<i>Table 17:</i>	Organizations that provided information on overuse, underuse and misuse in the area of back pain	115
<i>Table 18:</i>	Overview of diseases associated with smoking	125
<i>Table 19:</i>	Organizations that provided information on overuse, underuse and misuse in the area of lung cancer (including the prevention of tobacco use)	126
<i>Table 20:</i>	Organizations that provided information on overuse, underuse and misuse in the area of breast cancer	140
<i>Table 21:</i>	EUREF standards on the minimum number of mammographies per year	145

<i>Table 22:</i>	Organizations that provided information on overuse, underuse and misuse in the area of cancer or pain therapy	156
<i>Table 23:</i>	Organizations that provided information on overuse, underuse and misuse in the area of depressive disorders	159
<i>Table 24:</i>	Examples for concrete targets, conditions and estimated length of time needed for improving dental health care	178

### **List of Figures**

<i>Figure 1:</i>	Structure of the data base of survey results	38
<i>Figure 2:</i>	Model of the simultaneity and co-ordination of non-sequential courses of disease	61
<i>Figure 3:</i>	Algorithm for the diagnosis and treatment of back pain	116
<i>Figure 4:</i>	The innovation cycle	147
<i>Figure 5:</i>	Number of bone marrow transplants for breast cancer recorded in the EBMT Registry	148

## Preface

With Volume III of the report on "Appropriateness and Efficiency", the Advisory Council for Concerted Action in Health Care fulfils a substantial part of its legal tasks as defined in Germany's Social Health Insurance Law. In view of the scope of this task, it was necessary to focus Volume III - entitled "Overuse, underuse and misuse" - on selected diseases and target groups. Many topics that were suggested to the Council will have to be dealt with in the future. The legal mandate of evaluating the appropriateness of health care is a permanent task of health policy that requires many more resources than have been dedicated to it in the past.

The Council extends its gratitude to a large number of institutions, organizations and individuals. This pertains to the many organizations that participated in the survey of the Council and without whom the report could not have been completed in its present form (a list of the participants is provided in the appendix). Furthermore, the Council was always able to rely on the expert support of the German Ministry for Health.

In addition, the Council would like to thank the following persons: Ulrike Bahrdt, University of Applied Sciences Braunschweig-Wolfenbüttel; Dr. Anke Bramesfeld M.D., University of Hannover Medical School; Dr. Katja Broman MPH, University of Essen; Dr. Elke Jakubowski M.D./MSP, World Health Organization, Copenhagen; Prof. Dr. Karl-Heinz Jöckel M.D., University of Essen; Dr. Monika Grüßer M.D., Central Institute of Ambulatory Health Care in Germany, Cologne; Dr. Uwe Lenhardt, Social Science Research Center - Berlin; Dr. A. Mühlich, National Association of Statutory Health Insurance Physicians, Cologne; Ines Ney, University of Applied Sciences Braunschweig-Wolfenbüttel; Dr. Matthias Perleth M.D./MPH, University of Hannover Medical School; Prof. Dr. Dr. Heiner Raspe, University of Lübeck Medical School; Rüdiger Saekel, Ministerial Counsellor (retired), Meckenheim; Dr. Bettina Schmidt, University of Bielefeld; Dr. Angelika Schreiber-Wazlak MPH, Berlin; Prof. Dr. Dr. H. J. Staehle, University of Heidelberg; Dr. Ulla Walter, University of Hannover Medical School.

The preparation of the report placed an extraordinary strain on the resources of the Council's office and in particular on its professional and administrative staff, including Antje Freytag, Dr. Antonius Helou M.D./MPH, Dr. Ulrike Heyer M.D./MPH, Dr. Friederike Hoepner-Stamos, Dr. Karin Hummel, Dr. Sabine List M.D./MPH, Annette Riesberg MPH and the office director, Dr. Lothar Seyfarth. The Council owes special thanks to its office staff.

The Council thanks Renate Schneid, who handled the technical preparation of the report with great care and patience and is responsible for the presentation of the survey results in the internet ([www.svr-gesundheit.de](http://www.svr-gesundheit.de)). The Council also thanks Ingrid Aengenheyster, Sabine VanDen Berghe and Monika Weinberg for their support.

The final editorial tasks were completed under considerable deadline pressure by a small but dedicated staff. Formal and orthographic precision were sacrificed in the name of prompt public presentation of the results. The Council is alone responsible for any remaining errors.

Bonn, August 2001

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## **1. Introduction and Overview**

1. With this publication the Council submits the third volume of its Report 2000/2001.

Like Volumes I and II, this volume is published under the general title "Appropriateness and Efficiency", which refers to the legal task of the Council as defined in December 1999 (the legal text is printed in the appendix).

2. Volumes I and II focused on issues related to the general structure of the health care system, the quality of health care services and the need for placing the issues of health objectives, patient needs, quality and prevention at the center of health care activities. Volume III, entitled "Overuse, underuse and misuse" focuses in Part III.1 on

- basic issues and definitions with respect to the concept of appropriateness and to the concepts of overuse, underuse and misuse (III.1 chapters 2 and 3),
- the design and the results of a survey of 300 scientific organizations, societies and self-help groups in the health care system (III.1 chapters 4 and 5),
- views on differences in health status and health care in the eastern and western states following unification (III.1, Chapter 6) and
- problems in the organization and quality of care provided to persons with chronic diseases, including a "case study" of the care of diabetics in Germany (III.1, Chapter 7).

Chapters III.2 and III.3 include specific analyses of the burden of widespread diseases in Germany, prospects in these areas and modes of care:

- ischemic heart disease (III.2, Chapter 8),
- cerebrovascular diseases, especially stroke (III.2, Chapter 9),
- chronic obstructive lung disease (III.2, Chapter 10),
- back pain (III.3, Chapter 11),
- cancer (III.3, Chapter 12) and
- depression (III.3, Chapter 13).

3. The Council sees a great need for improvement in the treatment pathways for these diseases. In most cases there is a considerable and unutilized potential for primary prevention and in some cases for secondary and tertiary prevention (rehabilitation).

The case study on diabetes (Chapter 7<sup>1</sup>) – including a review of approximately 70 local and regional pilot projects that have been operating for more than 10 years without significant and lasting effect on the care of diabetics in Germany – provides evidence for the at least partial failure of the organizations involved in the "system of self-governance" in the German health care system. According to the available data, Germany has not met any of the central objectives of the St. Vincent Declaration of 1989.

Another partial failure is evidenced by the tolerance of so-called "gray" mammography screening - i.e. mammography exams that are not controlled by quality assurance measures - more than five years after publication of the "German Mammography Study" (1994), which identified grave deficiencies and specified the means for their improvement (Chapter 12.2). The initiation of improved pilot projects on a smaller scale in 2001 is commendable, but it is also an indicator of the failure of past measures.

Improved educational measures, the perfection of emergency medical and first-aid services and the establishment of competent hospital facilities for the treatment of "thorax pain" are needed to reduce the rate of premature mortality due to coronary heart disease (Chapter 8). To improve the imbalance between resource utilization and results of coronary intervention, the indications and quality of interventions must be improved. An integrated, overall approach for a "National Coronary Heart Disease Program" is needed to deal with the considerable problems of overuse and misuse in primary and secondary prevention on the basis of behavioral and setting-oriented interventions as well as through preventative pharmaceutical treatment.

There is a general need for information on cerebrovascular disease and especially on stroke (Chapter 9). Furthermore, health insurers must target patients with hypertension. There is a need for the qualified, early and long-term rehabilitation of stroke patients (from early rehabilitation to rehabilitation as an element of long-term care). The introduction of Diagnosis Related Groups (DRGs) in acute care hospitals will create additional problems, especially with respect to rehabilitative care. The existing problems arise from well-known problems in curative and rehabilitative therapy that have yet to be resolved within the system of self-governance.

For patients with asthma and other chronic obstructive lung diseases, the lack of coordination results in the inadequate schooling of patients both young and old (lack of

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1 Chapters in the parts III.1-III.4 are numbered consecutively (Chapter 1 to Chapter 14). Reference to the section it therefore unnecessary

agreements in schools; Chapter 10). There are not enough "asthma exercise groups". Drug therapy is a mixture of too much, too little and "off the mark", all of which indicates that there are deficits in the training and continuing education of doctors. As is the case for lung cancer (Chapter 12.1), the Council proposes a "National Anti-Tobacco Campaign" against active and passive smoking.

For cancer therapy in Germany the Council proposes the focus of expertise, increased transparency with respect to the quality of care and the establishment of guideline-based pain therapy on a broad basis (Chapter 12.3).

The Council identifies a surfeit of diagnostic imaging techniques and invasive procedures in the diagnosis and treatment of lower back pain. At the same time, there are clear deficits in the management of patients with chronic back pain, including the implementation of health promotion and secondary and tertiary preventive measures (see Chapter 11).

With its analysis of the care provided to patients who suffer from depression (Chapter 13), the Council would like to increase acceptance and improve treatment for patients with mental health disorders. In large metropolitan areas, psychiatric emergency cases are the most common grounds for emergency calls. Undiagnosed or undertreated psychiatric patients are "habitual users" of the health care system. Depression is one of the main factors for sick leave and hospital admissions. The Council identifies room for improvement in the treatment of these patients in the primary care sector, in pharmaceutical therapy and in public education measures (campaigns of the Federal Center for Health Education - BZgA) for increasing public awareness of and public acceptance for the disease. Problems are especially evident in the treatment of elderly patients with depression in homes for the aged and in nursing homes. The Council calls for special measures in these areas of health care provision.

**4.** The problems of dental health and orthodontic care discussed in Chapter 14 must be seen in a different light. These topics were not among the "priorities" chosen by the Council. External expertise requested by the Council builds the core of these sections. Some of the passages have a programmatic character, some point clearly to professional incentives to provide too many services ("practice marketing" aimed at patients) and some point to socially conditioned forms of "overuse" when aesthetic ideals prevail over medical and functional requirements (e.g. orthodontic care).

5. The diseases analyzed by the Council are responsible for approximately two-thirds of all expenditures on disease within the "system". They are therefore not a *quantité négligeable* in the health care system. Above all, they represent the greatest portion of the subjective burden of disease as experienced by patients with chronic diseases, their family members and caregivers.

6. The analysis of specific diseases in chapters 8 through 14 include the responses of 201 organizations and their views of overuse, underuse and misuse. In most cases, the Council had to abridge the responses and assessments of these organizations in both the description of the survey results (Chapter 5) and in individual chapters on diseases (chapters 8 through 14)<sup>2</sup>. The full text of 192 responses are available as PDF files on the Council's homepage ([www.svr-gesundheit.de](http://www.svr-gesundheit.de)). The survey consumed a great deal of resources, but the Council considered it indispensable given the complete lack of an overview of the health care situation in Germany. The Council informed the participating organizations of its basic criteria for definitions and chose the disease groups for the analysis a year in advance (see Chapter 4).

As was to be expected, however, the survey revealed a glaring lack of reliable data on health care both in the scientific professional societies and in the public bodies and corporations with responsibilities in the health care system (municipalities, city and county councils, associations of healthcare professionals and health insurers).

The Council therefore offers proposals for improving health care research that include the participation of scientific professional societies and patient representatives (Chapter 5.5). A regular survey of these organizations would have only limited value. However, it is clear that the level of information in health insurance funds, professional chambers, doctors' associations and other public corporations is wanting, despite their direct and indirect responsibility for the provision of high-quality and efficient health care throughout the country and, in particular, at local level. Furthermore, the available "routine" data can not simply be aggregated to improve the situation.

7. The report's conclusions are also based on the Council's research, including literature research (published studies and "gray" literature) as well as its own research and analysis. Each chapter on a specific disease (chapters 8 - 14) includes a discussion and evaluation of the situation from the Council's perspective and the recommendations based on this analysis.

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2 These passages are highlighted throughout the report by being printed in smaller type.

In view of the many problems to be addressed, the Council classified its evaluation on the basis of the level of knowledge in an area and the urgency of an issue (Table 1 and Chapter 4.3).

**Table 1: System for the classification of problems and solutions**

	Health care problem	Solution
A	Fairly certain	Fairly certain
B	Fairly certain	Operational measures
C	Fairly certain	Possible, but no operational measures
D	Reliable indicators	Fairly reliable or operational measures
E	Reliable indicators	Possible or not accessible to evaluation
F	No reliable indicators	-

*Source:* Advisory Council (Volume III.1, Chapter 4 "Survey methods and objectives")

The Council's recommendations (A) for solving the most pressing problems associated with overuse, underuse or misuse are summarized in the appendix. The Council sees an urgent need for action in these areas and has identified operational solutions to these problems. The logic behind the recommendations (Table 1) shows that recommendations of types B and C are not less important than those classified as "A". However, the solutions to these problems are not as clear. Inclusion in the classes D or E usually indicates a need for more research.

**8.** The reader may be surprised by the fact that there are many areas in both the disease-related chapters and in the description of the survey results that are characterized by underuse or potentially harmful misuse<sup>3</sup>. These results are surprising because

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3 See Chapter 5 and chapters 8 through 13. The published literature also contains more references to underuse than to overuse. The report of the Institutes of Medicine of the Academy of Sciences, Washington 2001, on the quality of health care in the USA deals with the same "bias" ([www.nationalacademies.org/iom/iomhome.nsf](http://www.nationalacademies.org/iom/iomhome.nsf)). The conclusion of this report is taken up in the

- most of the problems are not due to budget limits or fiscal restraint but are related to professional qualification, the organization of health care provision and the health care system as such;
- problems related to the quality of care in Germany are rarely discussed. In fact, leading groups in the German health care system often refer to it as "exemplary".

A recurring theme of the survey results and in particular of the responses of 41 patient organizations (Chapter 5.3) is that there are gaps in the provision of health care which are due to the delineation of responsibilities of health care providers. The valuable coordination of different stages and forms of health care (treatment, prevention, rehabilitation, social re-integration, fitting for handicap aids and training) is either lacking or malformed to the extent that it is no longer functional. Patient groups complain of a lack of educational material and participation in decisions. In general, there is the same pattern of outdated paradigms and modes of treatment across all diseases and patient groups (Chapter 7):

- the present system is characterized by the dominance of care that is aimed at the treatment of acute episodes of sickness and "one-dimensional" diseases, including an excess supply of structural facilities;
- "somatic fixation" of the health care system: there is often insufficient regard for the social, psychological, environmental and biographical dimensions of care needed by patients with chronic diseases and their families;
- "Active/passive problem": patients with chronic diseases are treated as the passive recipient of medical services. The focus of passive-oriented treatment is on "repair, rehabilitation and rest";
- Inadequate information, education and participation of patients and their most important person of reference;
- Lack of interdisciplinary and flexible forms of health care;
- Deviations from evidence-based guidelines;
- Inadequate incentives that make the chronically ill "bad risks" for health insurers and health care providers;

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Council's call for more independent – i.e. publicly supported – health care research (see Chapter 5.5).

- Inadequate consideration of the special needs of chronically ill patients in the education and socialization of health care professionals.

Overall, the survey results can contribute to the more realistic assessment of the quality of the German health care system (for further information, please refer to the documentation on the homepage of the Council at [www.svr-gesundheit.de](http://www.svr-gesundheit.de)).

**9.** Structural deficits of the German health care system include those in the area of prevention, which were also criticized in Volume I of this report. The Council believes that it would be useful for the survey to highlight gaps in preventive medicine from both the clinical and the patient's perspective, including an analysis of appropriate and modern secondary and tertiary prevention.

In addition to the comments on preventive medicine for the elderly and for the improvement of vaccinations and caries prophylactics in Volume I of the report, the Council focuses in this report on prevention policies that go well beyond the limits of social (and private) health insurance:

- The Council calls for a "National Anti-Tobacco Program" and provides a basic outline for such an urgently needed measure (see Chapter 12.1 and chapters 8 and 10). The benefits of such a program would be greater than the effect of preventing all traffic fatalities in Germany. The Council views this program as a testing ground for the initiation of credible preventive measures in Germany in an area in which they are urgently needed.
- The Council also supports the idea of a "National Program for the Prevention of Heart and Circulatory Diseases" (Chapter 8), e.g. modeled after the successful government program in Finland.
- The Council continues its support for the expansion of workplace health promotion (Chapter 11).

**10.** Under the provisions of the German Social Health Insurance Law, the Council's tasks include an evaluation of the "efficiency reserves" in the health care system. In view of the many problems with respect to the structure of the system and the provision of health care, which may always result in economic inefficiency, it is impossible to quantify the volume of "efficiency reserves" in monetary terms. Even a theoretical comparison of the activities and resources associated with overuse with the resources needed to solve the problems associated with the many different forms of underuse in the health care system does not indicate whether the one would outweigh the other. It is

also unclear whether the resources that are saved in one area may be used efficiently in other areas or if they would merely be expended on other "forms of waste".

New approaches that are based on guidelines, including so-called disease management programs, can result at most only in the partial and short-term solution of overuse problems, and only when all participants act in accordance with quality assurance considerations.<sup>4</sup>

**11.** The elimination of excess supply, the increase in efficiency and the establishment of a balance between prevention, treatment rehabilitation and long-term care require a long-term reform of the system on the basis of consistent health policy. Such efforts require a basic transformation in organization and incentives, in knowledge and values. They require that healthcare professionals and their organizations take on new responsibilities and working styles. The health care system must be organized around the needs and preferences of patients (Table 2 and Chapter 7).

Under these conditions, the elimination of the present forms of overuse is neither an easy undertaking nor is it likely to be a source of any substantial "internal funding".<sup>5</sup>

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4 I.e. not according to the solely monetary considerations associated with the redistribution of social health insurance revenues as called for under the planned combination of disease management programs with revenue sharing across the whole SHI system.

5 I.e. funding from within the health care system.

**Table 2: The new rules of health care in the 21<sup>st</sup> century**

<b>Present approach</b>	<b>New rules</b>	<b>Measures</b>
Care is based primarily on visits to doctors	Care is based on lasting healing relationships	Long-term care; targeted rehabilitation; behavior-based measures to change health risks
Professional autonomy is the source of considerable fluctuation in the provision of care	Health care is based on the preferences and values of patients	Individual treatment strategies; consideration of patient's social environment; broad, flexible and variable range of services.
Professionals control care	Patients are the source of control	Patients as self-responsible managers of their sickness and as a competent user of the health care system; participation
Information is an administrative act (retrospective, archived, passive, immobile)	Knowledge is imparted. There is a free flow of information	Information and training; evidence-based patient information; use of new information technologies
Decisions are based on training and experience	Decision are based on evidence	Evidence-based medicine; evidence-based guidelines; health technology assessment, decision analysis; health care research
The prevention of health risks is the responsibility of the individual	Safety is viewed as a characteristic of the system	Quality management; risk management
Secrecy is necessary	Transparency is necessary	Certification and publicly available evaluation reports; education
The system reacts to preferences	Preferences are anticipated	Comprehensive, individual assessment; population-based surveys; needs assessment
Policy is aimed at reducing costs	Waste (overuse) is reduced	Quality assurance, guidelines, evidence-based medicine, reward systems
The role models of the health professions are more important than the system	Co-operation among the health care providers/professions has priority	Integration, networking, multidisciplinary approach

*Source:* Based on the Institute of Medicine (2001) and modified on the basis of III.1, Chapter 7 "The Care of Patients with Chronic Diseases"

## **2. Observations on the Legal Tasks of the Council**

**12.** Under the health care reform legislation of December 22, 1999, the Advisory Council for the Concerted Action in Health Care is required to submit a report to the Ministry of Health and the legislative branches of the national government every two years, beginning in April 2001. The report is supposed to identify areas in which health care services are excessive, inadequate or inappropriate and to specify and analyze measures for solving these problems (German Social Code, Book V, §142 para. 2).

**13.** The tasks of the Council are to be seen in the context of the planned introduction of a global budget on health care spending as called for by the draft for the health care reform legislation. The Council is required to analyze a few core issues:

- Do the resources available to the health care system suffice to maintain high levels of quality in the provision of health care?
- Can a revenue-based expenditure policy maintain these levels in the future?
- Are there any "efficiency reserves"?

The global budget regulations were not part of the final legislation, which built instead on the continuation of the existing "sectoral" budgets. Limits on the flow of funding across sectoral boundaries in the health care system and the resulting perpetuation of inefficiency in each sector do not make the Council's task of providing a general perspective on the provision of health care unnecessary. Budgets, whether a global budget on total health care spending or "sectoral" budgets covering different areas of the health care system, limit not only the potential for medical and economic overuse; they are also a potential cause of direct or indirect rationing and thus for the inadequate or inappropriate provision of health care services. Furthermore, international studies – e.g. the reports of the Institute of Medicine (IOM) on the quality of the health care system in the USA - and national studies such as the NIDEP study, which was conducted as part of a pilot project the Ministry of Health, show that misuse as well as excessive or inadequate care exist independent of budget controls. Furthermore, these problems have not been studied adequately and have not yet become political issues.

**14.** The new legal remit reached the Council at a time when it was involved in the analysis of quality assurance and management in the health care system, the subject of the Health Minister's instruction for a report in May 1999 (see Appendix 1 of Volumes I and II of the Report 2000/2001). The information prepared for this report was inte-

grated in the reports submitted in the spring of 2001. They provide a theoretical framework for the report in the sense of German Social Health Insurance Law, as they focus on general problems and quality deficiencies in the German health care system. The present volume is concerned with the analysis and evaluation of the current situation of the health care system with respect to the provision of care for selected diseases.

**15.** The Council had to deal with a number of problems to fulfill its legal task of completing a report on the issues of overuse, underuse and misuse. These problems included the fact that the law uses terms such as "appropriate care", "overuse", "underuse" and "misuse" without giving them a legal definition. There is also no "official" definition of these terms by international organizations such as the WHO. The Council therefore had to prepare the actual analysis by first defining the basic concepts on the basis of current scientific discussions and in the context of German social security law (Chapter 3).

**16.** In the spring of 2000, the Council initiated a survey of organizations involved in the provision of health care in Germany (see Chapter 4). The survey results were combined with a detailed analysis of the health care system. The documentation of the views of actors and participants in the health care system provides a basis for productive discussion. The survey was designed to include data on health care providers and health insurers and their views, the studies and evaluations of the medical societies and empirically sound case studies of patient organizations – in the sense of the Council's call for a stronger focus on patients in Volume I, Chapter 3 of the Report 2000/2001. One aim of this approach was to avoid a biased appraisal of the health care system.

**17.** Precise quantitative data on "efficiency reserves" can not be derived directly from the present report on the health care system. The statements and recommendations of the Council are limited mostly to the description and evaluation of problems that are described in qualitative terms. However, these are an important clarification and specification of the quality assurance problems and problems of patient focus in the German health care system that the Council identified in Volumes I and II.

### **3. Need, Appropriate Care, Overuse, Underuse and Misuse**

#### **3.1 Background**

**18.** The concept of "appropriate care" - what it is and what it isn't - has never been defined in German social law; it was not defined when so-called "hospital need" plans were introduced by the Hospital Finance Law of 1972 and was not defined when "need-based" planning of office-based doctors was introduced under the Health Care Development Act of 1976. Furthermore, state hospital planning varies widely and state hospital laws have not defined common concepts and procedures. In the office-based sector, the Federal Committee of Doctors and SHI Funds issued a directive on "need-planning" in 1993. However, its pragmatic formal approach does not provide a basis for a sound theoretical definition of "need".

The Council must therefore specify what is meant by

- appropriate care,
- efficient care

and, in this context, by

- overuse,
- underuse and
- misuse

on the basis of current scientific discussion and in the context of the provisions of the German Social Code (see §142, para. 2 German Social Code Book V).

#### **3.2 Introduction**

**19.** Current literature on health care research as well as health economics literature make the same general distinctions in terminology: need is distinguished from demand and from the utilization of the health care system. The pendant to demand for health care is the supply of a service.

Demand is a subjective category based on the perspective of the insured or, in general, of consumers. Demand arises from the subjective desire for a service. There may be a demand for services that are not supplied. Such demand does not lead to a utilization of

the health care system. This is also the case when a service is refused to a customer or when utilization is hindered by objective barriers such as money, time or distance or by subjective hurdles such as fear. Demand in this case is referred to as latent demand. Conversely, the availability of a service may induce a hitherto non-existent demand (supply-induced demand).

In the health care context, demand can be defined as an individual's subjective desire or preference for a health care service and the actual intention to utilize the service. This subjective desire for a service (demand) is defined as "subjective need" (or "preference") in the literature.

**20.** Posited against this subjective need is a professional (qualified) or scientifically confirmed "objective" need. Objective need presupposes the presence of an illness or physical impairment or the threat of either: It need not be congruent with subjective need. Objective need without subjective need and without the utilization of the health care system is also referred to as "latent" need.

The need for health care thus consists of two different elements: Subjective need and the determination of an objective disease or disability.

**21.** The third element in the definition of need is the determination of an objective need for action, which presupposes the existence of procedures and facilities for the successful treatment of the illness, for avoiding its occurrence or for alleviating its effects. An example is age related bone atrophy: Hormone replacement treatment of women after menopause has created a situation in which the medical profession, scientific groups and the general public view this condition as preventable and treatable. The availability of hormone therapy has made the physiological "osteopenie" of aging into the pathological osteoporosis. In scientific circles, however, the "need" for treatment is still subject to dispute due to the many risks of hormone substitution.

The fourth element of the definition of need is the cultural context and social change.<sup>6</sup>

**22.** The determination of need therefore includes subjective, social, professional and scientific judgments on the necessity of action to treat a sickness or disability as well as professional or scientific judgment of the possible benefits of the available procedures and facilities for performing such action.

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<sup>6</sup> For example, many types of dental treatment, especially orthodontic care, vary between the criteria of "socially determined" and "individual" aesthetic and function.

On this basis, need can be defined as a condition that, if treated with specific measures, can be expected to result in health benefits.

The benefits of a measure or service in the health care system should be related to the improvement of the health status of an individual or target group or to an improvement in the length or quality of life of the individual concerned. Since health care measures are typically associated with risks (negative benefits) as well as benefits, the Council assumes that the health benefits always exceed the risks: i.e., the Council assumes there is a positive net benefit.

**23.** The term "rationing" can also be defined on this basis: rationing can be understood as the refusal to supply health care services despite demand and objectively determined need (or latent need).

The refusal to supply services when demand is given but there is no objectively determined need is not considered rationing in this sense. Such limits on the provision of health care are common in all types of health insurance, including private insurance: A customer desires a services and the insurer reviews whether there are reasonable grounds for providing the service under the conditions of the insurance policy. From the individual, subjective perspective, making the provision of a service contingent on the proof of objective need may also be seen as a form of rationing (subjective rationing in a broad sense), but it is essential for the functioning of an insurance system based on risk compensation. In this sense, rationing has always been an element of the German social health insurance system as well as of the private health insurance system. This "actuarial" rationing is not subject to dispute; it's the rationing described in the above paragraph – i.e. the refusal to provide health care when there is objective need – that is cause for health policy debate.

### **3.3 Observations on the German Social Health Insurance System**

#### *Concepts and regulations of the German Social Code, Book V*

**24.** The German Social Health Insurance system also follows the principle of actuarial rationing from the subjective perspective. The task of social health insurance is to maintain, restore or improve the health of the insured (§ 1 German Social Code, Book

V). The insured person is entitled only to those services that are necessary<sup>7</sup>, adequate and reasonable (§§2, 11 and 12 SGB V). The quality and efficacy of the services provided must be at the generally accepted standard of medical knowledge and may not be "uneconomical".

**25.** As long as lawmakers, the quality assurance committees for the hospital and office-based sectors or the Co-ordinating Committee have not introduced control measures for the coverage of certain procedures<sup>8</sup>, doctors are free to use the diagnostic and therapeutic procedures of their choice. The doctor<sup>9</sup> whom a patient consults (utilizes) on the basis of a subjective need and desire for treatment (demand) is responsible for making a general evaluation of what is necessary, reasonable and appropriate medical care. The doctor's decisions with respect to a sickness or disability and the means for treating it make up the determination of objective need.

The provision of goods and services on the basis of demand alone – as is the case in a competitive market model – is not possible in the Social Health Insurance system for legal reasons. The insured person's freedom of choice is limited to the choice of doctor (or doctors, if the insured person changes doctors): this is the only stage in the health care process at which "demand" plays a role. All diagnostic and therapeutic measures are determined and administered or prescribed by doctors. The doctor is free to make medical decisions within the limits defined by law and the directives of the quality assurance committees or other committees; this is so, because none of the concepts are defined in the German Social Code in a way that would allow for the development of concrete medical treatment guidelines.

Doctor's decisions, however, must be verifiable, i.e. they must correspond to objective and factual evidence and to the generally accepted standards of medical science. Fur-

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7 The concept of "necessity" also indicates that the health problem for which a patient seeks treatment should not be trivial, i.e. the condition should not heal spontaneously and quickly without intervention or treatment measures should not be within the realm of the self-responsibility of patients (§2 SGB V). Such "trivial" measures are specified for pharmaceuticals in § 34 para. 1 SGB V, which excludes cold remedies and pharmaceuticals for the treatment of obstipation, motion sickness and unspecific ailments of the mouth and throat; this list is not exhaustive in medical terms.

8 In the sense of limits on the coverage of procedures or the specification of their conditions of use.

9 The following also applies to dentists and to a certain extent to psychologists who are "certified" to provide psychotherapy.

thermore, the patient must consent to the treatment after being fully informed of its benefits and risks.<sup>10</sup>

**26.** The assessment of the medical necessity of a health care service, its appropriateness for a given treatment objective and thus the indication and expected effectiveness corresponds to the objectification of need (see above). The concept of "efficiency" in the German Social Code also includes aspects of quality and cost-benefit ratios (the appropriateness of costs with respect to expected treatment results or objectives; see § 106 SGB V), and thus goes beyond mere cost-minimization. Conversely, health care that is not appropriate can not be "efficient" in the sense of social legislation even if it is associated with low resource utilization.

Furthermore, in each individual case, the appropriateness of a treatment or health care service has priority over the evaluation of the cost-benefit ratio; i.e. first the effectiveness is assessed and then the economic rationale.

### *The concept of need and budgets*

**27.** In a strict sense, the budgeting policy in Germany's health care system is incompatible with the principle that social health insurance should cover the needs of patients. However, this is not the case when the structure and levels of the budgets are flexible enough to prevent the provision of unnecessary services to the extent that all necessary services may be provided despite budget restrictions. Furthermore, it may be required (and often is) that doctors choose the least costly alternative from a group of services that are equally beneficial or the alternative with the best cost-benefit ratio when the alternatives are associated with different benefits and costs. Acceptable cost-benefit ratios can also be required of measures for which there are no alternatives by comparing them to the alternative "no treatment". The assumption under the condition of budget limits could then be based on the fact that the medical decision making process in such cases is not yet perfected. A more general approach, that would require that doctors or hospitals provide such procedures and finance all or part of their costs would be inequitable and could not last very long.

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10 The (informed) consent of the patient is also a prerequisite for "appropriate care" in cases where there is a "latent need" for health care.

**28.** Budget measures –in Germany as well as in other European health care systems – create additional problems at system level as well as in the sub-sectors of the health care system. The concept of need takes on new meaning when the focus is not on individual health benefits but on a group of patients or the whole population. Depending on the scarcity of resources (e.g. due to budgets) and given need, procedures and facilities must be evaluated in terms of their cost-effectiveness or, when there are competing needs, that the alternatives are ranked according to their cost-benefit ratios.

Individual doctors alone can not make such lists or general decision-making schemes. What is needed are binding decision-making rules on the part of legally established organs that supercede the decision of the doctor and the demand of patients. For such situations, professional codes, civil law and criminal law must free the individual doctor of the potential risks of legal action due to such rationing measures. Many of the problems related to the design and implementation of such decision-making rules need to be solved.

### *Overuse, underuse and misuse*

**29.** On the basis of the above observations, the concepts of overuse, underuse and misuse can be defined in conformity with social health insurance law as follows:

1. The partial or full refusal of health care despite the presence of individually, professionally, scientifically or socially acknowledged need, although services are available that can be expected to provide a sufficiently proven net benefit and, compared to the medical alternatives, can be provided efficiently, is called "underuse".
2. The supply of service beyond the level needed is termed "overuse". It is the provision of services for which there is no indication or insufficient evidence of their clinical benefit (medical overuse), services that provide too few benefits to justify their cost or services that are provided inefficiently ("economic overuse").
3. Misuse is health care that causes an avoidable damage.<sup>11</sup> There are the following types of misuse:

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<sup>11</sup> Avoidable damage is thus equal to a foregone but nonetheless possible health benefit, e.g. if the service was provided properly and promptly.

- the provision of a service that is appropriate but which, due to its improper application, causes avoidable damages;
  - the provision of an inappropriate service that gives rise to an avoidable damage;<sup>12</sup>
  - the failure to provide appropriate care or the failure to provide appropriate care promptly.<sup>13</sup>
4. "Appropriate care" is care that is based on individually, professionally and scientifically acknowledged need, that applies services for which there is sufficient proof of their effectiveness and which are provided by professional caregivers. When that service which has the best or most "acceptable" cost-benefit ratio is used to provide, then the provision of health care is termed "efficient" in the sense of § 106, number 5 SGB V).
  5. "Efficiency reserves" in the sense of the German social health insurance law are the sum of medical and economic overuse. In addition, underuse and misuse may represent efficiency reserves in so far as the costs of undesired or avoidable results are greater than costs of appropriate and efficient care.

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12 There is thus some overlapping of misuse and overuse.

13 There is thus some overlapping of misuse and underuse; those types of underuse in which no care or contact with a health professional has taken place, however, is not classified by the Council as "misuse".

**Table 3: The definition of overuse, underuse and misuse**

<b>Need</b>	<b>Service<sup>a)</sup> provided by health-care professionals</b>	<b>Is not provided by professionals</b>	<b>Is not provided<sup>b)</sup></b>
objective need only, no subjective need (latent need)	appropriate care	misuse	(latent) underuse
subjective and objective need	appropriate care	misuse	underuse (misuse)
subjective need but no objective need	overuse (misuse)	overuse and misuse	appropriate care

a) Assumption: health care service with proven net benefit and acceptable cost-benefit ratio

b) Assumption: no alternative service are provided.

Source: Advisory Council

### 3.4 The application to population based issues

**30.** The previous passages dealt with individual need and the related concepts of overuse, underuse, misuse and "efficiency reserves" according to social health insurance law.

The following approaches are possible for the development of criteria that are applicable not only on a case by case basis but may be applied to defined target groups or, since almost 90 percent of the population is covered by social health insurance, to administrative regions as large as the whole country:

Judgments on appropriate care are not determined for each individual with a specific illness or disability but on the basis of all (or a sample of all) persons with a certain condition (regardless of individual variations in severity and assuming that all of those affected would demand and utilize health care services). This basis could be used to gather epidemiological of the prevalence and incidence of disease in the target population. These would be based on indication-based judgments of medical experts or expert groups that are arrived at in accordance with the principles for the development of evidence-based guidelines<sup>14</sup> (see Volume II, Chapter 2.4). When guidelines are lacking it

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14 This could provide a basis for the ideal – efficacy-based – model of health care as a reference for the deduction overuse, underuse and misuse.

will be necessary to rely on the judgment of individual experts or, ideally, expert groups.<sup>15</sup>

Determining the actual scope or rate of "appropriate" care in the target population under practical, day-to-day conditions also presents a problem. Due to the lack of reliable representative surveys, it will be necessary to rely on expert opinions or on the results of studies on the quality of health care and either make generalizations to apply these results to the whole population in question or use the results and expert opinions as "indicators" of possible overuse, underuse or misuse: However, it will not be possible on this basis to derive unambiguous quantitative data on the level of each in the health care system.

**31.** To reduce the subjective bias, other experts, e.g. the Advisory Council, could be interviewed on the same subject. The results of all surveys could be compared with respect to variance and the reasons given. The surveys should include patient groups as well as professional and scientific experts and expert groups, or use existing surveys of health care preferences and needs. Surveys of government authorities or organizations that service the public interest in the health sector, especially state governments, health insurers and the Medical Review Board of the SHI system are also promising sources of information.

**32.** A concept of "need" that differs from the above definitions, which focus on the care of individual patients, can be defined at system and policy level; e.g. prevention or protection-based health policy that is directed towards the reduction of health risks.<sup>16</sup> In English language public health literature this need is referred to as "public health needs" to distinguish it from the "health care needs" described above.

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15 The usual caveats are to be observed and the interest basis taken into consideration in the evaluation of these judgements.

16 For example, through the provision of mass vaccination programs, measures for the fluoridation of drinking water, educational programs on AIDS, heart and circulatory disease or accident prevention.

### 3.5 The level of supply

33. The German Social Code and the Hospital Finance Act contain definitions of "appropriate care" and the "appropriate level of supply"<sup>17</sup>, which refers primarily to existing capacities.

According to the sections 70, 99 and 100 - 102 of the German Social Code as well as to sections 1 and 6 of the Hospital Finance Act, "appropriate care" and the "appropriate level of supply" refer primarily to "instrumental" indices of the density of supply (doctors, hospitals/ hospital departments/ hospital beds or other health care facilities per inhabitant or per region); these indices are based on implicit assumptions or traditions with respect to individual or collective need as well as to the appropriate costs of access (such as waiting time, distance or money).

Indices of the density of supply alone provide information on the structure of supply. However, they do not provide information on appropriate care in the sense of the Council's definition. Additional qualitative information on the "structural" quality<sup>18</sup> of health care facilities and doctors is required for this purpose.

34. The following definitions for the appropriate level of supply may be derived on the basis of the above:

- The provision of health care services and facilities is considered to be at an "appropriate level" when it is sufficient to prevent avoidable health damages among individuals who demand services.
- The provision of health care services and facilities is considered inappropriate when it falls below the appropriate level of supply (supply at an "insufficient rate"), i.e. when the type and scope of provision or non-provision results in avoidable health damages to individuals who demand health care services.
- The provision of health care services and facilities is also considered inappropriate when it is more than the appropriate level of supply (supply at an "excessive rate"),

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17 See the following passages in the German Social Code, Book V: §§ 70 para. 1, 99 para. 1, 101 para. 5, 102 para. 2, 109 para. 3 clause 1 no. 2, 111 pra. 2 clause 1 number 2 SGB V. The law on long-term care insurance requires that the maintenance an "operational, efficient and quantitatively adequate nursing infrastructure". According to the regulations on long-term care insurance, the responsibility for these tasks resides with state governments.

18 Structural quality: type, amount, qualification/quality of personnel and equipment, including means of communication and co-operation.

i.e. the supply of services of a type and amount that provides no additional health benefits and can present unnecessary risks due to unwarranted treatment.

- "Misuse" is given when the amount and type of supplied services or facilities are appropriate, but the quality of supply – in particular the structural quality – is not consistent with the generally acknowledged state of knowledge and proficiency and therefore do not utilize the full potential of a health care procedure. As a result, avoidable damages are likely to occur.

## **4. Survey Objectives and Methods**

### **4.1 Background and goals of the survey**

**35.** The Council conducted a survey of the users, payers, providers, scientific professional societies and bodies with legal planning responsibilities (state governments, doctors associations and social health insurers) in the German health care system with the objective of gaining a balanced, realistic, and comprehensive picture of the health care situation across all of Germany. The survey thus served as an initial "inventory" of the health care situation in Germany from the perspective of different actors and with the participation of scientific and medical experts.

The Council also considered its function to be that of a "clearing house" for views of the different interest groups; i.e. the results on each topic and the reasons given for each answer are compared with respect to their variance as a means for reaching a realistic appraisal of the situation in the health care system.

### **4.2 Participants, survey design and evaluation of survey results**

**36.** The survey was designed to reach all organizations that are involved in a very broad sense in the provision of health care in Germany. This required going beyond the members of the Concerted Action in Health Care (KAiG) and extending the list of participants to include medical societies and patient groups. In total, 129 medical societies, 69 patient groups and 102 organizations in the category of "KAiG members and others" participated in the survey (a list of the groups surveyed and their addresses is given in the appendix).

**37.** The survey of the member organizations of the KAiG, medical professional societies and patient groups was based on a standardized form that nonetheless addressed issues specific to each group. The Council prepared survey documents for each target group in the form of non-standardized questionnaires with explanatory notes (questionnaire text).

The survey was designed as an indication-based (related to services and procedures for preventing or treating a particular disease or disability) and non-indication-based (related to the level of supply and the quality of the health care infrastructure) questionnaire. The questions in both areas probed for causal and well-founded empirical evi-

dence of overuse, underuse and misuse. In addition, the participants were requested to recommend measures for improving the identified problems.

**38.** The member organizations of the KAiG were requested to provide information on their thinking with respect to the following indications that the Council had identified as priority diseases<sup>19</sup>:

1. Ischemic heart disease, including infarction (ICD-9: 410-414; ICD-10: I20-I25),
2. Cerebrovascular disease, in particular stroke (ICD-9: 430-438; ICD-10: I60-I69),
3. Chronic obstructive lung disease and allied conditions (ICD-9: 490-496; ICD-10: J41-J44), including bronchial asthma in children (ICD-10: J45),
4. Lower back pain (ICD-9: 720-724; ICD-10: M49-M54),
5. Lung cancer (ICD-9: 162; ICD-10: C33-C34), breast cancer (ICD-9: 174; ICD-10: C50), malignant neoplasm of the colon and rectum (ICD-9: 153-154; ICD-10: C18-20),
6. Depression (ICD-9:296, 311; ICD-10:F30-39).

**39.** The survey documents (cover letter, questionnaire with short definition of terms) were sent on April 4, 2000. The deadline for returning the completed questionnaire was originally May 31, 2000. Due to many queries, the deadline was extended to June 30, 2000. Since the response rate was still very low (approximately 20 %) on this date, a reminder was sent out at the beginning of July 2000 and the deadline extended to August 31, 2000.

**40.** The documentation and evaluation of the responses were performed using a data base. The following data was recorded: "basic data" of the organization, "statements" on overuse, underuse and misuse, "recommendations" and "sources" (see Figure 1).

The statements on overuse, underuse and misuse as well as the recommendations were transcribed verbatim into the data base. In some cases, e.g. answers or recommendations that were not clearly delineated or which were repeated at different points in the questionnaire, the responses were paraphrased. The classification according to the categories

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<sup>19</sup> The Council based its choice on the following criteria: frequency of the health care problem, severity of the disease, direct costs of sickness, indirect costs of sickness, possible existence of a potential for further preventive measures, health problems of underprivileged groups and disputed health and health care problems that are capable of being resolved.

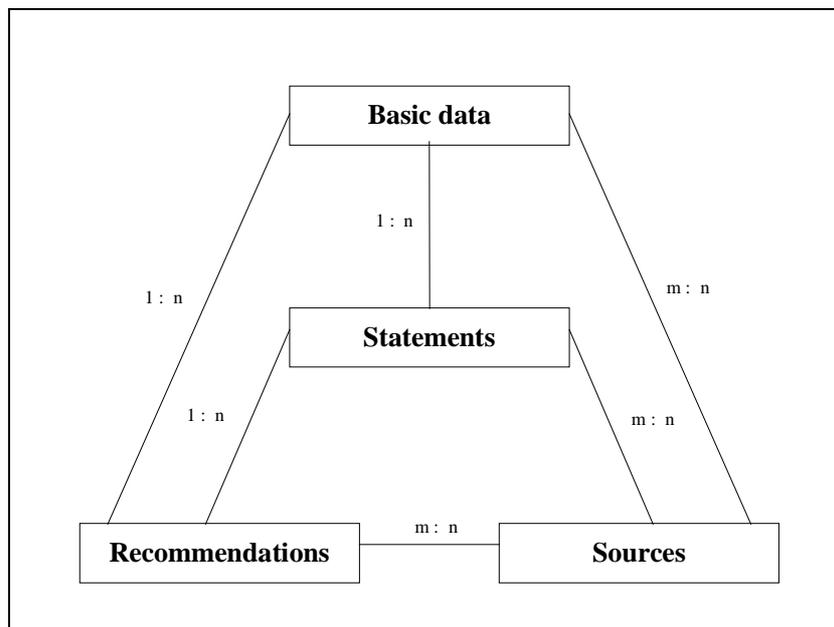
of the health care problems was also made on the basis of each respondent's view. If a respondent did not specify whether a problem was viewed as one of overuse, underuse or misuse, the classification was made by the person recording the data.

In addition to the actual wording of an answer or recommendation, the following information was recorded in the data base: indication group, health care provider and facility, sector of the health care system, type of service, technology, regional location and target group. These characteristics were also used - alone or in combination - as search criteria for the evaluation of the results.

### **4.3 Rating categories of the Council**

**41.** In order to derive recommendations for solutions to health care problems based on the survey results and on the additional literature research of the Council, a system was developed to rate the quality of the evidence and justification given for the statements and recommendations. The rating system differentiates between the need for intervention (Category A), the need for development (categories B and C) and the need for further investigation (categories D and E). Table 4 shows the evidence ratings and type of recommendations the Council gives for each: for the categories A, B and C the Council always provides recommendations; for the categories D and E the Council may formulate recommendations; for evidence in Category F ("residual group"), the Council makes no recommendations.

**Figure 1: Structure of the data base of survey results**



**„Basic data“**<sup>20</sup>: Address of the participant and other information such as affiliation with a target group (professional society, patient group, KAIG or other group) and the type of position

**„Statements“**<sup>21</sup>: Statements on overuse, underuse and misuse derived from the responses

**„Recommendations“**<sup>21</sup>: Recommendations for solving health care problems based on the responses in the questionnaires

**„Sources“**<sup>21</sup>: Bibliographic references given in the responses and an approximate classification of the evidence classes of the quoted sources

1 : n     *One* data record in a response can be related to *n* statements or recommendations and *one* statement can be related to *n* recommendations.

m : n     *m* sources can be related to *n* responses/statements/recommendations.

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

20     A list of the respondents is provided in the appendix.

21     Electronic copies of the responses are available in German at the internet site of the Council ([www.svr-gesundheit.de](http://www.svr-gesundheit.de)).

**Table 4: The need for intervention, development and investigation**

	<b>Recommendation category</b>	<b>Rating:</b> - <b>classification of the health care problem</b> - <b>classification of the solution</b>	<b>The Council recommends...</b>
<b>A</b>	Intervention	Problem: fairly certain  Solution: fairly certain	... implementation of solution(s)
<b>B</b>	Development I	Problem: fairly certain  Solution: "operational" measures are available	... pilot projects to analyze measures <sup>a)</sup>
<b>C</b>	Development II	Problem: fairly certain  Solution: appears possible, but no "operational" measures	... promotion of health care research projects to analyze solutions (if necessary, in trial projects <sup>b)</sup> )
<b>D</b>	Investigation I	Problem: not well defined, but reliable indicators  Solution: fairly certain or operational measures are available	...projects to evaluate problems and potential solutions (health care research or the development of the necessary data bases)
<b>E</b>	Investigation II	Problem: not well defined, but reliable indicators  Solution: possible or presently not appraisable	
<b>F</b>	Residual: no measures or monitoring	Problem: presently no reliable indicators	no recommendation at present

a) e.g. according to §§ 63-65 (trial projects), §§ 140 a-h (integrated care contracts) and § 20 (prevention and patient initiatives), § 43 no. 3 (education of persons with chronic diseases), § 65 a (patient bonus in gatekeeper models), §§ 135 a-137 German Social Code, Book V (quality assurance).

b) e.g. according to §§ 63-65 or §§ 20, 43 no. 3, 65 a, 135 a-137 SGB V or as part of the research tasks of the Ministry for Health, the Ministry for Education and Research or the Ministry for the Family, Elderly, Women and Youth.

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

## 5. Summary of the Survey Results

### 5.1 The response rate

42. Of the 300 organizations included in the survey, 201 submitted a completed response form, some of which were joint responses. Sixteen organizations did not wish to take part in the survey and 83 organizations did not respond. The overall response rate was 67 percent, but varied across the participating groups (see Table 5; a list of the addresses is given in the appendix). There was also considerable variation with respect to the type, quality and length of responses.

**Table 5: The number of responses**

	<b>Medical societies</b>	<b>Patient groups</b>	<b>KAiG and others</b>	<b>Total</b>
<b>Number of organizations that received survey</b>	129	69	102	300
<b>Number of responses</b>	84	43	74	201
<b>Response rate</b>	65.1 %	62.3 %	72.5 %	67 %

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

### 5.2 The survey of medical societies

43. In order to ensure that the responses to questions on particular diseases were as relevant as possible and also accessible to scientific scrutiny, the Council included professional medical societies in the survey. The Council wanted to reach professional organizations with tasks other than those that have to do primarily or exclusively with the representation of political interests. The medical societies were requested to name the diseases and reasons for treatment that they encounter most in their discipline and to focus on these in the response form.

Sixty-five percent of the medical societies responded to the Council's questionnaire. A list of the respondents is included in the appendix. The lists includes medical societies, societies for the health sciences and psychological societies. Large organizations and clinical societies as well sub-disciplines and organizations involved primarily in diagno-

sis and medical technology are also included. There is no systematic difference between the medical societies that responded and those that didn't respond.

**44.** The responses of the medical societies refer to a broad spectrum of diseases. They include rare as well as widespread diseases. Health problems are rarely seen as symptoms or as a functional impairment but as a "clinical picture". Approximately one-third of the responses were related to diseases that the Council identified as "priority diseases" for the survey as well as for its own work.

**45.** The responses highlight a specialist perspective that perceives problems in the provision of health care in a focussed form. Some of the responses were clearly driven by professional interests, a bias that is to be expected, given the social function of medical societies. However, the description and comparison of differing views of specific health care problems was an explicit goal of the survey. The Council was aware that a bias in the perception and evaluation of actual health care problems is unavoidable, despite intense efforts for as much objectivity as possible.

Sources of overuse and misuse, and in some cases even underuse, were identified by most of the medical societies, all of which seemed prepared to take a critical view of the practices of their members in university hospitals and other inpatient facilities as well as with the practices in the ambulatory sector.

Most of the medical societies complained of the lack of adequate data for evaluating current practices.

### **5.3 Survey of patient groups**

**46.** In Volume I, Chapter 3 of its report for 2000/2001, the Council called for more involvement of the users, i.e. citizens, the insured and patients, as the "third power" in the health care system. A survey of the quality of health care is incomplete, in the view of the Council, without input from the perspective of patients.

**47.** The self-help movement in Germany was an important impulse towards the redefinition of the role of the patient. Patient groups now play an important role in the support of patients and the representation of patient interests. The survey on overuse, underuse and misuse was therefore expanded to include self-help organizations. The main objectives of this approach were the following:

- Due to the severity and complexity of their diseases, the user groups represented by the patient organizations in the survey place a great demand on the health care system.
- Persons with chronic diseases or disabilities are particularly dependent on support from different sectors of the health care system, such as acute care facilities, long-term care, rehabilitation, and nursing facilities and social support. Their responses are thus particularly suited to illuminate the coordination across the sectors of the health care system.
- The Council views the authenticity of the responses alone as an indispensable contribution to the evaluation of the quality of health care in Germany.

The responses of the groups are a sensitive indicator of the quality of health care. Given this advantage, the Council was willing to accept the inadequate representativity of the sample.

### ***Key results***

**48.** The surveyed organizations see deficits in almost all health care tasks and areas of the health care system. The deficits are related primarily to the issues of quality, existing capacities, the organization of services and co-operation.

**49.** Quality problems are seen above all in the provision of ambulatory care by doctors, nurses and other health care professionals:

- General practitioners refer patients, especially patients with less common diseases, to specialists or special centers too late.
- Limited pharmaceutical budgets keep expensive but necessary treatment from patients.
- There are no binding therapeutic guidelines, or those that exist are not enforced.
- Unqualified prescriptions by providers (e.g. general practitioners, orthopedic specialists) result in the inappropriate provision of medical aids (ortheses, wheelchairs, hearing aids).
- Patients and family members criticize the fact that they are not well-informed, that the health care system lacks transparency and that there is a lack of understanding for the social and psychological effects of their situation.

**50.** The survey results contain many references to deficits in the structural framework of the health care system. The effects of these deficiencies are usually regarded as underuse.

The structural deficiencies are seen to reside both in the insufficient capacity of the existing infrastructure and in the existing facilities' limited ability to meet actual needs. There is a lack of facilities such as special centers for the professional treatment of patients with rare diseases.

There is also a lack of facilities such as special ambulatory centers and practices for common chronic diseases (e.g. arthritis).

**51.** Many of the responses on the topics of rehabilitation and long-term care refer to a lack of new forms of care to bridge the division between the ambulatory and stationary sectors. They point to a lack of part-time inpatient facilities, e.g. for short-term nursing and treatment. Outpatient rehabilitation, in particular for elderly patients, is seen as deficient. In addition, the respondents pointed to a lack of contacts for the family members of patients.

**52.** There is a broad consensus among the patient groups that underuse and misuse are due primarily to the lack of co-operation and the inadequate integration of care among healthcare providers. The existing infrastructure impedes the creation of efficient treatment pathways that are necessary for the care of patients with a chronic disease or disability. According to the respondents, the lack of interdisciplinary approaches and co-operation gives rise to serious problems in the provision of health care when the responsibility for a patient's care is passed from one sector to another.

**53.** All organizations see a need for change with respect to

- improving the provision of health care across sectoral boundaries,
- the creation of new types of infrastructures, in particular facilities for part-time inpatient care and outpatient rehabilitation,
- improving transparency with respect to treatment alternatives and their quality (e.g. disease registers similar to the cancer registries, access to records in nursing homes),
- improving the communication of and information provided by health care providers,
- the participation of patient groups in all decisions in the health care system that affect them.

### ***Recommendations***

**54.** The survey results for the patient organizations confirm the deficits identified by the Council in volumes I and II of the 2000/2001 report; the need for clearly defined objectives and a focus on them, increased prevention, improvements in quality and quality assurance measures and the participation of citizens, the insured and patients in decision-making processes at all levels of the health care system.

**55.** The survey results of the patient groups point to weaknesses in the health care system that are not reflected in the responses of the other groups. These refer primarily to the social and personal consequences of sickness on the performance of daily activities and to problems that result from the strict separation of the responsibilities of health care providers in different sectors and the lack of co-operation.

**56.** The Council views it as particularly grievous that the majority of patients complain about inadequate information and the lack of consideration for psycho-social issues on the part of health care providers. The Council views this as confirmation of its recommendations for improving user information (Volume I, Chapter 3) and increasing user competence. The results clearly indicate the existence of deficiencies in the social and communication skills of health care providers and, in particular, doctors; a fact that was pointed out by the Council in Volume II, Section I.1.

**57.** The Council views it as unreasonable that patients are often alone responsible for maintaining the "links" between health care providers, especially since the patients are inadequately informed. In a well-co-ordinated health care system, the responsibilities of each health care provider and especially of doctors should not be restricted to the care they provide but also to ensuring the smooth transition to the next health care provider in the treatment pathway.

**58.** The responses and recommendations of the patient groups also highlight the financial limits of the health care system, since they often call for increased services or facilities that serve solely their own interest. However, there are indicators for improving efficiency through

- the bundling of expertise (e.g. competence centers),
- compensation (e.g. early rehabilitation with social re-integration and fitting of appropriate medical aids) and
- services for those target groups that can benefit most (e.g. AIDS education for immigrants).

**59.** Patients should play a greater role in the evaluation of the quality of health care. Their contribution is indispensable for information on the appropriateness of health care and should be used to assess overuse, underuse and misuse.

## **5.4 Survey of state governments, doctors' associations and health insurance associations**

### *The state governments*

**60.** All state ministries and authorities with responsibilities in the health care system responded to the survey. However, the responses are quite varied. Some are brief comments indicating that no information is available to allow a reply to the Council's initial request, some are lengthy compilations of documents containing information collected for other purposes, in particular hospital bed plans. In general, the quality of the submissions from state authorities with a reputation as being "strict" is poorer than that of states with a reputation of being "lenient". In light of the responsibilities of state governments in the planning of health care facilities, the Council expected more qualified and detailed answers.

**61.** Despite the lack of methodologically sound data, a few states provided detailed information on the health care situation in Germany. To the extent that the state authorities provided information on hospital care, there is a common pattern of overuse with respect to indices of "technical density", especially with respect to hospital beds. There are only isolated references to supply below the appropriate level in special disciplines or facilities: acute psychotherapy facilities for patients with depression (Baden-Wuerttemberg), beds in pneumology departments (see Chapter 10), stroke units (see Chapter 9) and inpatient facilities for drug-dependent patients.

Overall, the results indicate an excess supply of acute care hospital beds in addition to those special areas indicated by state authorities. Based on a more differentiated view of the regional situation, there appears to be a potential for a further reduction in the number of beds in some regions. However, if the objective of equal access to hospital care is to be maintained, most of these excess bed are located in densely populated areas.

**62.** The only states reporting an excess supply ("overuse") of office-based doctors are Berlin, Bremen, the Saarland and Schleswig-Holstein. The Berlin authorities also note an excess supply of general practitioners, psychotherapists and dentists. Underuse is identified for particular diseases and problems; e.g. for pediatric and juvenile psychiatry (Berlin, Saarland), the care of patients with arthritis (Mecklenburg - Western Pomerania) and spina bifida (Berlin).

Germany has the highest ratio of acute-care hospital beds to population in Europe, but is only seventh with respect to the number of doctors per thousand inhabitants. The bed to population ratio therefore appears more pressing than the doctor to population ratio.<sup>22</sup>

### *Doctors' associations*

**63.** Two comprehensive responses were submitted by the doctors' associations that are members of the Concerted Action in Health Care, each of which included the responses of a broad range of health care providers: the joint response of the German Medical Association, the National Association of Statutory Health Insurance Physicians and the German Agency for Quality in Medicine and the response submitted by German Dental Association and the National Association of Statutory Health Insurance Dentists.

**64.** The responses of the associations refer to the priority disease categories indicated by the Council (back pain, stroke, obstructive lung disease, cancer, depression) and to other diseases, e.g. diabetes mellitus, hypertension, allergies, caries, periodontal disease and orthodontic indications.

The responses of the medical associations are based on a wealth of information (with respect to references to published studies<sup>23</sup>); the arguments and studies cited have been incorporated in the Council's analysis of the priority indications and problems (chapters 8 through 14).

### *Health insurance associations*

**65.** The responses of the social health insurers and related organizations were submitted as the joint response of the National Associations of the Social Health Insurance Funds and of the Medical Review Service of the National Associations (MDS). The private health insurers also provided a joint response through the Association of Private Health Insurance. The high degree of aggregation in the responses is related to a lack of data on

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22 However, this does not refer to the problem of "parallel specialist facilities".

23 However, neither the medical associations nor the SHI funds based their responses on their own routine regional data (see the Council's recommendations for improving health care research in Chapter 5.5).

specific states, regions or patient groups, especially in the responses of the social health insurers.

Even though no systematically compiled and well-founded data is available to the SHI funds (and the regional medical services), the Council expected that the wealth of data available to these organizations (some of which has been analyzed by the regional medical services) would provide a basis for some well-founded answers. The Council refers to Chapter 5 for its discussion of the need for more research of existing data sources.

**66.** The associations' answers refer primarily to the disease categories identified by the Council, i.e. back pain, coronary artery disease, stroke, obstructive pulmonary diseases, cancer of the lung and breast, depression and diabetes mellitus. In addition to the responses of the SHI associations, the Council also referred to published material of the SHI funds and associations.<sup>24</sup>

## **5.5 Recommendations for future surveys of the health care system**

**67.** According to the provisions social health insurance law, the Council is responsible for the ongoing analysis of the German health care system. The Council's tasks will grow and change in the course of the evaluation process. Future surveys could combine an open questionnaire on the health care situation with other important topics and a standardized, targeted probe of health care problems; issues for which the first survey could provide only preliminary data. Issues that remain to be addressed include regional disparities in the provision of health care, the health care of underprivileged groups and in particular of poor juveniles, migrants or asylum seekers, nursing services, accident prevention, semi-stationary care facilities, the services of health care technicians as well as emergency and transport services.

**68.** Some of these issues will be dealt with in the thirteen health care research projects that have been supported by the national SHI associations and the German Ministry for Education and Research since the beginning of 2001. The Council repeats its support for expanding the existing health care research program (see the Special Report 1995,

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24 E.g. the Pharmaceutical Index, the annual Pharmaceutical Report and Hospital Report of the Research Institute of the Local Health Insurance Funds (WIdO) and the "GEK Survey 2001" of the University of Bremen.

paragraphs 328, 329, 344, Table 12 and the Special Report 1997, especially paragraphs 196, 197 and 203-215). The Council supports a well funded, temporally limited and multi-faceted health care research program. The invitation of tenders for projects should focus on the medical professional societies. It may also be worth considering providing support for research by the large patient organizations. These groups should at least participate in the choice of topics, funding decisions and the discussion of study results.

**69.** Health care research should focus on strategic objectives, i.e. on long-term improvements in the health care system, and on short to medium term data analysis as a means to improve the provision of health care. There is a need for strategic data with respect to developing the health monitoring system towards a system for the analysis of need and for quality reports that provide a basis for co-ordinating all actors (politicians, self-governance organizations, citizens, the insured, patients) on the basis of quality criteria instead of on the basis of cost. In the short to medium term it is necessary to identify the existing flaws and develop innovative measures to overcome these deficiencies.

**70.** Health care research projects must be evaluated and promoted more systematically not only on the basis of the burden of a particular disease, the size of the target group or the existence of viable alternatives but also with respect to the ability to generalize the results (i.e. the studies should be representative with respect to the population, a region or a sector of the health care system). Furthermore, a "charta" of methodological standards for studies should be developed that focuses on study design as well as on the development of data sources and indices for the quality of health care processes and their results. The Council believes that the professional societies, the associations for public health and nursing research as well as the societies for biometrics and epidemiology should be involved in these tasks.

**71.** The complexity of these tasks requires the establishment of an office that has more than only short-term responsibilities. Furthermore, to promote implementation of legal provisions on prevention and self-help, the Council recommends the establishment of an advisory commission that is based on the organization of and experience with the "Advisory Commission on Primary Prevention and Workplace Health Promotion" of the national associations of the SHI funds. Such a commission should also be responsible for ensuring that studies of health care services deal not only with underuse but with overuse and misuse as well.

**72.** The Council calls on the medical societies and their members to use health care research as a tool for approaching the problems in their respective areas of responsibility and for focusing their research activities on issues with particular relevance to the improvement of the quality of health care. In order for these tasks to be performed impartially, adequate financial support is needed. One alternative is to request bids for defined health care research projects, e.g. in the framework of the research program proposed by the Council (see above).

Overall, these recommendations are aimed at increasing the utilization of the medical societies' expertise towards improvement of the health care system. By focussing efforts on central issues and ensuring the systematic integration of research results in practice, they could benefit the health care system and the population as a whole.

## **6. Indicators of Differences between the Eastern German States and the Western German States**

**73.** In evaluating trends in the health situation of the German population and the health care system in the eastern and western states, the Council could refer to only nine responses of the surveyed organizations. The small amount of consideration given to the differences in the health care situations in the eastern and western states ten years after re-unification could indicate that the situation of the social health insurance system is now similar in east and west. In light of the fundamental transformation in eastern Germany and its lasting effects on the health and well-being of the population, the Council believes that an "east-west comparison" is urgently needed. However, such a comparison would have to be based on an unsatisfactory inventory of published studies and statistical data.

### **6.1 Health status**

**74.** Health trends in the eastern states are characterized on the one hand by the adjustment of the health care system to the standards in the western states. On the other hand, the eastern states have retained unique features with respect to the morbidity structure, health behavior and health risks.

**75.** Average life expectancy is one of the most prominent indices, and increases in life expectancy in the eastern states have led to a decrease in the difference between the eastern and western states (Table 6).

**Table 6: Average life expectancy at birth in the eastern and western states (in years)**

Western states			Eastern states		
Year	males	females	Year	males	females
1949/51	64.6	68.5	1952	63.9	68.0
1960/62	66.9	72.4	1960	66.5	71.4
1970/72	67.4	73.8	1970	68.1	73.3
1980/82	70.2	76.9	1980	68.7	74.6
1986/88	72.1	78.7	1987	69.7	75.7
1991/93	73.1	79.5	1991/93	69.9	77.2
1995/97	74.1	80.2	1995/97	71.8	79.0
1997/99	74.8	80.7	1997/99	73.0	80.0

*Source:* Annual Report 1991, updated with current data of the German Statistics Office

**76.** There are still clear differences in risks to health that are characterized by a higher prevalence of hypertension, a larger number of overweight persons and higher alcohol consumption in the eastern states. There are clear indications that health behavior affects other specific characteristics of the morbidity structure in the eastern states of Germany.

**77.** High unemployment rates remain a considerable burden on the health status of the population in the eastern states. In addition, the migration of primarily younger people to the western states (1.7 million) has resulted in a higher proportion of "bad health risks" in the eastern states. According to the Enquete Commission on Demographic Change, national migration patterns will lead to changes in the distribution of the elderly and other persons representing a large health risk over the next two decades: regional differences in the share of the very elderly will decrease in the western states but grow in the eastern states. Rural regions will be characterized by a particularly high share of elderly and very elderly persons (e.g. growth rates of more than 60 % in Brandenburg and Mecklenburg - Eastern Pomerania).

**78.** Indices of morbidity rates and sick leave in the eastern and western states have converged over the past ten years. The low rates in the eastern states during the early 1990s, which were due largely to social views of sickness, have since increased to the levels in the western states. There are still differences in the types of sickness that result in sick

leave. Diseases such as chronic liver disease (+185 %), non-inflammatory afflictions of the cervix (+160 %) and hypertension (+120 %) are more common grounds for sick leave in the eastern states. Indications such as infectious diseases (-22 %) and skeletal disease (-16 %) are less common causes of sick leave in the eastern states.

**79.** There are also differences in the prevalence of certain diseases in the eastern and western states. Examples include common diseases of the circulatory system, higher mortality rates for heart attacks, the higher prevalence of diabetes mellitus and the greater number of juveniles and adults who suffer from parodontosis. However, there are fewer persons with allergies in the eastern states. The comparison of long-term prevalence data for the eastern and western states is hindered by differences in the statistics. As a result, comparisons of east and west are often inadequate as a basis for determining the future development of the health care infrastructure. Data on trends in incidence, however, are very important. For example, the incidence rates of cancer and of allergies in children and adolescents in the eastern states are now at levels comparable to those in the western states. This convergence reflects not only the standardization of statistical methods but also points to the role of changing life styles.

## **6.2 The health care situation**

**80.** Overall, the hospital sector and the ambulatory care sector in the eastern states have undergone an extensive transformation to bring them up to the levels in the western states. In the hospital sector, this process has been characterized by a drastic reduction in the number of beds, reductions in the average length of stay and an increase in the number of hospital patients. With respect to bed-to-population ratios, the eastern states still have more pediatric facilities and less beds in neurology, psychiatry and pediatric and adolescent psychology than the western states.

**81.** In relation to the number of beds, hospital staffing in the eastern states is comparable to that in the western states. In relation to the population, however, hospital staffing is lower in the east. This applies both to the medical and nursing staff.

With respect to technical equipment, hospitals in the eastern and western states are equally well equipped. In fact, it can be assumed that the equipment in the eastern states is newer than in the west, since all equipment has been renewed during the past ten years.

**82.** The provision of long-term inpatient care in the eastern states has made a qualitative and quantitative leap. The number of inpatient beds for long-term care patients has increased and been modernized. However, there is less trained personnel for patients in the eastern states than in the western states.

**83.** A comparison of resource utilization in the private practices of doctors in the eastern and western states is difficult due to the differences in the type of health insurance coverage (see Table 7). While virtually all patients treated by doctors in the eastern states have social health insurance, about one-tenth of the patients treated by office-based general practitioners and specialists in the western states have private insurance. It can be assumed that the revenues from their treatment may be used to subsidize the treatment of socially insured patients.

**Table 7: Health insurance status of the population<sup>a)</sup>**

Type of health insurance	Percent of population	
	western states	eastern states
Social health insurance	87.0	94.8
Private health insurance	10.1	3.6
Special forms of coverage <sup>b)</sup>	2.6	1.5
No health insurance	0.2	0.1

a) Results of the microcensus in April 1999

b) Welfare recipients, recipients of pensions for war injuries or recipients of support from the government.

*Source:* German Statistics Office

**84.** In addition, a much larger percentage of unemployed persons are covered by the social health insurance funds in the eastern states than in the western states (10 % versus 4.1 %). The lower social status, greater health risks and higher health care costs of the unemployed place a greater burden on the social health insurance funds in the eastern states.

Differences in the work burden of office-based doctors in the eastern and western states are related to the treatment of various diseases and result from differences in the availability of health counseling services and forms of treatment.<sup>25</sup>

### **6.3 Summary and recommendations**

**85.** Based on the above results, the Council believes that it will remain necessary to take the special situation and health problems of the population in the eastern states into consideration when analyzing the health care system in Germany. To remove the existing deficiencies and to prevent overuse, underuse and misuse in the eastern states, the Council recommends:

1. The organization of regional health campaigns. These could be actions in schools and other educational facilities. The public radio and television networks in the eastern states could broadcast series on topics such as healthy nutrition, health promotion through sports or for the issue of alcohol and youth (C)<sup>26</sup>.
2. To monitor current trends in the range of diseases as a basis for ensuring flexible reactions for the avoidance of underuse (D).
3. The reduction of regional disparities as a means for improving the situation in the care of psychiatric patients in the eastern states. Measures should be taken to offset the lack of facilities, e.g. for substance abuse and somatic sicknesses. These include the removal of east-west differences with respect to psychotherapy, which have not been satisfactorily offset by the increased role of general practitioners and psychiatrists in the eastern states (C).
4. Remove existing deficiencies in physiotherapy, logopedics, ergotherapy and health counseling as a means for improving the quality of care in the eastern states. Unmet needs in these areas increase the utilization of general practitioners and specialists in ambulatory care and thus increase cost pressure and the work burden on office-based practices in the eastern states (D).

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25 There were more than 12,062 ambulatory care facilities in the German Democratic Republic in 1989, including polyclinics, ambulatory centres, day clinics, government practices, first-aid centres staffed by doctors, first-aid centers staffed by nurses, community nurses and doctors in private practice. The Council has no information on the development of the remaining polyclinics (see Annual Report 1991, paragraphs 320-361).

26 See Chapter 4.3 for a description of the rating system.

## **7. The Care of Patients with Chronic Diseases**

### **7.1 Introduction**

**86.** The provision of adequate care to patients with chronic diseases poses the most important and greatest challenge to the health care systems of advanced industrialized nations. Chronic diseases are responsible for a significant share of the direct and - to an even greater extent - the indirect costs of diseases, e.g. productivity losses, sick pay and early pensions.

The significance of chronic diseases will increase even more in the future. One factor driving this trend is the relation between the aging of the population and the burden of chronic disease. Another factor that leads to an increase in the number of persons with chronic disease is medical progress itself: Diseases with high short-term and medium-term lethality can be better treated although no lasting cures for them exist (e.g. advances in the treatment of acute myocardial infarction) and advances in diagnosis result in the earlier diagnosis of disease, so that patients are considered "sick" for a longer period of time.

**87.** The significance of chronic diseases goes beyond the growing medical and economic burden they will pose in the future. It also has to do with their complexity and the resulting demands on the organization and co-ordination of various health policy measures (health promotion, prevention, therapy, rehabilitation and long-term care) across all health care facilities, health care providers and third-party payers. It is precisely this complexity that makes the care of patients with chronic diseases particularly susceptible to overuse, underuse and misuse.

**88.** A further problem is that patients with chronic diseases are "constant" or at least frequent users of the health care system. The need to use the health care system repeatedly or even continuously gives rise to problems that may seem trivial to an observer but are significant from an individual perspective, e.g. poor co-ordination between individual health care providers and between sectors of the health care system or poor counseling and information for patients and their families. The responses of the patient organizations in particular reveal how much of a burden such qualitative problems from the perspective of patients and their families.

## 7.2 The epidemiology and costs of chronic diseases

**89.** It is difficult to provide reliable figures on the burden of chronic disease. It is estimated that half of all patients receiving hospital and ambulatory care suffer from a chronic disease. The share of the chronically sick in the total population is approximately 40 percent.<sup>27</sup>

**90.** The estimates for Germany correspond well with data from the USA. In 1995, for example, 38 percent of all persons in America - which has a "younger" population than Germany - suffered from at least one chronic disease, 16 percent had more than one chronic disease (co-morbidity). Spending on the health care of persons with chronic diseases made up three-fourths of total health care expenditures in 1995. Persons with chronic diseases were responsible for

- 80 percent of all hospital days,
- 69 percent of all hospital cases,
- 66 percent of all ambulatory patient-doctor contacts,
- 83 percent of all pharmaceutical prescriptions,
- 96 percent of home care visits.

Analyses of this type are not available for Germany. Accounting data reviewed by the Central Research Institute of Ambulatory Health Care in Germany reveals that a relatively small portion (27 %) of chronically ill patients are responsible for 55 percent of the total annual treatment costs in the practices of "family doctors" specialized in internal medicine. The most costly group of "permanent patients" (5 % of all patients) were responsible for 20 percent of total annual treatment costs. The data of the GEK Drug Report also indicate that a relatively small number of patients "consume" a considerable amount of medical services. Approximately 50 percent of pharmaceutical expenditures were spent on drugs for 4 percent of the insured.

**91.** The elderly are not the only people who suffer from chronic diseases. However, the group of persons who suffer from multiple chronic diseases is made up mostly of the

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<sup>27</sup> The share of the chronically ill patients in the total population is approximately the same as the share of chronically ill patients in all patients because roughly 90 % of the population visits a doctor at least once a year.

elderly. The members of lower social classes are affected by multiple diseases earlier and more frequently than persons from higher social classes.

### **7.3 Requirements for the care of the chronically ill**

**92.** The Council formulated the following requirements for the provision of health care that observes the special needs of the chronically ill:

1. Appropriate care for the chronically ill takes into account the multidimensional character of diseases and frequent co-morbidity, particularly among the elderly. It accounts for the interdependency of risk factors and different diseases.
2. Since the chronically ill person must live with their sickness, social, environmental and biographical factors should be taken into consideration. The biomedical competence of the health care providers in the care of the chronically ill goes hand in hand with psychological and social competence.
3. Patients manage their treatment actively and autonomously to the maximum extent possible and with a minimum level of dependency on professional assistance. "Activating" approaches to treatment that promote independent life-styles and self-responsible coping with disease are preferred to "passive" approaches. The patient is involved in decision-making processes and the definition of objectives. The approach takes into account that it is not only the chronically ill person who is affected but the whole family and working environment of the patient. The means for promoting participation, competence and information discussed by the Council in Volume I, Chapter 3 of the 2000/2001 report play a key role in this context.
4. The health care system is directed towards the development of preventive, curative and rehabilitative strategies based on patient needs and towards the periodic assessment of the success of these strategies. For serious and complex chronic diseases this requires a regular multidisciplinary examination in well-equipped professional facilities.<sup>28</sup>

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28 Exemplary approaches can already be found in geriatrics and geronto-psychiatric rehabilitation.

5. The treatment of the chronically ill is based on the best available evidence. In a joint decision making process, this information is adjusted to the individual preferences of the patient and the experience of the doctor.
6. All health care providers in the different medical and social professions and all health care facilities work in close co-operation to ensure efficient care that fits patients' needs. The material and immaterial incentives are designed to ensure that structure and processes follow patient needs and not vice versa.
7. Prevention (health promotion, primary, secondary and tertiary prevention - see Volume I, Chapter 2) plays a central role, in particular due to the limited chances of attaining complete recovery (*restitutio ad integrum*). The objectives in this context are:
  - the prevention of the occurrence of a chronic disease through primary prevention and health promotion;
  - the use of primary prevention and health promotion to prevent the occurrence of other diseases (co-morbidity) that are unrelated<sup>29</sup> to a patient's chronic disease;
  - the use of secondary and tertiary prevention, regular check-ups and consistent early treatment to prevent consequential diseases, the deterioration of health, complications and the exacerbation of existing chronic diseases.
8. The appropriate rehabilitation process for a chronically ill patient is a self-evident task and its design and organization reflect the age-specific needs of patients. The rehabilitation process is based solely on the course of a disease and not on administrative exigencies. The coverage of rehabilitation measures for proven indications is not questioned or covered only by "supplementary" insurance packages. Depending on the phase of treatment and the severity of sickness as well as other conditions and preferences, rehabilitation services are provided on an outpatient basis, inpatient basis or on a "part-time inpatient" basis.
9. More intense health promotion efforts, information, schooling, prevention and rehabilitation of the patient as well as the routine monitoring of important indicators of outcomes and quality (on the basis of evidence-based medicine) are all means for the early detection of a worsening in a patient's health status and the avoidance or

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29 This includes other chronic and acute diseases that are not directly related to a patient's existing chronic condition.

minimization of invasive diagnostic or therapeutic interventions. Health status is seen by patients, providers, third-party payers and the public as an important indicator of the quality of health care for chronic diseases.<sup>30</sup>

10. The education, training and continuing education of the members of the health professions and related social services focuses on the care of the chronically ill, since most of their professional activities will focus on these patients. For example, medical students are not only taught about the causes of chronic diseases and the medical basis for their treatment, they also learn the principles of comprehensive preventive and rehabilitative care. This includes the acquisition of the management, communication and interpersonal skills needed for the provision of appropriate and comprehensive care.
11. The health care system creates (financial) incentives for improving the provision of care and hinders the selection of "good risks" or the exclusion of persons with chronic diseases by health care providers and health insurers.
12. There is a broad spectrum of co-ordinated and flexible facilities to meet the different health care needs of chronically ill patients.
13. Chronically ill patients are "constant users" and "frequent users" of the health care system and therefore have many contacts with the health care system in the course of their "patient careers". Modern information technology (telematics, telemedicine) should be utilized to reduce the resulting financial and temporal burden (tangible and intangible costs) on patients, their families, health care providers, third-party payers and the insured.<sup>31</sup>

Some of these requirements are interdependent and should therefore not be considered as clearly defined indicators.

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30 This is also one of the most important objectives of disease management programs.

31 However, it should not be forgotten that some groups (e.g. lower-income groups, the elderly, the handicapped) will not have access to modern information technology.

## 7.4 Overuse, underuse and misuse

**93.** The responses of the organizations and the Council's analysis show that the present situation with respect to the health care of the chronically ill is often far from meeting the named standards. There is a general pattern of overuse, underuse and misuse across some chronic diseases. Upon closer analysis, these are based on a small number of dated paradigms and common practices that stand in the way of universal access to high quality care for the chronically ill.

### *The dominance of acute care*

**94.** The many examples for overuse, underuse and misuse cited in this report support the hypothesis that the present health care system is poorly suited to the needs of patients with chronic diseases. Such deficiencies are due primarily to the fact that the health care infrastructure and the training and socialization of health care providers are based primarily on the paradigm acute health care.

**95.** For example, the growing volume of acute care services in cardiology (e.g. angiography, PTCA, stents, bypass operations) stand in stark contrast to the limited efforts in the areas of prevention and rehabilitation. Health care that focuses primarily on the treatment of acute conditions is apparently less successful in the long run.<sup>32</sup> As a result, the relatively high rate of cardiology interventions in Germany does not lead to lower morbidity and mortality rates (see Chapter 8).

Furthermore, appropriate educational measures and monitoring could prevent the effects of chronic diseases ( e.g. foot amputations, blindness and renal failure in patients with diabetes mellitus) that require costly curative care (e.g. surgery, dialysis) and long-term care services (see Chapter 7.5).

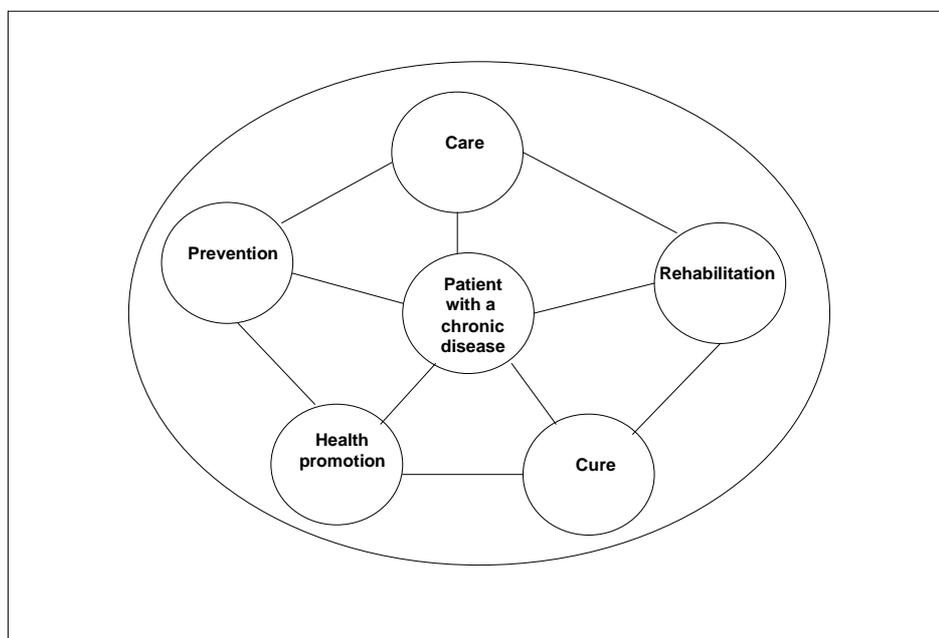
**96.** The narrow focus in the curative care of chronically ill patients is based on the traditional model of the "sequential course of disease", according to which health promotion, prevention, treatment, rehabilitation and long-term care are performed successively. However, in the co-morbidity typical of the chronically ill and the elderly, dif-

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32 This does not mean that a patient with a threatening acute condition should not be provided appropriate treatment. From the perspective of health prevention and the health care system as a whole, however, it is legitimate to view the sum of preventable risks and chronic diseases as a failure of the health care system.

ferent types and stages of disease and disabilities occur at the same time, even though there is always a potential for increasing self-responsible action and care. The simultaneous presence of many health disorders in various stages requires the simultaneous and equal application and co-ordination of health promotion, prevention, therapeutic, rehabilitative and nursing measures (Figure 2).

**Figure 2: Model of the simultaneity and co-ordination of non-sequential courses of disease**



*Source:* Schwartz, F.W. and Helou, A. (2000)

**97.** The functional integration and co-ordination of the various therapy approaches is difficult to realize as long as the existing legal framework, measures, facilities, ownership structure and funding mechanisms as well as the incentives that these create are based on traditional models of health care which are usually not co-ordinated in temporal, spatial and legal (and often financial) respects.

### *The "somatic focus" of the health care system*

**98.** The patient organizations criticize the fact that health care providers often underestimate the psychosocial burden of chronic disease. Doctors' offices tend to lack adequate information on existing psychosocial and pedagogic support (often because the doctors are poorly informed). In addition, many of the chronically ill and their families feel as if they are left alone with troubling diagnoses.

The somatic bias of the health care system is also criticized in the context of long-term care insurance. Criticism focuses on the lack of coverage for psychosocial services and the lack of support for family caregivers.

**99.** The fixation on organs and the resulting one-dimensionality of health care is based on the dominance of an "etiological" concept of sickness that is oriented towards the bio-medical pathogenesis and therapy of acute illnesses (historically, these are usually infectious diseases). This narrow bio-medical concept of disease is inadequate for dealing with the range of chronic diseases that are predominant in western industrialized countries and must be supplemented with a "conditional" concept of disease that takes psychosocial, environmental and behavioral factors into consideration. Such an approach is not new, but the result of a decades-long development, learning and adjustment process that has produced models (Table 8) closely related to changes in the spectrum of disease (trend towards chronic diseases). However, the traditional infrastructure of medical schools and health care facilities is very resistant to change; it lags behind demographic, economic, social and political change as well as behind changes in the diseases spectrum and in patients' social environment.

**100.** The somatic focus is particularly apparent in the care of psychiatric patients (see Chapter 13). Mild psychiatric disorders that nonetheless pose a considerable burden on patients and their environment<sup>33</sup> are often played down while patients with serious psychiatric disorders (e.g. psychotic patients) are stigmatized.<sup>34</sup>

**101.** The focus on somatic components of disease also affects support for research<sup>35</sup>. Due to the fact that medical progress is understood in the narrow sense of biomedical and technical progress, support for research focuses on the core areas of basic biomed-

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33 This includes not only family members but the indirect costs of sickness, e.g. in the form of sick leave and sick pay.

34 The playing down of psychiatric disorders and the patients affected by these diseases is a widespread social phenomenon that is found not only among health care providers but also among patients and their families.

35 In this context the Council points out that the number of professorships for psychosomatic medicine has decreased.

cal and clinical research and neglects research into the day-to-day and individual aspects of health care. This leads to an imbalance between the rapid rate of medical progress and its everyday use, because the scientific development and evaluation of practicable and patient-oriented health care can not keep pace with biomedical and technical progress.

**Table 8: Models, concepts and measures of health**

<b>Year</b>	<b>Causality</b>	<b>Concepts (models of health)</b>	<b>Health measures (indicators, indices)</b>
1900	<i>single cause</i> models (infectious diseases)	<i>ecological</i> model (agent-host-environment)	mortality morbidity (prevalence, incidence)
1920	<i>multiple cause</i> model ( <i>infectious disease cycle</i> , transition to chronic diseases)	<i>social-ecology</i> model (host-environment-behavior)	measures of work-related (sick leave, general disability)
1940		WHO model (physical, mental, social)	
1970	<i>multiple cause</i> model <i>multiple effect</i> model ( <i>chronic disease cycle</i> )	risk factor model holistic model (environment, biology, life style, health system) WHO: <i>Achieving Health for All</i> model	measures of risk factors, behavior, life style, environment
1980		wellness model ( <i>increasing conditions of wellness</i> )	measures of wellness, quality of life measures (QL, QALYs: <i>wellness and functioning</i> ) measures of resource allocation
1990	<i>multiple cause/multiple effect</i> model ( <i>social transformation disease cycle</i> )	WHO: <i>health promotion: development of healthy policies: politics-community-setting</i>	measure of equity social indices
2000			measures in all sectors of the economy and society with <i>health impact</i>

Source: based on Schwartz, F.W. et al. (1998) and Dever, G.E.A. (1991)

### ***"Active/passive" problem***

**102.** Many of the problems of the chronically ill identified in this report are closely related to the widespread belief that patients are the passive recipients of medical services. Passive treatment focuses on "restoration, recuperation and rest". This therapeutic approach of health care providers and the corresponding expectations of patients are often counterproductive for chronic diseases and lead to overuse, underuse and misuse. One example is the treatment of simple back pain, for which, as long as no other warning symptoms ("red flags") are present (Chapter 11), the use of imaging techniques and various passive forms of treatment (e.g. injections, fango and massage) are not efficacious. In fact, rest, convalescence and sick leave may even be harmful. The "passive" concept poses a particular threat to the elderly and the chronically ill, especially when health care providers - due to thoughtlessness, carelessness or an excessive work burden - "quiet" or sedate patients when "activating" care and mobilization are urgently needed.

### ***The neglect of prevention***

**103.** The survey results and the Council's analysis show that there are clear indicators for an underuse of preventive services for many chronic diseases; e.g. for ischemic heart diseases (Chapter 8), stroke (Chapter 9), bronchial asthma and COPD (Chapter 10), back problems (Chapter 11), lung cancer and smoking cessation (Chapter 12.1).

**104.** The Council believes that preventive measures (health promotion, primary, secondary and tertiary prevention) play a central role in the care of the chronically ill, in particular because of the limited chances for providing treatment that provides a complete cure "ad integrum" (see Volume I, Chapter 2). Preventive measures for the chronically ill are valuable from the medical perspective as well as from the economic perspective. According to estimates based on a simulation model, the benefits resulting from the primary prevention of coronary artery disease increase with the effectiveness of future therapies. This is due to the fact that the resulting increase in life expectancy of persons with heart disease leads to an increase in the total lifetime costs of care. For example, the increase in life expectancy for patients with coronary artery disease is accompanied by an increase in the number of cases of myocardial insufficiency due to coronary artery disease. The most important investment for maintaining the affordability of care for coronary artery disease is primary prevention.

### ***The neglect of rehabilitation***

**105.** Rehabilitation belongs right next to prevention as one of the major undersupplied areas in the treatment of chronically ill patients. This is the most important target group of social legislation on health insurance and rehabilitation. Like no other approach, modern rehabilitation provides a chance for the comprehensive and multidimensional care of the chronically ill. As an essential component in the care of the chronically ill, rehabilitation should therefore be a standard and not a discretionary benefit.

**106.** Many doctors and patients view the rehabilitation of the chronically ill as a one-time short-term intervention that is usually conducted on an inpatient basis. In order to integrate and apply the coping mechanisms and behavioral tools learned during the inpatient stay in the daily routine of chronically ill patients and their families, the rehabilitation of the chronically ill should be a continuous process that is adapted to the different phases of disease. This entails consideration of somatic and psychological aspects as well as of the professional and personal development of the patient and of the patient's social environment.

**107.** Such concepts are not yet an established component in the routine care of the chronically ill. Even though there is sound empirical evidence for the effectiveness of multidimensional and interdisciplinary rehabilitation - e.g. in the treatment of patients with ischemic heart disease and stroke patients - there is an undersupply with respect to rehabilitation measures. Due to the lack of conceptual approaches, changes in health behavior and the resulting positive influences on health risks are often not successfully transferred into the daily routine of patients and their families.

**108.** Even though these deficiencies have been known for years, Germany still lacks health care services that target the different phases of diseases, specific patient groups and specific patient needs; e.g. outpatient or "semi-stationary" rehabilitation facilities and appropriate rehabilitation services in nursing homes and homes for the elderly. The Council therefore calls for the rapid implementation of intersectoral and decentralized rehabilitation concepts that are patient-oriented and flexible.

**109.** The lack of well-co-ordinated outpatient services is due in part to legal problems. On the other hand, the legal framework allows for much more than has been utilized by the parties involved. If ambulatory rehabilitation is to have the appropriate status and share in the rehabilitation infrastructure, then it will be necessary to set up a uniform

legal framework for all providers and to establish an infrastructure with incentives that ensure the provision of targeted and flexible rehabilitation services.

Outpatient rehabilitation should be provided at the same level of quality as inpatient care. Patients in outpatient rehabilitation must have access to the health care services of an interdisciplinary team of qualified professionals. Establishing a nationwide infrastructure for ambulatory rehabilitation may fail due to a lack of qualified personnel (e.g. speech therapists and physiotherapists for stroke patients). Sectoral budgets pose another problem. A shift of care from the inpatient to the outpatient sector must be followed by a corresponding transfer of resources.

**110.** The opportunity for establishing a uniform legal framework for the flexible provision of service by all rehabilitation carriers that was presented by the amendment of the Rehabilitation Act was not utilized. The requirements for appropriate ambulatory rehabilitation have yet to be met. These include:

- co-ordination of basic principles for the provision of ambulatory and semi-stationary rehabilitation:
  - definition of indications and counter-indications for ambulatory and semi-stationary measures,
  - specification of the professional requirements of health care providers, in particular with respect to personnel, building requirements and equipment,
- creation of an infrastructure for the appropriate supply of flexible rehabilitation services, from the care provided by doctors in private practice to the integration of inpatient rehabilitation clinics in regional care networks and the creation of independent ambulatory rehabilitation centers.
- realization of the principles of "rehabilitation over nursing care" and "continued rehabilitation of nursing cases" by providing rehabilitation services for the some 500,000 residents of nursing homes and 1.2 million long-term care patients being cared for at home,
- measures for a comprehensive and systematic survey of the need for medical rehabilitation services by hospitals, office-based doctors and works doctors to the participation of third-party payers and the responsible Medical Review Board (*Medizinischer Dienst*), in particular through a simple and efficient reporting system.

**111.** Research efforts in the area of rehabilitation have intensified over the past few years in Germany. Since 1998, the German Ministry for Research and Education and the National Association of Pension Funds (without the participation of the SHI funds) have jointly promoted eight regional groups for rehabilitation research and have also initiated many projects. The Council acknowledges these activities as an important step for promoting the scientific nature of medical rehabilitation and its evaluation.

***Inadequate information, education and participation***

**112.** The quality of the care of the chronically ill depends to a great extent on the degree to which patients and their family members are integrated in the disease management process as responsible, informed and competent "users" of the health care system (see Volume I, Chapter 3).

**113.** The survey results and the Council's analyses make it clear that the information, education and participation of the chronically ill are lacking. This can reduce or fully offset the effectiveness of preventive and therapeutic measures due to a lack of patient compliance or other improper behavior. Inadequate information on the negative effects of poor posture and rest, for example, can promote the chronification of back pain (see Chapter 11). The insufficient supply of qualified asthma training courses results in the improper or inconsistent use of basic medication with inhaled corticosteroids (see Chapter 10). This leads to an avoidable aggravation of the underlying disease. The inadequate control of blood sugar levels by poorly trained diabetics leads to life-threatening imbalances in metabolism due to hyper and hypo-glycemia. Over time, it also leads to other common complications (e.g. amputation, blindness and renal insufficiency) (Chapter 7).

**114.** There is a need for more "patient education measures" at local level that promote patient motivation and compliance and maintain and reinforce changes in risk behavior, self-perception and physical fitness such as can be attained in the course of inpatient rehabilitation. Training centers offering specific educational programs at local level and for different diseases are also conceivable. The required development of patient education measures should not be allowed to fall victim to the financial considerations of health insurers and the self-governance committees.

### *The lack of interdisciplinary and flexible concepts of health care*

**115.** The responses of the participating organizations and the analysis of the Council show that the desired integration of different treatment approaches in the daily care of the chronically ill is often not realized.

**116.** Patient organizations in particular are critical of the lack of a holistic and interdisciplinary treatment approach. They point to a legal and financial framework that hinders the provision of comprehensive services and splits the therapy process into isolated treatment units. This results in the typical interface problem between the different health care providers, institutions and sectors. Patient groups point repeatedly to the lack of communication between general practitioners, specialists and hospital doctors.

The Council believes that - without improved co-operation at this interface - these problems will become even more acute after the introduction of DRGs and the resulting decrease in the average length of hospital stay.

**117.** The survey results, in particular the responses of the patient organizations as well as results health care research, make it clear that there is a need for a health care infrastructure that offers patients a flexible "menu" of health care services and maintains a network of "treatment pathways". This applies as well to older patients with many diseases, e.g. in nursing homes and homes for the elderly, for whom standard care does not always provide an adequate, multimodal and co-ordinated treatment with preventive, therapeutic and rehabilitative measures.

### *Deviations from evidence-based care*

**118.** The present care of the chronically ill is often far removed from the standards set by the best available evidence or evidence based guidelines. These deficiencies are due to a certain degree to the inadequate, delayed or incorrect understanding and implementation of scientific knowledge in daily practice (Volume II, Chapter 2.3). The Council discussed this problem in detail using selected examples of (chronic) diseases in Chapters 8 to 13.

### *The chronically ill as "bad risks"*

**119.** Adequate care of the chronically ill can be threatened when the provision of treatment to chronically ill patients is associated with financial risks or revenue losses for health insurers and health care providers.

In this context, patient groups provided numerous reports of chronically ill patients who were refused treatment (e.g. arthritis patients, diabetics) on economic and not medical grounds. This affected not only the prescription of costly medicines but also items such as the self-monitoring of glucose levels by diabetics.

**120.** The regulations governing the revenue sharing mechanisms across all SHI funds have not created incentives for improving the care of the chronically ill, because the existing system favors risk selection ("hunting for the healthy"). For this reason, the German health care system lags behind the health care systems of other countries with respect to the effective management of care for the chronically ill.

In the context of the reform of the revenue sharing scheme, disease management projects are to be developed for selected chronic diseases (e.g. back pain, diabetes, hypertension, coronary artery disease, cardiac insufficiency, stroke, asthma, breast cancer) as a means for improving the care of the chronically ill.

The Council greets all measures that create effective financial incentives for improving the care of the chronically ill. However, it will be necessary to create appropriate incentives and reimbursement mechanisms to improve health care for all and not only for selected groups of the chronically ill.

### *Inadequate qualification*

**121.** The Council discussed the reform of the education, training and continuing education systems for doctors and nurses in Chapter 1 of Volume II. There the Council calls for a stronger practice-orientation and more freedom from industry interests. Many of the measures and changes called for are of immediate importance to the chronically ill. These include:

- increased focus on health promotion, prevention, rehabilitation and geriatric care;
- increased consideration for patient needs with respect to information and participation;

- the encouragement of communication and counseling skills;
- the promotion of co-operation and co-ordination;
- the establishment of education and training in facilities other than acute care units;
- training in the methods of clinical epidemiology and evidence based medicine as well as in disease, case and quality management;
- the use of modern information technologies (telematics, telemedicine).

### **7.5 Lessons from ten years of diabetes care in Germany**

**122.** Many of the basic problems in the care of the chronically ill are particularly troublesome for patients with diabetes mellitus. The analysis of diabetes care reveals that in the case of this large group of the chronically ill there is a serious gap between what is medically possible and the actual situation in everyday care. In spite of many efforts and some regional success, there has not been a decisive improvement in the care of diabetes in Germany. The objectives of the St. Vincent Declaration from 1989 (Table 9) have not been attained in Germany.

**Table 9: Objectives of the St. Vincent Declaration of 1989**

1. Reduce new blindness due to diabetes by one third or more.
2. Reduce the number of people entering end-stage diabetic renal failure by at least one third.
3. Reduce by one half the rate of limb amputations for diabetic gangrene.
4. Cut morbidity and mortality from coronary heart disease in the diabetic by vigorous programs of risk factor reduction.
5. Achieve a pregnancy outcome in the diabetic woman that approximates that of the non-diabetic woman.

*Source:* WHO and IDF (1990)

**123.** Many of the responses from the organizations point to current deficiencies in the care of diabetics. One issue that is mentioned quite often is the underuse in regard to the early detection and treatment of the long-term complications of diabetes. The organizations feel that a good share of the large number of complications (foot amputations, blindness, renal insufficiency etc.) could be avoided if the necessary diagnostic and therapeutic measures as well as profes-

sional counseling (including training aimed at improving self-responsibility, motivation and patient compliance) were to be provided on the basis of sound medical knowledge.

**124.** There is a considerable difference of opinion with respect to the reasons for the unsatisfactory situation. The debate reveals a growing feeling of helplessness. Many decision makers are mystified by the fact that there has been no significant breakthrough in the care of diabetics even though all of the medical conditions seem to have been met:

- Diabetes mellitus type 1 and type 2 have been and still are subject to intensive research. The pathological mechanism of diabetes is well understood. There are simple, evidence-based and cost-effective measures for the diagnosis, treatment and control of diabetes and its complications.
- There is empirically sound data demonstrating that multi-modal diabetes therapy (careful control of glucose levels, blood pressure and lipid levels; training, behavioral modification and pharmaceutical treatment of risk factors) can lead to a considerable reduction in early and long-term complications, postpone or prevent such complications, and have positive effects on the life expectancy and quality of life of type 1 and type 2 diabetics.

**125.** The conditions for the appropriate care of diabetes have been met in more than just a medical respect. Many managerial tools have been developed and implemented over the past years (education and training materials for the healthcare providers involved in the care of diabetics, guidelines, quality indicators, computer programs, telematics) and health care approaches (e.g. models for integrated care).

The fact that these advances have not benefited all diabetics to the same extent indicates that organizational and structural problems still hinder the nationwide implementation of scientifically sound concepts.

**126.** The problems in the care of diabetics are by no means new. They have been known for years and have been the impetus for many policy initiatives and measures by the medical profession and the self-governance organizations in the German health care system. New forms for the improved provision of care to diabetics have been tested in numerous trial projects, some of which have had very promising results in comparison to standard care. Nonetheless, effective improvements in the care of diabetics are only to be found in isolated instances at local level.

**127.** In this context, many respondents point to the organizational, information-related and financial boundaries between the different sectors, institutions and professions as particular hindrances. Furthermore, there are the geographic and administrative boundaries between the different regional associations of statutory health insurance physicians as well as between the different types of social health insurance funds. This particularism and resulting "patchwork" of local initiatives, or the lack thereof, hinders the implementation of the provisions in social law that call for equal levels of health care throughout the country. Differences in the organization of diabetes training programs at regional level is a particularly glaring example of this problem.

**128.** Competition among the social health insurers has exacerbated this problem insofar as measures to improve the quality and organization of health care serve more as promotional measures for individual health insurance funds than as measures intended to lead to a general improvement in the provision of health care services. The results of regional projects on different forms for the provision of health care and the quality of care are not disclosed, revealed only partially, or published with unnecessary delay, in order to gain an advantage over other health care providers and third party payers (knowledge of quality = power, see Volume II, paragraph 333). Intransparency for the sake of competition is counterproductive. The Council therefore calls for the early disclosure of the results of local projects for review by expert groups and as a means for quickly improving the care of diabetics in general. Social health insurers and doctors' associations should agree on the best practice standards on the basis of medical benefits and cost-benefit ratios and harmonize their efforts towards quality improvement so that all diabetics in Germany have access to high quality treatment close to home.

The situation is not unique to the care of patients with diabetes. Other areas of care are also characterized by the lack of a general use of proven standards of care (see chapters 8 - 14). The Council therefore calls for the widespread implementation of innovative models and concepts of care that have proven successful in trial projects or other regional projects. To this end, the national and regional committees must be required to report and follow-up on successful trial projects and/or patient groups must be granted the right to apply for new forms of care to the responsible committees (National Standing Committee - BUB Committee, Hospital Committee, Co-ordinating Committee).

**129.** Expectations with respect to disease management are very high in Germany. Disease management is the systematic and comprehensive approach for improving the care for a particular disease. This entails co-ordinating care across existing structural

boundaries, and on the basis of guidelines, treatment protocols and information systems. Disease management approaches provide an opportunity for the organization of systematic, co-ordinated, interdisciplinary and patient-oriented health care, especially when the family doctors are involved. In the USA, however, disease management programs are used primarily as a means to control costs, they focus on the seriously ill and leave little room for patient participation. This fault should be avoided in the implementation of disease management programs in Germany through the consistent application of quality management, the creation of appropriate incentives and the introduction of such programs on a voluntary basis only.

### *New models in the 21<sup>st</sup> century*

**130.** The structural and organizational problems in the provision of health care of the chronically ill and the underlying conceptual approaches can not be overcome by "isolated" disease management approaches. New directions in the care of the chronically ill need new models and values. The belief that better formal management alone will solve the problem ("management solution paradigm") is not enough, because there is no such thing as a solution to all problems in the health sector. Problems and conflicts that arise because of limited resources or divergent goals, interests and needs are permanent factors of the health care system. What is needed is a new approach to health policy objectives, needs and interests.

This is also the main message of the recent report of the "Committee on Quality of Health Care in America - Institute of Medicine (IOM)" regarding the quality of health care and the need for reform in the health care system of the USA. Backed by considerable experience and numerous studies, the IOM takes a sober view of the management techniques used in the health care system of the USA. The success of approaches such as "disease management" do not depend alone on the quality of planning and implementation or on the technical conditions and qualification of health care professionals. They also must regard a few basic rules that will change and replace the present guiding principles of health care (Table 1).

## **7.6 The care of the terminally ill<sup>36</sup>**

**131.** Approximately three-quarter of a million adults die each year due to chronic diseases; of these mortalities, about 210,000 are due to cancer. The death process of chronically ill patients usually involves different institutions and organizations.

Data from the state of Lower Saxony indicates that approximately 80 percent of terminally ill cancer patients would prefer to die at home. Half of all deaths in Germany occur in the hospital<sup>37</sup>. There is no representative data on the preferences of the terminally ill with respect to the place of death. The Council believes that better surveys would be helpful to document these important humanitarian and planning issues.

**132.** Studies of the care of AIDS patients revealed that there are many hurdles in the way of the home care of terminally ill patients during the last phase of life. These include (1) the lacking qualification of health care professionals in social and medical areas, (2) the structural disintegration of different services and support systems, (3) inadequate co-operation, especially between doctors and nurses, (4) technically limited services that can not respond adequately to new problems and finally, (5) a legal and financial framework that is too restrictive for the adequate care of the seriously and terminally ill. Ultimately, the sum of these obstacles leads decision makers to choose the hospital as the "easier and more convenient" alternative, even though this contradicts the wishes of the patient.

**133.** Experience with the care of terminally ill patients who are in pain reveals problems at the interfaces between health care providers and at least some regional deficiencies. In this phase of life, the determination of need should closely follow the preferences or the subjective need of the patient. Respect for the personal dignity and integrity of the individual is the primary concern. Financial considerations should be secondary, as are the details of medical treatment, which can only have marginal medical benefits for the terminally ill.

**134.** A major problem from the medical perspective as well as from the perspective of patients is not only the fight against symptoms such as dyspnea, vomiting, bleeding, and fear but the adequate treatment of pain. It is particularly important in the treatment of

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36 The Council does not deal in the report with euthenasia or "physician-assisted death". The focus is on the present health care of the terminally ill and dying patients.

37 The total includes traffic fatalities, suicide or premeditated acts as an external cause of death.

cancer patients; a number of studies have revealed qualitative deficits in this area (see Chapter 12.3).

**135.** Terminally ill patients need special nursing, medical and psychological care and support. Deficits in these areas exist across all of Germany. A number of groups (e.g. ambulatory "hospices", therapeutic support services, counseling services, for example of churches and religious organizations), some of which are voluntary, try to cover unmet needs in this area. However, these services are not in the benefits catalogues defined under social health insurance law, private health insurance and long-term care insurance law. In addition, there are considerable differences in the provision of services across the regions.

## **7.7 Summary and recommendations**

**136.** The Council articulated requirements for the care of chronically ill patients that reflect the special needs of this clinically, medically and economically important patient group (see Chapter 7.3). Health care of the chronically ill in Germany must be measured according to the extent to which these requirements are actually met on a day-to-day basis across the country through measures that cross professional, institutional and sectoral boundaries, more intensive research programs, the increased flexibility of the system and the creation of targeted incentives.

**137.** The responses of the surveyed organizations and the Council's analysis show that the present situation is far from meeting the requirements for many chronic diseases. There is a congruence of the types of overuse, underuse and misuse for different diseases that is due to a number of outdated "paradigms" and models of health care:

- The dominance of acute care; the neglect of prevention and rehabilitation of the chronically ill.
- Insufficient consideration of the social, psychological, environmental and biographical references of the chronically ill and their families ("somatic fixation").
- "Active/passive problem": the chronically ill patient is treated as a passive recipient of medical services. Passive treatment focuses on "repair, cure and rest".
- Inadequate schooling, information and participation of patients and their families.
- The lack of an interdisciplinary and flexible health care infrastructure.

- The deviation from the principles of evidence-based medicine.
- Inappropriate incentives that make the chronically ill "bad risks" for health insurers and health care providers.
- Inadequate consideration of the special needs of the chronically ill in the education and training of health care professionals.

**138.** There is a clear imbalance between overuse in curative medicine and an underuse in the prevention and rehabilitation of chronic diseases. However, it is unknown whether the total resources bound up in the overuse of curative services (so-called "efficiency reserves") are enough to compensate for the many forms of underuse in other areas. Furthermore, it is unclear whether and how the resources that are freed in one area can be targeted in other areas. A short term and at most partial reduction of overuse is possible under guideline-based health care practices (e.g. disease management programs) as long as the latter are implemented correctly and the participants are cooperative (B).<sup>38</sup>

**139.** A lasting reduction in overuse and misuse as well as the establishment of an appropriate balance between prevention, treatment and rehabilitation in the care of the chronically ill requires a long-term re-structuring of the health care system that occurs in a number of steps based on consistent health policy objectives (A). It requires a basic reform of the health care infrastructure and the incentives, knowledge and values of the health care system (A).

**140.** Despite many efforts and some regional success over the past ten years, the health care of patients with diabetes mellitus in Germany has not improved significantly. The objectives of the St. Vincent Declaration of 1989 have not been met.

This disappointing situation is due to organizational and structural problems that hinder the general introduction of professional concepts in Germany. Besides the known organizational, information and financial barriers between sectors, institutions and professions, there are also regional barriers between the associations of statutory health insurance physicians (*kassenärztliche Vereinigungen*) and between the different types of social health insurance funds. This "fiefdom mentality" and the elaborate patchwork of local agreements - or lack thereof - hinders the realization of equal levels and quality of care as called for by German social law.

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38 See Chapter 4.3 for a description of the rating system.

**141.** Competition among health insurance funds has exacerbated this problem, since measures for improving the quality and the organization of health care services are intended primarily to improve the image of a health insurer. The Council therefore calls for the swift and broad implementation of innovative models and concepts of health care that have been proven in trial projects or other local projects. To expedite matters, the parties involved in the self-governance of the health care system must be obliged to take action or patient groups must be granted a voice in the decision-making processes of the self-governance committees (Federal Standing Committee of Doctors and SHI Funds, Hospital Committee, Co-ordination Committee) (A).

**142.** Both prevention and rehabilitation are the great areas of underuse in the care of the chronically ill. As the most important target group, this group is not adequately covered by the laws on social health insurance and rehabilitation. However, it is precisely modern approaches to rehabilitation which, more than any other treatment modalities, permit a comprehensive and multidimensional treatment of the chronically ill. Rehabilitation should not be a discretionary benefit but a standard component of a total benefits package for the chronically ill (A).

The amendment of rehabilitation laws provided an opportunity for the creation of a unified and comprehensive framework for the granting and provision of rehabilitation services. However, this opportunity was not utilized. The basis for the creation of the appropriate outpatient rehabilitation infrastructure has yet to be created (A).

The rehabilitation of the chronically ill should be conceived as a continuous process that adjusts to the different phases of a disease and regards not only the somatic and psychological development of the patient, but the patient's professional and personal development and social environment as well (A).

**143.** Overall, the health care of terminally ill patients in Germany is unsatisfactory. In light of the importance of this area of health care, the Council believes that intensified, quality-oriented research projects (D) and the expansion of hospices and other specialized outpatient and inpatient services (A) are needed.

## **8. Ischemic Heart Disease, Including Heart Attack**

### **8.1 The burden of disease**

**144.** Coronary heart disease is one of the most common causes of death worldwide. In Germany, cardiovascular diseases (ICD-10 I00-I99) account for roughly 50 percent of all deaths. About 21 percent of the German population dies as a result of the acute or chronic effects of coronary heart disease. Coronary heart disease is responsible for 54 to 70 percent of all cases of heart failure and thus the most common cause of a disease that is becoming a significant health problem. In 1998, only about 5 percent of all early retirement cases were due to coronary heart disease, the absentee rates per case are the second highest to patients with cancer. The occurrence of coronary heart disease is affected by age, sex, biomedical factors (e.g. dyslipidosis, arterial hypertension, diabetes mellitus, obesity), psychosocial factors and socioeconomic factors (e.g. social support, class-specific life styles, stress). Despite intense efforts in the treatment of acute cardiac distress, Germany has only been able to make moderate advances in the reduction of mortality due to cardiac disease in comparison with other countries.

### **8.2 The views of the interviewed groups**

**145.** Table 10 lists the organizations that responded to questions concerning ischemic heart disease in the Council's survey.<sup>39</sup> The respondents did not reach a broad consensus in this area. While the medical societies perceive underuse or misuse, the member organizations of the Concerted Action in Health Care are split between those who think that there is overuse or that care is appropriate and those who perceive underuse and/or misuse. Patient organizations cited primarily situations characterized by underuse.

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<sup>39</sup> The following summarizes the responses of the surveyed organizations. Electronic copies of the organizations' responses can be found at the Council's web site ([www.svr-gesundheit.de](http://www.svr-gesundheit.de)).

**Table 10: Organizations that provided information on overuse, underuse and misuse in the area of ischemic heart disease**

Name of the organization (A - Z)	Type of organization
<i>BÄK, KBV und Ärztliche Zentralstelle für Qualitätssicherung</i> German Medical Association, National Association of Statutory Health Insurance Physicians and the German Agency for Quality in Medicine	Concerted Action and others
<i>Bundesverband der Pharmazeutischen Industrie e.V.</i> Association of the German Pharmaceutical Industry	Concerted Action and others
<i>Bundesverband selbständiger PhysiotherapeutInnen</i> National Association of Independent Physiotherapists	Concerted Action and others
<i>Deutscher Berufsverband für Altenpflege e.V.</i> German Professional Association for Geriatric Nursing	Concerted Action and others
<i>Deutsche Gesellschaft für Allgemeinmedizin und Familienmedizin</i> German Society for General Medicine and Family Medicine	Professional society
<i>Deutsche Gesellschaft für Kardiologie, Herz- und Kreislaufforschung</i> German Cardiac Society	Professional society
<i>Deutsche Gesellschaft für Nuklearmedizin</i> German Society for Nuclear Medicine	Professional society
<i>Deutsche Gesellschaft für Pharmazeutische Medizin e.V.</i> German Society for Pharmaceutical Medicine	Professional society
<i>Deutsche Gesellschaft für Public Health e.V.</i> German Public Health Society	Professional society
<i>Deutsche Gesellschaft zur Bekämpfung von Fettstoffwechselstörungen und ihren Folgeerkrankungen e.V.</i> German Society for the Treatment of Metabolic Disorders and Resulting Diseases	Patient group
<i>Deutsche Herztiftung e.V.</i> German Heart Foundation	Patient group
<i>Deutscher Städtetag</i> German Council of Municipal Governments	Concerted Action and others
<i>Deutscher Paritätischer Wohlfahrtsverband Gesamtverband e.V.</i> German Non-Denominational Welfare Association	Concerted Action and others
<i>Ministerium für Frauen, Arbeit, Gesundheit und Soziales des Saarlandes</i> Ministry for Women, Labor, Health and Social Affairs of the Saarland	Concerted Action and others

<i>Niedersächsisches Ministerium für Frauen, Arbeit und Soziales</i> Ministry for Women, Labor and Social Affairs of Lower Saxony	Concerted Action and others
<i>Robert Koch-Institut</i> Robert Koch Institute	Concerted Action and others
<i>Sächsisches Ministerium für Frauen, Arbeit und Soziales</i> Ministry for Women, Labor and Social Affairs of Saxony	Concerted Action and others
<i>Spitzenverbände der GKV und der MDS</i> National Associations of Social Health Insurers and the Medical Review Board	Concerted Action and others
<i>Verband der privaten Krankenversicherung</i> Association of Private Health Insurance	Concerted Action and others
<i>Verband Forschender Arzneimittelhersteller</i> Association of research-Based Pharmaceutical Companies in Germany	Concerted Action and others
<i>Verband physikalische Therapie</i> Association for Physical Therapy	Concerted Action and others

### ***Prevention***

**146.** The effectiveness of primary prevention measures based on pharmaceuticals for lowering cholesterol levels is undisputed. Some respondents, however, point out that the benefit of such treatment is not predictable in each case. The indiscriminate prescription of cholesterol reducing medications could result in overuse or misuse, especially considering the possible side effects. In general, however, the majority of respondents feel that there is an underuse in primary prevention with respect to the prescription of pharmaceuticals to lower cholesterol levels. Many responses describe deficits in the non-pharmaceutical primary and secondary prevention. In particular those preventive measures such as life-style changes are seldom used even though they are known to be effective. There is a need for measures such as a "National Prevention Program", with which risk factors can be influenced as early as possible (when necessary, beginning in childhood). Preventive measures should follow evidence-based guidelines which, at present, are lacking in Germany.

### ***Diagnosis***

**147.** Some of the responses concerning coronary heart disease state that diagnosis in this area is appropriate or that there is an overuse. Criticism is voiced with respect to the high utilization of cardiac catheterization compared to other countries. Other respondents note that there is an undersupply of these services in some regions. Innovative diagnostic procedures for the non-invasive detection of coronary occlusion. There is a tendency for overuse or misuse in this area due to unfocused screening. There is unanimity that echocardiography, including stress echocardiography, is an important and reliable instrument for the diagnosis and control of therapy in the management of coronary heart disease. There is general recognition of the importance of

evidence-based guidelines, increased interdisciplinary co-operation and of quality controls for diagnostic procedures.

### ***Pharmaceutical therapy***

**148.** The responses reveal the controversy surrounding the use of pharmaceuticals for the reduction of cholesterol levels as a means of primary prevention. With respect to secondary prevention, however, there is a general consensus that lipid-lowering agents are not prescribed enough (underuse) or are used inappropriately (misuse). The causes of underuse in this area are seen in the failure to follow evidence-based guidelines, which are lacking in Germany, and the financial limits defined by the pharmaceutical budgets.

### ***Other forms of treatment***

**149.** As is the case for coronary angiography, the assessment of the situation with respect to invasive forms of therapy is also controversial. Some respondents complained of underuse in the utilization of innovative procedures: underuse that is largely seen as due to financial problems. In general, the use of costly technologies should be limited to authorized centers and university clinics. Despite all past efforts, there is still room for improvement in the treatment of acute heart attack. Furthermore, some respondents criticize the strong increase in the number of providers and in the volume of services, the uneven regional distribution of the volume of services. There is also the general view that there are too few intensive care beds and that the hospital length of stay is too long.

The (outpatient) provision of physical therapy and rehabilitative measures for ischemic heart disease is seen as appropriate. There is a general consensus with respect to the importance of evidence-based guidelines and the need for continued data collection, since the insufficient data currently available can not describe what the "optimum" amount of care should be.

## **8.3 The Council's viewpoint**

### ***The current situation in Germany***

**150.** A few indicators of the current situation and of the significance of ischemic heart disease and cardiology in Germany are summarized in Table 11.

**Table 11: Facts on cardiology in Germany (1999)**

<b>Number of cardiologists (total)</b>	<b>2,167</b> (26.4 / million population)
- cardiologists in private practice	1,752 (21.4 / million population)
<b>Number of beds in internal medicine</b> (acute care hospitals)	183,984
- beds for cardiology patients	15,378
- cardiology intensive care beds in internal medicine depts. (%)	9.7
- utilization rate of cardiology intensive care beds (%)	78.8
<b>Number of patients in internal medicine depts.</b>	5.76 Mio.
- number treated in cardiology departments	729,016
<b>Number of discharges for ICD-9 410-414</b>	849,557
<b>Number of beds for internal medicine (rehabilitation clinics)</b>	56,226
- rehabilitation beds for cardiology	11,751

*Source* : Advisory Council, based on data of the German Statistics Office (2001b) and Bruckenberg, E. (2000)

### ***Coronary interventions***

**151.** Invasive coronary interventions are an important cost factor in the treatment of coronary heart disease. Health insurers spent about DM 5.2 billion on cardiac catheterization, PTCA, stents and rehabilitation measures in 1999. Table 12 shows the substantial growth in the number of invasive diagnostic and therapeutic measures in cardiology for the period 1990 - 1999. There are distinct regional differences in cardiac mortality and the number of cardiac interventions performed. The regional burden of disease and the supply of facilities are not well balanced. Although there is an increasing international trend in the number of procedures, Germany has the highest number of interventions in Europe. In view of the high number of interventions and the amount of resources used, the decline in cardiac mortality in Germany has been relatively modest.

**Table 12: Trends in the number of invasive cardiologists, cardio-surgical facilities and the number of cardiological interventions (1990 - 1999)**

	<b>1990</b>	<b>1999</b>	<b>Change</b>
Cardiac catheterization units	233	513	+ 120 %
Coronary angiographies	193,673	561,623	+ 190 %
PTCAs	33,785	166,132	+ 392 %
Number of heart surgery centers	46	81	+ 76 %
Number of heart surgery procedures (with heart-lung machine)	38,712	96,906	+ 150 %

*Source:* Advisory Council on the basis of Bruckenberg, E. (2000)

**152.** This highly aggregated data does not allow for any conclusions with respect to the actual health care situation in this area. However, if they are combined with the mortality data or compared to the data from other countries, there is a clear imbalance between the amount of effort and the results. The population-based perspective leads to the conclusion that a one-sided strategy based on technical interventions is ineffective for reducing the morbidity and mortality associated with coronary heart disease. The survey results and available statistics indicate an imbalance between the large expenditures for pharmaceutical and technical measures and the relatively low resource input for preventive measures.

**153.** There is clear evidence for the positive correlation between the volume of services provided by a health professional or health care institution and the quality of outcomes, especially in the areas of cardiology and heart surgery. Therefore, for a given volume of services, an increase in the number of health care providers can therefore have negative effects on quality. An increase in the number of procedures with the growth in the number of health care providers ( key word: "supply-induced demand") can have adverse economic and medical effects. The regulation of the number of health care providers who perform surgical procedures and other interventions therefore seems appropriate from the quality assurance perspective as well as on economic grounds.

**154.** Since the volume of both diagnostic and therapeutic services in cardiology are likely to increase due to scientific and technical progress, demographic trends, the prevalence of risk factors associated with life-style and existing financial incentives, the Council holds the prevention of coronary heart disease to be of utmost importance. Ac-

According to simulation models, primary prevention grows more attractive from a health economics perspective the more optimistic the assumptions about future therapeutic advances; the increased life-expectancy of patients with coronary heart disease results in increased needs for the care of patients with chronic heart diseases. The evaluation of the situation should be based not only on the individual appropriateness of interventions, but should also include the overall ratio of the costs and benefits of these measures and existing alternatives.

### *Hypertension as a risk factor for coronary heart disease*

**155.** Arterial hypertension is considered to be a classical risk factor for cardiovascular events. High blood pressure is defined as anything over 140/90 mm Hg (WHO definition). The early and careful control of blood pressure to attain evidence-based target levels is decisive for the reduction of morbidity and mortality. The results of the National Health Survey highlight the importance of hypertension as a widespread disease. In 1998, 48 percent of all men and 39 percent of all women had blood pressure levels over 140/90 mm Hg.<sup>40</sup>

The data of the German Heart and Circulation Study show that the prevalence of hypertension has remained constant at about 30 percent. In the surveyed age groups between 18 and 69 years of age, 45 percent of the individuals in whom hypertension was diagnosed were aware of their condition, approximately 28 percent were on medication and 5 percent of the patients with hypertension were judged to be receiving adequate treatment. The results of the so-called MONICA study also point to deficits in the diagnosis of hypertension: Hypertension was diagnosed by a doctor in only 54 percent of the males and 64 percent of the females who had high blood pressure. While there is a positive trend in the USA with regard to the awareness of arterial hypertension, its treatment and control and a corresponding trend in cardiovascular morbidity and mortality, the opposite seem to be the case in Germany.

**156.** There are also indications that there is clear underuse with respect to the pharmaceutical and non-pharmaceutical treatment of high blood pressure. Surveys show that roughly two-thirds of all patients with hypertension in Germany do not receive adequate pharmaceutical therapy. According to the results of the National Health Survey in 1998,

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40 Prevalence data is based on the average for all age groups of adult males and females.

only 20 percent of the patients undergoing treatment for hypertension had a desired blood pressure level. Despite the steady increase in hypertension treatment of males and females by about 10 percent, there has not been a decrease in the number of inadequately treated hypertension patients. This implies that the therapy of hypertension is overly cautious and not aggressive enough and that existing evidence-based guidelines for hypertension are not being followed adequately.

Factors such as obesity, lack of exercise, alcohol and tobacco consumption as well as excessive salt intake are often neglected in the non-pharmaceutical treatment of hypertension. Since these factors are acknowledged to be general risk factors for the development of hypertension, they are important for preventive strategies. However, the objectives in primary and secondary prevention for the reduction of the incidence of hypertension in Germany through behavioral changes could also not be reached.

**157.** In summary, the situation in Germany is characterized by underuse in the diagnosis of hypertension, underuse and misuse in the pharmaceutical therapy of high blood pressure and underuse in particular in preventive measures and the non-pharmaceutical treatment of risk factors.

#### ***Primary prevention of ischemic heart disease***

**158.** In light of its often considerable effects on the lives of patients and the costs of disease, the primary prevention of ischemic heart disease is very important. Changes in behavioral risk factors could reduce the burden of disease associated with coronary heart disease by 20 - 30 percent, giving rise to annual savings of approximately DM 3 - 4 billion (based on 1994 data). Primary preventative measures for cardiovascular disease can be classified as population-based, group-based and individual interventions. Population-based preventive strategies are the best means for dealing with the high prevalence of many slightly elevated risk factors and at the same time with the health-related behavior that is their basis. The cost-effectiveness of population-based strategies increases when they are not associated primarily with costly mass screening programs. The Council believes that there is an underuse in the area of population-based primary prevention measures.

**159.** In contrast to primary prevention, group-oriented prevention focuses on sub-populations with a particular cardiovascular risk profile. Using modern information

technologies and cross-sectoral administrative networking, the target groups may be defined using standard data. Such data is presently collected and could be used to identify individuals in target groups. However, such programs have been blocked by data privacy regulations.

The effectiveness and efficiency of primary prevention that is oriented towards absolute individual risk is in dire need of evaluation under day-to-day conditions. Particular emphasis should be placed on the definition of the elements of the measures, the algorithms for their application and the adequate measures for ensuring their quality.

### *Secondary prevention and rehabilitation of ischemic heart disease*

**160.** In agreement with the organizations who responded, the Council notes that there is considerable underuse and misuse in pharmaceutical and behavioral measures for secondary prevention. Although pharmaceutical therapy in secondary prevention has a good cost-benefit ratio, recent studies indicate that these substances are not being used enough. With respect to the implementation of evidence-based pharmaceutical recommendations and to the attainment of therapeutic objectives, Germany is in the middle of the field in comparison with other countries. Behavioral changes as preventive measures are not put into practice enough, even though they have proven effects, have been included in guidelines for the prevention of coronary heart disease and are included in approaches for comprehensive cardiac rehabilitation (WHO concept of "comprehensive cardiac rehabilitation"). Since rehabilitation still usually takes place on an inpatient basis in facilities that are far from patients' homes, it is often difficult to transfer behavioral changes into the daily routine of patients and to ensure continuous professional support. In addition, the narrow focus secondary prevention and cardiac rehabilitation on biomedical concepts of risk factors has been criticized for a long time. Although there are effective and efficient measures for secondary prevention in coronary heart disease, their implementation in practice is lacking.

## **8.4 Summary and recommendations**

**161.** There are serious deficiencies in the health care of patients with ischemic heart diseases in Germany that are characterized by the simultaneous existence of overuse, underuse and misuse. Furthermore, there are considerable regional differences in the

provision of services. Put simply, the situation can be described as the neglect of prevention and rehabilitation in relation to (interventional) curative care. The special characteristics of the care of ischemic heart disease include the in some cases considerable overlapping of prevention, cure and rehabilitation. This applies, for example, to the motivation to exercise on a regular basis or to quit smoking and pharmaceutical treatment to lower blood pressure or cholesterol levels. The Council therefore believes that measures for the prevention, treatment and rehabilitation of coronary heart disease must be integrated and co-ordinated. In the Council's view, Germany has a poor international standing with respect to resource utilization and outcomes. The reasons for this situation include:

- underuse of primary preventative measures,
- underuse and misuse in the area of secondary prevention,
- underuse in the treatment of hypertension,
- underuse and misuse in the acute care of myocardial infarction,
- overuse of interventional cardiology measures,
- underuse and misuse in the area of rehabilitation.

**162.** To reduce the extent of overuse, underuse and misuse in the provision of health care for ischemic heart disease the Council recommends:

- The intensification of preventive efforts as part of an integrative multi-level concept for the prevention of heart and circulatory diseases in the sense of a "National Heart and Circulatory Disease Program" for Germany (including the recommended "Anti-Tobacco Campaign", see Chapter 12.1). Citizen participation, community focus and the socio-cultural context of target groups should be taken into consideration (A)<sup>41</sup>;
- the general implementation of population-based and group-specific behavioral and relational measures for primary prevention without additional costly screening programs (A);
- the general introduction of health promotion interventions based on the setting concept and beginning at an early age (A);
- the orientation of individual prevention towards the total absolute cardiovascular risk (individual risk stratification) (A);

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41 See Chapter 4.3 for a description of the rating system.

- increased efforts to promote the widespread use of evidence-based guidelines for secondary prevention and treatment of coronary heart disease in everyday medical practice (A);
- improvements in the diagnosis and treatment of arterial hypertension, in particular through the implementation of existing evidence-based guidelines and consideration of the health risk for resulting cardiac diseases (A);
- increasing the provision of evaluated prevention programs and the integration of group-related, behavior-modifying preventive interventions in case and disease management programs (A);
- improving acute care of myocardial infarction through the optimization of emergency care by health care professionals and lay people, primary treatment in hospitals ("door to needle time") and the implementation of evidence-based guidelines (A);
- increased consideration of health technology assessment (HTA) in marketing authorization and coverage decisions for high-cost and high-risk procedures;
- the optimization of quality management and the promotion of transparency in interventional cardiology, e.g. on the basis of mandatory standardized registration and the independent evaluation of the collected data, the establishment of models for second opinions and sampling, the creation of special centers for highly complex, innovative and very costly diagnostic and therapeutic measures and the increased use of health technology assessment (B);
- the development of the appropriate incentive and regulation systems for the promotion of an equal and equitable distribution of resources across the whole country, especially in the area of interventional cardiology (C);
- the evaluation of approaches for the reduction of morbidity and mortality due to coronary artery disease that are not based on individual and technical diagnostic and therapeutic interventions. This will require the promotion of research in prevention and health care (A).

**163.** According to the Council, these goals can be reached only through the cooperative and co-ordinated efforts of all actors in the health care system. Increased effectiveness may be expected through measures such as the combination of tasks in the context of case and disease management programs. The improvement of the situation with respect to the care of ischemic heart diseases will require the co-operation of pri-

vate individuals, politicians, the industry, the media and the school system. Concerted social and political activity for the development of a healthy environment should be the basis for an overall concept for prevention.

## **9. Cerebrovascular Diseases and Stroke**

### **9.1 The burden of disease**

**164.** Stroke is the third most frequent cause of death (11.4 %) in Germany after heart and circulatory diseases and cancer. Approximately 20 percent of the patients die within four weeks of a stroke and 37 percent within one year. The 5-year survival rate following the first stroke is between 40 and 50 percent.

Stroke is the most common cause of a life-long disability in Germany's adult population. The effects of a stroke range from limitations on daily activities and the inability to work to complete dependency on nursing care.

**165.** As is the case for many diseases, there is not much statistical data on stroke in Germany. The number of new cases of stroke each year in Germany are between 120,000 and 350,000. It is estimated that approximately 1 - 1.5 million people in Germany suffer from the effects of stroke; these numbers coincide with the averages across.

Studies have shown that the prevalence of stroke in Germany is higher in lower social classes than in the higher classes. This applies to both sexes and all age groups, although the class-specific differences decrease with age.

### **9.2 The views of the interviewed groups**

**166.** Twenty organizations, most of which were professional societies or members of the Concerted Action participated in the Council's survey of the situation in the provision of health care services for "cerebrovascular diseases and stroke" (Table 13).<sup>42</sup>

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42 The following pages contain the Council's summary of the central statements contained in the responses of the surveyed organizations. Electronic copies of the original responses are available at the web site of the Council ([www.svr-gesundheit.de](http://www.svr-gesundheit.de)).

**Table 13: Organizations that provided information on overuse, underuse and misuse in the area of cerebrovascular diseases and stroke**

<b>Name of the organization (A - Z)</b>	<b>Type of organization</b>
<i>Ärztliche Zentralstelle Qualitätssicherung (mit KBV und BÄK)</i> German Agency for Quality in Medicine (AQUMED) (National Association of Statutory Health Insurance Physicians and the German Medical Association)	Concerted Action and others
<i>Berufsverband Deutscher Nervenärzte</i> Association of German Nerve Doctors	Voluntary response
<i>Bundesarbeitsgemeinschaft Kind und Krankenhaus e. V. (BaKUK)</i> National Working Group "Kids and Clinics"	Patient group
<i>Bundesinstitut für Arzneimittel und Medizinprodukte</i> Federal Institute for Drugs and Medical Devices	Concerted Action and others
<i>Bundesverband selbständiger PhysiotherapeutInnen</i> National Association of Independent Physiotherapists	Concerted Action and others
<i>Bundesversicherungsanstalt für Angestellte</i> Federal Social Security Office	Concerted Action and others
<i>Deutsche Gesellschaft für Allgemeinmedizin und Familienmedizin</i> Germany Society for General Medicine and Family Medicine	Professional society
<i>Deutsche Gesellschaft für Angiologie</i> German Angiology Society	Professional society
<i>Deutsche Gesellschaft für Neurologie</i> German Neurology Society	Professional society
<i>Deutsche Krankenhausgesellschaft</i> German Hospital Federation	Concerted Action and others
<i>Deutscher Berufsverband für Altenpflege e.V.</i> German Association of Professionals in Geriatric Care	Concerted Action and others
<i>Deutscher Städtetag</i> Council of City Governments	Concerted Action and others
<i>Diakonisches Werk der Evang. Kirche in Deutschland e.V.</i> Deaconat of the Protestant Church in Germany	Concerted Action and others
<i>Ministerium für Frauen, Arbeit, Gesundheit und Soziales des Saarlandes</i> Ministry for Women, Labor, Health and Social Affairs of the Saarland	Concerted Action and others

<i>Ministerium für Frauen, Jugend, Familie und Gesundheit des Landes Nordrhein-Westfalen</i> Ministry for Women, Youth, the Family and Health of North Rhine-Westfalia	Concerted Action and others
<i>Niedersächsisches Ministerium für Frauen, Arbeit und Soziales</i> Ministry for Women, Labor and Social Affairs of Lower Saxony	Concerted Action and others
<i>Robert Koch-Institut</i> Robert Koch Intitute	Concerted Action and others
<i>Sozialministerium des Landes Baden Württemberg</i> Social Ministry of Baden Württemberg	Concerted Action and others
<i>Verband der privaten Krankenversicherung</i> Association of Private Health Insurance	Concerted Action and others
<i>Verband physikalische Therapie</i> Association for Physical Therapy	Concerted Action and others

Most of the responses on questions referring to cerebrovascular disease and stroke note the existence of underuse or misuse. None of the responses could be interpreted as having identified a strictly economic overuse. Overuse is identified in only a small number of cases.

**167.** The lack of primary and secondary prevention for known risk factors is criticized as misuse.

**168.** The treatment of stroke patients in hospitals with computer tomographs is misuse. Many stroke patients in Germany are still treated in small hospitals that lack the appropriate equipment for computed tomographic imaging (CAT scans), echocardiograms and doppler sonograms as well as the medical expertise necessary to care for stroke patients. Without such diagnostic equipment, doctors can not differentiate between a brain hemorrhage and a cerebral infarction.

**169.** The respondents criticize the fact that lyse therapy is applied to too few patients. The respondents also point out that therapy begins too late in routine care, and thus hurts more patients than it helps.

**170.** Some of the organizations criticize the fact that stroke units are not available throughout all of Germany. This hinders the provision of the intensive initial care required by patients. Other organizations recommend the training of experts in the existing intensive care units.

**171.** Underuse and misuse is due to the fact that professional therapists (physiotherapists, ergotherapists and speech therapists) are involved in the care of stroke patients too late, too rarely or not at all.

**172.** There is also criticism of the frequent lack of services for elderly stroke patients following release from the hospital or rehabilitation clinic. It is recommended that elderly patients be cared for in geriatric facilities that provide adequate therapy and rehabilitation of the neurological sickness as well as of any other conditions.

**173.** Respondents criticize the lack of outpatient facilities close to home for the rehabilitation of patients following hospitalization- e.g. provided by mobile rehabilitation services with multidisciplinary teams. The supply of rehabilitation services for young adults who have suffered a stroke - of which there is an increasing number - is also inadequate.

**174.** The length of time between the first symptoms of a stroke and the commencement of treatment determines the extent of long-term disability and is therefore a decisive factor for the success of treatment. The respondents recommend the use of educational measures and public information campaigns to raise awareness for the importance of the pre-hospital treatment of stroke patients.

Since stroke is of such importance from both a socio-medical and a health economics perspective, the optimization of health care in this area must follow evidence-based guidelines.

The organizations also recommend the establishment of an office for quality assurance in the treatment of stroke patients, similar to the established office for quality assurance in Hesse or the stroke project in Hamburg.

### **9.3 The Council's viewpoint**

#### ***Insufficient data***

**175.** The existing data basis of primary data on stroke has improved somewhat recently. New population-based registers and facility-based registers as well as a few population-based studies have contributed to this improvement. Additional data is being provided by the health monitoring system. However, as the organizations note, there is still no transparency with respect to the care of stroke patients. Table 14 provides an overview of existing surveys on the situation with respect to health care for stroke patients in Germany, but lays no claim to being comprehensive. Unfortunately, the criteria, methods and quality of the surveys are not always comparable; which points to the need for a transparent global survey of the incidence, prevalence, patient management procedures, outcomes and follow-ups for stroke patients.

**Table 14: Data sources on stroke in Germany**

Type of survey	Examples
Population registry	Erlangen Stroke Project (since 1994) Stroke Concept Baden Wuerttemberg (since 1998)
Stroke registry	WHO Stroke Registry Project (since 1972 in the former GDR, but on a reduced level since 1989) Stroke Data Base Project of the German Stroke Support Foundation Epi-Stroke Project of the German Stroke Support Foundation
Hospital registries	Stroke care in the Rhineland Palatinate (5/1993-2/1995) Survey of the Medical Review Board of the Saarland (1998) Düsseldorf "Stroke Project" University Hospital in Kassel, AOK and Eschwege County Hospital (since 9/2000) "Quality Assurance and Outcomes of Stroke Treatment" in Schleswig-Holstein, 11 hospitals and the Medical Review Board (10/2000-9/2001)
Population studies	Prospective Cardiovascular Study in Münster, PROCAM (1998) German Heart and Circulatory Disease Prevention Study, DHP (1984-1991) Augsburg Senior Citizen Study (1997/98) National Health Survey (1998)
Secondary data	Sample of the insured of the AOK Dortmund (1988)

*Source:* Based on Berger, K. (2000) and Fritze, J. (1999)

**176.** The high rate of long-term disability leads to an increase utilization of health care services that are financed by social and private long-term care insurance, These insurers have not yet published any analyses of the diseases that create the need for long-term care. Stroke patients make up approximately 17 percent of the hardship cases entitled to private long-term care insurance<sup>43</sup>. It is not clear whether this ratio is the same across all classes of long-term care.

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43 According to social health insurance law, a hardship case is given when the daily need for nursing care exceeds 7 hours, of which more than 2 hours occurs at night and requires two nurses.

### ***Primary prevention***

**177.** The risk factors for stroke are almost the same as those for other cardiovascular diseases (hypertension, smoking, obesity, lack of exercise, diabetes mellitus, metabolic diseases and arrhythmia).

**178.** The most important risk factor for stroke is hypertension. Although primary prevention, in particular with respect to the control of blood pressure, is supposed to reduce the risk of stroke considerably, only a few of the organizations referred to this issue. The once common concept of compensatory hypertension has been replaced by the concept of individual, clinically tolerable lowest blood pressure (see Chapter 8).

Together with the German Stroke Support Foundation, the National Conference for Heart and Circulatory Diseases proposed a risk stratification for this years recommendations; i.e. the identification of patients with an acute need for and thus large potential benefit from pharmaceutical therapy. This can provide the foundation for differentiated therapy that corresponds to patient needs and saves costs.

### ***Secondary prevention***

**179.** As many recent studies have shown, systematic secondary prevention plays an important role in the treatment of stroke patients. The basis for secondary prevention - an essential task of the patient - is a healthy life style, which often requires the use of pharmaceuticals of proven efficacy.

### ***Stroke units***

**180.** The "term stroke" unit is generally used to describe one of two types of special facilities for the treatment of stroke patients: intensive care units, usually directed by a neurologist, for the acute care treatment of stroke patients with the objective of preventing the destruction of brain tissue, and rehabilitation facilities in which the focus is on the mobilization of patients' remaining functional capacities through training to maintain or restore individual autonomy.

Stroke units that focus on early rehabilitation can apparently have a significant positive effect on the outcome following a stroke. Such effects have not yet been proven for in-

tensive care stroke units. The neurological professional societies have recommended a concept of inter-regional and regional stroke care that is based on existing hospital facilities:

- Inter-regional stroke unit: a specialized center within a complete network of maximum care hospitals.
- Regional stroke unit: Facility with less dedicated equipment and professional staff; should be established in the neurology or internal medicine departments of medium-sized general hospitals. The quality of the treatment process should be ensured through special qualifications of the health care professionals.

In the long term, the organizational and structural activities of regional stroke units thus aim at stroke disease management, including the creation of additional units for risk detection.

**181.** A German HTA report on stroke units assessed facilities for early rehabilitation on the basis of international studies. Overall, the metanalyses and older studies show clearly that early rehabilitation in special stroke units with a specially educated and thus highly motivated and skilled staff can have a positive effect on survival rates, the extent of disability and patients' ability to lead an independent life. Conclusive observations on the situation in Germany are not yet possible; the results of current studies are still pending.

### ***Rehabilitation***

**182.** The decrease in stroke mortality rates over the past 30 years is due largely to improvements in rehabilitation and nursing. Studies indicate that the intense dedication of the professional staff is the decisive factor for success. Early and thorough mobilization and training of daily activities can maintain function and independence and help prevent secondary complications.

According to the literature, 24 percent of all patients (32 % of all patients under 55 and 17 % of all patients over 80 years of age) enter a rehabilitation facility following release from the hospital. Following acute care treatment, patients either return home, where they may receive the services of ambulatory nursing units, or be admitted to an inpatient rehabilitation clinic, a geriatrics unit or a nursing home.

**183.** The care of stroke patients has a number of deficits that threaten prompt and appropriate rehabilitation. These include a disparate and sometimes deficient management at the interfaces between health care providers and an inadequate supply of ambulatory rehabilitation close to patients' homes. As a result, there is a need for ambulatory rehabilitation that is unmet (see Chapter 7).

#### **9.4 Summary and recommendations**

**184.** There is clear evidence that the primary and secondary prevention of stroke can be improved considerably. Awareness of the need to act during the acute phase must be raised. There is a clear interest and need in the general population for such educational campaigns. The Council recommends to intensify, evaluate and improve programs providing information on stroke (A).<sup>44</sup>

The Council recommends in particular, that health insurers focus on measures to prevent stroke in patients with hypertension (A).

Treatment with pharmaceuticals to affect blood coagulation (aspirin, anti-coagulants etc.) as a means of secondary prevention must be examined more thoroughly. There is a need for more research in this area (C).

**185.** The literature does not support claims that there is a general underuse of diagnostic procedures (computerized tomography, magnetic resonance imaging). However, there are regional differences in the availability of facilities and only 50 percent of all patients with a suspected diagnosis of acute stroke are admitted to a hospital within six hours.

There are clear indications that care at the interfaces of the sectors is inappropriate. Processes at the admission of patients (family doctor, emergency service, hospital) are still unwieldy and unorganized. Above all, they do not reflect the current guidelines for the acute treatment of stroke. The choice of the first facility responsible for the care of the stroke patient usually doesn't occur on the basis of treatment guidelines but on informal, regional referral agreements.

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44 The rating system is defined in Chapter 4.3

The Council recommends the development of adequate referral strategies to optimize synergies between the ambulatory, stationary and rehabilitation sectors (C).

**186.** There are clear indications that the early commencement of stationary rehabilitation measures has a positive effect on morbidity and mortality. There is underuse with respect to general access to rehabilitation facilities. This is true of ambulatory rehabilitation, early rehabilitation and rehabilitation overall.

The Council believes that incentives should be introduced to ensure the continuity of rehabilitation and to stabilize the past successes. This applies in particular to the ambulatory and the institutional sectors and to cases where the need for assistance is given or likely (A).

**187.** In the view of the Council, it is necessary to ensure the initiation of early rehabilitation and prevention of complications immediately after occurrence of an ischemic insult, to have a multidisciplinary team of professionals co-ordinate care and to ensure the continuous care of stroke patients across the different health care sectors (A).

The treatment of stroke patients in early rehabilitation stroke units improves the survival rates and recovery rates compared to the traditional treatment. The extent to which this international data is applicable to the situation in Germany has not yet been fully evaluated, but seems to the Council as likely. The value of intensive care stroke units can not yet be conclusively evaluated due to the lack of data.

**188.** There are promising models (e.g. stroke registries) to improve the lack of data on the care of stroke patients in Germany. The Council therefore recommends projects to increase the transparency of the care for stroke patients in Germany. The objective should be to collect data on incidence, prevalence, treatment regimes, outcomes and follow-ups (B).

**189.** The Council points out that the introduction of DRGs is likely to lead to the earlier release of stroke patients from acute-care hospitals. This will place new requirements on the seamless transfer of the patient and the necessary follow-up treatment, rehabilitation and nursing services (see Volume II, Chapter 4).

## **10. Chronic Obstructive Lung Disease**

### **10.1 The burden of disease**

**190.** Chronic lung diseases - in particular bronchial asthma as a disease with mostly reversible obstruction and the so-called chronic obstructive pulmonary disease (COPD) with mostly irreversible bronchial obstruction - have a high and increasing importance for the German health care system.<sup>45</sup>

According to data of the National Health Survey 1997/98, 3.7 percent of adults in the eastern states and 6.1 percent of adults in the western states suffer from asthma. Bronchial asthma is the most common chronic disease in children. The prevalence of this disease among children is estimated to be approximately 10 percent. The highest prevalence rates for asthma are found in the highly industrialized western countries. The allergic forms of this disease are expected to increase in the future.

There is often a connection with other atopic diseases (rhinoconjunctivitis, neurodermatitis, food allergies). Approximately half of all children with asthma "lose" the asthma related systems with adulthood; however, the symptoms sometime return later in life. Non-allergic (intrinsic) forms of asthma usually surface in middle age, are rarely reversible and are usually more serious.

**191.** Major risk factors for the development of (allergic) bronchial asthma include hereditary factors as well as the exposure to tobacco smoke at an early age and "western" life style (including building insulation, carpets, house pets, few children). The exposure to allergens at the workplace is an important factor in adult age groups. Breastfeeding (with no nutritional supplements before the fourth month of age) and the avoidance of tobacco smoke are assumed to have preventive effects. There are indications that the reduced contact with indoor allergens (especially dust mites and pet dander) leads to a reduction in sensitivity to these allergens.

In contrast to many other diseases, the prevalence of allergic asthma is higher in upper social classes than in lower classes. However, lower socioeconomic status is associated with a large number of undisclosed cases of undiagnosed asthma. The characteristic

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45 Due to conceptual problems, incongruent classification and the common etiological basis (risk factor "smoking") as well as the flowing boundaries between the different forms of the disease, "simple", non-obstructive chronic bronchitis, chronic obstructive bronchitis and emphysema are all referred to as COPD.

"lower social status" is correlated with a higher number of emergency treatments and greater mortality rates among asthma patients.

According to epidemiological studies, occupational exposure is responsible for 5-10 percent of asthma cases. The highest risks according to profession are among cleaning personnel, agricultural workers and workers in the plastics industry.

In 1999, 3,831 persons (approximately 0.4 % of all fatalities) died of asthma (ICD-10 J45-J46). Compared to other countries, asthma mortality in Germany is high.<sup>46</sup>

**192.** The epidemiological data on COPD is inadequate. An estimated 10 - 30 percent of adults in Germany suffer from chronic bronchitis.<sup>47</sup> Approximately 15-20 percent of these patients develop obstructive lung disease. Approximately 90 percent of all COPD cases are due to smoking. Other risk factors, all of which are considerably less significant than smoking, include: air pollution (e.g. sulfur dioxide), workplace exposure (e.g. the dusts of various substances), low socio-economic status, a lack of protease inhibitors.

The diagnosis "other chronic obstructive lung disease" (ICD-10 J44) is ninth among the ten leading causes of death in Germany and responsible for 21.2 deaths per 100,000 inhabitants.<sup>48</sup> According to forecasts of the WHO, COPD will be the third most common cause of death worldwide by the year 2020. COPD is more common among the lower social classes, due to the higher level of tobacco consumption and other possible factors such as environmental and workplace conditions. It is considered likely that COPD incidence among women will increase due to the increasing number of females who smoke tobacco.

**193.** The social effects of chronic obstructive respiratory disease are considerable. Asthma and COPD were responsible for 26 percent of the sick leave days (30 % of the sick days) of persons insured by local social health insurance funds (AOK) in 1998. 3,786 persons, mostly males, went into early retirement due to chronic bronchitis (ICD-

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46 However, about 3/4 of the fatalities in 1998 were over 65 years of age, which may be due to the poor diagnostic differentiation of COPD. This assumption is supported by epidemiological data, which indicates that the prevalence of asthma decreases in age groups over 40 years of age.

47 According to the WHO definition, "chronic bronchitis" is defined as coughing and expectoration of mucus for at least three months over the past two years.

48 It is questionable whether this data reflects the actual situation in Germany, since it can be assumed that the prevalence of COPD is underestimated.

9 491). The number of retirements due to respiratory disease has decreased slightly since the 1980s, but this trend probably does not reflect the actual burden of a disease that often first occurs after retirement and is also often not diagnosed. The consequences of changes in tobacco consumption (increasing share of young tobacco users and women who smoke) can not yet be estimated.

The direct and indirect costs of COPD in Germany are estimated at DM 12.3 to 16.5 billion per year. Bronchial asthma costs society approximately DM 4.2 to 5.1 billion annually. Depending on the severity of the disease, the annual costs per asthma patient range between DM 3,000 and DM 12,000.

## **10.2 The views of the interviewed groups**

**194.** The following 13 organization responded to the survey in the area of pulmonology (ICD-9 490-496 or ICD-10 J41-J46).<sup>49</sup>

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<sup>49</sup> The following contains the Council's summary of the central statements contained in the responses of the surveyed organizations. Electronic copies of the original responses are available at the web site of the Council ([www.svr-gesundheit.de](http://www.svr-gesundheit.de)).

**Table 15: Organizations that provided information on overuse, underuse and misuse in the area of chronic obstructive pulmonary disease**

<b>Organization (A - Z)</b>	<b>Type of Organization</b>
<i>Arbeitsgemeinschaft Allergiekranke Kind – Hilfen für Asthma, Ekzem oder Heuschnupfen e.V.</i> Association for Children with Allergies - Support for Asthma, Exzema and Hay Fever	Patient group
<i>BÄK, KBV und Ärztliche Zentralstelle für Qualitätssicherung</i> German Medical Association, National Association of Statutory Health Insurance Physicians and the German Agency for Quality in Medicine	Concerted Action members and others
<i>Bundesarbeitsgemeinschaft Kind und Krankenhaus e.V.</i> National Working Group "Kids and Clinics"	Patient group
<i>Bundesverband der Pharmazeutischen Industrie e.V.</i> Association of the German Pharmaceutical Industry	Concerted Action members and others
<i>Bundesverband selbständiger PhysiotherapeutInnen</i> National Association of Independent Physiotherapists	Concerted Action members and others
<i>Deutsche Gesellschaft für Kinderheilkunde und Jugendmedizin</i> German Society for Pediatrics and Juvenile Medicine	Professional society
<i>Deutsche Gesellschaft für Pneumologie</i> German Society for Pulmonology	Professional society
<i>Deutscher Städtetag</i> Council of City Governments	Concerted Action members and others
<i>Niedersächsisches Ministerium für Frauen, Arbeit und Soziales</i> Ministry for Women, Labor and Social Affairs of Lower Saxony	Concerted Action members and others
<i>Spitzenverbände der GKV und der MDS</i> National Associations of the Social Health Insurers and the Medical Review Board	Concerted Action members and others
<i>Verband der privaten Krankenversicherung</i> Association of Private Health Insurance	Concerted Action members and others
<i>Verband Forschender Arzneimittelhersteller</i> Association of Research-Based Pharmaceutical Manufacturers in Germany	Concerted Action members and others
<i>Verband physikalische Therapie</i> Association for Physical Therapy	Concerted Action members and others

### *Prevention*

**195.** The respondents note a considerable unused potential for prevention with respect to bronchial asthma and COPD. A large share of the COPD cases can be prevented through less tobacco use. Deficits in the education of parents on measures for preventing allergies and asthma are criticized along with the lack of anti-smoking campaigns and smoking cessation programs. The prevention of smoking (beginning in grade school) is considered to be very important. For the group of adolescents who already smoke, targeted secondary prevention programs should be developed and implemented. In general, smoking cessation programs should be accessible to all smokers throughout the country. The respondents also point to the importance of medication and patient education - including non-medical therapy and exercise - in secondary and tertiary prevention.

### *Diagnosis and therapy*

**196.** All respondents postulate undersupply in the diagnosis of chronic obstructive pulmonary disease and many see a need for structural changes in the provision of pulmonological care in Germany. The respondents point out the disproportionate increase in the volume of services for ambulatory diagnosis of allergy and the prescription of antiallergenic medications as well as the lacking quality assurance in the diagnosis and therapy of obstructive respiratory diseases.

### *Pharmaceutical therapy*

**197.** There is a broad consensus among the respondents that underuse and misuse of pharmaceutical therapy affects too many patients in Germany. Too few inhaled corticosteroids are used in the basic therapy of patients with bronchial asthma. Only about one third of the patients receive appropriate treatment. At the same time, there are too many prescriptions of quick-relief medications (inhaled beta2 agonists, inhaled anticholinergics). Pharmacological treatment is not adjusted often enough to the changing severity of the disease, which can result in grave consequences for patients. Inhaled beta2 agonists and anticholinergics are also used too frequently in the treatment of COPD, which is interpreted as misuse. Antibiotics are used too rarely or too late to treat respiratory infections in patients with COPD. This results in avoidable exacerbation of the underlying condition and direct and indirect costs.

The grounds for the simultaneous existence of overuse, underuse and misuse in pharmacological therapy are found primarily in the lacking qualifications of doctors, although the care provided by pulmonologists is better than that provided by doctors who are not pulmonologists. However, there are not enough pulmonologists to ensure sufficient access to qualified care nationwide.

### *Patient education*

**198.** The respondents also criticize the lack of patient education measures based on the state of modern medical knowledge. While there are educational programs, they are not accessible throughout the country. As a result, patients are poorly informed with respect to the proper use of their dispensers and medicines. Parents and family members are not involved enough in the care and education of children with asthma. There is also a lack of asthma exercise groups.

## ***Rehabilitation***

**199.** One patient organization reports of the frequent denial of rehabilitation measures for children with asthma. The rehabilitation of adults with obstructive pulmonary disease is often delayed (i.e. the period of time between the worsening of the patient's condition and the rehabilitation measure is too long). Furthermore, ambulatory or semi-stationary rehabilitation close to home is seen as desirable but not yet realized. Rehabilitation measures and acute care treatment as well as the facilities providing these services are not well co-ordinated. The respondents note the particular importance of rehabilitation for patient education, smoking cessation, physical exercise etc.

The reasons for the deficits are seen in the existing financial and structural framework conditions. The case management/disease management of asthma patients should therefore integrate ambulatory, stationary and rehabilitation measures - with the participation of the patient - and develop the necessary incentive systems for healthcare providers and patients.

### **10.3 Summary and recommendations**

#### **10.3.1 The structure of care**

**200.** The Council believes that the infrastructure for the provision of pulmonological measures for the prevention, treatment and rehabilitation of patients with asthma and COPD in Germany needs to be improved.

The deficits in the structure of pulmonological care have historical roots. The separation of pulmonology from developments in the other sub-disciplines of internal medicine and the concentration on the extra-academic, rehabilitation-oriented area has resulted in its lacking presence in teaching, research and the care of patients.

Given this background, the Council recommends the following measures:

- improved training and continued education in pulmonology for general practitioners and for specialists in internal medicine and pediatrics (A)<sup>50</sup>;
- improved measures for patient education and rehabilitation, including rules for the finance and monitoring of quality standards (A);
- more independent pulmonology departments with beds in general hospitals (A);
- professorships for pulmonology at all medical schools (B).

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50 The rating system is defined in Chapter 4.3

**201.** Stationary rehabilitation is not adequately coordinated with the rest of the treatment process and with the ambulatory care sector. The Council therefore calls for increased efforts towards the improved integration of rehabilitation in all aspects of pulmonary care as well as in teaching and research. This should include the direct referral to a rehabilitation clinic for special cases, e.g. deterioration of the condition of a patient with chronic obstructive pulmonary disease and the implementation of case management or disease management strategies for problem groups (A).

### **10.3.2 Asthma**

#### *Prevention*

**202.** The incidence of sensibilization can be reduced among children with an atopic disposition as well as in the non-risk population through measures such as parent education, counseling and information, breastfeeding, and the avoidance of passive smoking. There is room for improvement in the awareness for and the implementation of such measures, even in risk groups such as "atopic families". The Council therefore recommends the optimization of the primary prevention of allergies among infants and children through measures such as breastfeeding, the avoidance of passive smoking and the education of parents (A).

The reduction of household dust, refraining from keeping pets and the avoidance of occupational allergens are appropriate for persons with an atopic disposition, a sensibility or the first signs of sickness as a means for preventing a worsening of the condition. However, the measures are often not performed properly (e.g. with respect to the mite contamination of bedding and mattresses). The Council therefore believes that active and, when necessary, mobile counseling services (e.g. the examination of living quarters).

There are effective measures for the reduction of allergen concentrations indoors and for protecting workers from contact with allergenic materials. The Council recommends that these measures be implemented more vigorously (A).

### ***Diagnosis and therapy***

**203.** The increase in the volume of services for the diagnosis of allergies over the past years is partially due to the increased prevalence and incidence of sensibilizations and allergic diseases. However, the Council also sees serious indications for quality problems in diagnosis and the performance of diagnostic procedures. Although there are adequate quality standards, they are often not used in practice. The Council therefore believes that more medical training and continued education is required to optimize the efficiency of diagnosis and therapy (A).

**204.** The Council believes that there is a need for improvement in specific immunization therapy (secondary and tertiary prevention of persons who already have an allergic disease or allergic rhinitis). Subcutaneous immunotherapy has been sufficiently evaluated and should be used more frequently. However, it is necessary to ensure that the responsible doctor is appropriately qualified and - due to the risk of anaphylactic shock - has the equipment to monitor the patient, that the allergen extracts are standardized, that the therapy is documented and that the diagnosis was made on the basis of established guidelines (A).

### ***Patient education***

**205.** The positive effects of patient information and education on the quality of life, the frequency of symptoms, mortality, the utilization of the health care system and therapy compliance have been adequately studied and many programs have been evaluated. These interventions can be assumed to have a relatively favorable cost-benefit ratio or risk-benefit ratio. However, there is an underuse of patients (and their families) with respect to appropriate educational measures. Educational measures are used too infrequently, on the wrong target groups and are sometimes based on the wrong methods (e.g. for youths). The Council therefore believes that an intensification and improvement of patient education measures is called for (A).

There is no nationwide agreement for the provision of ambulatory (group) training of asthma patients. Regional and payer-specific regulations and different pilot projects are far from sufficient to meet needs in this area. The Council therefore calls for a general

regulation for the education of asthma patients (based if necessary on specific regulations of social health insurance law)<sup>51</sup> (A).

Meeting the need for education should not be the responsibility of office-based pulmonologists alone. Depending on the region and the target group, other services and resources should be available as benefits of the social health insurance system. Binding quality standards for patient education should be defined and quality management measures taken to ensure compliance with them. In addition, educational measures should be assessed under everyday conditions. Furthermore, the Council believes that the increased promotion of "asthma fitness groups" and self-help activities is necessary. (A)

**206.** Although the statements on patient information and education for asthma patients also apply to patients with COPD, it is necessary to differentiate between the measures for each disease. Physical exercise therapy plays an important role for COPD patients. Since there are not enough well-evaluated models for this patient group, the Council believes that more should be developed (B).

### ***Pharmaceutical therapy***

**207.** In the view of the Council, overuse, underuse and misuse are all evident in the care of asthma patients in Germany. Basic therapy with inhaled corticosteroids (or with other anti-inflammatory substances) is not performed frequently enough, while other substances such as xanthine derivatives, quick-relief medications such as inhaled beta2 agonists and mucolytics are prescribed too frequently or not according to evidence-based guidelines. Furthermore, treatment is not adjusted to the actual severity of the disease. Even though these problems, including the lack of patient compliance, are evident in other countries, Germany still has a relatively poor position in international comparisons.

The implementation of the existing evidence-based guidelines in daily practice is unsatisfactory. In order to change doctors' behavior, the Council recommends measures to promote training and continuing education as well as the implementation of guidelines (A). Linking fees to compliance with treatment standards (guideline-based remunera-

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51 This also applies to schooling for diabetics (see Chapter 7).

tion) could be taken into consideration (C). Pharmacological therapy should be supplemented with patient education, patient information and counseling (to promote compliance and the correct use of pharmaceuticals) (A).

### **10.3.3 COPD**

#### *Prevention*

**208.** The role of tobacco use for the occurrence of COPD is undisputed. The Council sees in Germany an underuse of the appropriate measures for the prevention of active and passive smoking and for smoking cessation. Many types of interventions at different levels have already been evaluated for a number of target groups and settings. The Council therefore makes an emphatic call for more efforts in this area (A) and for a national anti-smoking campaign for Germany (see Chapter 12.1).

#### *Diagnosis and treatment*

**209.** The diagnosis and treatment of COPD frequently occurs too late and is not based on guidelines. There is underuse, overuse and misuse in the pharmacological treatment of COPD. There are enough evidence-based treatment guidelines. Even though certain details are not as well evaluated as is the case for bronchial asthma (e.g. the value of corticosteroids and mucolytics in long-term therapy), there is a pressing need for the implementation of treatment recommendations. It is therefore necessary to promote measures that serve the implementation of guidelines and the improvement of medical schooling, training and continuing education (A).

**210.** The Council also notes the considerable importance of patient education, smoke cessation programs, exercise therapy and rehabilitation (A) (see asthma).

## 11. Back Pain

### 11.1 The burden of disease

**211.** Back pain<sup>52</sup> (ICD-9 720-724 "dorsalgia") is the most frequent health complaint in industrialized countries, including Germany. It is also one of the most common grounds for seeking medical care in the ambulatory and inpatient sectors and is responsible for the most sick-leave days and occupational disabilities. With a prevalence of 27 - 40 percent, an annual prevalence of 70 percent, a lifetime prevalence of 80 percent and a share of chronic back pain of 8 - 10 percent, the German population has an above average rate of back pain compared to other countries. The lifetime prevalence of radiating back pain or sciatica, however, at 1 to 5 percent, is comparable to the rates in other countries. There is not enough data to judge whether the frequency of back pain in Germany is increasing or decreasing.

**212.** The Council focuses in the following on simple back pain, especially chronic low back pain.<sup>53</sup>

**Table 16: A selection of important risk factors for the development of chronic back pain**

<b>Prior course of disease:</b> continuing and repeated episodes of back pain, sick leave > 4-6 weeks, radiating pain.
<b>Psychosocial factors:</b> Low educational level; continued personal problems and stress, perception of little social support; fear, depression, the feeling of being sick, high results on the <i>Minnesota Multiphasic Personality Inventory Scale for Hypochondria or Hysteria</i> , wish to retire.
<b>Working situation:</b> Heavy physical labor (especially lifting, bending and twisting, vibration); neck pain: abnormal, one-sided posture, working at a monitor or looking up; repeated, one-sided movements, whole body vibration; working in cold or varying temperatures; monotonous work loads; perceived low level of control of working conditions and lack of support of colleagues and supervisors; low job satisfaction, job insecurity, unemployment.

*Source:* Compiled by the Advisory Council on the basis of Lenhardt, U. et.al. (1997); IOM (2001); Nachemson, A. et.al. (2000); Waddel, G. (1998)

52 Back ailments are classified in the ICD-9 as inflammatory dorsalgia (ICD-9 720), degenerative dorsalgia (ICD-9 721), spinal affectations, disc syndrome (ICD-9 722), cervical disorder (ICD-9 723) and in other unspecified back pain (ICD-9 724). With 80-85 % of all cases, the last group is the largest group of simple back pain.

53 The Council does not deal in this context with those types of back pain caused by fractures due to osteoporosis, which also represent an important disease burden.

Psychosocial and physical stress play a central role in the genesis and chronification of back pain. Since these factors are more common in lower social classes, they explain a good deal of the difference in back pain across social classes.<sup>54</sup>

**213.** In approximately 90 percent of all cases, acute lower back pain without complications recedes within a few weeks. However, over 70 percent of these patients have repeated acute episodes of lower back pain. After one year, 14 percent of the patients report that they are still impaired and 10 percent suffer from intense pain. The chance for complete recovery and return to work decline with the duration of back pain. In 1994, approximately 45 percent of all patients with back pain could be re-integrated into the work force after six months of sick leave and approximately 25 percent after one year of sick leave.

In view of the direct and indirect costs (approximately DM 50 million per year in Germany), back pain is considered the "most expensive" disease in industrialized countries.

## **11.2 The views of the interviewed groups**

**214.** A total of 17 organizations provided responses on the health care situation with respect to back pain, primarily professional societies and member organizations of the Concerted Action (Table 17)<sup>55</sup>.

### ***Prevention***

**215.** A few respondent classify "back school programs" as an example for overuse. A common fault of back school programs is the promotion of unhealthy movements and postures as well as of patient uncertainty (misuse). Furthermore, these measures are often unrelated to the workplace (underuse).

An increase in behavioral prevention and occupational setting prevention as well as the implementation of back school programs as an integral part of the health care of patients with chronic back pain is generally recommended.

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54 Social class and in particular educational level also affect the probability of losing a job due to back problems, the likelihood that one can return to work following sick leave or rehabilitation for an occupational disability.

55 The following contains the Council's summary of the central statements contained in the responses of the surveyed organizations. Electronic copies of the original responses are available at the web site of the Council ([www.svr-gesundheit.de](http://www.svr-gesundheit.de)).

## Diagnosis

216. The respondents note an overuse of imaging techniques, in particular x-rays, but also computer tomography, magnetic resonance imaging and diskograms. Contrary to the recommendations of evidence-based guidelines, diagnostic imaging is used too early in the course of disease, is repeated too often and is not focussed (e.g. image of the whole spine instead of just the affected area). Examinations are often of limited value due to quality problems. In addition, the respondents describe surfeit of clinical-chemical diagnostic procedures. This gives rise to medical and economic overuse as well as misuse: patients are unnecessarily exposed to x-rays and are provided with an inadequate disease concept. Furthermore, the clinical findings often lead to invasive measures that are not indicated.

The reasons for overuse and misuse are seen to lie in financial incentives, disregard of evidence-based guidelines and deficits in the training and continuing education of general practitioners and specialists.

**Table 17: Organizations that provided information on overuse, underuse and misuse in the area of back pain**

Organization (A - Z)	Type of Organization
<i>Arbeitsgemeinschaft der Spitzenverbände der gesetzlichen Krankenkassen</i> Working Group of the National Associations of the Social Health Insurance Funds	Concerted Action members and others
<i>Ärztliche Zentralstelle für Qualitätssicherung gemeinsam für Bundesärztekammer und Kassenärztliche Bundesvereinigung</i> German Agency for Quality in Medicine as a joint response of the German Medical Association and National Association of Statutory Health Insurance Physicians	Concerted Action members and others
<i>Bundesverband selbständiger PhysiotherapeutInnen</i> National Association of Independent Physiotherapists	Concerted Action members and others
<i>Bundesversicherungsanstalt für Angestellte</i> Federal Social Security Office	Concerted Action members and others
<i>Deutsche Gesellschaft für Allgemeinmedizin und Familienmedizin</i> German Society for General Medicine and Family Medicine	Professional society
<i>Deutsche Gesellschaft für Manuelle Medizin e.V.</i> German Society for Manual Medicine	Professional society
<i>Deutsche Gesellschaft für Neurologie</i> German Society for Neurology	Professional society
<i>Deutsche Gesellschaft für Orthopädie und Traumatologie e.V.</i> German Society for Orthopedics and Traumatology	Professional society
<i>Deutsche Krankenhausgesellschaft</i> German Hospital Federation	Concerted Action members and others

<i>Deutscher Berufsverband für Altenpflege e.V.</i> German Association for Geriatric Nurses	Concerted Action members and others
<i>Deutscher Städtetag</i> Council of City Governments	Concerted Action members and others
<i>Ministerium für Frauen, Arbeit; Gesundheit und Soziales des Saarlandes</i> Ministry for Women, Labor, Health and Social Affairs of the Saarland	Concerted Action members and others
<i>Niedersächsisches Ministerium für Frauen, Arbeit und Soziales</i> Ministry for Women, Labor and Social Affairs of Lower Saxony	Concerted Action members and others
<i>Robert Koch-Institut</i> Robert Koch-Institute	Concerted Action members and others
<i>Verband der privaten Krankenversicherung</i> Association of Private Health Insurance	Concerted Action members and others
<i>Verband Deutscher Rentenversicherungsträger e.V.</i> Federation of German Pension Insurance Institutes	Concerted Action members and others
<i>Verband physikalische Therapie</i> Association for Physical Therapy	Concerted Action members and others

### ***General aspects of inpatient and outpatient therapy***

**217.** It is generally assumed that there is misuse in the treatment of acute back pain, because the vast majority of patients who experience back pain for the first time are pain free within six to eight weeks regardless of the type of therapy used. The trend towards passive therapy is dominant. Although studies show that active movement therapy and the prescription of simple analgesics are more effective than rest, which is still prescribed frequently, passive therapeutic approaches dominate. The chances for conservative therapy in the outpatient sector are not fully utilized and patients with unclear spinal pain are often treated in hospital departments for internal medicine or general surgery without specific, functional therapies.

### ***Pharmaceutical therapy***

**218.** The respondents report of overuse and misuse of simple back pain through the use of pharmaceutical therapy based on frequent injections (with local anesthetics, glucocorticoids and substances for the destruction of nerves such as alcohol). The value of computer controlled paravertebral injections is questionable from both a medical and economic perspective.

### ***Surgical procedures***

**219.** There is a general consensus that there is an overuse of surgical procedures for back problems. Despite the large number of surgical procedures, the indication for an operation is less clear for patients with disc problems or degenerative diseases than is often assumed. The rapid diffusion of new and unevaluated procedures, especially minimally-invasive techniques, was considered as an example of overuse.

The frequent diagnosis of a need for an intervention and the lack of pre-surgical conservative treatment is thought to be due in part to a lack of knowledge and in part to the costs of labor-intensive conservative therapy. In addition, psychological factors are neglected prior to surgery although they have a clear influence on the prognosis following an operation.

### ***Manual therapy by doctors***

**220.** The respondents note underuse of easily accessible and qualified specialists for manual therapy (e.g. chiropractors). However, they note an oversupply of the manual forms of pain therapy that are often applied without question (by "twisting") and a failure to integrate manual therapy in a more complex treatment program.

### ***Psychotherapy***

**221.** Many organizations report that not enough attention is paid to psychological and social factors in the treatment of patients with back pain. Treatment that is begun in an inpatient setting can often not be continued on an outpatient basis, even though this would be important for the transfer into daily activities. It is also pointed out that there is usually no meaningful combination or integration of somatic therapy with psychotherapy. Therapies and rehabilitation services have either somatic or a psychological approach.

### ***Physiotherapy and Medical Aids***

**222.** There is a general consensus that there is an underuse of physical therapy. Active physiotherapy is insufficient or provided too late in both therapy and as primary and secondary prevention. An inappropriate extension of the indication (overuse) has occurred in the area of exercise therapy (in the framework of muscle training, expanded outpatient physiotherapy and ambulatory rehabilitation).

The use of medical aids is classified as misuse. Poorly prescribed and fitted "hand me downs" in the form of mobility aids or wheelchairs often aggravate back pain.

### ***Rehabilitation***

**223.** Underuse and misuse are identified in the area of rehabilitation of patients with chronic back pain, in particular with reference to rehabilitation facilities that are close to home. The long duration of hospital care and post-hospital inpatient recuperation was considered to be an example of overuse. Within the framework of rehabilitation, the respondents noted an oversupply or misuse of passive therapeutic approaches similar to that in curative care. In reference to evidence-based guidelines it was recommended to provide ambulatory rehabilitation services that are close to patients' homes and permit for at least part-time employment.

### *Nursing care*

**224.** Elderly patients with back pain suffer either from underuse or misuse when the caregivers are not well-versed in new nursing methods (Bobath method, kinesthetic etc.). It is recommended to provide the necessary training courses on a nationwide basis.

### *The healthcare infrastructure*

**225.** There is a lack of doctors specialized in chirotherapy (manual medicine), psychological pain therapy and special facilities for the acute care and rehabilitation of chronic and complex back pain.

## **11.3 The Council's viewpoint**

**226.** The approach to the treatment of (lower) back pain has undergone a transformation in the recent past. The attempt to provide a specific somatic diagnosis has been replaced by an approach that focuses on symptoms and function. The latter approach is aimed primarily at differentiating between progressive and dangerous cases (less than 1 % of the causes of back pain in all age groups), radiating back pain (approximately 5 %) and uncomplicated back pain (80 to 85 %).

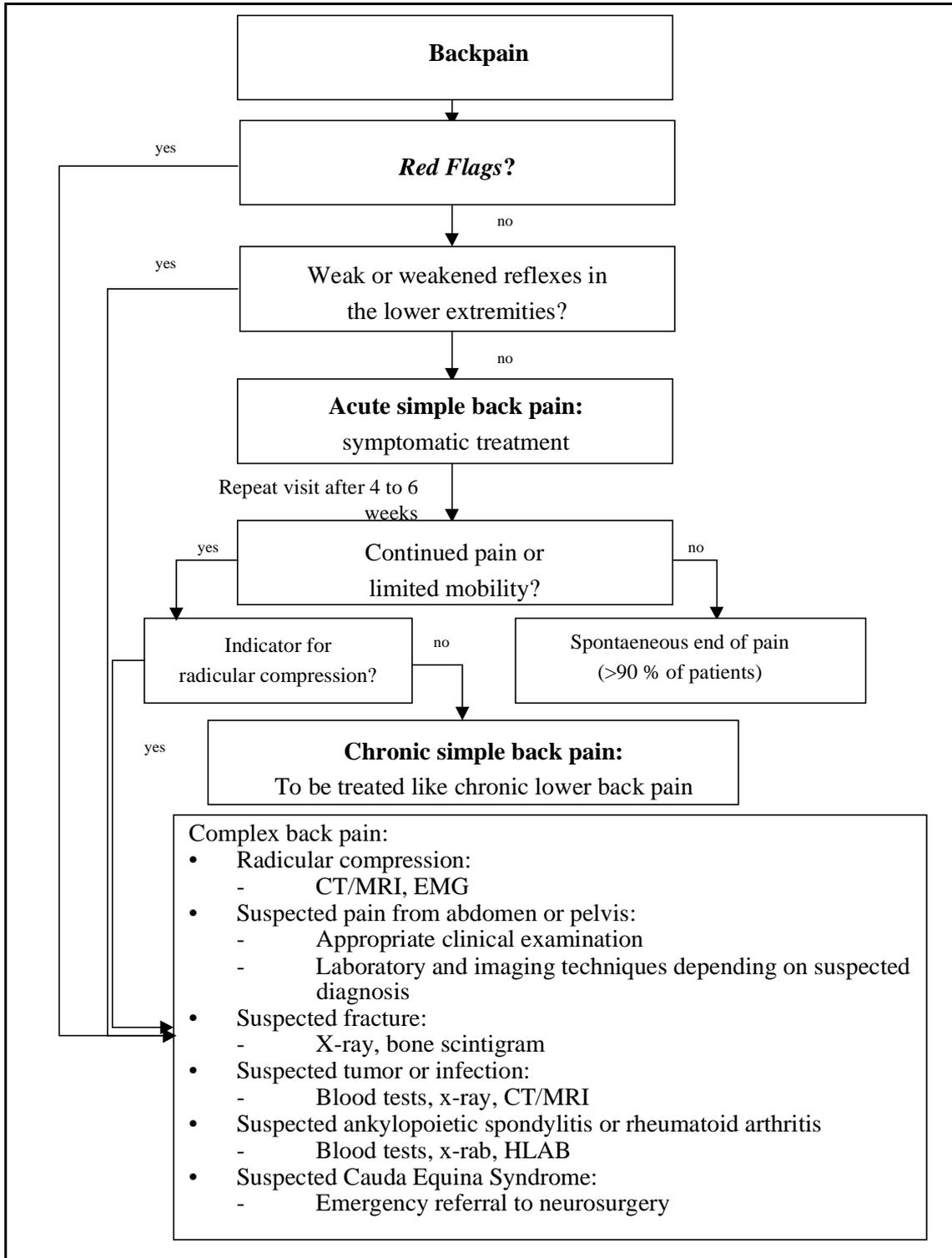
In the majority of cases of simple back pain, it is not possible to clearly identify a pathological anatomical change as the cause of pain. Such deviations from the norm are also present in many patients without pain. They therefore have no value from a diagnostic perspective and no therapeutic relevance.

**227.** Careful anamnesis and clinical examination are the central pillars in the diagnosis of back pain. If the common warning signs ("red flags") are not present, the diagnostic options are similar for all patients (Figure 3).

**228.** Laboratory tests or the use of diagnostic devices (x-rays) are not called for in the diagnosis of most patients unless the anamnesis of clinical examination reveals such "red flags". This conservative view of the value of diagnostic equipment has not yet had an effect on actual care: outpatient and inpatient care are characterized by an overuse of imaging techniques and invasive therapies. At the same time, there is an underuse of activating therapy and psychosocial measures for patients with chronic back problems. Such a constellation stands in contradiction to the recommendations of evidence-based guidelines.

Since primary and secondary prevention play an important and as yet underrecognized role in the treatment of back pain, the Council focuses on selected types of prevention, including workplace health promotion.

**Figure 3: Algorithm for the diagnosis and treatment of back pain**



Source: Sloan, P.D. et al. (1998)

## **11.4 Prevention and workplace health promotion**

**229.** The prevention of back pain follows three main objectives:

- Primary prevention (e.g. "back schools", exercise, ergonomic measures) and multimodal approaches such as workplace health promotion target healthy individuals with the objective of preventing the occurrence of back pain.
- Secondary prevention targets individuals who have or have experienced recurring back pain with the objective of reducing pain or preventing the recurrence of back pain episodes.
- Tertiary prevention targets patient with chronic back problems of back problems that threaten to become chronic. The objective here is to prevent the deterioration of the patient's health status or to reverse the deterioration and restore the patient's ability to function at home and at work.

There is no scientific evidence for the efficacy of many products and procedures that are used in the prevention of back pain (e.g. lower back supports or corsets, simple interventions with written or oral information). However, there is good evidence that regular exercise can help prevent the occurrence or "chronification" of back and cervical pain.

**230.** Back schools are the most common preventive measures in Germany. These programs supply information and behavioral training for proper movement and posture, lifting and carrying techniques and pain management. They focus on the communication of biomechanical (and, if necessary, psychosomatic) relations as well as on the modification of individual behavior, but do not include environmental factors and their modification. A health technology assessment report and literature surveys show that back schools for primary and secondary prevention increase patients' knowledge, but if they are provided outside of the workplace, they do not improve the health status and functionality of patients. However, back schools provided at the workplace also usually do not reduce patients' pain. The literature on back schools in secondary and tertiary prevention reveals both positive and negative results.

### *Secondary and tertiary prevention of back pain*

**231.** The efficacy of back school as a means for secondary and tertiary prevention was analyzed for the AOK health insurance fund in Lower Saxony under special conditions and for patients in groups that are otherwise hard to target. The concept includes the active, preparatory counseling of the insured, who were chosen on the basis of the routine data of the health insurer. The back school program was offered to patients with simple lower back pain.

This approach made it possible to reach primarily younger employed males - a target group that is difficult to reach through the traditional approaches. Positive effects on health were evident in all areas immediately following completion of the course. The positive net effects had diminished somewhat six months after the course, but were still evident one year after completion. Participants under 45 years of age seem to profit more in the medium to long term than older patients, and patients who have had back pain for a long time more than patients who are experiencing back pain for the first time. Persons who were physically inactive at the beginning of the course showed more improvement a year later with respect to physical factors than patients who were active in sports at the beginning of the course. Overall, there were 14 sick days less within the first five quarters after the course, most of which was related to the decline in diagnoses related to back pain. One and one half years after the back school course, the sick days of the participants was similar to that of the control group.

The study shows that back school as a means for secondary and tertiary prevention can lead to net savings if the participants are carefully selected. The prevention project realized a return on investment of up to 1 : 3.2 and is thus a worthwhile investment.

### *Primary prevention of back pain through workplace health promotion*

**232.** Despite the complex and not fully understood etiology of back ailments, it may be assumed on the present base of knowledge that occupational factors play an important role in the development of these symptoms (see Table 16).

The proven effects of physical and psychosocial factors on back pain and the widespread presence of these factors in the workplace setting lead to the conclusion that the workplace has a considerable potential for the primary prevention of back pain. Fur-

thermore, the workplace provides a relatively favorable setting for the implementation of preventive measures.

Despite the fact that projects and programs for integrated workplace health promotion are not very widespread, a number of projects have already succeeded in implementing important components of this broader approach to prevention.

***Synopsis 1: Responsibilities and regulations in workplace health promotion***

**233.** Employers are responsible for the organization and implementation of safety measures at the workplace. They are supported by the mandatory works doctors and other safety specialists. Occupational safety agencies of the state governments are responsible for controlling and implementing government workplace safety laws (laws and codes). The carriers of the socially organized workers compensation funds also play an important role: It is their task to "take appropriate measures" for the prevention of workplace accidents, occupational diseases and - since 1996 - work-related health risks. To this end they formulate safety codes that are binding for the member companies; they also control the implementation of the codes and advise companies and the insured.

Regulations related specifically to the prevention of work-related back problems refer only to (certain) mechanical risks. According to an ordinance on occupational diseases, only those lumbar disc problems that were caused by the lifting and carrying of heavy loads over a period of many years, years-long work-related activity in a stooped position or years-long exposure to full-body vibration in a sitting position are acknowledged as occupational diseases. Although companies are required to take measures to avoid occupational diseases, the workers compensation funds have not issued any regulations on the lifting and carrying of heavy loads and only partial regulations on whole-body vibration. However, work with heavy loads is dealt with in government occupational safety law, which requires that employers take measures to avoid or reduce as much as possible the hazards associated with such activity.

However, this narrow focus on overexertion and repetitive motion (for which no consistent guidelines exist) has been broadened by the 1996 reform of German workplace safety law in the course of implementing EU directives. The Workplace Safety Act requires employers to prevent "work-related health hazards, including taking measures for the humane design of the workplace" based on the "state of technology labor medicine and hygiene as well as other results of established labor science". The measures are to be planned with the objective of "linking technology, the organization of work, other working conditions, social relations and environmental factors to the workplace". Ultimately, this means that the obligation to prevent hazards is also given even when there are no specific legal guidelines. Furthermore, prevention at the workplace must focus more on risks for the development of back problems other than the technical and physical/material hazards (e.g. risks that are related to the organization of work processes of physical exertion that results from the duration of working time). In principle, the latter requirement has also applied to the workers compensation funds since 1996, even though these organization - like those with responsibility at the company level - are still bound by the limits of their traditional approach to occupational safety.

The social health insurance funds could be an important stimulus for a broader concept of prevention, including a reduction of the occupational hazards related to back problems. Since 2000, the law allows social health insurers to take measures that "support occupational safety meas-

ures" as part of workplace health promotion (see Volume I, no. 129). However, in order to be implemented, the measures must meet a number of quality standards.

***Synopsis 2: "Good Practice" in workplace health promotion***

**234.** Workplace health promotion can only be implemented successfully and as an effective means for prevention if it meets certain structure and process requirements. Based on practical experience, the following central points - which are in accordance with the European Union's 1997 "Luxembourg Declaration on Workplace Health Promotion" - can be derived:

1. Measures for health promotion should be developed on the basis of information and data on the health situation and health hazards (and the potential health resources) of a workplace. For this purpose (and as a foundation for the subsequent evaluation) it is necessary to prepare workplace health reports. The original intent of such reports was to compile a "microepidemiology of the workplace" based on different data sources (accident reports, workplace medical reports, surveys). Due to the considerable effort needed for such tasks and methodological problems, a more practical approach has evolved: Health reports focus largely on accident data and are intended as a "first step" in the discussion of work-related health problems. The identification of possible causes in the working conditions, on the other hand, has been shifted to the process itself and the participants in the process, e.g. through employee surveys, focus groups etc.

2. The interpretation of health problems, decisions on health care priorities and the planning and management of health promotion measures should occur on a discursive and co-operative basis with the participation of all relevant actors and decision-makers in the company - this means primarily: the management (including personnel and department managers), worker representatives and occupational safety experts. This would require central non-partisan organizations (e.g. a "Health Circle" or "Health Care Forum") directed by experts (e.g. employees of health insurance funds).

3. Concrete indicators for work-related health problems and the need for change and improvement should be analyzed "at the basis", supported by the perceptions, experience and problem-solving skills of employees. This can be organized in moderated health circles for which there are different models (with respect to size, duration, frequency of meetings and composition. The basic approach is always the participation of the individuals immediately affected by the workplace conditions based - since the results of Italian occupational medicine in the 1970s - on the principle that the employees are experts with respect to their own (health) concerns.

4. Workplace health promotion should focus on structural measures that integrate the technical, organizational and social conditions of the workplace with its complex effects on the health of employees - including psychosocial effects and resources. Behavioral measures (e.g. back school) should not be implemented in isolation (or exclusively) but in combination with setting-based prevention and based as much as possible on actual working conditions.

5. A project-based approach is appropriate in workplaces where the initial objective is to establish health promotion concepts. This is - at least from the perspective of a social health insurance fund - a limited engagement with defined tasks and aimed at enhancing the actors ability to identify and solve problems on their own and to stimulate collective change (organizational development). Workplace health promotion should be designed in a way that permits it to become integral and thus permanent part of the normal decision-making structures and processes in the workplace.

**235.** The available information on the diffusion and effectiveness of workplace health promotion and prevention with respect to back problems can be summarized as follows:

1. According to the available data, occupational safety measures have not resulted in any considerable improvements in decreasing work-related risks for back problems. Although there is a basic group of activities that are commonly accepted as causes of back problems (working while standing and certain unnatural positions, lifting and carrying heavy loads), a number of psychological factors (especially time and performance pressure) show an increasing trend. However, it is not possible to make conclusive statements on the extent, quality and effectiveness of workplace health safety measures - and thus on their contribution to the prevention of back problems - since there is no routine data system for the monitoring of workplace health promotion measures.
2. It is unlikely that workplace health promotion measures will offset this deficit. Besides their limited diffusion, they have tended to focus on courses for behavioral approaches (e.g. back schools) and have not been combined with strategies for improving workplace conditions. Studies indicate that current workplace health promotion leaves much to be desired. Some health insurance funds (as the primary carrier of workplace health promotion) have dropped the behavioral approach and now follow a more comprehensive, integrative approach. Due to the particular conditions for the implementation of workplace health promotion (they are voluntary, competing insurers have particular interests) it appears highly unlikely that such measures can have a sufficiently widespread effect for prevention policy. Even the quality assurance supported approach to workplace health promotion on the basis of social health insurance law is no substitute for modern occupational safety measures.
3. Although the measurement of the effectiveness of good practice models of workplace health promotion (see Synopsis 2) for back pain presents some problems, the careful documentation of workplace health promotion projects and the evaluation of their effectiveness has been the exception to the rule. The results of scientific studies support the conclusion that these measures can have a considerable effect by reducing the frequency and severity of musculo-skeletal afflictions and back problems and the associated sick leave. At least this applies to prevention measures that focus primarily on the improvement of working conditions, and combine ergonomic and organizational measures as well as measures affecting the structure of the organization and company structures for co-operation and communication. Behavioral meas-

ures (lifting training, back school) can serve supporting function but are largely ineffective when used alone.

4. The studies report that the rate of work accidents decreased by 22 to 36 percent within a period of three to five years. The decline in days of sick leave due to work accidents is even more pronounced at 43 to 78 percent, depending on the control group and base value. This rate of decrease in work-related accidents is evidence that these effects are due to workplace health promotion measures.<sup>56</sup> Despite the many methodological problems, the results justify the conclusion that workplace health promotion measures are capable of leading to a significant reduction in back problems and sick leave due to back problems if:
  - they are planned and managed in a systematic and co-operative way;
  - the employees participate in the analysis of problems and the development of solutions;
  - prevention and health promotion are integrated gradually into the "normal" structures and processes at the workplace;
  - ergonomic, organizational, communication and management aspects of the workplace situation as well as behavioral factors are combined.

## **11.5 Summary and recommendations**

**236.** There is sufficient evidence that "back school" education programs as isolated measures and are ineffective as a means of primary prevention, regardless of whether they are workplace-oriented. On the other hand, there is sufficient evidence showing that back schools are effective and cost-saving measures for secondary and tertiary prevention when they focus on narrowly defined target groups and the participants are carefully selected.

The Council therefore recommends health insurers not to provide back schools as primary prevention and instead to focus on programs for the important group of patients with chronic and recurring back problems. The Council recommends the increased use,

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<sup>56</sup> Workplace health promotion also lead to a clear drop in the amount of sick leave due to numerous other diseases such as heart and circulatory diseases.

evaluation and optimization of (pilot) programs for the secondary and tertiary prevention of back pain for clearly defined target groups (B)<sup>57</sup>.

**237.** There is sufficient evidence that the potential of workplace health promotion is not fully exploited. Operational approaches for appropriate solutions are available on the basis of the analysis of projects conducted by health insurers and the international literature. The Council recommends the increased use and evaluation of workplace health promotion projects with a participative approach and combined behavioral and setting-based prevention (B).

**238.** There is evidence of an oversupply of surgical procedures in the treatment of patients with back pain and with or without neurological symptoms. Due to the inadequate evidence, there are no clear criteria for defining the indication for and evaluating the appropriateness of surgical interventions (at least for patients with neurological problems) The alternatives to surgery include traditional conservative and rehabilitative approaches that are based on guidelines. There is clear evidence of overuse with respect to diagnostic imaging, injections, the prescription of rest and the prescription of passive therapy - e.g. pain medication or passive physical therapy - lasting beyond the acute stage. Furthermore, there is underuse with respect to the adequate counseling and psychosocial support of patients with back pain.

In this context, the Council recommends that back pain is chosen as one of the priority diseases for the development of quality assurance measures called for by law (A).

**239.** The Council recommends the development of evidence-based guidelines for the treatment of simple back pain and for the delineation of surgical indications in the context of the German health care system for general practitioners and specialists, the propagation of these guidelines in the professional and lay public and the use of quality assurance measures to ensure that the guidelines are used in doctors' practices and hospitals (A).

**240.** Due to its epidemiological and economic importance and because of the proven deficits in the health care system, back pain should be given priority in the development of guideline-based disease management programs (B). Multimodal rehabilitation for patients with chronic back pain should be developed and their use and funding increased

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57 See Chapter 4.3 for a description of the rating system.

(B). The Council also recommends the increased use of part-time work in cases of work disability (C).

**241.** In the area of nursing the Council recommends that the topic of back pain (in addition to diet, exercise and pain therapy) be established as a main topic of a new project to be initiated and certified as "Health Promotion in Residential Care and Nursing Homes" (see Volume I, Chapter 2.3.2) (C).

## 12. Oncological Diseases

### 12.1 Lung cancer

#### 12.1.1 The burden of disease

**242.** Lung cancer (ICD-9: 162; ICD-10: C33 - C34) is the most common malignant cancer in males (28,200 new cases per year and 17 % of all new cases of malignant tumors) and the fifth most common cancer among females (8,900 new cases per year and 5 % of all new cancer cases). The survival prognosis is very poor for lung cancer: The relative 5 year survival rate is 9 percent for males and 17 percent for females. While the incidence among males has decreased slightly over the past 20 years, incidence among females has grown at an annual rate of 3 percent. Compared to the rest of Europe, the incidence of lung cancer in Germany is average.

**243.** At least 90 percent of lung cancer cases in males are due to smoking. Among females, smoking is responsible for 30 - 60 percent of the lung cancer cases.

37.3 percent of adult males and 27.9 percent of adult females in Germany are smokers. Overall, the studies on smoking behavior in Germany have revealed the following:

- men smoke more often and larger amounts than women. There has been a slight decrease of smoker among men but no among women;
- although the number of smokers decreases with age there has been an increase in the number of young smokers over the past years;
- the average daily consumption of cigarettes is lower in the eastern states than in the western states but is increasing;
- smoking is more widespread in lower social classes than in other groups.

**244.** Smoking increases the risk for a number of diseases (see Table 18).

**Table 18: Overview of diseases associated with smoking**

<b>Relation to smoking</b>	<b>Cancers</b>	<b>Other diseases</b>
Certain	lung, mouth/nose and throat, larynx, esophagus, pancreas, bladder	Coronary heart disease, aortic aneurysms, COPD, stroke, pneumonia
Probable	Kidney, stomach, leukemia, cervix	

*Source:* Becker, N and Wahrendorf, J. (1998)

Tobacco-related mortality in 1993 amounted to more than 100,000 premature fatalities and 1.5 million life years lost. 23 percent of all premature deaths of males and 6 percent of the premature deaths of females can be traced to tobacco-related diseases. In addition, there are 31,000 early retirement cases and 17.7 million days of sick leave per year due to tobacco. The direct costs amount to approximately DM 34 billion or 1.07 percent of gross domestic product. Lung cancer is responsible for costs of about DM 5.3 billion.

### 12.1.2 The views of the interviewed groups

245. Six organizations responded to questions on the health care situation with respect to lung cancer. Since of the importance of tobacco smoking for the development of lung cancer, the following chapter also includes the responses pertaining to the prevention of smoking<sup>58</sup>.

**Table 19: Organizations that provided information on overuse, underuse and misuse in the area of lung cancer (including the prevention of tobacco use)**

Organization (A - Z)	Type of organization
<i>Arbeiterwohlfahrt Bundesverband e.V.</i> National Association of Workers' Relief	Concerted Action and others
<i>BÄK, KBV und Ärztliche Zentralstelle für Qualitätssicherung</i> German Medical Association, National Association of Statutory Health Insurance Physicians and the German Agency for Quality in Medicine	Concerted Action and others
<i>Bundeszentrale für gesundheitliche Aufklärung</i> Federal Center for Health Education	Concerted Action and others
<i>Deutsche Gesellschaft für Allgemeinmedizin und Familienmedizin</i> German Society for General Medicine and Family Medicine	Professional society
<i>Deutsche Gesellschaft für Angiologie</i> German Society for Angiology	Professional society

58 The following contains the Council's summary of the central statements contained in the responses of the surveyed organizations. Electronic copies of the original responses are available in full length at the web site of the Council ([www.svr-gesundheit.de](http://www.svr-gesundheit.de)).

<i>Deutsche Gesellschaft für Gynäkologie und Geburtshilfe</i> German Society for Gynecology and Obstetrics	Professional society
<i>Deutsche Gesellschaft für Hämatologie und Onkologie</i> German Society for Hematology and Oncology	Professional society
<i>Deutsche Gesellschaft für Kardiologie, Herz- und Kreislaufforschung</i> German Cardiac Society	Professional society
<i>Deutsche Gesellschaft für Medizinische Informatik, Biometrie und Epidemiologie</i> German Society for Medical Informatics, Biometrics and Epidemiology	Professional society
<i>Deutsche Gesellschaft für Pneumologie</i> German Society for Pulmonology	Professional society
<i>Deutsche Gesellschaft für Psychiatrie, Psychotherapie und Nervenheilkunde</i> German Society for Psychiatry, Psychotherapy and Neurology	Professional society
<i>Deutsche Gesellschaft für psychosomatische Geburtshilfe und Gynäkologie e.V.</i> German Society for Psychosomatic Obstetrics and Gynecology	Professional society
<i>Deutsche Gesellschaft für Public Health e.V.</i> German Public Health Society	Professional society
<i>Deutsche Gesellschaft für Thoraxchirurgie</i> German Society for Thoracic Surgery	Professional society
<i>Deutsche Gesellschaft zur Bekämpfung von Fettstoffwechselstörungen und ihren Folgeerkrankungen e.V. (Lipid-Liga)</i> German Society for the Treatment of Metabolic Disorders and Resulting Diseases (Lipid League)	Patient group
<i>Deutsche Leukämiehilfe, Bundesverband der Selbsthilfeorganisationen zur Unterstützung von Erwachsenen mit Leukämien</i> German Leukemia Support, National Association of Self-Help Groups for the Support of Adults with Leukemia	Patient group
<i>Deutscher Paritätischer Wohlfahrtsverband Gesamtverband e.V.</i> German Non-Denominational Welfare Association	Concerted Action and others
<i>Deutscher Städtetag</i> German Municipal Council	Concerted Action and others
<i>Sozialministerium des Landes Baden-Württemberg</i> Social Ministry of the state of Baden Wuerttemberg	Concerted Action and others
<i>Spitzenverbände der GKV und MDS</i> National SHI associations and the Medical review Board	Concerted Action and others
<i>Verband der privaten Krankenversicherung</i> Association of Private Health Insurance	Concerted Action and others

### *Prevention*

**246.** There is a general consensus that the widespread use of tobacco indicates an underuse in the area of primary prevention. Primary prevention of smoking is considered to be the most effective means for reducing the lung cancer mortality rate. Respondents call for rigorous programs for the primary prevention of inhaled smoking; programs that should be implemented with the same intensity seen in the AIDS educational campaigns of the recent past. Non-smoking should be understood as a positive factor for the quality of life and educational measures should begin in elementary school. There is an urgent need for large-scale programs that target specific groups, e.g. pregnant women.

The implementation of existing guidelines is called for with respect to prevention at the workplace and environmental risk factors. The extent of exposure as well as the large number of workers who are exposed to carcinogens (e.g. radon in eastern Thuringia and western Saxony) calls for a thorough taking of stock, careful continued monitoring and the provision of medical assistance to the affected persons.

### *Diagnosis*

**247.** The respondents feel that the diagnosis of lung cancer could be improved. Invasive measures such as endoscopy and functional diagnosis could improve the quality of the early detection of lung cancer. Screening tests (radiology, tumor markers, fluorescence bronchoscopy or immune dyes of sputum) are seen by the respondents as an example for overuse without medically and economic justification.

Co-ordination problems at the interface between the ambulatory and stationary sectors, in particular in the area of radiology, lead to delays in the diagnosis of lung cancer. Diagnostic procedures in the course of follow-up care and rehabilitation are not made on the basis of guidelines. New diagnostic procedures should be validated before they are introduced on a broad scale.

### *Therapy*

**248.** The use of pharmaceutical therapy in lung cancer detected at a late stage and not in accordance with treatment guidelines is viewed as an example of misuse. In the ambulatory sector in particular, there is a growing trend to terminate the provision of appropriate services during the last months of the course of the disease on economic grounds. The responses on the surgical treatment of lung cancer highlighted the importance of the size, qualifications and location of treatment facilities. Many patients are treated in unqualified facilities, which results in misuse. The respondents recommend requiring a fairly large number of operations for each surgeon as a means of ensuring fulfillment of quality standards. Specialized facilities and new procedures in thorax surgery should be concentrated in centers at accessible locations. Adequate pulmonological care should be guaranteed.

### *The health care infrastructure*

**249.** The interdisciplinary coordination of therapy in the treatment of lung cancer is not conducted regularly but erratically and depends on the department of the hospital in which a patient is first treated. The provision of systematic therapy and the invoicing of services is not restricted

to doctors with certified qualifications (focus of competence, interdisciplinarity, quality assurance, and the documentation of care) or to qualified centers, but may be performed by any doctor independent of medical specialty and experience.

The respondents criticize the increasingly inadequate staffing for the treatment of cancer patients. Administrative tasks (requests for documentation and information) now make up such a considerable part of clinical routine that they displace the actual tasks of doctors and nurses.

Deficits are noted in psycho-oncological care and in the ability to respond to the preferences and information needs of patients.

### **12.1.3 The Council's viewpoint**

**250.** Current efforts for the prevention of smoking as the primary prophylactic against lung cancer are inadequate. General programs aimed at the whole population as well as programs that focus on the needs of special target groups (e.g. children, adolescents, pregnant women) are what is called for. The Council therefore decided to use the example of the prevention of tobacco use to illuminate the particular problems of underuse in prevention policy and to put forth proposals for political action beyond the narrow framework of health insurers and the SHI system.

#### **Synopsis 3: Prevention of smoking**

**251.** A quick and significant decrease in tobacco and, in particular, in cigarette consumption can not be realized through isolated educational measures but requires planned multimodal campaigns based on widely communicated and binding political decisions. The WHO, for example, recommends economic and health policy measures such as increased taxes on tobacco, measures against smuggling, the prohibition of direct and indirect advertising, the prohibition of sales to minors, protection of non-smokers at the workplace and in public buildings as well as regulation on product contents and packaging. However, the high standards of this program stand in sharp contrast to Germany's reality.

In the opinion of the Council, the current level of knowledge on the effectiveness of different prevention approaches is sufficient for the development and implementation of a coherent policy against tobacco smoking.

**252.** In general, anti-smoking campaigns have three objectives:

- to keep non-smokers from smoking (primary prevention of tobacco smoking). This focuses on adolescents, who are at a particular risk to be led into smoking, develop a smoking habit and then addiction;
- to get smokers to quit or reduce the smoking of tobacco ("quit now" courses, primary, secondary and tertiary prevention);

- to protect the general population from passive smoking (primary prevention of passive smoking)<sup>59</sup>.

All measures must take the considerable addictive potential of tobacco into consideration.

**253.** Only few people become regular smokers after they are out of their teens. For this reason, primary prevention during adolescence is decisive. The most effective method is the prevention of the beginning of tobacco use. In addition, studies show that the long-term damages associated with tobacco are particularly pronounced in smokers who started at an early age.

Educational measures can be defined as follows:

- cognitive measures can affect knowledge but hardly have an effect on attitude and behavior;
- affective measures and those aimed at alternative modes of behavior have a moderate short-term effect on knowledge, attitude and behavior;
- "social vaccination" measures are designed to empower youths to recognize and resist social determinants such as advertisements and peers. These measures seem to have the best potential for affecting attitudes and behavior at present.

Measures that are limited to educational instruments can delay the commencement of smoking by one or two years, but not always prevent it.

**254. Multidimensional community-based programs:** Multidimensional community-based programs or target group programs<sup>60</sup>, such as those that have been conducted in many states in the USA and in New Zealand, seem to have been successful. Programs are usually based on three pillars:

- many community projects (across the whole spectrum from behavior-oriented prevention and treatment to social policy efforts to modify tobacco related incentives and environmental factors),
- nation-wide campaigns in the mass media to introduce, and support anti-smoking efforts and based on
- nationwide network of support services that have the primary task of qualifying health care professionals, other professionals and lay people in tobacco prevention measures.

Prevention campaigns for which there is (limited) scientific evidence of their effectiveness are to be integrated in a comprehensive prevention infrastructure that is based on general political agreement and designed to be broad in scope, flexible and organized on a participative basis.

The following measures have been shown to be effective and important elements of a comprehensive prevention policy:

**255. Mass media campaigns:** Prevention based on mass media alone has only a minimal effect on youth. However, it can be useful since it reaches a large number of youths and adults and thus creates awareness.

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59 Unpublished results of the German Health Survey 1998 indicate that 55 % of non-smokers inhale tobacco smoke involuntarily. 21 % of the non-smokers were exposed at their workplace, 13 % at home and 43 % in other locations. 64 % of the non-smokers find passive smoking annoying.

60 Including the participation of different professional groups, social groups and institutions (e.g. parents, school, the participation of firms, clubs, supported through tobacco tax, media campaigns, community action, the creation of smoke-free areas).

**256. Price increases:** Price increases are considered the most effective single instrument for reducing tobacco consumption. Price and tax increases can lead to a significant reduction in tobacco consumption.<sup>61</sup> Whether price increases can prevent someone from beginning to smoke, however, is subject to controversy. A minority of smokers compensates price increases, for example, by smoking cigarettes with more nicotine content. The expected health effect of price increases is considered to be greater than these undesired effects. This also applies to the problem of social injustice: price increases have a two-fold effect on the poor, since they must pay a greater share of their income for cigarettes and are also more likely to smoke. It is not surprising, however, that low-income groups are particularly responsive to price changes, so that the positive health effect of price increases is particularly high in this group.

**257. Prohibitions on advertising:** The importance of advertising is not restricted to its ability to incite or promote consumption. It also brings the act of smoking in association with positive images and conveys the image of cigarette smoking as a normal and widespread of daily behavior. Studies show the relation between spending on advertising and tobacco consumption as well as the relation between advertising prohibitions and tobacco consumption. For example, it can be shown that the prohibition of advertising reduces consumption and that tobacco advertising among youths increases group specific consumption.

Limited prohibitions on advertising, for example, for television, are worthless since they lead to compensatory measures such as increased advertising in other media, or to the use of other marketing strategies, e.g. sponsoring. The restriction of advertising to certain groups, in particular adults, is also ineffective since youths also see billboards that are more than 100 meters away from their schools. Furthermore, these regulations are often not followed in practice. The prohibition of advertising, however, can only be one of many measures. Otherwise, there will be no noticeable change. Innovative anti-advertising has a considerable effect and is effective.

**258. Sales restrictions:** In contrast to the sale of alcohol to juveniles, which is regulated under the Youth Protection Act, the law only prohibits smoking in public but does not prohibit the selling of tobacco to or purchase of tobacco by juveniles under 16. A nationwide prohibition of the sale of tobacco to minors, as is common in other countries, may convey an ambivalent message: smoking is bad for health and therefore not freely available or cigarettes are "forbidden fruit".

**259. Cigarette vending machines:** Two-thirds of all youths who smoke in Germany buy cigarettes from vending machines. Although the quantitative significance of this form of distribution has declined in the last years, there are still 800,000 cigarette vending machines installed in public places in Germany. A general prohibition of cigarette vending machines is likely to have a significant effect on the number of smoked cigarettes. In the USA, it has also been shown that the prohibition of small packs, e.g. with 10 cigarettes per pack, can also be effective, since juveniles are the primary consumers of these pack sizes.

The proposal of some cigarette industry representatives to introduce "chip money" for cigarette vending machines is likely to have an effect similar to limits on the sale of cigarettes, namely the incentive for youths to obtain "chip money" as a symbol of the adult world.

**260. General prohibition of smoking:** Local prohibitions on smoking and smoke-free areas reduce the probability of smoking as well as the average number of cigarettes consumed. Limitation smoking reduce the number of opportunities to smoke and modify the cultural climate for smoking. In addition, limits on smoking in public also serve to protect non-smokers from passive smoking and are therefore very important.

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61 The price elasticity is between -0.4 and -0.7; among adolescents it is -1.2.

**261. Prohibition of smoking for minors:** According to the "Youth Protection Act", juveniles under 16 years of age are not allowed to smoke in public. This regulation, which has been existence for a long time, has not been enforced for decades. However, smoking prohibitions for juveniles are seen critically by public health experts, since they only make sense if they are enforced.

Smoking prohibitions for juveniles in certain settings, e.g. schools, have contradictory results. However, strictly enforced prohibitions at school and binding prohibitions at home are moderately successful strategies for reducing the tobacco consumption of juveniles.

**262. Product regulations:** Legal controls on products that make cigarettes as harmless as possible can contribute to solving the problem in the sense that they help reduce the damages from smoking. Tobacco smoke contains more than 4,000 chemical substances of which at least 43 are known to cause cancer and the rest of which are generally considered as damaging to health. Many of these toxic substances do not have to be part of cigarettes, but are added to the tobacco, such as ammonia, to increase the addictive effect of nicotine and enhance the effect of low-nicotine cigarettes.

**263. Warnings:** There is little research on the effectiveness of warnings (at least for youths). However, available studies indicate that the success rate is low.<sup>62</sup>

**264. Anti-smuggling activities:** Measures against cigarette smuggling are among the priorities of the worldwide anti-smoking policy. Of particular relevance for Germany is the fact that smuggled cigarettes allow particularly vulnerable groups (the poor, juveniles) to either begin smoking or not to reduce or stop smoking, because the smuggled cigarettes are usually less costly.

**265.** In conclusion, it is estimated that comprehensive anti-smoking campaigns could postpone or even prevent smoking among youths in about 20 to 40 percent of the cases. For such comprehensive programs it is important that funding comes from public sources and that the influence of the tobacco industry is neutralized.

#### *Reducing consumption and smoke cessation*

**266.** Strategies for the reduction of tobacco smoking include self-help groups and treatment. Virtually none of the programs for smoke cessation have been evaluated with respect to their effectiveness. At present, there seems to be an increase in the scientific and commercial activities in the area of reducing cigarette consumption with the support of pharmaceuticals. Whether this is merely the market adjusting to the long-term trend towards the individualization of prevention or if this will lead to epidemiologically relevant results remains to be seen.

**267. Self-help measures:** Self-help measures that are based on the initiative of the smoker can be grouped into those that are based on media services, OTC preparations and technical aids. The advantage of such measures is that they have a low threshold. However, they are less effective than the more complicated treatment measures and they increase the probability of smoke cessation only minimally. Only 2 percent of those who have stopped smoking in Germany have used such materials, often at considerable cost. There is also an almost complete lack of studies on the evidence for German-language self-help measures.

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62 Nonetheless, warnings - such as package leaflets on ingredients and side effects - are important and necessary for consumer protection. Furthermore, misleading information on cigarette packages and advertisements with terms such as "light" or "ultra light" should be prohibited. Overall, however, demand-oriented measures (behavioral prevention, mass media campaigns, price increases, prohibition of advertising) are considered more effective than supply-oriented measures.

**268. Treatment:** The concept of individual or group treatment is based on the combination of multimodal, cognitive-behavioral elements and nicotine substitution. These rather high-level measures presume that there is motivation on the part of the participant and are more effective than the self-help measures. According to a recent report of the US Surgeon General, 20 to 25 percent of the users of this approach are abstinent one year after treatment. It is unclear whether group treatment or individual therapy is more effective. Treatment with bupropion (alone or in combination with nicotine substitutes) seems promising, but additional studies are needed. Clonidine and Nortriptylin appear to have a certain positive effect, but this evidence is based on only a few studies. Bupropion and Clonidine have considerable undesirable side effects. Other forms of treatment and medication for which there is little evidence of their efficacy include mecamylamine, acupuncture, hypnosis, anxiolytics and lobelin. The last two substances are currently classified as ineffective. Aversive smoking, in particular smoking fast, appears to have a positive effect on some smokers.

**269. Doctor's advice:** According to international studies, a doctor's advice to a patient to "quit smoking" has only a moderate effect in each case. However, since the doctor reaches a large number of patients, the total effect may be considerable.

#### *Protection from passive smoking*

**270.** There are many laws and ordinances related to this issue in Germany. These serve the protection of non-smokers both indirectly (e.g. fire safety laws, restaurant codes, youth protection) and directly (e.g. labor law, traffic codes). Attempts to pass a law for the protection of non-smokers have been unsuccessful in Germany.

An important source of health disorders due to passive smoking is exposure "in-utero". International studies have shown the education of pregnant women to be effective and should therefore be used more through the doctors in private practice.

#### *Attitudes toward anti-smoking measures*

**271.** It can be assumed that the implementation of cost-neutral and resource consuming measures for the control of tobacco use would be accepted by the public. Numerous studies have shown the positive attitude of the population and health-related organizations toward strategies for the control of tobacco consumption.

#### *The finance of tobacco control strategies*

**272.** Avoiding the use of tobacco by persons who have not yet smoked, reducing the tobacco consumption of smokers and reducing the exposure to smoke in public places requires sufficient financial and human resources.

If German health policy makers were to decide for a consistent and integrated anti-smoking campaign, present funding sources would not be enough to cover the campaign's costs. According to an estimate of the National Office for Health Education, the costs of a comprehensive anti-smoking campaign would average - after higher initial expenses - DM 30 to 40 million per year. In the Council's view, this spending should not be seen simply as additional costs and thus subject to the principle of short-term cost containment. Instead, the costs should be seen primarily as a means for reducing the costs of health care and of the health care system in the medium term.

It should also be noted that the federal government has considerable revenues from tobacco tax: after the petroleum tax, the tobacco tax is the most lucrative consumer tax with annual revenues

of approximately DM 22 billion. The fear of massive revenue losses due to a comprehensive anti-smoking campaign, however, are unfounded. Increases in the tax on tobacco, which are an integral part of any consistent prevention campaign, first lead to an increase in revenues. A reduction in revenues occurs in the medium to long term, so that there is enough time to adjust to these revenue losses.

#### *Quality assurance / evaluation*

**273.** Anti-tobacco campaigns must be based on careful planning. They must include validated quality assurance measures and they must be open to modification and correction on the basis of the results of the continuous evaluation of the measures and instruments.

### **12.1.4 Summary and recommendations**

**274.** The Council calls emphatically for a new start of anti-smoking policy in Germany. The need for such a measure is supported by epidemiological data, positive results of publicly induced modification of behavior, the implementation of effective and sustainable prevention campaigns in other countries as well as the success of campaigns in other areas, such as AIDS prevention. A "National Anti-Tobacco Campaign" on the basis of these successes can be initiated and implemented (A)<sup>63</sup>.

**275.** Despite the favorable conditions for a nationwide anti-smoking campaign, the Council has identified serious hurdles to the implementation of comprehensive controls on tobacco. Special attention must be paid to these factors and measures for neutralizing or offsetting them should be taken into consideration in the design of the campaign.

This applies in particular to the tobacco industry's interest in large and growing sales volumes, which has succeeded often enough in blocking effective prevention. Agreements with the tobacco industry and cigarette manufacturers on voluntary self-control, e.g. in advertisement and promotion, have proven to be ineffective.

**276.** As part of an effective anti-smoking campaign, the Council recommends three objectives:

- Non-smoking and smoke-free environs should be established as the "normal" case and smoking - but not smokers - should be socially marginalized.
- Preventing people from starting to smoke. This applies in particular to adolescents, since people usually start smoking at a young age.

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63 See Chapter 4.3 for a description of the rating system.

- Make smoke cessation or a reduction in tobacco consumption easier. This requires the establishment of widespread programs that focus on specific target groups and are easily accessible for all smokers.

**277.** The Council proposes three levels for comprehensive prevention campaigns:

1. Population-based strategies, general messages and incentives

In addition to comprehensive and continued mass media campaigns, including anti-advertising, population-based strategies include price increases, a complete prohibition of advertising and sponsoring for the cigarette industry, effective measures against cigarette smuggling and suitable limits on the availability and public consumption of tobacco.

2. Target group and setting-specific campaigns

Measures that focus on defined target groups are necessary to ensure the effectiveness of prevention. The prime target groups which require increased attention by smoking prevention programs are females, juveniles and the socially disadvantaged. These groups must be reached through measures that are designed with their specific work and leisure settings in mind. The workplace, educational facilities, clubs, health care facilities and even labor unions and churches are suitable settings for this purpose. Individuals with a comparable socio-cultural background ("peers") are particularly well suited to convey prevention information. At this level, a central task of government anti-smoking policy is to stimulate and make possible decentralized and group-specific activities.

3. Personal communication, counseling and treatment

At the personal level it is particularly important that the primary prevention message is explained and repeated and that low-threshold support is offered to smokers who want to quit and to ex-smokers. Measures should also be offered to smokers who are undecided and those who do not want to quit. "Social vaccination" measures for the identification of high-risk situations and for enhancing the resistance to risky behavior can be effectively used in the context of personal-communicative measures.

**278.** It may be assumed that a campaign is all the more successful, the more it fulfils the criteria of consistency and integration.

The term "consistency of a campaign" means

- that the instruments used address all relevant aspects of the problem. For example, the message "smoke-free is better" or "smoke free - we can make it" must not only be known throughout the whole population; all politically controllable incentives are to be set for the whole population, specific target groups and individuals so that abiding by such slogans is made easier while not following them is made difficult. This pertains to
  - information and educational measures (mass media and anti-advertising, prohibitions on advertising and sponsoring and warnings),
  - material incentives (price increases, anti-smuggle activities),
  - accessibility (limitations on sales, cigarette vending machines),
  - restrictions on smoking (prohibition of smoking in public buildings, prohibition of smoking in public by juveniles under 16),
  - broad information on smoking cessation programs and access to affordable and scientifically proven programs (if necessary, through subsidies),
  - the standardization and implementation of the indoor protection of non-smokers;
- that they must be supported by all relevant actors. In other words, it is not enough that the federal government alone promulgates an anti-smoking campaign. Representatives of all levels of government, the educational system, clubs and groups for leisure and sports activities, the economy, social security institutions etc. must be gained for material and moral support and for active participation in such campaigns;
- that the program is not self-contradictory. This criteria is not met, for example, as long as public buildings are declared smoke free, but rules are not enforced or as long as there is advertising in public for cigarettes.

An anti-smoking campaign is considered to be integrated when

- the tasks are distributed so that all actors can make the contributions that are expected of them. This includes the representatives of educational facilities include evening education schools, sports and other leisure activity clubs, health care and rehabilitation institutions , social and juvenile services, labor unions and employer associations, social security organizations and churches. A "National Anti-Tobacco Campaign" has the obligation of providing topics with the required public resonance and to act as a lobby for the necessary legislative action. The National Office

for Health Education should be entrusted with the implementation of operative measures and with the co-ordination of the many campaigns focused on target groups, topics and settings. Based on its activities in areas such as AIDS prevention, this authority already has the experience needed for such tasks. Doctors can provide an optimal contribution when their advice is clearly based on generally known educational campaigns and also reflects the personal situation of the individual seeking professional counsel;

- it is integrated in the overall framework of government and social efforts for improving general health status. This means, for example, the anti-smoking policy should also be subject to a broad public debate of the goals of health policy. It also means that the relation between social status and the probability of smoking should not only be subject to public discussion but should also be taken into consideration in the instruments for campaigns aimed at target groups and specific settings.

**279.** The results of past anti-smoking policies in Germany are not satisfactory and pale in comparison with the results of campaigns in other countries. Anti-tobacco policy in Germany requires a new start that is founded on new knowledge. In light of the broad and diversified experience with respect to the conception, implementation and quality assurance of anti-smoking campaigns it should be possible to limit the period of time needed for the preparation of a comprehensive, long-term campaign to 12 months. The duration of the first cycle of the overall campaign should be not less than four years in addition to the year of preparation. A simple continuation of "business as usual" or "a bit more of everything" is unacceptable in the Council's view.

Following these guiding principles results in an intervention model that

- operates primarily with non-medical and
- when possible with non-repressive measures,
- through the continuous provision of information on risks and avoidance strategies,
- that reflect the life styles, milieus and settings of the target groups and
- builds primarily on opportunities for personal communication and counseling and
- established group-oriented and self-organized incentive systems and social norms
- that make risk avoidance, i.e. non-smoking, the norm and marginalizes smoking.

In light of international experience with anti-smoking campaigns and with other approaches for politically desired changes in behavior the Council recommends a policy

mix in which services with a low level of government intervention and those which convey a positive attitude towards life have priority over measures based on more interventionist measures.

**280.** The Council recommends that the implementation of a "National Anti-Tobacco Campaign" is combined with social and epidemiological research, including cost-benefit analysis, for the evaluation of the program. The task of the social research is to describe the processes for dealing with the components of the policy mix while the epidemiological research should focus on the measurement of objectives such as the prevalence of smoking, average tobacco consumption and the morbidity and mortality of selected diseases that are related to tobacco use. In addition, the social research should conceive of smoking not as an isolated social phenomenon, but also to analyze alcohol, other drugs, recuperation and individual stress. In the design of individual services and programs it is important to offer long-term and comprehensive counseling and care that deal with the consequences of changes in smoking behavior. This should serve on the one hand to prevent people who quit smoking from turning to other drugs or unhealthy life styles. On the other, it should reflect the fact that ex-smokers may be disappointed over the consequences of their decision to quit smoking, e.g. weight gain and withdrawal, and start smoking again.

**281.** The first step for the initiation of such a challenging health policy project is a clear acknowledgment of the federal government and state governments. With this as a foundation, it should be possible to recruit the relevant actors for a "National Anti-Smoking Campaign".

## **12.2 Breast cancer**

### **12.2.1 The burden of disease**

**282.** Approximately 46,000 women are diagnosed with breast cancer each year, approximately 17,000 under the age of 60. The median age at the time of diagnosis is 63.5 years. In 1999, 17,616 women died of breast cancer. Breast cancer is thus the most common cancer among women and is responsible for 26 percent of all new cancer cases and for 17 percent of total cancer mortality. The relative 5-year survival rate is presently approximately 73 percent. Breast cancer is responsible for 310,000 life years lost, the most of any cancers for women in Germany.

Compared to the rest of the EU, the incidence of breast cancer in Germany is about average. The highest rates are to be found in the Netherlands, Denmark, Finland and Sweden and the lowest in the southern countries of Spain, Greece and Portugal. Over the past years, the incidence of breast cancer in Germany, as in all other EU countries, has shown an increasing trend.

### **12.2.2 The views of the interviewed groups**

**283.** The organizations listed in Table 20 provided responses on the health care situation with respect to breast cancer.<sup>64</sup> The responses referred to a great extent to questions of early detection, diagnosis and the treatment of breast cancer.

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<sup>64</sup> The following contains the Council's summary of the central statements contained in the responses of the surveyed organizations. Electronic copies of the original responses are available in full length at the web site of the Council ([www.svr-gesundheit.de](http://www.svr-gesundheit.de)).

**Table 20: Organizations that provided information on overuse, underuse and misuse in the area of breast cancer**

<b>Organization (A - Z)</b>	<b>Type of Organization</b>
<i>Deutsche Gesellschaft für Allgemeinmedizin und Familienmedizin</i> German Society for General Medicine and Family Medicine	Professional society
<i>Deutsche Gesellschaft für Senologie</i> German Senologic Society	Professional society
<i>Deutscher Landkreistag</i> German Council of County Governments	Concerted Action members and others
<i>Deutscher Paritätischer Wohlfahrtsverband Gesamtverband e.V.</i> German Non-Denominational Welfare Association	Concerted Action members and others
<i>Deutscher Städtetag</i> German Council of Municipal Governments	Concerted Action members and others
<i>Sächsisches Ministerium für Frauen, Arbeit und Soziales</i> Ministry for Women, Labor and Social Affairs of Saxony	Concerted Action members and others
<i>Verband der privaten Krankenversicherung</i> Association of Private Health Insurance	Concerted Action members and others
<i>Verband Forschender Arzneimittelhersteller</i> Association of Research-Based Pharmaceutical Manufacturers in Germany	Concerted Action members and others
<i>Verband physikalische Therapie</i> Association for Physical Therapy	Concerted Action members and others

### ***Early detection of breast cancer***

**284.** There is unanimous opinion that the early detection of breast cancer in Germany does not comply with European guidelines<sup>65</sup> on the quality assurance of early detection (mammography screening). As a result, the expected reduction in the mortality rates of 50 to 70 year old women has not been realized. Furthermore, because breast cancer is detected at later stages, more breast amputations have been performed and adjuvant local and systemic treatment provided than would have been the case otherwise.

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<sup>65</sup> This refers to the "European guidelines for quality assurance in mammography screening" of the European Commission (Perry, N.M. et.al. 2001), which is now in its third printing.

## *Diagnosis*

**285.** The majority of responses point to an overuse and misuse in the diagnosis of breast cancer. This pertains to mammography as a curative<sup>66</sup> and a screening measure as well as to additional diagnostic measures (percutaneous biopsy). The large number of mammography procedures on women under 50 was pointed out as an example. The quality of diagnosis in Germany suffers from the fact that there are too many operators of mammography equipment with low utilization rates. This has a negative effect on the technical quality of images and doctors do not gain enough experience in the interpretation of clinical findings. As a result, the risk of making a wrong decision increases.

The lack of interdisciplinary facilities ("breast centers") with mandatory quality management in all areas and the resulting deficits in qualification (continuing education in radiology and pathology) are named as the primary causes of the identified problems in the area of diagnosis.

## *Therapy*

**286.** Quality deficits with respect to individualized and interdisciplinary services for primary and secondary reconstruction procedures are seen in the surgical in the treatment of breast cancer (misuse). Overall, too many breast amputation (mastectomy instead of lumectomy) and high-dose chemotherapy procedures are performed (misuse, overuse).

Despite acknowledged guidelines, approximately half of all breast cancer patients are not provided systemic adjuvant treatment and too few women receive adjuvant beam therapy following reconstructive surgery.

The regular compilation and update of health technology assessment reports on therapeutic procedures and compliance with evidence-based guidelines are seen as a basis for improving the treatment of breast cancer.

## *Structural and capacity problems*

**287.** The respondents are unanimous in the opinion that there is a lack of co-operative, interdisciplinary facilities in Germany (interdisciplinary breast centers) that provide diagnostic services (radiology, pathology), surgical/reconstructive services (surgery, gynecology), and pharmaceutical (gynecology, internal oncology) and radio-oncological therapy. Interdisciplinary forms of co-operation in diagnosis and therapy are also required for the implementation quality assured screening programs.

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66 Editorial note: "Curative (aka "diagnostic") mammography is performed when breast symptoms are present (e.g. a lump in the breast). When a mammography is performed on healthy women with no known breast symptoms, it is called a "screening mammography" (early detection mammography).

### 12.2.3 The Council's viewpoint

#### *The benefits of mammography screening*

**288.** There has been repeated criticism of the methods of the randomized studies that have been accepted as the empirical evidence for the benefits of mammography screening. Nevertheless, the majority of experts agree - on the basis of eight randomized controlled studies on approximately 500,000 women in four countries - that there is sufficient evidence for the benefits of quality assured, population-based mammography screening of women between 50 and 70 years of age. The reduction in relative mortality in this age group lies between 20 and 30 percent. The benefits of breast cancer screening in women under 50 are subject to controversy. If the results of the available studies are combined for women between 40 and 49 years of age, there may be (minimal) benefits of screening after 8 to 12 years.

**289.** The expected benefits of screening are the reduction of mortality due to breast cancer and an improvement in the quality of life, since the cancer is diagnosed at an early - and possibly curable - stage and less invasive therapies can be used to control the disease. Furthermore, a negative diagnosis is a relief for women, especially those who with high risk profile.

Undesirable side effects of screening arise through false-positive and false-negative results, which can be reduced through quality assurance but never avoided completely. Furthermore, improvements in sensitivity (i.e. a reduction in the number of false-negative results) lead to poorer specificity (i.e. an increase in false-positive results) and vice versa.

**290.** The available results show clearly that the average individual benefit of population-based mammography screening is low. Only a small number of women benefit from screening programs. The difference between expected benefits and damages is very small, even in excellent, quality assured mammography programs.

**291.** A decisive argument for the introduction of quality assured mammography screening in Germany is the avoidance of damages and costs that are caused by the "gray"<sup>67</sup> screening. Furthermore, the introduction of quality assured mammography

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<sup>67</sup> In contrast to curative mammography procedures, mammography screening is not part of the benefits catalogue of the Social Health Insurance system "Grey" (also called "wild", "hidden" or opportunistic") screening is the term for the practice of invoicing early detection mammography as "curative" mamography.

screening could stimulate a process for the concentration of expertise that may extend to other links in the health care chain (e.g. diagnosis, therapy). This would create additional health benefits beyond the pure screening effects, especially in comprehensive screening programs that include the qualitative optimization of the whole treatment pathway.

### ***Quality-assured mammography screening programs***

**292.** There is at present no nationwide quality assured mammography screening program in Germany. Furthermore, early detection mammography is not listed in the standard benefits catalogue. Nonetheless, there is a considerable gray area of mammography screening that is performed as curative procedures and which is not subject to quality assurance. It is estimated that there are 2 - 4 million such mammographies each year. Due to the lack of quality controls and documentation, it is impossible to provide precise estimates of the consequences of such practices. It is suspected that more than 100,000 women undergo an unnecessary invasive procedure (surgical biopsy) each year. For this reason, the current practice of offering mammography screening as a private service outside of social health insurance coverage can be justified neither on medical nor on ethical grounds. The Council appeals to doctors and health insurers to remove early detection mammography from the IGEL catalogue.

**293.** Since an acceptable risk-benefit ratio of mammography screening depends to a great extent on quality, the basic requirement for all screening measures is: no mammography screening without quality assurance. If the decision is made to introduce nationwide mammography screening, this should occur only within the framework of organized and quality-assured programs in accordance with the European guidelines.

### ***Pilot projects of the Federal Standing Committee of Doctors and Social Health Insurance Funds***

**294.** The serious qualitative deficits in all areas of mammography diagnosis - from the equipment to the interpretation of results and additional diagnostic analysis- have been known for years and were overcome through targeted quality management measures. A basic problem in the German health care system, is that successful pilot projects are implemented in routine care by the responsible parties either with a considerable time

lag or not at all. The Council views this as a partial failure of the system of joint self-administration by doctors and health insurers.

**295.** Although the Council has a positive view of the pilot projects despite delays in their implementation, it does not believe that it is justifiable, on the basis of past experience and studies, to keep quality-assured mammography screening from women outside the project regions. Millions of other women would remain subject to "gray" mammography screening - which is provided without flanking quality assurance measures - until the pilot projects, which last three years, are completed and the Federal Standing Committee has made its decision. The Council calls on the self-government to offer a nationwide screening program that complies with the European guidelines for all women between 50 and 69 years of age during the pilot projects. This would include e.g. that each specialist performs at least 5,000 mammographies per year, the a qualified second opinion, the participation in a cancer registry and certification according to EUREF. The immediate action program should be flexible enough to allow for the quick integration of results from the pilot projects into the standard benefits catalogue.

**296.** The implementation of the standards required by the European guidelines, especially the minimum number of 5,000 mammographies per year and the obligatory second opinion are hard to meet in the given decentralized structure of the German health care system. Existing centralized and qualified facilities, such as tumor centers and oncology centers, should therefore be used to expedite the implementation of nationwide quality-assured mammography screening.

The Council believes that it is important to integrate the expertise and facilities of office-based doctors in mammography screening programs. Local conditions can be used to determine who is responsible for what in the early detection of breast cancer.

### ***Curative mammography***

**297.** The results of the German Mammography Study, the existence of "gray" screening and evidence of repeated quality problems make it clear that systematic quality assurance must also be intensified in the area of curative mammography.

**298.** There are no general requirements on curative mammography that cover all necessary aspects of ensuring the quality of health care structures, processes and outcomes. The self-government's planned procedures for certification and re-certification do not go

far enough, because they don't meet the quality standards of the European guidelines and the EUREF certification protocol (Table 21) and don't reflect the lessons from the German Mammography Study.

**Table 21: EUREF standards on the minimum number of mammographies per year**

<b>Certification category</b>	<b>Annual number of mammographies</b>
<b>Certification for curative mammography:</b>	
Diagnostic mammography facility	1,000
Breast Assessment Center	2,000
<b>Certification for mammography screening:</b>	
Regional centers	5,000
European reference centers	10,000

*Source:* Based on Perry, N. et. al. (2001).

**299.** The Council believes that quality assurance for curative mammography must meet the following requirements:

- The Co-ordinating Committee and the AQS should develop standardized quality guidelines - i.e. quality guidelines that apply to all sectors, professions and institutions - for all areas of curative mammography (i.e. that cover everything from technical quality, to the qualification of staff and the assessment of outcomes).
- The regulations should meet the standards of the European guidelines and the EUREF protocol (e.g. with respect to the minimum number of mammographies per year and second opinions).
- The regulations should result in a standard certification and re-certification concept for all mammography facilities. Certification is limited and re-certification required every five years.

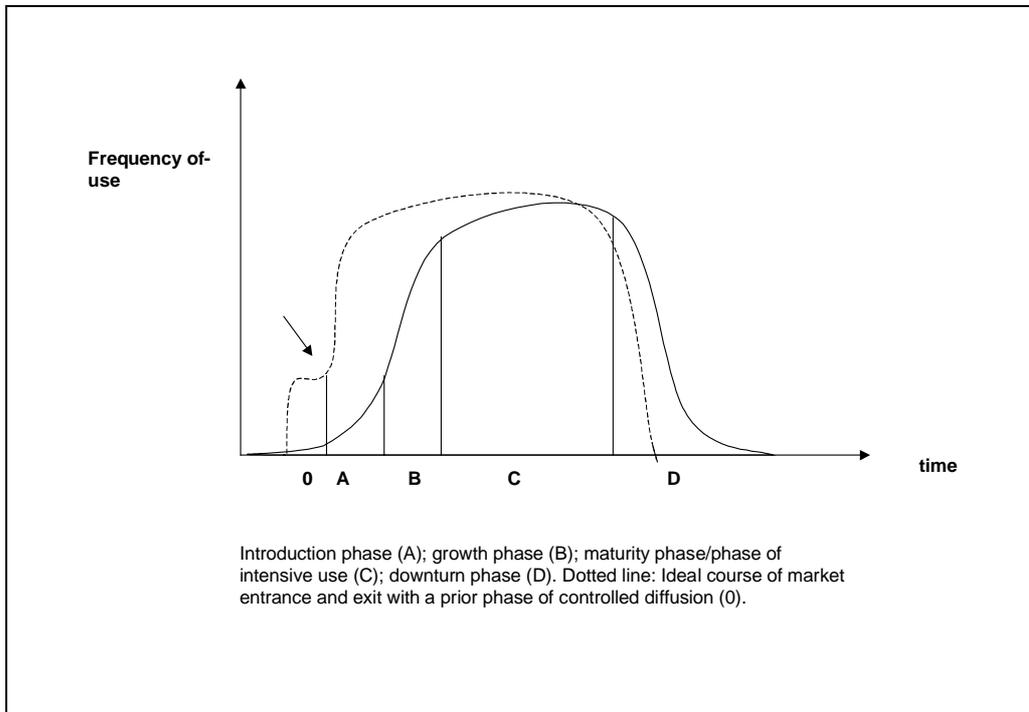
### *The treatment of breast cancer*

**300.** The responses of the interviewed organizations and the preliminary results of the German field studies provide clear indications for differences between current practice and the accepted guidelines for the treatment of breast cancer. For example, reconstructive surgery is performed on only a portion of the patients in tumor stage T1M0, and a considerable number of the patients with reconstructive surgery are not treated with radiological therapy. The Council sees a need for analysis in this area to clarify the scope and the causes of the problems and to provide a foundation for the development and implementation of quality assurance programs.

### *Managing medical innovation in cancer therapy*

**301.** A general problem in medicine is to ensure that medical innovation with proven benefits quickly become part of routine care for all patients, and at the same time to prevent the premature introduction of innovations that have not been adequately evaluated, especially when they are associated with considerable risks or costs. However, parallel to the controlled introduction of medical innovation, obsolete procedures must be phased out in a rapid and controlled manner (Figure 4).

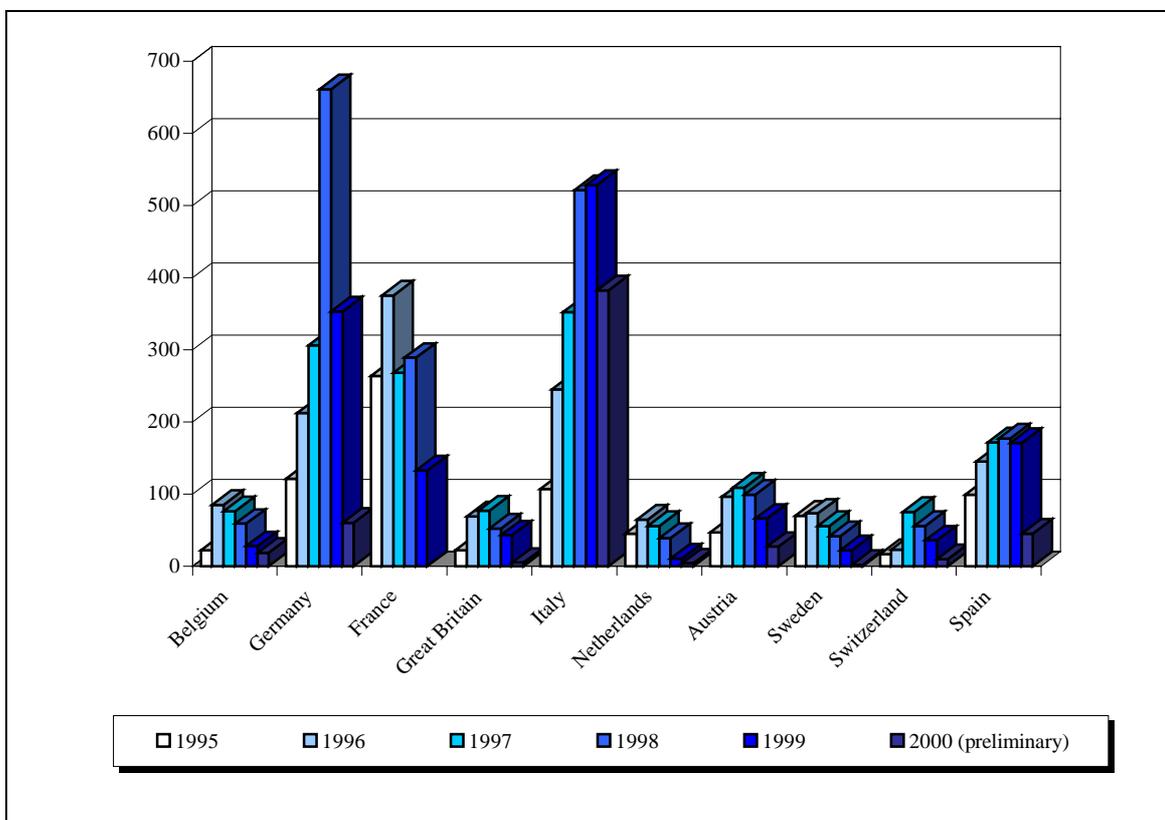
**Figure 4: The innovation cycle**



*Source:* Schwartz, F.W. and Helou, A. (2000)

**302.** High-dose chemotherapy with autologous stem cell transplantation (HDC/AST) for the treatment of breast cancer is an impressive example of misuse and overuse that is the result of a hasty and uncontrolled diffusion of new, costly and risky medical technologies (Figure 5). Experience has shown that the publication of HTA reports and evidence-based guidelines is not enough to control the introduction, utilization and management of medical procedures from a medical and an economic perspective.

**Figure 5: Number of bone marrow transplants for breast cancer recorded in the EBMT Registry**



Source: Based on the data of the European Bone Marrow Transplant Group (EBMT)

**303.** Management problems in the introduction of medical innovations for cancer therapy occur mostly in the hospital sector. The Council believes that the establishment of the Hospital Committee and the Co-ordinating Committee provides an opportunity - similar to that of the Federal Standing Committee in the office-based sector - to control the diffusion of medical innovation (including those still in an experimental stage) on the basis of evidence-based guidelines.

***Follow-up care of breast cancer patients***

**304.** The results of controlled randomized studies provide evidence for the equivalence of symptom-oriented clinical follow-up and the conventional and costly follow-up with technical apparatus in women with breast cancer. Furthermore, there are sufficient indicators that symptom-oriented clinical follow-up is less costly and less of a burden on

patients. The Council therefore calls for the rapid implementation of symptom-oriented and quality-assured breast cancer follow-up care on the basis of guidelines and in combination with psycho-social counseling.

#### **12.2.4 Summary and recommendations**

**305.** The responses of the interviewed organizations and the Council's analysis reveal deficits in the care of breast cancer patients that affect the whole treatment pathway (early detection, diagnosis, treatment, follow-up care). Measures for improving the provision of care to breast cancer patients therefore can not be related to only one aspect of care alone (e.g. mammography screening) but must be related to the whole treatment pathway (early detection, diagnosis, treatment and follow-up care) (A)<sup>68</sup>.

**306.** Since the results of the German Mammography Study have been available since 1994, the Council calls emphatically for the termination of "gray" mammography screening without quality assurance and the speedy introduction of nationwide quality-assured mammography screening in accordance with the terms of the European guidelines, including the performance of at least 5,000 mammographies per year and the qualified second opinion (A). The programs must also be linked to the cancer registries (A). To ensure the high quality of diagnostic and therapeutic services the Council also calls for the organizational and structural integration of mammography screening in existing tumor centers and oncology centers with the participation of qualified office-based specialists (A).

**307.** Although the use of mammography for early detection is not in the benefits catalogue of the Social Health Insurance system, a considerable amount of "gray" screening is conducted without quality assurance for supposedly "curative" (diagnostic) purposes. Mammography screening is also provided outside the framework of quality assured early detection programs on a private basis as a so-called "IGEL" service. These practices can not be justified on ethical or medical grounds, since mammography screening that does not meet quality assurance requirements produces a high rate of false-positive and false-negative results. Furthermore, a treatment pathway that does not meet quality assurance requirements hurts patients more than it helps them. The Council calls on the medical profession and on health insurers to take effective measures to put a stop to

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68 See Chapter 4.3 for a description of the rating system.

"gray" screening (A) and to remove early detection mammography from the list of IGEL procedures (A).

**308.** The Co-ordinating Committee should draw up a set of standard quality guidelines that cover all sectors, professions and institutions and cover all aspects of diagnostic mammography (A). The regulations should meet the standards of the European guidelines and the EUREF protocol (e.g. with respect to the minimum number of mammographies and second opinions). and results in a standard certification and re-certification for all mammography facilities (A).

**309.** There are serious indications of considerable differences between the current treatment of breast cancer and acknowledged guidelines for which there is no medical justification. The Council sees an urgent need to ensure the high quality treatment of women with breast cancer by introducing targeted quality measures and focussing expertise at regional level (A).

**310.** The current practice of simply publishing research results and guidelines does not provide an adequate framework for controlling the introduction, application and performance of risky and costly innovative procedures in the treatment of cancer, as is made evident by the example of high-dosage chemotherapy of breast cancer. The Council believes that the Co-ordinating Committee represents an opportunity for controlling the diffusion of medical innovations across all sector boundaries on the basis of binding, evidence-based guidelines (A).

**311.** The results of randomized controlled studies available since the mid-1990s provide sufficient evidence for the medical equivalence of symptom-oriented clinical follow-up care and conventional and costly follow-up with technical apparatus. The Council therefore calls for the rapid and nationwide implementation of symptom-oriented breast cancer follow-up treatment with supporting psycho-social care instead of an "equipment overuse" (A).

### **12.3 General aspects of the care of cancer patients**

**312.** This section summarizes those responses on the care of cancer patients that were not included in the sections on lung cancer (Chapter 12.1) and breast cancer (Chapter 12.2). The health care of cancer patients encompasses a number of aspects that can not be fully enumerated in this report. The Council focuses instead on the analysis of treat-

ment with strong pain killers. Furthermore, unutilized opportunities for the prevention of cancer are discussed.

### **12.3.1 The burden of disease**

**313.** The number of new cancer patients each year in Germany is estimated at 164,900 males and 173,400 females. Of these newly diagnosed patients, 1,740 are children under 15 years of age. The number of new cancer cases each year in Germany among males is at the average level for the European Union as a whole and approximately 6 percent above average for females. More than half of all cancer cases occur in persons over 75 years of age. The share of children under 15 years of age in the total number of cancer patients is under one percent. The number of cancer patients who suffer from chronic pain is estimated at 220,000.

The survival rates of cancer patients have increased over the past three decades. The 5-year survival rates of children who are diagnosed with cancer before they reach 15 increased from about 38 percent in 1970 to 69 percent in 1997. The average 5 year survival rate of cancer patients in the Saarland rose from 46 percent in the early 1970s to 53 percent for female patients diagnosed between 1985 and 1988 and over the same period from 26 percent to 43 percent for male cancer patients in the Saarland. Higher survival rates over time, for young age groups, females and in the western German states are due in part to the infrequent occurrence of cancers with a poor prognosis. Furthermore, early detection exams and improvements in diagnosis and treatment have resulted in a noticeable increase in the survival rates for most types of cancer.

Cancer is the second most common cause of death among juveniles and adults. The average age at death for male cancer patients was 69.5 years of age in 1999, which is 0.9 years less than the average age at death (70.6 years). The average age of death for female cancer patients was 73.3 years, which is 6.1 years less than the average age of death of the female population (79.4).

Lower social status is associated with higher disease rates and lower survival rates for cancer than for the population as a whole. Differences in the disease rate (by a factor of 1.2 to 2) can be ascribed only in part to risks that are known to affect socially disadvantaged groups more than other groups, e.g. smoking and unhealthy working conditions.

### 12.3.2 The views of the interviewed groups

314. Table 22 provides an overview of the organizations that provided responses on different types of cancer (except breast cancer and lung cancer, see Chapter 12.1 - 12.2), on general aspects of oncological care or on pain therapy.<sup>69</sup>

**Table 22: Organizations that provided information on overuse, underuse and misuse in the area of cancer or pain therapy**

<b>Name of the Organization (A - Z)</b>	<b>Type of organization</b>
<i>Arbeitsgemeinschaft der Spitzenverbände der Krankenkassen und MDS</i> Working Group of the National Associations of SHI Funds and the Medical Review Service	Concerted Action and others
<i>Ärztliche Zentralstelle Qualitätssicherung, Bundesärztekammer und Kassenärztliche Bundesvereinigung</i> German Agency for Quality in Medicine, German Medical Association and the National Association of Statutory Health Insurance Physicians	Concerted Action and others
<i>Bundesverband privater Alten- und Pflegeheime und ambulante Dienste e. V.</i> German Association of private nursing homes, residences for the elderly and ambulatory care centers.	Concerted Action and others
<i>Bundesverband selbständiger PhysiotherapeutInnen</i> German Association of Independent Physiotherapists	Concerted Action and others
<i>Deutsche Dermatologische Gesellschaft</i> German Dermatology Society	Professional society
<i>Deutsche Gesellschaft für Allgemeinmedizin und Familienmedizin</i> German Society for General Medicine and Family Medicine	Professional society
<i>Deutsche Gesellschaft für Experimentelle und Klinische Pharmakologie und Toxikologie</i> German Society for Experimental and Clinical Pharmacology and Toxicology	Professional society
<i>Deutsche Gesellschaft für Gynäkologie und Geburtshilfe e. V.</i> German Society for Gynecology and Obstetrics	Professional society

<sup>69</sup> The following contains the Council's summary of the central statements contained in the responses of the surveyed organizations. Electronic copies of the original responses are available at the web site of the Council ([www.svr-gesundheit.de](http://www.svr-gesundheit.de)).

<i>Deutsche Gesellschaft für Hals-, Nasen-, und Ohrenheilkunde, Kopf- und Halschirurgie</i> German Society for Otolaryngology, Head and Neck Surgery	Professional society
<i>Deutsche Gesellschaft für Hämatologie und Onkologie</i> German Society for Hematology and Oncology	Professional society
<i>Deutsche Gesellschaft für Kinderheilkunde und Jugendmedizin</i> German Society for Pediatrics and Juvenile Medicine	Professional society
<i>Deutsche Gesellschaft für Neurochirurgie</i> German Society for Neurosurgery	Professional society
<i>Deutsche Gesellschaft für Nuklearmedizin</i> German Society for Nuclear Medicine	Professional society
<i>Deutsche Gesellschaft für Psychologische Schmerztherapie und -forschung</i> German Society for Psychological Pain Therapy and Research	Professional society
<i>Deutsche Gesellschaft für Psychosomatische Geburtshilfe und Gynäkologie</i> German Society for Psychosomatic Obstetrics and Gynecology	Professional society
<i>Deutsche Gesellschaft für Radioonkologie</i> German Society for Radiation Oncology	Professional society
<i>Deutsche Gesellschaft zum Studium des Schmerzes</i> German Society for the Study of Pain	Professional society
<i>Deutsche Leukämie-Hilfe, Bundesverband der Selbsthilfe zur Unterstützung von Erwachsenen mit Leukämien und Lymphomen e.V.</i> German Leukemia Aid Society, National Association of Self-help for the Support of Adults with Leukemia and Lymphoma	Patient group
<i>Deutscher Paritätischer Wohlfahrtsverband, Gesamtverband e.V.</i> German Non-Denominational Welfare Association	Concerted Action and others
<i>Deutscher Städtetag</i> German Council of Municipal Governments	Concerted Action and others
<i>Diakonisches Werk der Evangelischen Kirche in Deutschland e. V.</i> Deaconat of the Protestant Church in Germany	Concerted Action and others
<i>Ministerium für Frauen, Arbeit, Gesundheit und Soziales des Saarlandes</i> Ministry for Woman, Labor, Health and Social Affairs of the Saarland	Concerted Action and others
<i>Sächsisches Staatsministerium für Soziales, Gesundheit, Jugend und Familie</i> Ministry for Social Affairs, Health, Youth and the Family of Saxony	Concerted Action and others

<i>Sozialministerium Mecklenburg-Vorpommern</i> Social Ministry of Mecklenburg Eastern Pomerania	Concerted Action and others
<i>Verband der privaten Krankenversicherung</i> Association of Private Health Insurance	Concerted Action and others
<i>Verband Forschender Arzneimittelhersteller</i> Association of Research-Based Pharmaceutical Companies in Germany	Concerted Action and others

### ***Prevention and early detection***

**315.** Many organizations state that there is underuse in the area of prevention. There is a lack of educational measures and supporting measures to prevent tobacco consumption, poor nutrition, a lack of exercise and alcohol consumption. In comparison to other countries, cancer early detection programs are conducted infrequently in Germany. The differences of risks across the age groups is not adequately reflected in early detection of breast cancer, cervical cancer and intestinal cancer.

### ***Treatment***

**316.** A number of organizations report misuse in the provision of surgical treatment, especially in the treatment of colon cancer and sarcoma

In regard to radiotherapy, the organizations are critical of the organizational aspects, which separate ambulatory from inpatient treatment and result in underuse and misuse as well as overuse.

They also criticize the frequent undersupply and misuse in the provision of primary and neo-adjuvant chemotherapy to adult cancer patients, which is often due to a lack of interdisciplinary co-operation.

In contrast to the care of adult cancer patients, some organizations viewed the quality of medical procedures in the care of children with cancer as appropriate. This is due largely to the fact that care is provided according to evidence-based guidelines in 95 percent of the cases.

### ***Pain therapy and palliative treatment***

**317.** A number of respondents noted serious underuse and misuse in the provision of opiates to cancer patients with extreme pain. The fact that pain therapy is all too often provided through a single specialist is a structural problem of the health care system. There is a shortage of pain treatment centers and the existing facilities are often underfunded. Doctors and psychologists often lack the proper qualifications for the treatment of pain patients. There is also a lack of qualified doctors and nurses in palliative care and in the provision of special services for inpatient or home care.

### *Counseling, rehabilitation and nursing*

**318.** Most of the responses report an underuse of psycho-social care and counseling for children and adult cancer patients. Underuse is particularly acute in the areas of psycho-oncological care and counseling of acute cases and as follow-up measures.

**319.** With respect to rehabilitation, the respondents criticize the lack of ambulatory services. There is often a shortage of qualified personnel, interdisciplinary co-operation and adequate funding for the provision of home care to seriously ill cancer patients.

### *Capacities and structural problems*

**320.** The fact that treatment measures is not routinely co-ordination by all those involved in the process is noted as a structural problem by a number of organizations. There is a lack of comprehensive cancer care centers for the provision of care to adult cancer patients, such as those that have been successful in France, Italy, the Netherlands and the USA. The number of treatment centers for children with cancer is sufficient. However, staffing, in particular with respect to psycho-social support, as well as the funding for co-ordination measures and quality assurance is lacking.

**321.** Many of the organizations recommend strengthening multidisciplinary co-operation and promoting more rigorous quality assurance measures in oncology. Guidelines and treatment protocols are indispensable in the treatment of adults and children. The reimbursement of oncological procedures, especially in chemotherapy, must be contingent on the professional qualifications of the specialist who performs them. In addition, many organizations recommend that pain therapy be included in the medical education, training and continuing education of doctors and psychologists.

### **12.3.3 Summary and recommendations**

**322.** The Council believes that the opportunities for the primary prevention of cancer are by no means exhausted. The Council reiterates its recommendation (see Volume I, Chapter 2) that prevention be emphasized not only in the context of the health insurance system but also in the context of a broader, intersectoral, preventive health care policy. The Council refers in this context to its recommendations for a "National Anti-Tobacco Campaign" (see Chapter 12.1).

**323.** Cancer early detection programs do not reach enough of the people who are at risk in Germany. The Council believes that enough models have been evaluated in Germany and in other countries that have shown that the systematic invitation of persons from high risk groups can lead to a significant increase in the participation rates of cancer early detection programs. The Council believes that there is sufficient evidence to sup-

port the effectiveness of the early detection programs for cervical cancer and for intestinal cancer (the early detection of breast cancer is discussed in Chapter 12.2).

Based on the recommendations in Volume I , Chapter 2.3.1, the Council therefore recommends the establishment of a procedure for the invitation to early detection measures of individuals with a high risk of cervical or intestinal cancer (A)<sup>70</sup>. Considerations of professional law and the individual economic perspective are secondary to the expected benefits for patients and society as a whole.

**324.** To improve the treatment of cancer, the Council reiterates its recommendation (see Volume II, Chapter 3.1), to pay more attention to the relationship between quantity and quality in the reimbursement of services. If there is evidence that such a relationship exists for certain surgical procedures, the Council believes that it the definition of a minimum number of procedures per year as a requirement for specialists is worth looking into (B).

**325.** The alleviation of pain is a central task of doctors. Pain is a psychological burden and limits daily activities. Appropriate pain therapy is therefore a precondition for maintaining the quality of life of pain patients. Freedom from pain or effective alleviation of pain can be obtained for the majority of individuals suffering from cancer pain.

However, there are indications that the pain of many cancer patients is not provided adequate treatment. In this context, the Council welcomes the initiatives for continued improvement in the care of cancer pain patients based on the development of evidence-based guidelines. The recent publication of a guideline clearing report offers a good foundation for continuing education as well as for the development and implementation of a national guideline on tumor pain. The Council calls on the organizations involved in the clearing procedure and on all medical, psychological and nursing organizations to refer to this report in the development of evidence-based guidelines and to take a constructive role in their diffusion, implementation and evaluation (A) (see Volume II, Chapter 2).

In this context, the Council also refers to its recommendation to improve the provision of hospices and other specialized outpatient and inpatient facilities for terminally ill patients and to implement research projects on the quality of care in this area (see Chapter 7).

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70 See Chapter 4.3 for a description of the rating system.

**326.** The Council also recommends that pain therapy is given more emphasis in the schooling, training and continuing education of doctors and other healthcare professionals (see Volume II, Chapter 1.1) (A). It is particularly important to demonstrate the efficacy and necessity of a guideline-based opiate therapy and to transmit an understanding for the treatment of acute and chronic pain as an independent task. In addition to providing knowledge, it is imperative to improve attitudes and the ability to counsel patients, to perform pain therapy and to prevent and treat any side effects. Interdisciplinary co-operation, including co-operation with specialists for pain therapy, should also be optimized.

## **13. Depressive Disorders**

### **13.1 The burden of disease**

**327.** Depression is one of the most common diseases in the general population and in general medical practice. If all persons with clinically relevant depressive disorders are combined without regard to their differential diagnostic classification, the 4 week prevalence of depression as defined in the ICD 10 or the DSM-IV is 6.3 percent for adults between 18 and 65 years of age in Germany. This corresponds to about 3.1 million people. Women are affected more often (7.8 %) than men (4.8 %). If the time period for measuring prevalence is extended to 12 months prior to the examination, the prevalence rate for at least one episode of depression rises to 11.5 percent.

**328.** Measured in terms of YLD (years lived with disability), which reflects the frequency and term of a disease as well as the associated disability, unipolar depression is by far the most common disease in industrialized countries. If the years of life lost to premature mortality are also included, unipolar depression is the second most common disease after cardiovascular disease.

**329.** In addition to the psychological, somatic and social burden, patients with a depressive disorder also have an increased risk for suicide. For persons who have undergone inpatient treatment for major depression, the probability is 15 percent. A large portion of all suicide cases are due to depression.

**330.** Depressive disorders cause considerable indirect costs due to the incapacity for work. In acute stages as well as in the further course of the disease, depression can have massive effects on labor productivity and even lead to an incapacity to work.

### **13.2 The views of the interviewed groups**

**331.** Table 23 lists the professional societies, member organizations of the Concerted Action and patient groups that provided responses that referred explicitly to the care of patients with a depressive disorder.<sup>71</sup>

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<sup>71</sup> The following contains the Council's summary of the central statements contained in the responses of the surveyed organizations. Electronic copies of the original responses are available at the web site of the Council ([www.svr-gesundheit.de](http://www.svr-gesundheit.de)).

**Table 23: Organizations that provided information on overuse, underuse and misuse in the area of depressive disorders**

<b>Name of the Organization (A - Z)</b>	<b>Type of organization</b>
<i>Arbeitskreis Depressionsstationen</i> Working Group of Depression Stations	Concerted Action and others
<i>Ärztliche Zentralstelle Qualitätssicherung (gemeinsam mit Bundesärztekammer und Kassenärztlicher Bundesvereinigung)</i> German Agency for Quality in Medicine (with the German Medical Association and the National Association of Statutory Health Insurance Physicians)	Concerted Action and others
<i>Berufsverband Deutscher Nervenärzte</i> Professional Association of German Nerve Specialists	Concerted Action and others
<i>Bundesdirektorenkonferenz Psychiatrischer Fachkrankenhäuser</i> National Conference of the Directors of Psychiatric Hospitals	Concerted Action and others
<i>Bundes(fach)verband der Arzneimittel-Hersteller e.V.</i> German Manufacturers' Association (BAH)	Concerted Action and others
<i>Bundesfachvereinigung Leitender Krankenpflegekräfte in der Psychiatrie e.V.</i> National Professional Association of Head Nurses in Psychiatric Units	Concerted Action and others
<i>Bundesinstitut für Arzneimittel und Medizinprodukte</i> Federal Institute for Drugs and Medical Devices	Concerted Action and others
<i>Bundesverband der Vertragspsychotherapeuten e.V.</i> National Association of Psychotherapists for SHI Patients	Professional society
<i>Deutsche Gesellschaft für Allgemeinmedizin und Familienmedizin</i> German Society for General Medicine and Family Medicine	Professional society
<i>Deutsche Gesellschaft für Gerontopsychiatrie und -psychotherapie e.V.</i> German Society for Gerontological Psychiatry and Psychotherapy	Professional society
<i>Deutsche Gesellschaft für Psychiatrie, Psychotherapie und Nervenheilkunde</i> German Society for Psychiatry, Psychotherapy and Nerve Medicine	Professional society
<i>Deutsche Gesellschaft für Psychoanalyse, Psychotherapie, Psychosomatik und Tiefenpsychologie e.V.</i> German Society for Psychoanalysis, Psychotherapy, Psychosomatic Medicine and Depth Psychology	Professional society
<i>Deutscher Berufsverband für Altenpflege e.V.</i> German Professional Association for Geriatric Nurses	Concerted Action and others
<i>Deutscher Städtetag</i> German Council of Municipal Governments	Concerted Action and others

<i>Max-Planck-Institut für Psychiatrie</i> Max Planck Institute for Psychiatry	Professional society
<i>Ministerium für Frauen, Arbeit, Gesundheit und Soziales des Saarlandes</i> Ministry for Women, Labor Health and Social Affairs of the Saarland	Concerted Action and others
<i>Niedersächsisches Ministerium für Frauen, Arbeit und Soziales</i> Ministry for Women, Labor and Social Affairs of Lower Saxony	Concerted Action and others
<i>Robert Koch-Institut</i> Robert Koch Institute	Concerted Action and others
<i>Senatsverwaltung für Arbeit, Soziales und Gesundheit Berlin</i> Office for Labor, Social Affairs and Health of Berlin	Concerted Action and others
<i>Sozialministerium des Landes Baden-Württemberg</i> Social Ministry of Baden-Wuerttemberg	Concerted Action and others
<i>Verband der privaten Krankenversicherung</i> Association of Private Health Insurance	Concerted Action and others
<i>Verband Forschender Arzneimittelhersteller</i> Association of Research-Based Pharmaceutical Companies in Germany	Concerted Action and others
<i>Verband physikalische Therapie</i> Association of Physical Therapists	Concerted Action and others

### ***Diagnosis***

**332.** The organizations participating in the survey report unanimously that depressive disorders are often not diagnosed or diagnosed too late. As a result of diagnostic underuse and misuse, patients are not provided the necessary anti-depression therapy (in the form of anti-depressive medication and/or psychotherapy) or are treated too late (underuse and misuse). However, undetected or misunderstood depression can result in unnecessary and potentially harmful (somatic) diagnoses and treatment (overuse and misuse). This includes, for example, long-term treatment with benzodiazepines when it is not indicated. Respondents point to a similar relation between underuse and misuse in the diagnosis of depression and underuse and underestimation of the risk of suicide.

### ***Pharmaceutical therapy***

**333.** The quality of the medicinal treatment of depressive disorders is judged to be lacking in many cases. Prescription behavior is dominated by the prescription of "classic" tricyclic antidepressants with unfavorable side effects instead of modern antidepressants with fewer side effects. Only few patients are provided treatment with modern anti-depressants that reflect the current state of science. There is also unanimity that the opportunities for providing prophylactic treatment for repeated episodes (e.g. with lithium, carbamazepine or valproate) were not fully utilized.

### ***Psychotherapy***

**334.** The review of the many responses indicates that overuse, underuse and misuse exist simultaneously in the psychotherapy provided to patients with social health insurance. On the one hand, too much treatment is provided for too long to patients who do not need it (overuse), while seriously ill patients and problem patients are not provided enough care (underuse and misuse). Controls on the utilization of ambulatory psychotherapy through prior authorization and time quotas are considered to be "unmedical". The duration of treatment is not determined on the basis of medical necessity but on the basis of the time quotas approved by the third-party payers.

**335.** Only a few responses point to a problem in the choice of psychotherapeutic method. In these cases, it is assumed that the choice of psychotherapy depends less on the needs of the patient than on the education and training of the therapist and his/her ideological preferences, which contributes to misuse. It is therefore felt that there is considerable need for research with respect to the precise indications for different methods of psychotherapy.

### ***Rehabilitation***

**336.** Only few responses refer to rehabilitative care for patients suffering from depression. The respondents criticize the fact that rehabilitative measures for patients with mental health problems are provided primarily by facilities that are far from patients' homes, thus endangering the continuity of care. The high early retirement rate among patients with depression or manic depression is seen as an indicator for problems in rehabilitation, since both of these diseases may go into complete remission. The respondents also point to the intransparency of rehabilitative care and its outcomes and called for the publication of the results of quality assurance measures in rehabilitation clinics.

### ***Supply of health care services***

**337.** A number of responses refer to capacity problems. However, in most cases, these do not refer to depression alone but to all psychiatric diseases. The assessment of the current situation is varied. Reference is made to clear differences in the provision of psychiatric and psychotherapeutic services at regional and local level that are not due to differences in morbidity alone. It is also made clear in this context that due to the lack of data on medical outcomes, the differences in the supply of services can not be clearly identified as overuse, underuse or misuse. However, there is a preponderance of responses that identify underuse - especially from a regional perspective - with respect to:

- the availability of office-based specialists (psychiatrists and neurologists),
- the availability of office-based doctors and psychologists for psychotherapy,
- the provision of specialist care to psychiatric patients in homes,
- the socio-psychiatric care of patients with serious mental health disorders.

### **13.3 The Council's viewpoint**

#### **13.3.1 General issues in the care of psychiatric patients**

**338.** The adequate care of psychiatric patients poses a challenge to the health care system and is at the same time a task for all of society. Despite the many advances achieved since the publication of the Enquete Commission Psychiatry Report in 1975, many patients with psychiatric diseases don't experience the same acceptance and care as patients with somatic diseases. Psychiatric patients are still stigmatized and subject to discrimination.

On World Health Day in April 2001, the WHO initiated a one year campaign on mental health. One objective of the program is to put an end to the discrimination of psychiatric patients. According to the WHO, discrimination is the greatest hindrance to the appropriate care of persons with mental health problems. As long as the topic of mental health remains hidden behind a wall of silence and shame, the chances for early and appropriate care will not be utilized sufficiently.

**339.** The Council is aware that the extremely complex problems in the care of persons with psychiatric disorders can not be dealt with in the necessary scope and depth within the framework of this report. The Council's assessment of this area is therefore restricted initially to two aspects in the care of depressive patients. The first focus is on the problems of the detection and treatment of depressive disorders in general practice. The Council makes use of empirical data that is surprisingly well-founded for German conditions: the results of a special survey on "mental health disorders" that was part of the National Health Survey 1998/99, the nationwide "General Practitioners Study" and the "Depression 2000" study. The second focus is a critical review of the current situation in the care of elderly patients with depression.

**340.** In addition to the problems in the care of depressive patients, there are problems in the care of other mental health disorders that must be dealt with in more detail by the responsible health policy decision-makers. There are fairly certain indications and in some cases serious indications of overuse, underuse and misuse in a wide range of mental disorders. Apparently, only a relatively small number of persons with psychiatric disorders are provided care that can be judged as adequate on the basis of modern treatment guidelines.

**341.** One unresolved problem in the evaluation of the appropriate level of care is the relationship between the prevalence of diagnosed psychiatric disorders and the need for treatment. Furthermore, there are no reliable models for estimating the level of need. This applies to the need for ambulatory psychotherapy, which is basically the planning of distribution on the basis of normatively determined density ratios that determine the number of inhabitants per doctor, whereby the current ratio is set on a fixed day as the level of a future target ratio. Since it can not be assumed that the current number of psychotherapists is adequate in all regions across Germany, the current planning practice perpetuates regional imbalances.

In this context, the Council points out that a large number of psychotherapy practices have been established recently in some regions. In metropolitan areas, especially those with university clinics and training facilities for psychotherapy, there are indications of regional overuse. In poorer regions and in particular in rural areas, on the other hand, there are indications for underuse. In addition to the differential between the eastern and western states there is apparently also an north-south differential.

In light of the problems in the planning of psychotherapy services, the Council recommends replacing the current planning models with a differentiated model based on indices. To provide a reliable estimate of needs and facilities, three types of indices should be used:

- Population-based indices that describe the total population according to certain features and thus provide the basis for the analysis of the need for care. This includes the age, sex and regional structure of the population.
- Indices of need, measured primarily as the number of disorders that require treatment. These indices also include the severity of the psychiatric disorder (the extent of need for treatment), utilization rate (depends on the information on and acceptance of the available forms of psychotherapy) and the extent of care (e.g. "the number of therapy hours per patient"; whereby clear differentiation is made between the needs of acute and long-term patients).
- Indices of facilities are determined by the existing infrastructure of psychotherapy services. This includes the amount of treatment (the number of services actually provided), the duration of treatment (the average period of time over which psychotherapy services are utilized) and the utilization rate or reserve capacity.

It is also necessary to differentiate between adult psychotherapists and pediatric or juvenile psychotherapists and to consider the compensating effects of other healthcare providers.

### **13.3.2 The diagnosis and treatment of depressive disorders in family practice**

**342.** The majority of depressive patients are in the care of family doctors. Depression is not diagnosed in at least one third of the patients and not treated properly in at least 50 percent of the cases. Since good therapies are available, it's unacceptable that only a small number of depressive patients receive anti-depressive treatment *lege artis*. The results of the National Health Survey 1998/99 and two recent studies in Germany provide clear indications that

- about 10 percent of the patients treated by family doctors have depressive disorders and approximately 4 percent suffer from severe depression;
- depressive patients classified according to ICD-10 as suffering from "mild" depression experience extreme distress, have a significantly lower labor productivity and a higher utilization of health care facilities - including somatic services - than patients who do not suffer from depressive disorders. Depressive patients are therefore an important group of the so-called "frequent users";
- despite improvements over the results of studies conducted during the 1990s, the detection rate and treatment rate in general practice must be improved;
- patient-related factors (especially behavior with respect to self-presentation, asking for help and the grounds for consulting a doctor) have a considerable effect on the detection of a depressive disorder by doctors;
- the prescription behavior of general practitioners often diverges from evidence-based and consensual guidelines;
- general practitioners tend to wait too long before referring depressive patients to specialized psychiatric and or psychotherapy facilities.

### ***Recommendations***

**343.** In light of the above problem analysis the Council makes the following recommendations:

- Due to the considerable need and the documented problems, approaches for improving the treatment of depressive patients should focus on general practitioners (A)<sup>72</sup>.
- The Council indicated in Volume II (paragraph 38) that psychiatry is not yet a required part of the training of general practitioners or doctors for internal medicine. The Council calls once again for the inclusion of more psychiatric topics in the training of general practitioners and in their continuing education (A).
- Full certification to provide care as a general practitioner to psychiatric patients should depend in part on the participation in binding, quality-assured continuing education programs that have been evaluated with respect to their learning outcome (A).
- Regular counsel of a psychiatrist should be required for patients with severe depression who are treated in the primary care sector (A).
- Symptom-oriented guidelines for the diagnosis and treatment of depressive disorders should be developed and implemented in general practice. The guidelines should also contain concrete parameters that control the referral (and re-referral) to psychiatric or psychotherapeutic care. Compliance with the parameters should be supported by reimbursement incentives. Furthermore, the guidelines should contain special sections for problem groups (e.g. young males) (A).
- There is need for more research on the extent to which the routine use of valid and practical patient questionnaires (e.g. the Depression Screening Questionnaire - DSQ) can contribute to a significant improvement in the detection rate of depressive disorders (B).
- Socially conditioned prejudices play an important role in the poor detection and treatment of depressive disorders. For this reason it is important to improve general awareness for the frequency and the nature of depressive disorders, to promote the acceptance of psychiatric patients and to dismantle existing shame barriers (A).

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72 See Chapter 4.3 for a description of the rating system.

### **13.3.3 Depression in the elderly**

**344.** The ambulatory care of elderly patients with depressive disorders is provided primarily by general practitioners. Care in gerontological-psychiatric facilities by an office-based nerve specialist or psychiatrist is the exception to the rule. International studies indicate that the treatment of elderly psychiatric patients in specialized ambulatory facilities or by a psychiatrist or neurologist with special qualifications in gerontology can be more effective than care by a general practitioner. The extent to which this applies in Germany can not be estimated due to the lack of data. For example, it is not known whether German psychiatrists and nerve specialists are qualified in gerontological psychiatry. Gerontological psychiatry is not a required part of the curriculum in the training of psychiatrists and only a minority of psychiatrists and nerve specialists are qualified in "clinical geriatrics". The Council sees a need for continuing education in this area.

**345.** Although the number of office-based neurologists and psychiatrists appears adequate, elderly patients with depressive disorders utilize the existing facilities either too late or too infrequently. Treatment by the family doctor is usually preferred to treatment by a psychiatrist or in a gerontological psychiatric day-care unit, which is usually affiliated with a psychiatric hospital. Many elderly patients refrain from treatment by a specialist in psychiatry because they fear being stigmatized. As described above, the Council believes that this problem should be dealt with through improved education of patients and the public.

**346.** The Council views the number and distribution of gerontological-psychiatric centers and ambulatory units as insufficient in the sense of under treatment. This applies in particular to gerontological psychiatric centers and day-care centers that promote a visiting care, in which case it is necessary to promote co-operation with general practitioners. The extent to which there is a need for day-care centers that do not provide any home care is not clear, but it is clear that the small number of patients utilizing this form of care indicate that it will not play a significant role in overall care. Instead their role is to serve as a filter to determine the necessity of hospital treatment.

**347.** In general, the data on the quality of the primary care of gerontological psychiatric patients is poor, although existing studies indicate that there are deficits in this area. This applies in particular to persons living in homes for the elderly or in nursing homes. Pharmaceutical therapy, as an indicator of the quality of treatment by doctors, is lacking. At most, patients with depressive disorders are treated with anti-depressives in sub-

therapeutic dosages. Instead of an adequate anti-depressive treatment, doctors prescribe tranquilizers that are not indicated. It can be assumed with sufficient certainty that there is an overuse, underuse and misuse of elderly patients with depressive disorders.

The main cause is the lacking expertise of the responsible doctors in the diagnosis and treatment of depression in elderly patients and in the use of psycho-pharmaceuticals. The lack of supporting care for nursing homes by psychiatrists and neurologists with special qualifications in gerontology and the lacking qualifications of nursing staff in psychiatric care contribute to the deficits in care. To reiterate the demands formulate in Volume II, paragraph 118, the Council believes that improvements in the training and continuing education of gerontological psychiatry are urgently required (A).

**348.** The infrastructure of the social-psychiatric service and ambulatory nursing services would be helpful for the ambulatory socio-therapeutic and nursing care of elderly patients with depressive disorders. While the ambulatory nursing services often lack competence in gerontological psychiatry, the socio-psychiatric service - as a visiting service - is usually confronted by the patients when they start behaving conspicuously (e.g. suicide attempt, self-neglect). Given the lack of established ambulatory socio-therapeutic and nursing services and concepts, the Council sees an urgent need in this area (C).

**349.** The past increases in the number of gerontological-psychiatric departments in psychiatric hospitals is commendable, since these facilities are better suited to meet the particular needs of elderly psychiatric patients, many of whom also suffer from other diseases (the presence of specialists in internal medicine and integration in gerontological psychiatric networks). Due to the lack of data, it can not be determined whether the currently available beds in gerontological psychiatry are sufficient. In general, inpatient facilities should be provided as close to home as possible. However, semi-stationary care is usually preferable to inpatient care. Only a small number of patients receive such care due to the insufficient number of gerontological psychiatric day-care clinics. The current supply of day-care clinics, which is far from being "nationwide", can, with sufficient certainty, be described as underuse that results in misuse and (economic) overuse when patients are treated on an inpatient basis due to the lack of day-care facilities. The creation of day-care facilities is therefore urgently needed (A).

**350.** In addition to or in combination with the above described measures, other outpatient services such as visiting ambulatory services, nursing services and counseling offices with socio-psychiatric qualifications should be created. Scattered elements of ge-

gerontological psychiatric care are already present in many regions; e.g. a group of dedicated nurses or a day-care clinic. However, there is usually no link between the different health care providers. As pilot projects have already demonstrated, qualified gerontological psychiatric networks could be created under expert direction. The Council believes that such structure should be established on a nationwide basis. Since some preliminary scientific analysis has already been conducted in the review of pilot projects, efforts should focus primarily on the creation of the needed structures or the reinforcement of co-operation among the existing health care providers (A).

**351.** The fragmentation of responsibilities for gerontological psychiatric care across the various sub-systems of the health and welfare systems has a decisive share in the hitherto unsatisfactory situation ("Diffusion of Responsibilities"). The focus and institutionalization of efforts in different sectors should be oriented towards the needs of patients. Strengthening the role of gerontological psychiatry in scientific and professional circles and establishing gerontological psychiatry as an integral part of policies for the elderly should be appropriate measures. It should be emphasized that gerontological psychiatry is by no means solely the treatment of dementia but also the treatment of "classical" psychiatric diseases such as depression and anxiety.

**352.** To strengthen the scientific and political position of gerontological psychiatry, the Council holds the following measures for helpful:

- Introduction of gerontological psychiatry as an integral part of the training of psychiatrists and psychotherapists(e.g. 6 months practical experience in gerontological psychiatry) (A).
- Promotion of gerontological psychiatric research and education (A).
- Integration of gerontological psychiatric experience in the training of gerontological nurses. e.g. based on 3-6-month's experience in gerontological psychiatric facilities(B).
- Increased consideration of gerontological psychiatric issues in the training of psychiatric nurses (A).
- Routine counseling of nursing homes and homes for the elderly by specialists in gerontological psychiatry; binding agreements with the responsible doctors in nursing homes; obligations for the administration of the facility to take defined measures (B).

- When necessary, create a legal basis for agreements on gerontological psychiatric care with the responsible regional association of statutory health insurance physicians (C).

**353.** The Council points out that the situation in homes for the elderly and in nursing homes could be improved. There is a need not only for improved continual medical care but also for the implementation of existing concepts for activating care and for the rehabilitation of patients in nursing homes and homes for the elderly (A). Mental health and the sicknesses of the elderly should be given more consideration in the planning, design and staffing of nursing homes, in the implementation of new structures and in the conception of a policy for the elderly (A)

**354.** The Council is aware that depression in the elderly is a complex syndrome that is rooted in a combination of physical ailments and disabilities with no biographical perspective and an often an emptiness with a tendency towards withdrawal and social isolation. The rootlessness and loneliness of the elderly is evidenced by the high rate of depressive disorders in homes for the elderly. This is why measures for improved drug treatment are not enough. The Council believes that the fulfillment of life at old age is a social responsibility that is not to be met by medical care alone. Improved health care structures should therefore go hand in hand with the search for models of new and above all activating forms of aging that promote communication.

## **14. Oral, Dental and Orthodontic Health**

### **14.1 The views of the interviewed groups**

**355.** Five organizations provided responses on oral, dental and orthodontic health: The German Dentists' Association provided a joint response with the National Association of Statutory Health Insurance Dentists, the National Association of Workers' Relief, the Office for Health and Social Affairs of Berlin and the German Society for Oral, Maxillo and Facial Surgery.<sup>73</sup>

**356.** The organizations point out that the fluoridation of toothpaste and table salt, group prevention in kindergartens and schools and individual prevention as part of social health insurance coverage have led to clear improvements with respect to the prevention of caries in children and young people. The remaining deficits are concentrated on a sub-group of children and juveniles in lower social classes. The organizations call for the special focus of prevention and early detection measures on this high risk group. Underuse in the area of caries prevention was due less to a lack of facilities than to the lack of demand for prevention services and treatment in this group. This indicates that there is an increased need for further educational measures by all institutions. Dental care and counsel of women during pregnancy is seen as an opportunity for improving the oral health of children.

Inflammatory diseases of the periodontium (gums) are considered to be an often underestimated indication. However, there is no population-based data on periodontal disease and the level of care. In order to achieve lasting improvements, prevention measures in this area must also rely in part on individual initiative, which can be stimulated through a bonus system. The organizations saw a general undersupply and misuse in dental care for immobile, handicapped and disabled persons. Orthodontic treatment is subject not only to medical criteria but also to individual and social norms, which makes it difficult to determine the presence of overuse or underuse.

Fixed subsidies are considered to be more equitable than cost-sharing based on coinsurance, since the former prevent patients who are able to finance higher sums from placing an excess burden on the health insurance system. The planning of capacities in this area has not been able to reduce the existing structural overuse. In this context the respondents propose a reduction in educational capacities and thus in the number of students.

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73 The following contains the Council's summary of the central statements contained in the responses of the surveyed organizations. The original responses are available in full length at the web site of the Council ([www.svr-gesundheit.de](http://www.svr-gesundheit.de)). The response of the German Society of Dentistry and Oral Medicine, including the responses of the German Society for Restorative Dentistry and the German Society for Parodontology were not submitted until April 2001. They could not be included in the evaluation but are available on the homepage of the Advisory Council.

## **14.2 Overuse, underuse and misuse in general dentistry**

### **14.2.1 Current problems in dentistry**

**357.** As mentioned in the organizations' responses, the dental health of juveniles has clearly improved in the recent past. The so-called DMFT rate (decayed, missing, filled teeth) was 1.7 for 12-year olds in 1997 and thus well below the WHO target of 2. However, oral diseases are quite widespread in older age groups. For example, with respect to the number of missing teeth, prevention measures have not been successful in the age group 35 - 44 years over the past 14 years.

**358.** The observed reduction in oral disease among young people is due to a number of interrelated factors. In addition to the effect of fluoride, factors such as diet, oral hygiene, smoking behavior and food additives and medicines affect the development of caries. The oral health of an individual is therefore not only the result of their behavior but the product of many endogenous and exogenous variables, i.e. of behavioral and environmental factors. Epidemiological studies also reveal a relationship between social class and oral health in Germany.

**359.** Compared to the situation in other countries, the level of dental care in Germany is seen as high. Although the epidemiological data base has improved in recent years, it only allows for limited statements on overuse, underuse and misuse. With respect to supply, there is a lack of experts in special areas of dentistry - e.g. endodontology, pediatric dental medicine, parodontology or preventive dentistry - although the number of general dentists is adequate or high. Compared to other countries, Germany lacks specialists in qualified dentists and experts in preventive dentistry for the implementation of restorative and preventive strategies. On the other hand, Germany is the only country in Europe with more dental technicians than dentists.

**360.** Dental health needs can not be clearly classified into an objective or normative component in the sense of "need dentistry" and a subjective component of "want" or "elective dentistry". Dental practice often consists of the combination of necessary with unnecessary services. This overlapping prevents a clear distinction between necessary basic services and unnecessary services. Such a delineation can not be made on the basis of (dental) medicine, but requires other criteria. A number of studies that indicate a wide range of treatment alternatives in restorative dentistry support this thesis. Many areas of dental medicine lack the reference of guidelines or expert opinions only a few measures are considered evidence-based.

**361.** The existing codes for invoicing basic diagnostic procedures, which are restricted largely to the so-called "01 finding", are not adequate for a more differentiated approach. There is a considerable need for research in the definition of operational criteria for distinguishing between restorable and renewable approaches to restoration. Regardless of the uncontested existence of overuse, underuse and misuse, no generally accepted scientific data is available for making an estimate of their actual quantitative extent. Finally, there is a lack of co-ordination between dentists and doctors with respect to dental diagnostic procedures.

**362.** Opportunities for the primary and secondary prevention of oral diseases are not well utilized, in particular with respect to health promotion and general collective prevention measures. For example, the diffusion of fluoridated table salt is only at 50 percent and only a modest portion of the money earmarked by lawmakers for group prevention has been used. Although overuse in the areas of primary and secondary prevention is associated with a relatively low risk of damages, this area is more likely characterized by a general underuse. This applies in particular for measures that reduce caries in higher age groups and for the estimate of risk and monitoring of periodontal disease in adults

**363.** There are still too few incentives in the area of tertiary prevention to avoid invasive surgical procedures or prosthetic interventions through the use of the appropriate restorative or parodontological measures. In particular, there is underuse in the care of persons with a high risk for oral disease and in the restorative treatment of children. Compared to the prevalence of caries, it is more difficult to make general statements on the situation with other oral diseases, e.g. periodontopathies. The discrepancy between the prevalence in the population and the number of treatments of periodontal diseases, however, indicates that there may be an underuse in the provision of periodontal care.

A problem that is at least as significant as underuse is the overuse and misuse provided in the course of tertiary prevention. There is a long list of possible types of overuse in the area of restorative dentistry. The outdated or incomplete directives of the SHI system in the area of periodontology allow the conclusion that there is significant overuse in this area. However, the available epidemiological data does not allow for a representative estimate of the extent of overuse, underuse and misuse. Partial surveys indicate that the opportunities for restoring teeth are not utilized to the extent that is desirable and too many teeth are capped instead of restored with less invasive procedures.

**364.** Modern methods for the restoration of teeth will probably question the traditional distinction between "conservative" and "prosthetic" treatment. The current trend in the diffusion of bonded tooth-colored materials makes it difficult to justify the use of metallic restoration materials such as amalgam or metallic caps as standard care while bonded tooth-colored materials are treated as cosmetic procedures that are not part of the standard benefits catalogue. The overlapping of "conservative" and "prosthetic" care can have concrete consequences on the principle of efficiency in the Social Health Insurance system. For example, the reconstruction of a tooth using composite materials that are mixed on-site is much more expensive than an amalgam filling but less expensive than pre-fabricated prosthetics.

**365.** With respect to consumer protection, there is a lack of consensus on the establishment of a co-ordination nationwide network of autonomous patient counseling centers with the participation of dentists, health insurers, consumer counseling services, consumer protection groups and other institutions. The present means for control demand, which are often based not only on medical criteria but on economic interests have a considerable potential for the considerable overuse and overtreatment. This applies not only to the information of private manufacturers, associations and internet publications but to the campaigns of public law corporations (e.g. "proPatient", "Initiative pro-Dente").

A particularly grave example in this context is the activity of representatives of "alternative medicine", who have scared patients with misinformation on the health effects of filling materials. Such scare tactics have negative dental, psychological and economic effects on patients and the insured and often lead to the replacement of intact fillings or the extraction of strategically important teeth. Based on the present state of medical knowledge, the likelihood that dental materials, including amalgam, can have a toxic effect on patients is virtually nil when they are prepared and implemented properly. Nonetheless, surveys have revealed that half of all Germans have reservations with respect to dental filling materials and amalgam. There is a clear discrepancy between the state of scientific knowledge and public opinion that is shaped and promoted in part by the marketing activities of profit-oriented dental firms.

**366.** Some of the problems in this area are due to deficiencies in education, training and continuing education. The outdated licensing procedure for dentistry from 1955 focus too much on mechanical and technical skills and neglects health promotion and prevention as well as the maintenance of oral structures. In the area of teaching and research,

deficits in post-graduate programs lead to a disadvantage in international competition. Despite the participation of highly qualified institutions and a lively interest on the part of dentists, the diversified continuing education programs are still too unstructured. Finally, the continuing education of dentists contains too few offers in special areas that are particularly relevant.

#### **14.2.2 Current activities for the improvement of quality**

**367.** Even though there is a lack of independent institutions for the collection and analysis of data on the incidence and prevalence of oral diseases, the Institute of German Dentists deserves credit for developing improved approaches for the description of national and regional health objectives. The long overdue eradication of quality deficits will not be attained through the continuation of the blame-shifting between dentists and third party payers. Rather, what is needed is an improvement of quality aspects in the name of patients, e.g. improving patients' access to care, the appropriateness of treatment, technical quality and art of care (in the sense of patient participation and support of the team of oral health care specialists). Measuring the patient's degree of satisfaction in this context is not enough.

**368.** Various institutions in German dentistry are currently working on a redefinition of the services in dental, oral and orthodontic health care and have established joint working groups for this purpose. The diagnosis, planning and patient counseling and differentiation according to basic clinical findings and, when medically appropriate, additional procedures have priority in this context. Guidelines for the provision of treatment on the basis of current standards are being developed under the auspices of the German Society of Dentistry and Oral Medicine. However, activity in this area has just begun. There are also concrete proposals for redefining the benefits catalogue with the objective of strengthening diagnostic services and preventative care.

**369.** Despite the presence of clear deficits in their practical implementation, the importance of health promotion and group prevention for improving oral health is acknowledged by almost all relevant institutions. A co-ordinated overall strategy of health promotion, with population-based, group-based and individual measures using age-specific social parameters is increasingly viewed as necessary and has become an issue in the activities of professional societies. In addition, there is a broad consensus that there are deficits in certain areas, such as periodontology.

**370.** Dentists, third-party payers and other institutions are testing different models for the improvement of consumer health protection. However, the different approaches and activities lack sufficient co-ordination.

**371.** There are numerous proposals of different institutions for the reform of the dental licensing laws but hardly any initiatives for the creation of post-graduate university programs based on the examples of other countries. The German Dentists Association, in co-operation with the German Society of Dentistry and Oral Medicine and the Association of University Teachers of Dentistry and Oral Medicine, has published general guidelines for the nationwide co-ordination of continuing education activities. Regional dentists associations are also making more efforts to increase the qualifications of dental assistants.

#### **14.2.3 Future approaches for improving quality**

**372.** In regard to the improvement of the epidemiological basis for making decisions, the problem is not only one of acquiring new data on the type and quality of dental care, but of publishing and analyzing the available data. The data should make it possible to compare costs and quality with the costs and quality in other types of health care systems, such as Sweden or Switzerland. The responsible institutions should have the necessary expertise for such tasks and be non-partisan.

**373.** In the course of redefining prevention-oriented dental medicine, diagnostic services, planning and counseling should be given a stronger emphasis. There is also a need in this context for co-operation and co-ordination with other medical disciplines. The current proposals of the German Dentists Association, the National Association of Statutory Health Insurance Dentists, the Society of Dentistry and Oral Medicine and the Association of University Teachers of Dentistry and Oral Medicine for the reform of diagnosis, planning and counseling should be discussed with other institutions as soon as possible in order to reach a professional consensus at an early stage.

The continued expansion of health promotion and collective prevention measures is targeted at factors such as an increased awareness for the risk of oral disease associated with certain foods and foodstuffs. For example, the market share of fluoridated table salt could be increased from its present level of 50 percent to more than 80 percent in the next five years. The responsible institution should be given concrete targets by lawmak-

ers for the implementation of widespread and effective group prevention and be required to document and prove their attainment of these objectives in regular reports. Increased emphasis on primary and secondary prevention could also lead to noticeable improvements in the oral health of adults under 35 years of age.

In the context of tertiary prevention it is necessary to introduce more reconstructive measures in the benefits catalogue and ensure that the fees for these services adequately reflect their costs. The dental health of senior citizens is particularly critical at present. The increased use of reconstructive interventions promises to lead to a long-term improvement in the oral health of the elderly and the restoration of oral structures.

**374.** The creation of competent and non-partisan offices for the counseling of patients with respect to oral health and dentistry would serve to satisfy the considerable information needs of patients and work to prevent the manipulation of demand. Existing institutions could develop and implement consensual counseling standards. Medical scientific societies and universities should be more involved in such efforts.

**375.** The long-term improvement of dental health care in Germany requires the creation of better working conditions at universities. At present, for example, the professional prospects for university professors in dentistry look poor. The reform of the study of dentistry should place more emphasis on preventative dentistry and medical and biological subject matter from the very beginning of education. The past focus of education on individual, patient-oriented issues must be expanded to include problems that are related to whole groups in the population. Following completion of studies, there are two parallel options for the further qualification of dentists: a large number of dentists participate in a structured training course while a relatively small number chooses further specialization.

#### **14.2.4 Measures for improving the framework**

**376.** The quality deficits in the provision of dental care are not only due to mistakes made by the dentists' association, but arise from a framework on which dentists and their professional representatives have little or no influences. Table 24 provides a synopsis of the problems discussed and combines them with concrete targets or measures and the estimated amount of time needed to reach these targets. It also must be analyzed whether and to what extent the realization of certain targets requires the reform of legal

regulations. A regular health monitoring system should then provide information on the realization of these objectives.

**377.** Improving the framework includes the medical side in the sense of professional qualification and an adequate benefits catalogue as well as the patient side, i.e. health awareness, counseling, education and consumer protection. The different facets of dental health care can be analyzed using the example of endodontology, which is a key discipline for tertiary prevention. epidemiological data indicates that the level of endodontological care and its quality in Germany is not as good as in other countries, e.g. the Scandinavian countries. Surveys conducted by health insurers reveal that a relatively small number of dentists is responsible for a relatively large number of endodontological failures, i.e. repeated root canal fillings and extractions. Isolated measures are not enough to reduce these deficits. What is required is a co-ordinated package of measures, including reimbursement measures. For example, the analysis of costs and the payment of dental services revealed that the payment of endodontic procedures by social health insurance funds do not cover doctors' costs.

**Table 24: Examples for concrete targets, conditions and estimated length of time needed for improving dental health care**

<b>Problem area</b>	<b>Examples of measures</b>	<b>Estimate time needed</b>
Expansion of dental diagnosis, planning and counseling	Definition of new benefits catalogue and fee schedule Promotion of quality management measures	less than 2 years within the next 5 years.
Creation of adequate primary and secondary prevention measures and of measures for the restoration of tooth structure as part of tertiary prevention	Definition of clear health targets for primary, secondary and tertiary prevention measures (e.g. using differentiated DMF and CPI rates). Legal requirement of annual reports by participating institutions on the implementation of measures and the results. Implementation of general, nationwide measures for group prevention; increase in spending on quality assured group prevention by 15 - 20 % per year until the level of expenditures targeted by lawmakers is reached Increasing the market share of fluoridated table salt from its present level of 50 % to 80 % Definition of new benefits catalogue and fee schedule for primary, secondary and tertiary prevention; determination of the proper ration between primary prevention (presently under 5 %), secondary prevention (presently approximately 5 %) and tertiary prevention (presently approximately 90 %) Promotion of quality management measures	within the next 2 years.  can begin immediately  within the next 5 years  less than 2 years; two-fold increase in the share of primary and secondary prevention within the next 5 years  within the next 5 years
Expansion of consumer health protection	Establishment of working groups for dental health counseling and funded by the dentists association, health insurers, public health agencies and other institutions	within the next 5 years
Limitation of demand manipulation	Concerted action of dentists, payers, public health agencies and other institutions	within the next 5 years
Re-orientation of education, training/specialization and continuing education	Introduction of a new licensing regulations for dentists  Implementation of structured continuing education programs for dentists and dental assistants Implementation of programs for specialization	In principle possible in the short term; has been blocked for years by different parties, including state governments  within the next 3 years within the next 5 years.

Source: Advisory Council

### **14.2.5 Economic effects**

**378.** Estimates of whether the intensive promotion of prevention in dental health will reduce the future need for treatment and thus reduce costs are subject to controversy. Analyses from countries with long-term experience in preventive measures for dental health do not indicate that costs will decrease in the future, in fact, some even forecast an increased need for dental health care. Factors that could lead to a reduction in spending such as a reduction in the prevalence of caries and periodontal diseases are opposed by factors that have the opposite effect such as an increase in tooth decay due to causes other than caries and a shift of periodontal diseases into middle and old age. Assuming that the current supply structures in Germany remain, then it is unlikely that there will be a short-term reduction in spending.

**379.** Attempts to conserve the existing dental benefits of the social health insurance system as a means to maintain the current distribution of earning opportunities will result ultimately in a situation in which all new procedures are left to the area of private services. Over time, the Social Health Insurance system will cover only outdated procedures and services, while the finance of innovative treatment concepts is left to the area of self-medication or supplemental private insurance. Both the attractiveness and the acceptance of the Social Health Insurance system would suffer from such a split. From the economic perspective, the issue is ultimately not whether modern dental health care with a stronger orientation towards prevention will lead to more or less costs in the future, but which health outcomes these services produce, what is their benefit-cost ratio and what priority do they have with respect to the determination of objective need in a health insurance system that is based on social principles.

### **14.3 Overuse, underuse and misuse in orthodontics**

**380.** At DM 2.1 billion, expenditures on orthodontic treatment make up approximately 7.5 percent of total spending on dental health care. The spending on orthodontic treatment has grown at higher rates over the past decade than spending for conservative surgical treatment. Despite this growth, compared to activities in other areas of the health care system, little attention has been paid to the epidemiology and health economics of orthodontics.

Almost all expenditures on orthodontic treatment are made for children between the ages of 6 and 16, with the peak at the 12 to 13-year olds. The average annual spending on dental health care for 12-year olds was approximately DM 250 in 1997, DM 180 of which was spent on orthodontic treatment alone. Approximately two-thirds of all 12 to 13-year olds in Germany receive orthodontic treatment, and this share has grown even more in the past years. Since the reduction in the caries of baby teeth has led to a decrease in the incidence of abnormal dentition, supply induced demand and or an increase in social expectations.

**381.** More than 70 percent of orthodontic treatment in Germany is done using removable braces, even though fixed braces provide better results in less time. The fact that, according to a study conducted in the western states in 1989, only 3 percent of the 13 to 14-year olds have ideal dentition indicates that there is considerable room for discretion in the determination of need for orthodontic treatment. For years, there was no generally accepted index of the need for orthodontic treatment that provided valid, reproducible and easily collected data on the need for orthodontic treatment. According to the Index of Orthodontic Treatment Need (IOTN), the need for treatment of juveniles ranges between 25 percent and 45 percent, depending on whether mild abnormalities are included. The need for treatment as determined according to the Dental Aesthetic Index (DAI) that is recommended by the WHO is only 12.5 percent to 35 percent. Even the higher of these results (45 %) is more than a third less than the rate in Germany's Social Health Insurance system (63 %).

**382.** The desire for treatment among children lies between 15 percent and 25 percent or less than half as much as the need for treatment as determined by the orthodontist. These issues point to the need for more objective diagnosis on the basis of the IOTN or the DAI and more binding regulations concerning second opinions. The reform of the fee schedule and financial incentives for dentists could increase efficiency of orthodontic treatment by changing the fees for removable and fixed braces and curbing volume increases by introducing fees for groups of services.

#### **14.4 Summary and recommendations**

**383.** There is underuse and misuse in the provision of dental care for basic clinical diagnosis, the prevention and early treatment of oral diseases and the reconstructive treatment of damaged teeth. The available alternatives for the restoration of teeth are

often not utilized to the desired extent, which results in part in an overuse and misuse with very invasive interventions that destroy the teeth.

**384.** In light of the experience of other countries with long-term success in the prevention of oral diseases, the problems in Germany could be solved with measures such as the reinforcement of health promotion and education, increasing resources for risk-oriented group and individual prevention measures and increasing the market share of fluoridated table salt . The Council recommends the prompt realization of these solutions (A)<sup>74</sup>.

The share of restorative structural interventions should be increased substantially in the area of tertiary prevention. The requirements for this measure include a re-definition and re-calculation of the fee schedule for dentists (A).

**385.** To improve the educational qualifications of dentists, the Council recommends that the personnel and material resources that are no longer needed when the number of students has been reduced be dedicated to improving the quality of research and teaching. Improvements at university hospitals should soon be followed by a reform of licensing laws for dentistry (A).

More programs for the continuing education and specialization of dentists should be offered under the co-ordination of regional dental associations, professional societies and universities. In analogy to the education, training and continuing education of dentists, the higher qualification of dental assistants should be improved (A).

The Council believes that the number of qualified personnel providing preventive care under the supervision of a dentist should be increased (A).

**386.** To improve the quality of consumer health protection, the Council believes that more pilot projects should be initiated and tested for their effectiveness and efficiency and continually optimized (B).

**387.** The Council also recommends increasing the research of dental care. Systematic evaluations of the results of quality controls can be used as a basis for optimizing the quality management of dental care, the continuing education of dentists and the education of the population (C). To provide an objective basis for dentists diagnoses, it is necessary to develop indices of treatment needs and apply them in practice to establish

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74 See Chapter 4.3 for a description of the rating system.

diagnosis classifications based on clinical findings that provide a more precise definition of the need for treatment than prior systems (D).

**388.** Removable braces are still predominant in orthodontic treatment even though fixed braces are known to lead faster to better results. The reform of the fee schedule for dentists should include a change in the fees for removable and fixed braces and prevent unnecessary overtreatment by defining fees for groups of services (B).

The rate of orthodontic treatment of juveniles is, at 60 percent, higher than all comparable international values, which range between 12.5 and 45 percent. The rate is even higher than the desire for treatment of the young patients. These striking differences speak for an objectivation of diagnostic findings on the basis of valid indices. The IOTN or the DAI could be used for this purpose (C). A more formal and binding use of second opinions could be used as a flanking measure.

**15. Appendix**

**15.1 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

Support for the Concerted Action; the 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, insufficient or inappropriate and identify opportunities for increasing efficiency. 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.

## 15.2 Surveyed organizations

### *Professional societies*

<b>Organization</b>	<b>Address</b>	<b>Response submitted</b>	<b>Copy of response on the homepage of the Advisory Council: <a href="http://www.svr-gesundheit.de">http://www.svr-gesundheit.de</a></b>
<i>Allgemeine Ärztliche Gesellschaft für Psychotherapie</i> General Medical Society for Psychotherapy	Postfach 22 12 80 41435 Neuss	X	X
<i>Allianz psychotherapeutischer Berufs- und Fachverbände<sup>a)</sup></i> Alliance of Associations of Psychotherapy Professionals <sup>a)</sup>	Gosslerstr. 14 37073 Göttingen	X	X
<i>Arbeitsgemeinschaft der Psychotherapeutenverbände in der Gesetzlichen Krankenversicherung -Richtlinienverbände-</i> Working Group of the Associations of Psychotherapists in the Social Health Insurance System - "Directives Association"	Salzstr. 52 48143 Münster		
<i>Arbeitsgemeinschaft für Verhaltensmodifikation e. V.<sup>a)</sup></i> Working Group for Behavioral Modification <sup>a)</sup>	Dr. Haas-Str. 4 96047 Bamberg	X	X
<i>Berufsverband der Kinder- und Jugendlichenpsychotherapeutinnen und Kinder- und Jugendlichenpsychotherapeuten e.V.<sup>a)</sup></i> Association of Pediatric and Juvenile Psychotherapists <sup>a)</sup>	Von-Rath-Str. 24 47051 Duisburg	X	X
<i>Bundesverband der Vertragspsychotherapeuten e.V.</i> National Association of SHI-certified Psychotherapists	Schwimmbadstr. 22 79100 Freiburg	X	X

<i>Deutsche Akademie für Kinderheilkunde und Jugendmedizin</i> German Academy for Pediatrics and Juvenile Medicine	Carl-Neuberg-Str. 1 30625 Hannover	X	X
<i>Deutsche Arbeitsgemeinschaft für Klinische Nephrologie</i> German Association for Clinical Nephrology	Pacelliallee 4 36043 Fulda		
<i>Deutsche ärztliche Gesellschaft für Verhaltenstherapie</i> German Medical Society for Behavioral Therapy	Nymphenburger Str. 185 80634 München		
<i>Deutsche Dermatologische Gesellschaft</i> German Dermatological Society	Hauptstr. 7 79104 Freiburg	X	X
<i>Deutsche Diabetes Gesellschaft</i> German Diabetes Society	Bürkle-de-la-Camp Platz 1 44789 Bochum	X	X
<i>Deutsche Fachgesellschaft für tiefenpsychologisch fundierte Psychotherapie e.V.<sup>a)</sup></i> German Professional Association for Psychotherapy based on Deep Psychology <sup>a)</sup>	Humboldtstr. 50a 22083 Hamburg	X	X
<i>Deutsche Gesellschaft für Allergologie und klinische Immunologie</i> German Society for Allergology and Clinical Immunology	Bledersteinerstr. 29 80802 München		
<i>Deutsche Gesellschaft für Allgemeinmedizin und Familienmedizin</i> German Society for General Medicine and Family Medicine	Moorenstr. 5/Geb. 14.97 40225 Düsseldorf	X	X
<i>Deutsche Gesellschaft für Analytische Psychologie<sup>b)</sup></i> German Society for Analytical Psychology <sup>b)</sup>	Holgenburg 2 73728 Esslingen	X	X

<i>Deutsche Gesellschaft für Analytische Psychotherapie und Tiefenpsychologie</i> German Society for Analytical Psychotherapy and Deep Psychology	Agnes-Grosche-Str. 41 06120 Halle		
<i>Deutsche Gesellschaft für Anästhesiologie und Intensivmedizin</i> German Society for Anesthesiology and Intensive Care Medicine	Roritzerstr. 27 90419 Nürnberg	X	X
<i>Deutsche Gesellschaft für Andrologie</i> German Society for Andrology	Gaffkystr.14 35385 Giessen	X	X
<i>Deutsche Gesellschaft für Angiologie</i> German Society for Angiology	Fetscherstr. 74 01307 Dresden	X	X
<i>Deutsche Gesellschaft für Arbeitsmedizin und Umweltmedizin</i> German Society for Occupational Medicine and Environmental Medicine	Ratzeburger Allee 160 23538 Lübeck		
<i>Deutsche Gesellschaft für Chirurgie</i> German Surgical Society	Moorenstr. 5 40225 Düsseldorf	X	X
<i>Deutsche Gesellschaft für Endokrinologie</i> German Society for Endocrinology	Deutschhausstr. 1-2 35037 Marburg	X	X
<i>Deutsche Gesellschaft für Ernährungsmedizin</i> German Society for Clinical Nutrition	Sauerbruchstr. 7 38440 Wolfsburg		
<i>Deutsche Gesellschaft für Experimentelle und Klinische Pharmakologie und Toxikologie</i> German Society for Experimental and Clinical Pharmacology and Toxicology	Fahrstr. 17 91054 Erlangen	X	X

<i>Deutsche Gesellschaft für Gefäßchirurgie</i> German Society for Vascular Surgery	Röntgenstr. 1 88048 Friedrichshafen		
<i>Deutsche Gesellschaft für Geriatrie</i> German Society for Geriatrics	Am Falder 6 40589 Düsseldorf		
<i>Deutsche Gesellschaft für Gerontologie und Geriatrie / Gesellschaft für Geriatriische Medizin</i> German Society for Gerontology and Geriatrics / Society for Geriatric Medicine	Germaniastr. 3 45356 Essen	X	X
<i>Deutsche Gesellschaft für Gerontopsychiatrie und -psychotherapie e.V.</i> German Society for Gerontological Psychiatry and Psychotherapy	Von-Siebold-Str. 5 37075 Göttingen	X	X
<i>Deutsche Gesellschaft für Gynäkologie und Geburtshilfe e.V.</i> German Society for Gynecology and Obstetrics	Pettenkoferstr. 35 80336 München	X	X
<i>Deutsche Gesellschaft für Hals-Nasen-Ohren-Heilkunde, Kopf- und Hals-Chirurgie</i> German Society for Otolaryngology, Head and Neck Surgery	Hittorfstr. 7 53129 Bonn	X	X
<i>Deutsche Gesellschaft für Hämatologie und Onkologie</i> German Society for Hematology and Oncology	Ernst-Grube-Str. 40 06120 Halle	X	X
<i>Deutsche Gesellschaft für Handchirurgie</i> German Society for Hand Surgery	Hohe Weide 17 20259 Hamburg	X	X
<i>Deutsche Gesellschaft für Humangenetik e.V.</i> German Society for Human Genetics	Augustenburger Platz 1 13353 Berlin	X	X

<i>Deutsche Gesellschaft für Hygiene und Mikrobiologie</i> German Society for Hygiene and Microbiology	J.-Schneider-Str. 2/ Bau 17 97080 Würzburg	X	X
<i>Deutsche Gesellschaft für Immunogenetik</i> German Society for Immunity Genetics	Delitzscherstr. 135 04129 Leipzig		
<i>Deutsche Gesellschaft für Individualpsychologie<sup>b)</sup></i> Germany Society for Individual Psychology <sup>b)</sup>	Ruhrstr. 39 58452 Witten	X	X
<i>Deutsche Gesellschaft für Infektiologie e.V.</i> German Society for Infectious Diseases	Delitzscherstr. 141 4129 Leipzig	X	X
<i>Deutsche Gesellschaft für Innere Medizin</i> German Society for Internal Medicine	Klinikstr. 36 35392 Giessen	(X)	
<i>Deutsche Gesellschaft für Internistische Intensivmedizin und Notfallmedizin</i> German Society for Internal Intensive Medicine and Emergency Medicine	Marchionistr. 15 81377 München		
<i>Deutsche Gesellschaft für Kardiologie - Herz- und Kreislaufforschung</i> German Cardiac Society	Albert-Schweitzer-Str. 33 48129 Münster	X	X
<i>Deutsche Gesellschaft für Kieferorthopädie e. V.</i> German Society for Orthodontics	Uniklinikum (Haus 29) 60590 Frankfurt am Main	Declined participation	
<i>Deutsche Gesellschaft für Kinder- und Jugendpsychiatrie und -psychotherapie e.V.</i> German Society for Juvenile and Adolescent Psychiatry and Psychotherapy	Hans-Sachs-Str. 6 35033 Marburg	X	X

<i>Deutsche Gesellschaft für Kinderchirurgie</i> German Society for Pediatric Surgery	Widumerstr. 8 44627 Herne	X	X
<i>Deutsche Gesellschaft für Kinderheilkunde und Jugendmedizin</i> German Society for Pediatrics and Adolescent Medicine	Holwedestr. 16 38118 Braunschweig	X	X
<i>Deutsche Gesellschaft für Klinische Chemie e.V.</i> German Society for Clinical Chemistry	Moltkestr. 90 76133 Karlsruhe	X	X
<i>Deutsche Gesellschaft für Klinische Neurophysiologie (EEG-Gesellschaft)</i> German Society for Clinical Neurophysiology	Heidelberger Landstr. 379 64297 Darmstadt		
<i>Deutsche Gesellschaft für Klinische Pharmakologie und Therapie e.V.</i> German Society for Clinical Pharmacology and Therapy	Schaal 26 35435 Wettenberg		
<i>Deutsche Gesellschaft für Krankenhaushygiene</i> German Society for Hospital Hygiene	Henkelstr. 67 40589 Düsseldorf		
<i>Deutsche Gesellschaft für Laboratoriumsmedizin</i> German Society for Laboratory Medicine	Albert-Schweitzer-Str. 33 48149 Münster	X	
<i>Deutsche Gesellschaft für Manuelle Medizin e.V.</i> German Society for Manual Medicine	Obere Rheingasse 56154 Boppard	X	X
<i>Deutsche Gesellschaft für Medizinische Informatik, Biometrie und Epidemiologie</i> German Society for Medical Informatics, Biometrics and Epidemiology	Joseph-Stelzmann-Str. 9 50931 Köln	X	X

<i>Deutsche Gesellschaft für Medizinische Psychologie</i> German Society for Medical Psychology	Liebigstr. 21 4103 Leipzig		
<i>Deutsche Gesellschaft für Medizinische Soziologie</i> German Society for Medical Sociology	Hebelstr. 29 79104 Freiburg		
<i>Deutsche Gesellschaft für Mund-, Kiefer- und Gesichtschirurgie</i> Germany Society for Oral, Facial and Maxillo Surgery	Richmodstr. 10 50667 Köln	X	X
<i>Deutsche Gesellschaft für Neurochirurgie</i> German Society for Neurosurgery	Moorenstr. 5 40225 Düsseldorf	X	X
<i>Deutsche Gesellschaft für Neurologie</i> German Society for Neurology	Lohmühlenstr. 5 20099 Hamburg	X	X
<i>Deutsche Gesellschaft für Neuropathologie und Neuroanatomie</i> German Society for Neuropathology and Neuroanatomy	Langenbeckstr. 1 55131 Mainz	X	X
<i>Deutsche Gesellschaft für Neuroradiologie</i> German Society for Neuroradiology	Breisacher Str. 64 79106 Freiburg	X	X
<i>Deutsche Gesellschaft für Nuklearmedizin</i> German Society for Nuclear Medicine	Hugstetter Str. 55 79106 Freiburg	X	X
<i>Deutsche Gesellschaft für Orthopädie und Traumatologie</i> German Society for Orthopedics and Traumatology	Pauwelsstr. 30 52074 Aachen	X	X
<i>Deutsche Gesellschaft für Osteologie</i> German Society for Osteology	Postfach 11 29 85764 Neuherberg		

<i>Deutsche Gesellschaft für Pädiatrische Infektiologie e.V.</i> German Society for Pediatric Infectious Diseases	Oststr. 21-25 04317 Leipzig	X	X
<i>Deutsche Gesellschaft für Pädiatrische Kardiologie</i> German Society for Pediatric Cardiology	Hufelandstr. 44 45122 Essen	X	X
<i>Deutsche Gesellschaft für Pädiatrische Radiologie</i> German Society for Pediatric Radiology	Lutherplatz 40 47806 Krefeld		
<i>Deutsche Gesellschaft für Palliativmedizin</i> German Society for Palliative Medicine	Mühlenstr. 1 24937 Flensburg		
<i>Deutsche Gesellschaft für Pathologie e.V.</i> German Society for Pathology	Krankenhausstr. 8-10 91054 Erlangen	X	X
<i>Deutsche Gesellschaft für Pharmazeutische Medizin e.V.</i> German Society for Pharmaceutical Medicine	Schubertstr. 38 63069 Offenbach	X	X
<i>Deutsche Gesellschaft für Phlebologie</i> German Society for Phlebology	Lippestr. 9-11 26548 Norderney	X	X
<i>Deutsche Gesellschaft für Phoniatrie und Pädaudiologie</i> German Society for Phoniatriy and Pediatric Audiology	Robert-Koch-Str. 40 37075 Göttingen	X	X
<i>Deutsche Gesellschaft für Physikalische Medizin und Rehabilitation, Balneologie und medizinische Klimatologie</i> German Society for Physical Medicine and rehabilitation, Balneology and Medical Climatology	Englschalkingerstr. 77 81925 München		
<i>Deutsche Gesellschaft für Plastische und Wiederherstellungschirurgie</i> German Society for Plastic and Restorative Surgery	Elise-Averdieck-Str. 17 27356 Rothenburg		

<i>Deutsche Gesellschaft für Pneumologie</i> German Society for Pulmonology	Universitätsklinikum 66421 Homburg/Saar	X	X
<i>Deutsche Gesellschaft für Psychiatrie, Psychotherapie und Nervenheilkunde</i> German Society for Psychiatry, Psychotherapy and Nerve Medicine	Pauwelsstr. 30 52074 Aachen	X	X
<i>Deutsche Gesellschaft für Psychoanalyse, Psychotherapie, Psychosomatik und Tiefenpsychologie e.V.<sup>b)</sup></i> German Society for Psychoanalysis, Psychotherapy, Psychosomatics and Deep Psychology <sup>b)</sup>	Goetheallee 8 37073 Göttingen	X	X
<i>Deutsche Gesellschaft für psychologische Schmerztherapie und -forschung<sup>a)</sup></i> German Society for Psychological Pain Therapy and research <sup>a)</sup>	Bunsenstr. 3 35037 Marburg	X	X
<i>Deutsche Gesellschaft für Psychosomatische Geburtshilfe und Gynäkologie e.V.</i> German Society for Psychosomatic Obstetrics and Gynecology	Luisenstr. 57 10117 Berlin	X	X
<i>Deutsche Gesellschaft für Psychotherapeutische Medizin</i> German Society for Psychotherapeutic Medicine	Marsbruchstr. 179 44287 Dortmund	X	X
<i>Deutsche Gesellschaft für Public Health e. V.</i> German Society for Public Health	Universitätsstr. 25 33615 Bielefeld	X	X
<i>Deutsche Gesellschaft für Radioonkologie e.V.</i> German Society for Radiooncology	Fetscherstr. 74 01307 Dresden	X	X

<i>Deutsche Gesellschaft für Rechtsmedizin</i> German Society for Forensic Medicine	Von-Esmarch-Str. 62 48149 Münster	X	X
<i>Deutsche Gesellschaft für Rehabilitationswissenschaften</i> German Society for Rehabilitation Science	Martinistr. 52- Pav.69 20246 Hamburg		
<i>Deutsche Gesellschaft für Rheumatologie</i> German Society for Rheumatology	Röntgentaler Weg 66 13125 Berlin		
<i>Deutsche Gesellschaft für Schlafforschung und Schlafmedizin</i> German Society for Sleep Research and Sleep Medicine	Schimmelpfengstr. 2 34613 Schwalmstadt-Treysa	X	X
<i>Deutsche Gesellschaft für Senologie</i> German Society for Breast Pathology	Pilgrimstein 3 35037 Marburg	X	X
<i>Deutsche Gesellschaft für Sexualforschung e.V.<sup>a)</sup></i> German Society for Sexual Research <sup>a)</sup>	Martinistr. 52 20246 Hamburg	X	X
<i>Deutsche Gesellschaft für Sozialmedizin und Prävention</i> German Society for Social Medicine and Prevention	Leipziger Str. 44 39120 Magdeburg		
<i>Deutsche Gesellschaft für Sportmedizin und Prävention e.V.</i> German Society for Sports Medicine and Prevention	Hölderlinstr. 11 72074 Tübingen	X	X
<i>Deutsche Gesellschaft für Suchtforschung und Suchttherapie</i> German Society for Addiction Research and Therapy	Wilhelmstr. 125 59067 Hamm		
<i>Deutsche Gesellschaft für Thorax-, Herz- und Gefäßchirurgie</i> German Society for Thoracic and Cardiovascular Surgery	Parkstr. 1 61231 Band Nauheim		

<i>Deutsche Gesellschaft für Thoraxchirurgie</i> German Society for Thoracic Surgery	Zum Heckeshorn 33 14109 Berlin	X	X
<i>Deutsche Gesellschaft für Transfusionsmedizin und Immunhämatologie</i> German Society for Transfusion Medicine and Immunohematology	Krankenhausstr. 12 91054 Erlangen		
<i>Deutsche Gesellschaft für Tropenmedizin und Internationale Gesundheit</i> German Society for Tropical Medicine and International Health	Keplerstr. 15 72074 Tübingen	X	X
<i>Deutsche Gesellschaft für Unfallchirurgie e.V.</i> German Society for Emergency Medicine	Stenglinstr. 1 86156 Augsburg	X	X
<i>Deutsche Gesellschaft für Urologie</i> German Society for Urology	Ürdingerstr. 64 40474 Düsseldorf		
<i>Deutsche Gesellschaft für Verbrennungsmedizin</i> German Society for Burn Medicine	Berufsgenossenschaftliche Unfallklinik 67071 Ludwigshafen	X	X
<i>Deutsche Gesellschaft für Verdauungs- und Stoffwechselkrankheiten</i> German Society for Digestive and Metabolic Diseases	Carl-Neuberg-Str. 1 30625 Hannover		
<i>Deutsche Gesellschaft für Verhaltenstherapie e.V. <sup>a)</sup></i> German Society for Behavioral Thereapy <sup>a)</sup>	Neckarhalde 55 72070 Tübingen	X	X
<i>Deutsche Gesellschaft für Zahn-, Mund- und Kieferheilkunde</i> German Society for Dental, Oral and Orthodontic Care	Wimphelingstr. 7 67346 Speyer	X	X
<i>Deutsche Gesellschaft für Zytologie</i> German Society for Cytology	Albertstr. 19 79104 Freiburg		

<i>Deutsche Gesellschaft zum Studium des Schmerzes e.V.</i> German Society for the Study of Pain	Joseph-Stelzmann Str. 9 50924 Köln	X	X
<i>Deutsche Hypertonie Gesellschaft / Deutsche Liga zur Bekämpfung des hohen Blutdrucks e.V.</i> German Hypertension Society / German League Against Hypertension	Berliner Str. 46 69120 Heidelberg	X	X
<i>Deutsche Interdisziplinäre Vereinigung für Intensiv- und Notfallmedizin</i> German Interdisciplinary Association for Intensive Care and Emergency Medicine	Langenbeckstr. 1 55131 Mainz	X	X
<i>Deutsche Interdisziplinäre Vereinigung für Schmerztherapie</i> German Interdisciplinary Association for Pain Therapy	Schwanenweg 21 24105 Kiel		
<i>Deutsche Krebsgesellschaft</i> German Cancer Society	Hanauer Landstr. 194 60314 Frankfurt/Main		
<i>Deutsche Ophthalmologische Gesellschaft</i> German Ophthalmological Society	Berliner Str. 14 69120 Heidelberg		
<i>Deutsche Psychoanalytische Vereinigung e.V.<sup>b)</sup></i> German Psychoanalysis Association <sup>b)</sup>	Körnerstr. 11 10785 Berlin	X	X
<i>Deutsche Psychologische Gesellschaft für Gesprächspsychotherapie<sup>a)</sup></i> German Psychological Society for Psychotherapy <sup>a)</sup>	Von-Melle Park 5 20146 Hamburg	X	X
<i>Deutsche Röntgengesellschaft, Gesellschaft für Medizinische Radiologie e.V.</i> German Radiology Society, Society for Medical Radiology	Postfach 13 36 61283 Bad Homburg		

<i>Deutsche Transplantationsgesellschaft</i> German Transplantation Society	Hugstetter Str. 55 79106 Freiburg i.Br.	X	X
<i>Deutscher Fachverband für Verhaltenstherapie</i> German Professional Association for Behavioral Therapy	Salzstr. 52 48143 Münster		
<i>Deutscher Psychotherapeutenverband e.V.</i> <sup>a)</sup> German Association of Psychotherapists <sup>a)</sup>	Am Karlsbad 15 10785 Berlin	X	X
<i>Deutsches Kollegium für Psychosomatische Medizin</i> German College for Psychosomatic Medicine	Stoyst. 3 07740 Jena	X	X
<i>Fachgruppe Klinische Psychologie und Psychotherapie der Deutschen Gesellschaft für Psychologie</i> <sup>a)</sup> Expert Group on Clinical Psychology and Psychotherapy of the German Psychology Society	Gosslerstr. 14 37073 Göttingen	X	X
<i>Gesellschaft für Arzneimittel- anwendungs- forschung und Arzneimittel- epidemiologie</i> Society for the Research of the Use of Medicines and Pharmaceutical Epidemiology	Fiedlerstr. 27 01307 Dresden		
<i>Gesellschaft für Neonatologie und Pädiatrische Intensiv- medizin</i> Society for Neonatology and Pediatric Intensive Care Medicine	Wiener Str. o.Nr. 39112 Magdeburg	X	X
<i>Gesellschaft für Nephrologie</i> Society for Nephrology	Augustenburger Platz 1 13353 Berlin		
<i>Gesellschaft für Neuropädiatrie</i> Society for Neuropediatrics	Dr. Friedrich-Steiner-Str.5 45711 Datteln		
<i>Gesellschaft für Neuropsychologie e.V.</i> <sup>a)</sup> Society for Neuropsychology <sup>a)</sup>	Dr. Born-Str. 9 34537 Bad Wildungen	X	X

<i>Gesellschaft für Thrombose- und Hämostaseforschung e.V.</i> Society for the Research of Thrombosis and Hemioistasis	Ziemssenstr. 1 80336 München	X	X
<i>Gesellschaft für Virologie</i> Society for Virology	Robert-Koch-Str. 17 35037 Marburg	X	X
<i>Max-Planck-Institut für Psychiatrie</i> Max Planck Institute for Psychiatry	Kraepelinstr. 2-10 80804 München	X	X
<i>Milton Erickson Gesellschaft für Klinische Hypnose<sup>a)</sup></i> Milton Erickson Society for Clinical Hypnosis <sup>a)</sup>	Eppendorfer Landstr. 56 20249 Hamburg	X	X
<i>Verband der Vertragspsychotherapeuten Südwürttemberg</i> Association of SHI Certified Psychotherapists in Southern Wuerttemberg	Nikolaiplatz 3 72764 Reutlingen	X	X
<i>Verband für integrative Verhaltenstherapie e. V.</i> Association for Integrative Behavioral Therapy	Kastanienallee 80 15907 Lübben		
<i>Vereinigung Analytischer Kinder- und Jugendlichen-Psychotherapeuten</i> Association of Analytic Psychiatherapists for Juveniles and Adolescents	Birkholzweg 8 60433 Frankfurt am Main	X	X
<i>Vereinigung der Kassenspsychotherapeuten</i> Association of SHI-certified Psychotherapists	Riedsaumstr. 4a 67063 Ludwigshafen	X	X
<i>Vereinigung für Operative und Onkologische Dermatologie</i> Association for Operative and Oncological Dermatology	Fetscherstr. 74 01307 Dresden		
<i>Vereinigung psychotherapeutisch tätiger Kassenärzte</i> Associations of SHI Doctors for Psychotherapy	Kurbrunnenstr. 21a 67098 Bad Dürkheim		

### *Patient Groups*

<b>Organization</b>	<b>Address</b>	<b>Response submitted</b>	<b>Copy of response on the homepage of the Advisory Council: <a href="http://www.svr-gesundheit.de">http://www.svr-gesundheit.de</a></b>
<i>Aktionskomitee KIND IM KRANKENHAUS</i> Action Committee "Kids in Clinics"	Kirchstr. 34 61440 Oberursel	X	X
<i>Arbeitsgemeinschaft Allergierkrankes Kind- Hilfen für Asthma, Ekzem oder Heuschnupfen e.V.</i> Coalition "Children with Allergies - Support for Asthma, Eczema and Hay Fever"	Nassaustr. 32 35745 Herborn	X	X
<i>Arbeitsgemeinschaft Spina-bifida und Hydrocephalus e.V.</i> Coalition on Spina Bifida and Hydrocephalus	Münsterstr. 13 44145 Dortmund		
<i>Arbeitskreis der Pankreat-ektomierten e.V.</i> Working Group of People without a Pancreas	Krefelder Str. 52 41539 Dormagen		
<i>Arbeitskreis Kunstfehler in der Geburtshilfe e.V.</i> Working Group on Malpractice in Obstetrics	Rheinhöhenweg 75 53424 Remagen		
<i>Bund diabetischer Kinder und Jugendlicher e.V.</i> Association of Diabetic Children and Adolescents	Hahnbrunnerstr. 46 67659 Kaiserslautern		
<i>Bundesarbeitsgemeinschaft Kind und Krankenhaus e.V.</i> National Coalition "Children and Hospitals"	Dr. Friedrich-Steiner-Str.5 45711 Datteln	X	X
<i>Bundesinteressengemeinschaft Geburtshilfe-geschädigter e.V.</i> National Interest Group of Victims of Obstetric Damages	Nordseher Str.30 31655 Stadthagen	X	X

<i>Bundesselbsthilfeverband für Osteoporose e.V.</i> National Self-Help Association for Osteoporosis	Kirchfeldstr. 149 40215 Düsseldorf	X	X
<i>Bundesverband der Angehörigen psychisch Kranker e.V.</i> National Association of the Families of Persons with Mental Health Problems	Thomas-Mann-Str. 49a 53111 Bonn		
<i>Bundesverband der Kehlkopfloren e.V.</i> National Association of Laryngectomy Patients	Obererle 65 45897 Gelsenkirchen-Buer		
<i>Bundesverband der Organtransplantierten e.V.</i> National Association of Organ Transplant Recipients	Paul-Rücker-Str. 22 47059 Duisburg	X	X
<i>Bundesverband für die Rehabilitation der Aphasiker</i> National Association for the Rehabilitation of Aphasics	Robert-Koch-Str. 34 97080 Würzburg		
<i>Bundesverband für Körper- und Mehrfachbehinderte e.V.</i> National Association for Persons with Physical and Multiple Handicaps	Brehmstr. 5-7 40239 Düsseldorf	X	X
<i>Bundesverband Herzkranker Kinder e.V.</i> National Association for Children with Heart Disease	Robensstr. 20-22 52070 Aachen	X	X
<i>Bundesverband Hilfe für das autistische Kind – Verein zur Förderung autistischer Menschen e.V.</i> National Association "Support for Austistic Children" - Group for the support of autistic children	Bebelallee 141 22297 Hamburg		
<i>Bundesverband Neurodermitiskranker in Deutschland e.V.</i> National Association of Neurodermitis Patients in Germany	Oberstr. 171 56154 Boppard	X	X

<i>Bundesverband Poliomyelitis e.V.</i> National Association for Poliomyelitis	Alisostr. 67 59192 Bergkamen	X	X
<i>Bundesverband Psychiatrie-Erfahrener e. V.</i> National Association of Mental Health Patients	Thomas-Mann-Str. 49a 53111 Bonn	X	X
<i>Bundesverband Schädel-Hirn-Patienten in Not e.V.</i> National Association "Patients with Cranial and Brain Injuries in Need"	Bayreuther Str. 33 92224 Amberg		
<i>Bundeverband Selbsthilfe Körperbehinderter e.V.</i> National Association "Self-Help of the Physically Handicapped"	Postfach 20 71236 Krautheim/Jagst		
<i>Bundesverband Skoliose-Selbsthilfe e.V.</i> National Association "Scoliosis Self-Help"	Weisskirchener Str. 4 71067 Sindelfingen	X	X
<i>Bundesvereinigung Lebenshilfe für Menschen mit geistiger Behinderung</i> National Association for the Support of People with Mental Handicaps	Raiffeisenstr. 18 35043 Marburg		
<i>Bundesvereinigung Stotterer-Selbsthilfe e.V.</i> National Association "Stutterers' Self-Help"	Gereonswall 112 50670 Köln	X	X
<i>CF-Selbsthilfe Bundesverband e.V. – Hilfe bei Mukoviszidose</i> CF- Self-Help Association - Support for Patients with Cystic Fibrosis	Meyerholz 3a 28832 Achim	X	X
<i>Dachverband Psychosozialer Hilfsvereinigungen e.V.</i> National Association of Psycho-social Support Groups	Thomas-Mann-Str. 49a 53111 Bonn		
<i>Deutsche Aids-Hilfe e.V.</i> German AIDS Support	Dieffenbachstr. 33 10967 Berlin	X	X

<i>Deutsche Alzheimer Gesellschaft e.V.</i> German Alzheimer Society	Friedrichstr. 236 10969 Berlin	X	X
<i>Deutsche Epilepsievereinigung e.V.</i> German Epilepsy Association	Zillestr. 102 10585 Berlin	X	
<i>Deutsche Gesellschaft für Muskelkranke e.V.</i> German Society for Patients with Muscular Diseases	Im Moos 4 79112 Freiburg i. Br.	X	X
<i>Deutsche Gesellschaft zur Bekämpfung von Fettstoffwechselstörungen und ihren Folgeerkrankungen e.V.</i> German Society for the Treatment of Metabolic Disorders and Resulting Diseases	Waldklausenweg 20 81377 München	X	X
<i>Deutsche Gesellschaft zur Förderung der Gehörlosen und Schwerhörigen e.V.</i> German Society for the Promotion of the Deaf and the Hard of Hearing	Niemöllerallee 18 81739 München		
<i>Deutsche Hämophiliegesellschaft zur Bekämpfung von Blutungskrankheiten e.V.</i> German Society for the Treatment of Hemophilia	Halenseering 3 22149 Hamburg	X	Declined participation
<i>Deutsche Herzstiftung e.V.</i> German Heart Foundation	Vogtstr. 50 60322 Frankfurt am Main	X	X
<i>Deutsche Ileostomie Colostomie Urostomie Vereinigung</i> German Association of Ileostomy, Colostomy and Urostomy Patients	Landshuter Str. 30 85356 Freising	X	X
<i>Deutsche Interessengemeinschaft für Verkehrsunfallopfer</i> German Coalition for the Victims of Traffic Accidents	Friedlandstr. 6 41747 Viersen	X	X

<i>Deutsche Gesellschaft für Patienten mit PKU und verwandten angeborenen Stoffwechselstörungen e.V.</i> German Society for Patients with PKU and other Congenital Metabolic Disorders	Adlerstr.6 91077 Kleinsendelbach	X	X
<i>Deutsche Leberhilfe e.V.</i> German Liver Support	Möserstr. 56 49074 Osnabrück	X	X
<i>Deutsche Leukämie-Forschungshilfe, Aktion für Krebskranke Kinder e.V.</i> German Fund for the Support of Leukemia Research, Action for Children with Cancer	Joachimstr. 20 53113 Bonn		
<i>Deutsche Leukämie-Hilfe, Bundesverband der Selbsthilfeorganisationen zur Unterstützung von Erwachsenen mit Leukämien und Lymphomen</i> German Leukemia Fund, National Association of Self-Help Organizations for the Support of Adults with Leukemia and Lymphoma	Johanna-Kirchner-Str. 12 31139 Hildesheim	X	X
<i>Deutsche Morbus Crohn / Colitis ulcerosa Vereinigung e.V.</i> German Morbus Cron /Colitis Ulcerosa Association	Paracelsusstr. 15 51375 Leverkusen		
<i>Deutsche Multiple Sklerose Gesellschaft</i> German Multiple Sclerosis Society	Vahrenwalder Str.205-207 30165 Hannover	X	X
<i>Deutsche Myasthenie Gesellschaft e.V.</i> German Myasthenia Society	Langemarckstr. 106 28299 Bremen		
<i>Deutsche Parkinson Vereinigung e.V.</i> German Parkinson Association	Poststr. 7 64354 Reinheim	X	X
<i>Deutsche Rheuma-Liga Bundesverband e.V.</i> German Rheuma League	Maximilianstr. 14 53111 Bonn	X	X
<i>Deutsche Tinnitus-Liga e.V.</i> German Tinnitus League	Postfach 21 03 51 42353 Wuppertal	X	X

<i>Deutsche Vereinigung Morbus Bechterew e.V.</i> German Association "Morbus Bechterew"	Metzgerstr. 16 97421 Schweinfurt	Declined participation	
<i>Deutsche Zöliakie-Gesellschaft e.V.</i> German Gee-Thayson Society	Filderhauptstr. 61 70599 Stuttgart	X	X
<i>Deutscher Allergie- und Asthmabund e.V.</i> German Allergy and Asthma Association	Hindenburgstr. 110 41061 Mönchengladbach		
<i>Deutscher Blinden- und Sehbehindertenverband e.V.</i> German Association of the Blind and Visually Impaired	Bismarckallee 30 53173 Bonn	Declined participation	
<i>Deutscher Diabetiker-Bund e.V.</i> German Diabetics Society	Danziger Weg 1 58511 Lüdenscheid	X	X
<i>Deutscher Gehörlosen Bund e.V.</i> German Association of the Deaf	Paradeplatz 3 24768 Rendsburg		
<i>Deutscher Neurodermitiker-Bund e.V.</i> German Association of Patients with Neurodermitis	Spaldingstr. 210 20097 Hamburg	Declined participation	
<i>Deutscher Psoriasis Bund e.V.</i> German Psoriasis Association	Oberaltenallee 20a 22081 Hamburg	X	X
<i>Deutscher Schwerhörigenbund e.V.</i> German Association of Persons with Impaired Hearing	Breite Str. 3 13187 Berlin	X	X
<i>Deutsches Hepatitisforum e. V.</i> German Hepatitis Forum	Postfach 20 01 08 41201 Mönchengladbach	X	X
<i>Dialysepatienten Deutschlands e.V.</i> Dialysis Patients in Germany	Weberstr. 2 55130 Mainz	X	X
<i>Frauenseלבsthilfe nach Krebs Bundesverband e.V.</i> Women's Cancer Self-Help Group	B6, 10/11 68159 Mannheim	Declined participation	

<i>Interessengemeinschaft Fragiles-X e. V.</i> Coalition "Fragile-X"	Marlenestr. 39 13505 Berlin	X	
<i>Kuratorium für Dialyse- und Nierentransplantation e.V.</i> Curatorium for Dialysis and Kidney Transplant	Martin-Behaim-Str. 20 63263 Neu-Isenburg	Declined participation	
<i>Kuratorium ZNS für Unfall- verletzte mit Schäden des zen- tralen Nervensystems e.V.</i> Curatorium CNS for Accident Victims with Injuries to the Central Nervous System	Rochusstr. 24 53123 Bonn	X	X
<i>Mukoviszidose e.V.</i> Cystic Fibrosis	Bendenweg 101 53121 Bonn	X	X
<i>Pro Retina Deutschland e.V.</i> Pro Retina Germany	Lutherstr. 4-6 61231 Bad Nauheim	X	X
<i>Schilddrüsen-Liga Deutsch- land e.V.</i> Thyroid League Germany	Matthias-Grünewald- Str. 11 53175 Bonn	X	X
<i>Selbsthilfevereinigung für Lip- pen-Gaumen Fehlbildungen</i> Self-Help Group for Patients with Lip and Palate Deformi- ties	Hauptstr. 184 35625 Hüttenberg		
<i>Verband arbeits- und berufsbedingt Erkrankter</i> Association of Patients with Occupational Diseases	Industriestr. 17 63647 Altenstadt		

*Member of the Concerted Action in Health Care and other groups*

<b>Organization</b>	<b>Address</b>	<b>Response submitted</b>	<b>Copy of response on the homepage of the Advisory Council: <a href="http://www.svr-gesundheit.de">http://www.svr-gesundheit.de</a></b>
<i>Aktion Psychisch Kranker - Vereinigung zur Reform der Versorgung psychisch Kranker</i> Action Group of Mental Health Patients - Association for the Reform of the Care of Mental Health Patients	Brungsgasse 4-6 53117 Bonn	X	X
<i>AOK-Bundesverband<sup>c)</sup></i> Federal Association of the AOK <sup>c)</sup>	Kortrijker Str. 1 53177 Bonn	X	X
<i>Arbeiterwohlfahrt Bundesverband e.V.</i> National Association of Workers' Relief	Oppelner Str. 130 53119 Bonn	X	X
<i>Arbeitgeber- und Berufsverband privater Pflege e.V.</i> Professional Association for Private Nursing	Roscher Str. 13a 30161 Hannover	Declined participation	
<i>Arbeitsgemeinschaft der Verbraucherverbände</i> Working Group of Consumer Protection Associations	Heilsbachstr. 20 53123 Bonn		
<i>Arbeitsgemeinschaft deutscher Schwesternverbände und Pflegeorganisationen e.V.</i> Working Group of German Nursing Associations	Reinhäuser Landstr. 19-21 37083 Göttingen		
<i>Arbeitskreis Depressionsstationen</i> Working Group of Depression Treatment Units	Nordring 2 95445 Bayreuth	X	X
<i>Ärztliche Zentralstelle Qualitätssicherung<sup>d)</sup></i> German Agency for Quality in Medicine <sup>d)</sup>	Aachener Str. 233-237 50931 Köln	X	X

<i>Bayerisches Staatsministerium für Arbeit, Sozialordnung, Familie, Frauen und Gesundheit</i> Bavarian State Ministry for Labor, Social Affairs, the Family, Women and Health	Winzererstr. 9 80797 München	X	X
<i>Behörde für Arbeit, Gesundheit und Soziales der Freien und Hansestadt Hamburg</i> Office for Labor, Health and Social Affairs of the City of Hamburg	Hamburger Str. 47 22083 Hamburg	X	X
<i>Berufsverband der Kinderkrankenschwestern und Kinderkrankenpfleger e.V.</i> Association of Pediatric Nurses	Janusz-Korczak-Allee 12 30173 Hannover	X	X
<i>Bund Deutscher Hebammen e.V.</i> Association of German Midwives	Steinhäuserstr. 22 76135 Karlsruhe	X	X
<i>Bund freiberuflicher Hebammen</i> Association of Independent Midwives	Am alten Nordkanal 9 41748 Viersen		
<i>Bundesarbeitsgemeinschaft der Freien Wohlfahrtspflege e.V.</i> National Working Group of Independent Social Services	Oranienburger Str. 13-14 10178 Berlin	Declined participation	
<i>Bundesarbeitsgemeinschaft der Heilmittelverbände e.V.</i> National Working Group of Therapist's Associations	Deutzer Freiheit 72-74 50679 Köln		
<i>Bundesarbeitsgemeinschaft für Rehabilitation</i> National Working Group for Rehabilitation	Walter-Kolb-Str. 9-11 60594 Frankfurt	X	X
<i>Bundesarbeitsgemeinschaft Hauskrankenpflege e.V.</i> National Working Group "Home Nursing"	Humboldtstr. 49b 14193 Berlin		

<i>Bundesarbeitsgemeinschaft Hilfe für Behinderte e.V.</i> National Working Group "Help for the Handicapped"	Kirchfeldstr. 149 40215 Düsseldorf	(X)	
<i>Bundesarbeitsgemeinschaft Leitender Krankenpflegepersonen e.V.</i> National Working Group of Nurse Managers	Ludwig-Erhard-Str. 100 65199 Wiesbaden	X	X
<i>Bundesärztekammer<sup>d)</sup></i> German Medical Association <sup>d)</sup>	Herbert-Lewin-Str. 1 50931 Köln	X	X
<i>Bundesdirektorenkonferenz Psychiatrischer Fachkrankenhäuser</i> National Conference of the Directors of Psychiatric Hospitals	Nordring 2 95445 Bayreuth	X	X
<i>Bundes(fach)verband der Arzneimittel-Hersteller e.V.</i> German Manufacturers' Association	Ublerstr. 71-73 53173 Bonn	X	X
<i>Bundesfachverband Medizinprodukte Industrie e.V.</i> German Medical Technology Association	Hasengartenstr. 14c 65189 Wiesbaden	X	X
<i>Bundesfachvereinigung Leitender Krankenpflegekräfte in der Psychiatrie e.V.</i> National Association of Nurse Managers in Psychiatric Hospitals	Meckerstr. 15 52353 Düren	X	X
<i>Bundesinstitut für Arzneimittel und Medizinprodukte</i> Federal Institute for Drugs and Medical Devices	Friedrich-Ebert-Allee 38-40 53113 Bonn	X	X
<i>Bundesknappschaft<sup>e)</sup></i> Miners' Provident Fund <sup>e)</sup>	Pieperstr. 14-28 44789 Bochum	X	X
<i>Bundesverband ambulanter Dienste</i> National Association of Home Care Providers	Krablerstr. 136 45326 Essen		

<i>Bundesverband Chiro-Gymnastik e.V</i> National Association "Chirogymnastics".	Gartenstr. 8 56414 Dreikirchen		
<i>Bundesverband der Betriebskrankenkassen<sup>c)</sup></i> Federal Association of Company Health Insurance Funds <sup>c)</sup>	Ebertstr. 24 10117 Berlin	X	X
<i>Bundesverband der Innungskrankenkassen<sup>c)</sup></i> National Association of Guild Health Funds <sup>c)</sup>	Friedrich-Ebert-Str. (Technologie-Park) 5149 Bergisch Gladbach	X	X
<i>Bundesverband der landwirtschaftlichen Krankenkassen<sup>c)</sup></i> National Association of Agricultural Sickness Funds <sup>c)</sup>	Weissensteinstr. 70-72 34131 Kassel	X	X
<i>Bundesverband der Pharmazeutischen Industrie e. V.</i> Association of the German Pharmaceutical Industry	Karlstr. 21 60329 Frankfurt/Main	X	X
<i>Bundesverband des Sanitätsfachhandels e.V.</i> German Association of Medical Supply Stores	Salierring 44 50677 Köln	X	X
<i>Bundesverband Deutscher Privatkrankenanstalten e.V.</i> German Association of Private Hospitals	Bundeskanzlerplatz 2-10 53113 Bonn	X	X
<i>Bundesverband für Rehabilitation und Interessenvertretung Behinderter e.V.</i> German Association for the Rehabilitation and Representation of the Interests of the Handicapped	Humboldtstr. 32 53115 Bonn		
<i>Bundesverband privater Alten- und Pflegeheime und ambulanter Dienste e.V.</i> German Association of Private Nursing Homes And Residences for the Elderly and Home Care Services	Wendestr. 377 20537 Hamburg	X	X

<i>Bundesverband privater Altenheime</i> National Association of Private Residences for the Elderly	Adolfsallee 59 65185 Wiesbaden		
<i>Bundesverband selbständiger PhysiotherapeutInnen</i> National Association of Independent Physiotherapists	Königsallee 178a 44799 Bochum	X	X
<i>Bundesvereinigung der Deutschen Arbeitgeberverbände</i> Confederation of German Employers' Associations	Breite Str. 29 10178 Berlin	X	X
<i>Bundesvereinigung Deutscher Apothekerverbände</i> Federation Union of German Associations of Pharmacists	Carl-Mannich-Str. 26 65760 Eschborn/Ts.	X	X
<i>Bundesversicherungsanstalt für Angestellte</i> Federal Social Security Office	Ruhrstr. 2 10704 Berlin	X	X
<i>Bundeszahnärztekammer<sup>e)</sup></i> German Dental Association	Universitätsstr. 71-73 50931 Köln	X	X
<i>Bundeszentrale für gesundheitliche Aufklärung</i> Federal Center for Health Education	Ostmerheimer Str. 220 51109 Köln	X	X
<i>Deutsche Angestellten-Gewerkschaft</i> German Union for Salaried Employees	Johannes-Brahms-Platz 1 20355 Hamburg		
<i>Deutsche Gesellschaft für Fachkrankenpflege e.V.</i> German Society for Professional Nursing Care	Hermann-Simon-Str. 7 33334 Gütersloh		
<i>Deutsche Gesellschaft für Medizinische Rehabilitation e.V.</i> German Society for Medical Rehabilitation	Buschstr. 22 53113 Bonn		
<i>Deutsche Gesellschaft für Soziale Psychiatrie e.V.</i> German Society for Social Psychiatry	Stuppstr. 14 50823 Köln		

<i>Deutsche Krankenhausgesellschaft</i> German Hospital Federation	Tersteegenstr. 9 40474 Düsseldorf	X	X
<i>Deutscher Beamtenbund</i> German Civil Service Federation	Peter-Hensen-Str. 5-7 53175 Bonn	Declined participation	
<i>Deutscher Berufsverband für Altenpflege e.V.</i> German Society for Geriatric Nurses	Sonnenwall 15 47051 Duisburg	X	X
<i>Deutscher Berufsverband für Pflegeberufe e.V.</i> German Society for the Nursing Professions	Hauptstr. 392 65760 Eschborn	X	X
<i>Deutscher Bundesverband für Logopädie</i> German Association for Speech Therapy	Augustinusstr. 9d 50220 Frechen	X	X
<i>Deutscher Caritasverband e.V.</i> German Caritas Association	Karlsstr. 40 79104 Freiburg i.Br.	X	X
<i>Deutscher Generika-Verband e.V.</i> German Generics Association	Hardtstr. 11 82436 Tauting	X	X
<i>Deutscher Gewerkschaftsbund</i> German Union Alliance	Burgstr. 29-30 10178 Berlin		
<i>Deutscher Heilbäderverband e.V.</i> Association of German Health Spas	Schumannstr. 11 53113 Bonn	X	X
<i>Deutscher Landkreistag</i> German Council of County Governments	Lennestr. 17 10785 Berlin	X	X
<i>Deutscher Paritätischer Wohlfahrtsverband Gesamtverband</i> German Non-Denominational Welfare Association	Heinrich-Hoffman-Str. 3 60528 Frankfurt am Main	X	X
<i>Deutscher Pflegerat</i> German Nursing Council	Postfach 31 03 80 10633 Berlin	X	X
<i>Deutscher Pflegeverband e.V.</i> German Nursing Association	Mittelstr. 1 56564 Neuwied		

<i>Deutscher Städte- und Gemeindebund</i> Association of German Cities and Municipalities	Marienstr. 6 12207 Berlin	Declined participation	
<i>Deutscher Städtetag</i> German Council of Municipal Governments	Lindenallee 13-17 50968 Köln	X	X
<i>Deutscher Verband der Ergotherapeuten e.V.</i> German Association for Ergo-therapists	Postfach 22 08 76303 Karlsbad	X	X
<i>Deutscher Verband der Leitungskräfte von Alten- und Behinderteneinrichtungen</i> German Association of Ad-ministrators of Facilities for the Elderly and the Handi-capped	Heineckeweg 15 13627 Berlin	Declined participation	
<i>Deutscher Verband für Physiotherapie - Zentralverband der Physiotherapeuten / Krankengymnasten e.V.</i> German Association for Physiotherapy - Central Association of Physiotherapists	Postfach 21 02 80 50528 Köln	X	X
<i>Deutsches Rotes Kreuz</i> German Red Cross	Friedrich-Ebert-Allee 71 53113 Bonn		
<i>Diakonisches Werk der Evang. Kirche in Deutschland e.V.</i> Deaconat of the Protestant Church in Germany	Stafflenbergerstr. 76 70184 Stuttgart	X	X
<i>Gesellschaft für Epilepsie-forschung e.V., Bethel</i> Society for the Research of Epilepsy, Bethel	Maraweg 21 33617 Bielefeld	X	X
<i>Hessisches Sozialministerium</i> Social Ministry of the state of Hesse	Postfach 31 40 65021 Wiesbaden	X	X
<i>Kassenärztliche Bundesver-einigung<sup>d)</sup></i> National Association of Statu-tory Health Insurance Physi-cians <sup>d)</sup>	Herbert-Lewin-Str. 3 50931 Köln	X	X

<p><i>Kassenzahnärztliche Bundesvereinigung<sup>e)</sup></i> National Association of Statutory Health Insurance Dentists<sup>e)</sup></p>	<p>Universitätsstr. 71-73 50931 Köln- Lindenthal</p>	X	X
<p><i>Medizinischer Dienst der Spitzenverbände der Krankenkassen e.V.<sup>c)</sup></i> Medical Advisory Service of Social Health Insurance<sup>c)</sup></p>	<p>Lützowstr. 53 45141 Essen</p>	X	X
<p><i>Ministerium für Arbeit, Frauen, Gesundheit und Soziales des Landes Sachsen-Anhalt</i> Ministry for Labor, Women, Health and Social Affairs of Saxony-Anhalt</p>	<p>Seepark 5-7 39116 Magdeburg</p>	Declined participation	
<p><i>Ministerium für Arbeit, Gesundheit und Soziales des Landes Schleswig-Holstein</i> Ministry for Labor, Health and Social Affairs of Schleswig-Holstein</p>	<p>Adolf-Westphal-Str. 4 24143 Kiel</p>	X	X
<p><i>Ministerium für Arbeit, Soziales und Gesundheit Rheinland-Pfalz</i> Ministry for Labor, Social Affairs and Health of the Rhineland-Palatinate</p>	<p>Bauhofstr. 9 55116 Mainz</p>	Declined participation	
<p><i>Ministerium für Arbeit, Soziales, Gesundheit und Frauen des Landes Brandenburg</i> Ministry for Labor, Social Affairs and Health of Brandenburg</p>	<p>Heinrich-Mann-Allee 103 14473 Potsdam</p>	Declined participation	
<p><i>Ministerium für Frauen, Arbeit, Gesundheit und Soziales des Saarlandes</i> Ministry for Women, Labor, Health and Social Affairs of the Saarland</p>	<p>Franz-Josef-Röder-Str. 23 66119 Saarbrücken</p>	X	X

<i>Ministerium für Frauen, Jugend, Familie und Gesundheit des Landes Nordrhein-Westfalen</i> Ministry for Women, Youth, the Family and Health of North Rhine Westfalia	Fürstenwall 25 40219 Düsseldorf	X	X
<i>Netzwerk der Geburtshäuser-Verein zur Förderung der Idee der Geburtshäuser in Deutschland e. V.</i> Network of Birth Houses - Association for Promoting the Idea of Birth Houses in Germany	Tizianstr. 23B 53844 Troisdorf	X	X
<i>Niedersächsisches Ministerium für Frauen, Arbeit und Soziales</i> Ministry for Women, Labor and Social Affairs of Lower-Saxony	Postfach 141 30001 Hannover	X	Declined participation
<i>Paul-Ehrlich-Institut</i> Paul Ehrlich Institute	Paul-Ehrlich-Str. 51-59 63225 Langen	Declined participation	
<i>Robert Koch-Institut</i> Rober Koch Institute	Nordufer 20 13353 Berlin	X	X
<i>Sächsisches Staatsministerium für Soziales, Gesundheit, Jugend und Familie</i> Minsitry for Social Affairs, Health, Youth and the Family of Saxony	Albertstr. 10 01097 Dresden	X	X
<i>Senator für Arbeit, Frauen, Gesundheit, Jugend und Soziales der Freien und Hansestadt Bremen</i> Senator for Labor, Women, Health, Youth and Social Affairs of the City of Bremen	Postfach 10 78 67 28078 Bremen	X	X
<i>Senatsverwaltung für Arbeit, Soziales und Gesundheit Berlin</i> Berlin Office for Labor, Social Affairs and Health	Oranienstr. 106 10969 Berlin	X	X

<i>Sozialministerium des Landes Baden Württemberg</i> Social Ministry of Baden-Wuerttemberg	Postfach 10 34 43 70029 Stuttgart	X	X
<i>Sozialministerium Mecklenburg-Vorpommern</i> Social Ministry of Mecklenburg Eastern Pomerania	Werderstr. 124 19048 Schwerin	X	X
<i>Thüringer Ministerium für Soziales, Familie und Gesundheit</i> Ministry for Social Affairs. the Family and Health of Thuringia	Postfach 612 99012 Erfurt	X	X
<i>Verband der Angestellten-Krankenkassen / Arbeiter-Ersatzkassen-Verband<sup>c)</sup></i> Association of Statutory Health Insurance Funds for Salaried /Association of Statutory Health Insurance Funds for Workers <sup>c)</sup>	Frankfurter Str. 84 53721 Siegburg	X	X
<i>Verband der privaten Krankenversicherung</i> Association of Private Health Insurance	Postfach 51 10 40 50946 Köln	X	X
<i>Verband deutscher Alten- und Behindertenhilfe</i> German Association for Aid to the Elderly and Handicapped	Im Teelbruch 126 45219 Essen		
<i>Verband Deutscher Rentenversicherungsträger e.V.</i> Federation of German Pension Insurance Institutes	Eysseneckstr. 55 60322 Frankfurt	X	X
<i>Verband Forschender Arzneimittelhersteller</i> Association of Research-Based Pharmaceutical Manufacturers in Germany	Hausvogteiplatz 13 10117 Berlin	X	X
<i>Verband physikalische Therapie</i> Association for Physical Therapy	Hofweg 15 22085 Hamburg	X	X

<i>Zentralverband des Deutschen Handwerks</i> Central Association of German Craftsmen	Mohrenstr. 20/21 10117 Berlin	X	X
<i>Zentralwohlfahrtsstelle der Juden in Deutschland</i> Central Relief Fund for Jews in Germany	Hebelstr. 6 60318 Frankfurt/Main		

*Organizations that responded spontaneously to the Council's survey*

<b>Organization</b>	<b>Address</b>	<b>Response submitted</b>	<b>Copy of response on the homepage of the Advisory Council: <a href="http://www.svr-gesundheit.de">http://www.svr-gesundheit.de</a></b>
<i>Berufsverband der deutschen Chirurgen e.V.</i> Association of German Surgeons	Luisenstr. 58/59 10117 Berlin	(X)	
<i>Berufsverband Deutscher Nervenärzte</i> Association of Doctors for Nerve Medicine	Friedenstr. 7 97318 Kitzingen	X	X
<i>Deutsche Gesellschaft für Medizinische Psychologie und Psychopathometrie</i> German Society for Medical Psychology and Psychopathometry	Klarastr. 7 60433 Frankfurt am Main	X	X
<i>Endometriose-Vereinigung Deutschland e.V.</i> German Endometriosis Association	Bernhard-Göringstr. 152 4277 Leipzig	(X)	
<i>Gesundheit Berlin e.V. Landesarbeitsgemeinschaft für Gesundheitsförderung</i> Health Berlin, State Working Group for Health Promotion	Wiesener Str. 17 12101 Berlin	X	X

<i>Kreis für Eltern von Kindern mit Speiseröhrenmissbildungen e.V.</i> Parents of Children with Esophagol Deformities	Sommerrainstr. 61 70374 Stuttgart	X	X
<i>Verbund Deutscher Selbsthilfen in der Schlafmedizin</i> Association of German Self-Help Groups in Sleep Medicine	Postfach 11 07 42751 Haan	(X)	
<i>Verein für Eltern chromosomal geschädigter Kinder e.V.</i> Association of Parents of Children with Chromosomal Defects	Auf dem Klei 2 44263 Dortmund	X	X

- a) Joint response of the Alliance of the Associations of Psychotherapy Professions, the Working Group for the Modification of Behavior, Association for Juvenile and Adolescent Psychotherapy, German Society for Deep Psychology Psychotherapy, German Society for Psychological Pain Therapy and Research, German Society for Sexual Research, Group for Clinical Psychology and Psychotherapy of the Germany Society for Psychology, German Society for Behavior Therapy, German Psychological Society for Psychotherapy, German Association of Psychotherapists - Association of Psychological Psychotherapists, Society for Neuropsychology, Milton Erickson Society for Clinical Hypnosis
- b) Joint response of the German Society for Analytical Psychology, German Psychoanalysis Society, German Association for Psychoanalysis, German Society for Individual Psychology and the German Society for Psychoanalysis, Psychotherapy, Psychosomatic Medicine and Deep Psychology.
- c) Joint response of the Working Group of the National Associations of the Social Health Insurance Funds with the Federal Association of the AOK, the National Association of Company Funds, the National Association of Guild Health Funds, the Maritime Health Insurance Fund, the National Association of Agricultural Sickness Funds, the Miners' Provident Fund, the Association of Salaried Employees' Health Insurance Funds, the Association of Wage Workers Substitute Funds and the Medical Review Board of the National Associations of Social Health Insurers.
- d) Joint response of the German Agency for Quality in Medicine, the German Medical Association, and the National Association of Statutory Health Insurance Physicians.
- e) Joint response of the German Dentists Association and the National Association of Statutory Health Insurance Dentists

## 15.3 Text of the survey<sup>75</sup>

### 1. General considerations

Based on the provisions of the health care reform law of December 12, 1999, the Advisory Council is "responsible for the compilation of reports on trends in the Social Health Insurance system. The reports shall identify and analyze areas in which the provision of health care is excessive, insufficient or inappropriate and identify opportunities for increasing efficiency".

To fulfil the task, the Council is conducting a survey of the member organizations of the Concerted Action, professional societies, patient groups and other organizations in the health sector.

The objective of the survey is to identify areas of the health care system in which there is overuse, underuse or misuse. The survey targets both indication-related issues and non-indication related issues (level of care, density ratios, structural quality). Short definitions of the concepts are provided as an enclosure to this letter. A more detailed description and definition of the concepts of need, appropriate care, overuse, underuse and misuse can be obtained from the offices of the Advisory Council.

### 2. Subject of the Survey

#### 2.1 Indication-based questions

**Survey of the member organizations of the Concerted Action and other organizations in the health sector:**

*Note: For organizations with very general responsibilities (e.g. social partners) it may be advisable to go directly to Chapter 2.2 (non-indication-based questions).*

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<sup>75</sup> The survey of the different organizations (professional societies, patient groups, member organizations of the Concerted Action and other organizations) was based on a standard template. Parts of the survey were modified to address certain target groups. These sections are printed in frames.

In the indication-based survey we ask you to provide us with information on overuse, underuse and misuse in indication areas that are important<sup>76</sup> from your perspective. Regardless of the relevant areas that you have defined, the Council requests that you provide information on the following six indications and special areas of health care:

1. Back pain (ICD 9: 720-724)
2. Ischemic heart disease including myocardial infarct (ICD 9: 410-414)
3. Cerebrovascular disease, especially stroke (ICD 9: 430-438)
4. Lung cancer, breast cancer, colon and rectal cancer (ICD 9: 162, 174, 153-154)
5. Chronic obstructive pulmonary diseases, including COPD in children (ICD 9: 490-496)
6. Depressive disorders (ICD 9: 296, 311)

We request that you provide the following information on these indications and on any other indications that you consider important:

### **Survey of the professional societies and the patient groups**

As part of the indication-based survey we ask you to provide information on overuse, underuse and misuse in the following three areas:

1. The main indications of your medical specialty / focus of your patient group.
2. Other indications in your medical specialty / focus of your patient group that you think are important.
3. Indications that are related to your medical specialty / focus of your patient group but in which other health care providers serve patients.

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<sup>76</sup> Criteria for determining relevance include e.g. the prioritization criteria of different organizations (e.g. IOM, Field 1995, Battista and Hodge 1995, SIGN 1999). The Council recommends using prevalence, severity of disease, direct and indirect costs, controversial health or health care problems and the health problems of vulnerable groups in the population.

You are free to choose the indications that you think are important.<sup>77</sup> However, in cases in which a large number of indications have been named, the Council reserves the right to make its own prioritization.

We request that you provide the following information for each area (1 to 3):

- a) Problem description: Please name the indications that you believe are characterized by overuse, underuse and misuse (see Appendix) and provide sufficiently detailed information to justify your choice (causally or empirically - see b).

We also request that you specify your statements with the following information:

- regional relevance (nationwide or certain regions),
- target groups (total population or specific sub-groups),
- health care providers / facilities / technologies<sup>78</sup>.

- b) Sources: Sources should preferably be published studies or representative German data. In the case that foreign studies are used, we request that you provide a reason for transferability to Germany. For German studies, justification should be given for the generalization to the whole country of study results made in specific regions or facilities unless the intention is related only to specific regions or facilities.

The responses of patient organizations may also include empirically sound case studies.

*We would like to point out that statements that are not adequately supported by evidence may not be considered by the Council.*

- c) Recommendations: In addition to the identification of problem areas we request that you recommend measures that could be used to improve the problems you describe. The measures could be related, for example, to the following areas:

- the number and qualifications of professionals,
- available technologies<sup>79</sup> (including the choice and utilization of innovative procedures and the "retirement" of old procedures),

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77 See footnote 76.

78 See footnote 79

- structure of care (e.g. the "interface problem", communication issues),
- substitution possibilities (measures, procedures or facilities that could be dispensed with so that the resources could be dedicated to areas in which there is an underuse),
- reimbursement/finance/costs.

We request that you provide causal and empirical evidence for your recommendations.

## 2.2 *Non-indication-based survey*

*Note: The following "non-indication-based survey may not require any further information from professional societies / patient organizations that represent a very narrow specialty / very narrow indication.*

The non-indication-based survey focuses on the level of health care. It refers primarily to "instrumental density ratios" (e.g. doctors, other health care professionals, hospitals/hospital departments/hospital beds, dialysis units, supply of large medical equipment or important technical procedures, each in relation to the number of inhabitants in a geographic area), access to health care and structural quality<sup>80</sup>.

We request that you provide information on the general level of health care in the sense of non-indication-based definitions of overuse, underuse and misuse (see Appendix) for important areas in your area of responsibility. We also request that you provides reasons for you choice and information sources. Your responses can include reference to the presence, access and structural quality of

- the number and qualifications of professionals,

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79 The term "technology" is used here in the sense of the WHO definition to encompass all diagnostic (including early diagnostic), therapeutic, rehabilitative and nursing measures and procedures. In addition to the procedures performed by doctors, dentists and pschotherapists this definition expressly includes pharmaceuticals, para-medical therapy and medical aids in the sense of German health insurance law and special transport services (rescue units).

80 Structural quality: the type, amount and qualifications/quality of healthcare professionals/healthcare insfrastruktur and communications and cooperation network.

- available technologies (including the selection and utilization of innovations and the "retirement" of old procedures),
- structure of care (e.g. the "interface problem", communication issues),
- substitution possibilities (measures, procedures or facilities that could be dispensed with so that the resources could be dedicated to areas in which there is an underuse),

and to the issues of reimbursement, finance and costs.

### ***3. Appendix: Short definitions of "appropriate and efficient care, overuse, underuse and misuse"***

#### **– Indication-based definitions**

- Appropriate care: Service are indicated, have a positive net benefit<sup>81</sup> and are provided according to professional standards.
- Efficient care: Appropriate care that's provided economically, i.e. with an acceptable cost-benefit ratio.
- Underuse: Appropriate and efficient care is not provided or is inaccessible.<sup>82</sup>
- Overuse: Services that are provided in excess of the level of appropriate care (medical overuse) or services that are provided in an inefficient manner (economic overuse).<sup>83</sup>
- Misuse: Health care that causes an avoidable damage.<sup>84</sup> There are the following types of misuse:

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81 Medical benefits (e.g. life expectancy, quality of life) are greater than potential damages (health risks/undesired side effects).

82 The partial or full refusal of health care despite the presence of individually, professionally, scientifically or socially acknowledged need, although services are available that can be expected to provide a sufficiently proven net benefit and, compared to the medical alternatives, can be provided efficiently, is called "underuse".

83 The supply of service beyond the level needed is termed overuse. It is the provision of services for which there is no indication or insufficient evidence of their clinical benefit (medical), services that provide too few benefits to justify their cost or services that are provided inefficiently ("economic").

84 Avoidable damage is thus equal to a foregone but nonetheless possible health benefit, e.g. if the service was provided properly and promptly.

- the provision of a service that is appropriate but which, due to its unqualified application, causes an avoidable damage;
  - the provision of an inappropriate service that gives rise to an avoidable damage;<sup>85</sup>
  - the failure to provide appropriate care or the failure to provide appropriate care promptly.<sup>86</sup>
- **Non-indication-based definitions**
- Appropriate level of care: The amount of health care facilities and services that is sufficient to prevent avoidable health damages among individuals who seek health care.
  - Underuse: The "inappropriate" supply of health care facilities and services characterized by undertreatment, i.e. the type and scope of services provided (or not provided) results in avoidable health damages to individuals who seek health care.
  - Overuse: The "inappropriate" supply of health care facilities and services characterized by overtreatment, i.e. the supply of services of a type and amount that provides no additional health benefits and can present unnecessary risks due to unwarranted treatment.
  - Misuse: Health care services are inappropriate when the amount and type of supplied services or facilities are appropriate, but the quality of the service – in particular the structural quality<sup>87</sup> – is not consistent with the state of medical knowledge or standard professional skills.

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85 This is a point in common with overuse, but only with that that is the source of medical damages.

86 This is a point in common with underuse. However, those types of underuse in which no treatment at all has taken place are not classified as "misuse".

87 Structural quality: type, scope, quality/qualification of staff, technical equipment and communication and co-operation structures.

**15.4 Summary of the Council's most urgent recommendations (A) for reducing overuse, underuse and misuse in the health care system**

**Table A1: Recommendations (A) for reducing overuse, underuse and misuse in the care of patients with chronic diseases (Chapter 7)**

<b>Competition among health insurers</b>	Despite competition among health insurance funds, the Council calls for the quick and large scale implementation of scientifically proven standards and concepts of care. This means that the self-government must be required to implement such measures or that patient groups be granted a voice in the decision-making process.
<b>A new orientation for health care</b>	<p>A short-term and at best partial reduction of overuse, underuse and inappropriate treatment in the care of patients with chronic diseases could be realized on the basis of guideline-based approaches or appropriate disease management programs, provided that they are implemented correctly and the participants are co-operative.</p> <p>A sustainable reduction in overuse and misuse as well as the establishment of a new balance between prevention, treatment and rehabilitation in the care of patients with chronic diseases requires a long-term re-orientation of the health care system based on a multi-stage health policy with consistent goals. It requires a basic transformation in structures, incentives, knowledge and values.</p>
<b>Rehabilitation</b>	The creation of an infrastructure for the provision of appropriate ambulatory rehabilitation services.
<b>Rehabilitation</b>	The rehabilitation of patients with chronic diseases should be seen as a continuous process that runs in parallel to the whole course of disease and which considers not only the somatic and psychological factors but the professional and personal development of the patient and the social environment.
<b>Rehabilitation</b>	Rehabilitation should not be seen as an elective benefit but as a self-evident component in the comprehensive care of patients with chronic diseases
<b>Terminally ill</b>	Overall, the provision of care to terminally ill patients is still not without problems in Germany. The Council sees a need for the expansion of hospices and other specialized ambulatory and inpatient facilities.

**Table A2: Recommendations (A) for reducing overuse, underuse and misuse in the care of patients with ischemic heart disease (Chapter 8)**

<b>Acute care</b>	The improved acute care treatment of patients who have suffered a myocardial infarction requires the optimization of emergency treatment by professionals and laypeople, primary treatment in the hospital ("door to needle time") and the consistent implementation of evidence-based guidelines
<b>Diagnosis and therapy</b>	The improvement of diagnosis and therapy of arterial hypertension requires the implementation of existing evidence-based guidelines and consideration of the health risk for consequent diseases of the heart.
<b>Medical innovations</b>	The results of health technology assessment should play a more important role in the authorization and coverage decisions for costly and risky innovations.
<b>Prevention</b>	The development of a multi-level concept for the prevention of heart disease and circulatory diseases (National Heart and Circulatory Disease Prevention Program for Germany) is urgently needed.
<b>Prevention</b>	Population-based and group-specific behavioral and setting oriented primary prevention measures should be implemented on a broad scale and involve as few screening measures as possible.
<b>Prevention</b>	Individual prevention should be oriented more towards absolute cardiovascular risk (individual risk stratification)
<b>Prevention</b>	Increase efforts are needed to realize the nationwide introduction of evidence-based guidelines for secondary prevention and the treatment of coronary heart disease in daily practice.
<b>Prevention</b>	More evaluated prevention programs should be offered and combined with case management and disease management programs.

**Table A3: Recommendations (A) for reducing overuse, underuse and misuse in the care of patients with cerebrovascular disease (Chapter 9)**

<b>Education</b>	The public should be better informed of the appropriate behavior as lay helper during an acute stroke
<b>Prevention</b>	Health insurers should implement preventive measures that target patients with hypertension
<b>Rehabilitation</b>	Ensure the continuity of rehabilitation and the stabilization of rehabilitation results, in particular for patients who are disabled or threatened by disability
<b>Treatment pathway</b>	Early rehabilitation and prevention measures immediately following occurrence of the stroke, co-ordinated treatment by a multi-professional team and provision of continuous care throughout the treatment pathway.

**Table A4: Recommendations (A) for reducing overuse, underuse and misuse in the care of patients with chronic obstructive lung disease (Chapter 10)**

<b>Asthma: Diagnosis and therapy</b>	A guideline-based and quality assured subcutaneous hyposensitization should be used at an earlier stage of the disease and more often to improve prevention
<b>Asthma: Drug therapy</b>	Drug therapy should be optimized by implementing evidence-based guidelines and qualified measures for the training and continuing education of pulmonologists
<b>Asthma: Prevention</b>	The primary prevention of allergic diseases in infants and small children should be optimized through measures such as breastfeeding, avoiding exposure to tobacco smoke and the education of parents.
<b>Asthma: Prevention</b>	The available effective interventions for reducing the concentration of allergens in buildings and the workplace or for the prevention of contact with allergenic work materials should be rigorously implemented.
<b>Asthma: Education</b>	General agreements on the quality assurance and targeted ambulatory education of asthma patients should be concluded. These should make use of existing regional services and resources.
<b>Asthma: Education</b>	The quality of drug therapy and patient compliance should be optimized through improved information, education and empowerment of patients.
<b>COPD: Treatment</b>	Patient education, smoking cessation programs, training therapy and rehabilitation should play an important role in treatment.
<b>COPD: Diagnosis and therapy</b>	Diagnosis and therapy should be optimized through the implementation of evidence-based guidelines and through the qualified training and continuing education of pulmonologists.
<b>COPD: Prevention</b>	The development of a "National Anti-Tobacco Campaign" is urgently needed (see Table A6)
<b>The healthcare infrastructure</b>	Improved training and continuing education in pulmonology for general practitioners, pediatricians and specialist in internal medicine
<b>The healthcare infrastructure</b>	The structures for ambulatory patient education and rehabilitation, including financial regulations and quality assurance measures, should be improved.
<b>The healthcare infrastructure</b>	More independent pulmonology departments should be established in general hospitals
<b>The healthcare infrastructure</b>	Pulmonological rehabilitation should be better integrated with all other areas of pulmonological care (e.g. the direct referral to certified rehabilitation clinics to treat chronic obstructive lung diseases) as well as with research and teaching.

**Table A5: Recommendations (A) for reducing overuse, underuse and misuse in the care of patients with back pain (Chapter 11)**

<b>Guidelines</b>	Evidence-based guidelines designed for the German health care context should be developed for the diagnosis and treatment of back pain by general practitioners and specialists, disseminated in all target groups (doctors, patients, the public) and implemented in combination with quality assurance programs.
<b>Quality assurance</b>	Lower back pain should be chosen as one of the first diseases for the application of the quality assurance measures that have been called for by law but not yet implemented.

**Table A6: Recommendations (A) for reducing overuse, underuse and misuse in the care of oncological diseases (Chapter 12)**

<b>Lung cancer (Chapter 12.1), anti-tobacco campaign</b>	A "National Anti-Tobacco Campaign" should be initiated and implemented immediately
<b>Breast cancer (Chapter 12.2), treatment pathway</b>	Measures for improving the care of breast cancer patients should not focus on one aspect of care (e.g. mammography screening) but consider the whole treatment pathway (early detection, diagnosis, treatment, follow-up).
<b>Breast cancer (Chapter 12.2), mammography screening</b>	The rapid introduction of a nationwide quality assured mammography screening program in Germany according to the quality standards of the European guidelines (including a minimum number of 5,000 mammographies per year and a qualified second opinion) is necessary.
<b>Breast cancer (Chapter 12.2), mammography screening</b>	Quality assured mammography screening programs should be linked to cancer registries.
<b>Breast cancer (Chapter 12.2), mammography screening</b>	Quality-assured mammography screening programs should be linked to existing tumor centers and oncology centers - utilizing the existing expertise of office-based doctors - as a means for ensuring the high quality of the diagnostic and treatment pathway.
<b>Breast cancer (Chapter 12.2), 'gray' screening</b>	Doctors and health insurers should work to effectively prevent "gray" screening
<b>Breast cancer (Chapter 12.2), IGEL services</b>	Early detection mammography must be removed from the catalogue of IGEL services.
<b>Breast cancer (Chapter 12.2), quality assurance of curative mammography</b>	The Co-ordinating Committee should develop quality guidelines that cover all areas of curative mammography and apply to all sectors, professions and institutions.

<b>Breast cancer (Chapter 12.2), quality assurance of curative mammography</b>	Regulations on curative mammography should meet the requirements of the European guidelines and the EUREF protocol (e.g. with respect to the minimum number of mammographies per year and second opinion) and serve as the basis for the introduction of a certification and re-certification concept for all mammography facilities.
<b>Breast cancer (Chapter 12.2), therapy</b>	There is an urgent need for targeted quality measures that ensure a guideline-based and high quality treatment of women with breast cancer.
<b>Breast cancer (Chapter 12.2), medical innovations</b>	The Co-ordinating Committee should apply binding, evidence-based directives to control the diffusion of medical innovation across the whole health care system.
<b>Breast cancer (Chapter 12.2), follow-up care</b>	Symptom-oriented breast cancer follow-up without "technical overuse" but with accompanying psychosocial care should be implemented quickly and on a nationwide scale.
<b>Oncological diseases (12.3), early detection</b>	Sub-groups of the population with a high risk for cervical cancer or intestinal cancer should be invited to participate in early detection measures.
<b>Oncological diseases (12.3), guidelines for pain therapy</b>	All medical, psychological and nursing organization are called upon to participate in the diffusion and implementation of the evidence-based guidelines of the German Agency for Quality in Medicine (AQUMED), the German Cancer Society and others for the pain therapy of tumor patients
<b>Oncological diseases (12.3), guidelines for pain therapy</b>	Pain therapy of tumor patients should be a major topic in the education, training and continuing education of doctors and other health care professionals.

**Table A7: Recommendations (A) for reducing overuse, underuse and misuse in the treatment of patients with depressive disorders (Chapter 13)**

<b>Elderly patients with depression</b>	The improvement of gerontological psychiatric training is urgently needed.
<b>Elderly patients with depression</b>	The nationwide creation of day-care facilities is urgently needed.
<b>Elderly patients with depression</b>	Qualified networks for gerontological psychiatry should be created on a nationwide basis and the co-operation of existing facilities improved.
<b>Elderly patients with depression</b>	Gerontological psychiatry should be an integral component in the training of specialists in psychiatry and psychotherapy.
<b>Elderly patients with depression</b>	Research and teaching in gerontological psychiatry should receive more support.
<b>Elderly patients with depression</b>	Gerontological psychiatry should be granted more weight in the educational curriculum of psychiatric nurses.

<b>Elderly patients with depression</b>	There is a need for improvement in the situation in nursing homes and homes for the elderly. There is not only a need for improvements in the continuity of medical care but also for the implementation of existing concepts for activating nursing and for the rehabilitation of the residents of nursing homes and homes for the elderly.
<b>Elderly patients with depression</b>	The mental health and morbidity of the elderly should be taken more into consideration in the design, construction and staffing of residences for the elderly, the implementation of care concepts and the design of health care policies for the elderly.
<b>Education</b>	Socially transmitted prejudices play an important role in the hampering the diagnosis and treatment of depressive disorders. It is therefore important to improve public awareness of the frequency and nature of depressive disorders, to promote the acceptance of mental health patients and to lower the shame barrier.
<b>Primary care</b>	Due to the large number of patients and the evidence for deficits in this area, measures for improving the care of depressive patients should focus on primary care.
<b>Primary care</b>	Psychiatry should be given more emphasis in the training and continuing education of specialists in general medicine.
<b>Primary care</b>	The full certification of a general practitioner to provide care to psychiatric patients should depend in part on the participation in binding , quality-assured and outcomes-tested continuing education programs.
<b>Primary care</b>	The regular consulting of a psychiatrist should be required for patients with severe depression who are in the care of general practitioners.
<b>Primary care</b>	Symptom-oriented evidence-based guidelines for the diagnosis and treatment of depressive disorders in general practice should be developed and implemented. The guidelines should also contain concrete indices to control the referral (and re-referral) to a qualified (i.e. specialized) psychiatric or psychotherapeutic facility. Financial incentives should be implemented to support adherence to the indices.

**Table A8: Recommendations (A) for reducing overuse, underuse and misuse in oral, dental and orthodontic health (Chapter 14)**

<b>Primary and secondary prevention</b>	The development of health promotion and education, funding for risk-oriented group prevention and individual prevention and the increase in the market share of fluoridated table salt should be realized as quickly as possible.
<b>Prevention personnel</b>	The number of personnel providing a significant amount of preventive measures under the supervision of a dentist should be increased considerably.
<b>Tertiary prevention (late treatment of oral diseases)</b>	Without a clear increase in the provision of appropriate restorative, endodontic and periodontological treatment it will be very difficult to reduce the need for treatment in the area of dental prosthesis in the medium term. For this reason, the Council recommends that the share of restorative interventions in tertiary prevention is increased significantly.
<b>Qualification</b>	Training in dentistry should be improved by reducing the number of students but maintaining the level of personnel and material resources to improve the quality of teaching and research. Improvements in the university hospitals should be succeeded by a reform of the licensing law for dentists.
<b>Qualification</b>	Following completion of university education, there should be an increased number of structured continuing education and specialization programs that are co-ordinated by the dentists associations in co-operation with professional societies and universities. The opportunities for the further specialization of dental assistants should also be improved.

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