

Cooperation and Responsibility

Prerequisites for Target-Oriented Health Care

ADVISORY COUNCIL
on the Assessment of Developments
in the Health Care System

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**Prerequisites for Target-Oriented
Health Care**

Report for 2007
Abridged version

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Foreword

This is the abridged version of the Council's Report for 2007, entitled "Cooperation and Responsibility. Prerequisites for Target-Oriented Health Care". In addition to cooperation between the health care professions, the report focuses on integrated health care, the hospital system, the quality and safety of health care, and primary prevention in vulnerable groups. The Council thus fulfils its mandate formulated in Section 142 Para. 2 of Book V of the German Social Security Code (SGB V), i.e. to identify priorities for the elimination of health care deficits and existing overuse, as well as ways and means of further developing the health care sector, taking into account the financial framework conditions and existing efficiency reserves.

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The Council bears the responsibility for any errors in the report.

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1. Introduction: Cooperation and responsibility as prerequisites for target-oriented health care

1. In connection with the debates concerning the Act to Strengthen Competition in the SHI System (GKV-WSG), the German health sector, and particularly statutory health insurance (SHI), was again the focus of interest in social and economic policy. In this context, the political decision-makers found themselves facing the task not only of making the SHI funding system more sustainable, but also of improving the efficiency and effectiveness of health care. Since the determination of weak growth of the existing basis for funding the SHI system does not rule out the existence of still remaining efficiency and effectiveness reserves, both tasks constitute starting points for target-oriented reform measures from the overall economic and social point of view. While the funding problems of SHI are still awaiting a sustainable solution, the present Report deals with the expenditure or benefits side of health care. The thoughts can thus proceed from numerous reform measures introduced by the legislature in recent years that have created better prerequisites for efficient and effective health care in some fields. The statements also directly follow the statutory mandate to identify deficits in provision, as well as existing overuse and misuse, and to propose possibilities for exploiting rationalisation potentials. Addressing the topic of efficiency and effectiveness reserves has its normative justification, regardless of the thesis, repeatedly expressed by the Council, that the German health sector offers insureds and patients a high standard of medical services throughout the nation, also in an international comparison.

2. The provision of target-oriented health care, which primarily encompasses allocative aspects in this Report, but also distributive aspects, presupposes corresponding cooperation, both among the service providers and also between them and the health insurance funds, as well as clearly regulated responsibilities that do justice to the specific qualifications of the parties involved in the processes of providing health-related services. Based on this overriding aspect, the individual chapters deal with the following topics:

- The development of cooperation between the health care professions as a contribution towards efficient and effective health care provision (Chapter 2),
- Integrated health care in SHI: development, status, managed care and prospects (Chapter 3),
- Hospital planning, funding of investment costs and further development of the G-DRG system (Chapter 4),

- Quality and indicators of patient safety: impact of the publication of quality data and quality-based remuneration (Chapter 5), and
- Primary prevention in vulnerable groups (Chapter 6).

With an eye to efficiency and effectiveness aspects, the statements consistently aim to present proposals for improvements that can build directly on the existing structures as adaptive reform steps. Reform proposals for evolutionary further development of the German health sector are also capable of contributing to strengthening the international competitiveness of this growth industry.

3. The provision of targeted-oriented health care is based on a benefit concept that goes beyond absolute effectiveness and also includes patient and social preferences. The concept of adequacy makes the determinants of relative effectiveness accessible to allocation issues, in which context the importance of absolute effectiveness, as the primary, necessary condition for the benefit of a procedure, is not diminished. In this spirit, with regard to the envisaged health outcomes, the provision of target-oriented health care first and foremost requires a medical orientation. This approach is intended to prevent any health reforms from getting no further than pure cost-containing measures. In recent years, health policy – particularly in the fields of prevention, integrated health care and the supply of medicines – took up and implemented a number of outcome-oriented and other recommendations made by the Council. Nevertheless, a contribution calling for "more health orientation" as the introduction to the following five chapters would like to recall central objects of desire that still remain. This primarily relates to the following deficits:

- German health policy still lacks explicit target orientation.
- Despite a number of positive initial steps, health promotion and prevention still have substantial, hitherto unexploited potentials as regards the improvement of health outcomes.
- The participation and self-responsibility of patients are still not given their due importance in the context of health care.
- For avoiding or minimising overuse, underuse and misuse, there are still further possibilities for improvement as regards the quality of care, despite visible efforts and some progress.

- Work in (health services) research needs more promotion. The same applies to the provision of impartial scientific advice on health policy and the evaluation of health projects by independent experts.

4. The second chapter discusses current cooperation between the health care professions and examines the optimum deployment of personnel resources to exploit the potentials of the different occupational groups for providing efficient and effective health care. This issue is acquiring growing importance against the backdrop of increasing transparency and rising expectations of insureds and patients, foreseeable demographic developments, changes in the morbidity spectrum, progressing specialisation and diverse new technical possibilities. The recommendation of greater involvement of non-physician health care professions and the call for improved cooperation primarily aim at more efficient and more effective provision of health-related services and less at taking precautions for the event of a shortage of physicians. As in the other chapters, the search for new forms of cooperation and corresponding responsibilities is targeted at optimum resource allocation in the health sector. However, heading for this goal presupposes that all health care professions demonstrate a willingness to arrive at redistribution of the fields of activity according to qualification, and to accept corresponding responsibility, in the framework of new, team-oriented forms of work. Since both numerous physicians and several other occupational groups consider the current situation to be unsatisfactory in view of their potential, the reassignment of tasks could benefit all players involved in health care provision. After all, the patients benefit from more efficient and qualitatively better care, this ultimately being the decisive criterion when searching for new forms of cooperation and changed responsibilities.

5. A changed distribution of tasks between the health care professions, and thus the implementation of new forms of cooperation and the responsibilities associated with them, could most obviously be tested in the framework of integrated health care, which is the subject of the third chapter. In the last ten years, the legislature laid the foundations for the choice of several, special forms of health care provision, which enable the potential contract partners, i.e. health insurance funds and Regional Associations of SHI-Accredited Physicians or groups of SHI-accredited physicians, to organise the provision of health care along interdisciplinary and intersectoral lines. Various elements of managed care can thus be integrated into the provision of health care, primarily including target-oriented, intersectoral coordination and cooperation between all players involved in the process of providing treatment. This kind of integrated, cooperative provision of services can be implemented in inter-indication, population-related health care net-

works, or also in the framework of disease and case management. Population-related health care networks, which impose high demands on target-oriented coordination and cooperation, usually make provision for a contact selected by the insured, this mostly being a family doctor. Regarding access to integrated health care and in case management, specialised nursing professionals can, for example, likewise take on certain tasks in cooperation with physicians, depending on the requirements profile. From the sectoral point of view, however, the pure integration of hospitals and outpatient physicians is not enough to achieve an improvement in the efficiency and effectiveness of health care provision. Instead, what is additionally needed is suitable incentive structures and outcome-oriented coordination of all players involved in providing health care. This presupposes the existence of outcome indicators that reflect the quality of care, preferably in quantitative form, and thus indicate the health-related benefit gained by patients from the provision of health care.

6. Intersectoral optimisation at the interfaces between the outpatient and the inpatient sector, and also associated outcome-oriented incentive structures, e.g. based on functioning competition between hospitals and outpatient physicians/specialists, are among the central elements of promising health care integration. Moreover, for logistical reasons alone, hospitals are obvious starting points for all-encompassing, regional health care networks. As discussed in the fourth chapter, hospitals are moreover currently facing a changed regulatory framework as regards Länder planning, an increase in private ownership and further development of the fee-per-case payment system, as well as the possibility of a change in the financing of investments. Insofar as framework hospital planning replaces detailed supply planning by the Länder, the hospitals will acquire greater autonomy. This would offer them the opportunity to better adapt their capacities to the regional demand and thus cut back excess capacities more speedily. Moreover, a switch to monistic financing would put them in a position to (more swiftly) seize locally emerging market opportunities with the help of a targeted investment policy. However, the transition from detailed planning to framework planning by the Länder, and from dual to monistic financing, does not release the state from its responsibility for guaranteeing the necessary hospital care, this necessitating accompanying monitoring of the supply structures. Introduction of the fee-per-case payment system was accompanied by a decrease in the length of stay and improved transparency, although the associated quality effects are unknown owing to the lack of outcome-oriented evaluation. In the spirit of evolutionary reform steps, the Council recommends that the fee-per-case payment system initially be further developed with the help of fixed prices and only partially opened to price competition. However, if and insofar as the contract partners agree

on a different payment system in the framework of integrated health care, such as inter-sectoral complex fees, the importance of this partial maximum-price system declines.

7. The fifth chapter analyses the quality of care and patient safety – important determinants and elements of health outcomes. Valid quality and patient safety indicators are capable of providing valuable information regarding the benefit gained by patients from treatment, and thus also of contributing to the target orientation of health care. In the framework of benchmarking with other forms of care, the evaluation of integrated health care projects could be based on, among other things, a system of valid indicators for quality and patient safety. The 30 patient safety indicators proposed in this chapter, which also include drug safety, are to be seen as a pool from which a selection can be made for Germany in the context of implementing quality assurance. As confirmed by empirical studies, the obligatory publication of quality data and quality-related payment systems hold the promise of improving the quality of care. Given public dissemination of data concerning risk-adjusted outcomes, hospitals, in particular, have greater incentives to invest in quality management and subject the outcome of treatment to continuous controlling. Quality-related payment, which is usually combined with public disclosure, has the potential to eliminate quality deficits, and also to pursue population-related health targets. This development could trigger quality-based competition among the service providers, which would ultimately benefit the patients. Independently of corresponding ethical obligations, quality-based competition of this kind is a strong incentive for institutions and occupational groups in the health sector to practise target-oriented coordination and assume responsibility.

8. The sixth chapter addresses the topic of primary prevention in vulnerable groups, giving an exemplary description of the problems and solution approaches in the groups of unemployed persons, socially disadvantaged old people and the homeless, as well as in relation to HIV/AIDS. Since most of the fields of intervention for primary prevention, i.e. for measures and strategies aimed at reducing the causes and risks of diseases, lie outside the medical health care system, there is often a need for cooperation in areas and institutions beyond the health sector. Depending on the problem situation, this can mean, for example, municipalities, the Federal Employment Agency, charitable organisations or institutions and agencies that offer psychosocial support. According to current experience and knowledge, the interventions should be geared to the worlds in which the respective target groups live, although this approach runs into certain obstacles in the case of the unemployed and the homeless, in that there are limits to which the living situations of these groups can be pooled in settings suitable for interventions. In con-

trast, sustainability and development prospects are revealed in coordinated pilot projects in schools, as well as in networking and quality assurance together with health-related social projects. Of fundamental importance for the implementation and quality assurance of target-oriented interventions is participatory involvement of the respective target groups. Another prerequisite for effective and efficient primary prevention is target formulation, which is still underdeveloped in Germany, and the associated definition of priorities. In contrast to other health projects, proof of effectiveness is not always suitable as a criterion for the justification or worthiness of promotion of complex prevention programmes, since their health outcomes are hard to detect and measure. Based on current knowledge, projects should also be eligible for implementation if only a conclusive effect model and – at least partial – empirical evidence exist. However, quality assurance and adequate documentation are always required in order to be able to establish and expand an information base for assessment and learning processes.

2. The development of cooperation between the health care professions as a contribution towards efficient and effective health care provision

9. Who is to do what in future? What kind of division of labour meets the demands on the health system of the future? Those are the questions forming the basis of the Federal Government's commission to examine new forms of cooperation between the health care professions in the provision of health care for the population in Germany. The Council conducted extensive research into the resources of the health care professions and the current – particularly legal – framework conditions for practising their profession. In addition to this analysis, it launched a written survey among the Länder Ministries in early summer 2006 regarding regional developments in the professional mix in the health care sector and organised a hearing of professional associations on future-oriented models for the division of labour, which was held in summer 2006.

Aims of a new division of labour between the health care professions

10. Reorganisation of the division of labour in the health sector can benefit all health care professions, if it leads to a better match between the requirements of a constantly changing health care system and the aims, tasks and competencies of its players. The current, rapid changes taking place in the health sector are of a complexity that far exceeds past experience. They fuel anxieties among employees, e.g. regarding the threat of job losses or closure of the practice, and they lead to dissatisfaction owing to excessive work loads, the restriction of professional autonomy and inadequate, e.g. monetary, recognition.

11. Instead of the previously favoured concentration on the individual interests of the respective occupational group and the attempt to optimise the situation exclusively within the occupational group, expanding cooperation between the health care professions can be far more advantageous for all concerned, and not least for the patients, than sticking to old patterns. This is particularly true if the self-image of the health care professions changes in that flat, networked team structures are seen as being sensible and viable. The realisation of this development should be geared to the following targets:

- The justification for a new distribution of tasks should be derived from the reduction of current deficits and an improvement in the quality and efficiency of the health care services provided for patients.

- Health care provision and the occupational groups cooperating in teams must pay equal attention to both the quality aspect and cost-effectiveness in this context. Services must always be rendered where this can be done with the least input of resources while maintaining at least the same quality of care.
- The current debate on patient safety, in particular, reveals the dependence of a modern health system on intact communication, flat team structures and the separation of functional and hierarchical competencies.
- The changed roles of the health care professions must be structured flexibly, appropriately for the prevailing local conditions and in a manner permitting further development, so as to be able to react optimally to future necessities that are not always foreseeable.
- The new job descriptions should offer the realistic option of improving the job satisfaction of the occupational groups by means of a sensible division of labour and should guarantee that activities can be performed in accordance with an individual's level of qualification.
- The change in the distribution of tasks among the health care professions must contribute to reducing the dependence of the burden of disease on socio-economic status.

12. Following detailed examination and after obtaining several statements by legal experts, the Council points out that any change in cooperation and the division of labour between the health care professions existing today necessitates a review and, where appropriate, amendment of the statutory requirements. Moreover, the assumption of new spheres of work, or changed responsibility (liability), presupposes adjustments in the field of the respective primary qualifications of the individual professions, or corresponding specialist training.

Status quo of cooperation between the health care professions

13. The health sector is a major economic factor. The number of people employed in this sector in 2005 was 4.3 million, which is equivalent to 11 % of all employed persons in Germany. Health care predominantly involves the provision of personal services. The rendering of services by the health care professions usually necessitates very close co-

operation, communication and co-production with patients, and also with other service providers in the system. Cooperation between the health care professions currently displays a number of deficits that should be remedied in the process of developing an improved distribution of labour:

- The distribution of activities between the occupational groups does not match the demographic, structural and innovation-related requirements,
- A high degree of legal uncertainty exists as regards the division of labour between the health care professions, particularly between physicians and the nursing sector,
- There is too little interprofessional standardisation¹, making cooperation and delegation substantially more difficult,
- Health care appears to be physician-centred, which is not always efficient, and
- Training in the health care professions does not offer adequate preparation for cooperation with other health care professions.

14. The central position of physicians in health care is partly a result of the statutory framework conditions. For physicians, the Federal Medical Code states that practice of the medical profession means the practice of medicine under the professional title of "physician". Only the Alternative Medical Practitioners Act (HPG) of 1939 offers a definition of medicine ("any activity, undertaken professionally or commercially, for determining, healing or alleviating diseases, suffering or physical injury in humans"). According to the HPG, the physician (or alternative medical practitioner) would have to render all health care services personally. In addition, the obligation of the physician to render services personally is embodied in various other legal norms (professional code for physicians, social law, remuneration law). In the everyday provision of health care, however, numerous health care professions are in fact directly involved in the determination, healing and alleviation of diseases (and thus in medicine). The HPG makes no reference whatsoever to the non-physician health care professions. Moreover, the definition of medicine in the HPG is incomplete from today's point of view, since it does not describe preventive tasks, for instance.

¹ Involvement of all relevant occupational groups in the elaboration of standards, i.e. also non-physician health care professions. Moreover, the standards should increasingly also describe the work shares performed by non-physician professions and the possibilities for assumption of activities by them.

15. If tasks are to be redistributed between the professions, and the possibility of transferring activities (e.g. from physicians to non-physician health care professions) is to be assessed, recourse has to be taken to case law. This situation repeatedly leads to problems and uncertainties, especially when the transfer of tasks to non-physician health care professions is involved. Moreover, the players face the question as to the extent to which independent action of non-physician health care professions is possible and how liability is shared. This results in legal uncertainty on the part of many employees and operators of institutions in the health sector. Together with the absence of standardisation and a lack of knowledge regarding the content of the work of the other occupational groups, this uncertainty leads, on the one hand, to the performance of tasks below an individual's level of training – for example, physicians often give infusions or do administrative work – and can, on the other hand, contribute to deteriorating quality of care, unnecessary jeopardisation of patients and, therefore, inefficient health care provision.

16. The inadequate elaboration of interprofessional guidelines is a further indication of the lack of coordinated cooperation between the health care professions. It is primarily interdisciplinarity between physicians that is to be found in the elaboration of guidelines up to now. Other health care professions have now also begun to develop standards, e.g. in nursing or physiotherapy, but without appropriately involving physicians. This fails to exploit the opportunity to create new, more efficient and scientifically based cooperation structures between the health care professions.

17. In terms of content, training in all health care professions gives only inadequate consideration to later cooperation, i.e. the training content in the different occupations is not coordinated.

Current and future demands on the health care professions

18. People working in the health sector must face challenges that result from several developments and are greatly accelerating reorganisation of the occupational division of labour: the complexity of the organisations in the health sector is high and has increased even further in recent years. Against this backdrop and in view of progressing specialisation (division of labour), the primary aim is to improve the integration of the activities and services of different health care professions. Demographic trends and changes in the morbidity spectrum are further challenges for the health care system and its players. Areas in the German health system where overuse, underuse and misuse prevail are com-

ing under growing pressure as a result of the rise in the number of older, chronically ill and increasingly multimorbid patients. A change in the needs and requirements of the users of the system also necessitates reorganisation of the responsibilities for the wide range of tasks in health care provision. The central problem is inadequate intersectoral health care provision and the lack of interdisciplinary and flexible health care structures. Covering the growing demand for personnel resources for the provision of health care services in a progressively ageing society is becoming increasingly important. Apart from the recruitment of young staff, one of the key demands on all health care professions is adequate qualification and preparation for the changed user realities. Finally, developments resulting from progress in medical technology, which has a major influence on work structures, the content and forms of work in the health care sector, give rise to a need to adjust the distribution of tasks between the professions in the health sector. The influence of progress in medical technology results not only from medical interventions, but also from advances in biotechnology or in information and communication technology.

19. Modern forms of cooperation are already being practised in response to changes in the health system, as will be illustrated below. These forms of cooperation between the health care professions need to be sensibly developed and expanded in the future:

- The multiprofessional outpatient team, whose task is to provide health care for an ageing population that is increasingly suffering from chronic and multiple diseases and that encompasses all occupational groups necessary for providing ubiquitous health care,
- Transsectoral case management, the aim of which is to handle cases in the three sectors of outpatient, inpatient and rehabilitational care, and that focuses on new functions, primarily with regard to patient-oriented coordination of treatment when moving between sectors and on achieving joint treatment success, and
- The highly specialised treatment team in a hospital, which develops and applies innovation-oriented methods, taking recourse to specialisation and new forms of cooperation between the occupational groups, since the innovation could otherwise not be realised.

20. The need for reorganisation of the cooperation between the health care professions is not least emphasised by the occupational groups themselves. Thus, all the professional associations attending the hearing state that they will react to the new demands

on health care provision in the health sector by developing their respective professions accordingly, although their ideas occasionally differ greatly. The representatives of the professional associations unanimously speak of the great importance of basic training, specialist training and continuing education for better cooperation. They also mentioned various areas in which teamwork could be improved: early recognition and care of neglected children, treatment of children, adolescents and adults with certain psychological disorders, new care concepts (e.g. integrated health care, DMP), rehabilitation, health care provision in rural areas (with a shortage of physicians), health care for addicts, patient counselling and training, oncology, palliative and hospice care, care of dementia patients, the chronically ill, multimorbid and elderly patients, patients in need of long-term care and care of patients with complex social problems. Some professional associations point out the importance of legally regulated distribution of tasks and competencies, addressing the problem of segmentation of the health care system and the different funding agencies. At the same time, multiprofessionally elaborated guidelines are named as an important basis for improving cooperation between the occupational groups. Opinions regarding the need for reform of the (statutory) framework conditions for cooperation range from the view that there is basically no need for changes, all the way to far-reaching proposals affecting several statutory regulatory systems. It is in this context that various non-physician professional associations put up for discussion what they consider to be the overly dominant role of physicians in health care provision and propose changes that assign them a more independent role in practising their (health) profession. As regards the assignment of physicians' activities to other occupational groups, there is discussion not only of the standard form of delegation (under the instructions and supervision of a physician), but also of totally independent performance of certain activities. Corresponding competencies on the part of the substitute are considered to be the prerequisite for delegation. Separation of the rendering of services by non-physician health care professions from prescription by a physician in Book V of the Social Security Code (SGB V) is partly advocated and partly rejected. Advocates name the following individual services: prescription of remedies and therapeutic appliances, repeat prescription of medication for chronically ill patients, rights to hospitalise certain patient groups, dispensation with referral by a physician in favour of direct patient access to certain service providers. Opponents point out the high standard of health care provision in Germany that is achieved because many activities are performed by highly qualified physicians, and also the danger of an increase in the volume of benefits and services if other health care professionals are permitted to prescribe.

21. The Länder Ministries surveyed by the Council primarily describe their efforts to shape the future of the mix of professions in health care provision in the context of the impact of demographic change. The associated initiatives focus on regional specifics. On the one hand, Federal Länder with a low population density, in particular, support the safeguarding of outpatient care by means of physician-relieving and community-oriented projects, such as the AGnES project²; on the other hand, Federal Länder with a high population density accompany projects involving new competence profiles for non-physician health care professions. New occupations have already developed in this way, e.g. that of surgical assistant. In addition, funding is provided for models aimed at increasing academicism, e.g. in the nursing occupations.

22. On the whole, the Council can say that there are numerous initiatives of the individual health care professions and the responsible Länder Ministries for improving the division of labour. Empirical evidence that planned and implemented models for a changed distribution of labour lead to better health care provision is naturally still missing, owing to a lack of model evaluation.

2.1 Recommendations on cooperation

23. The debate about new forms of cooperation and competencies of health care professions must be held not primarily from the point of view of the occupational groups, but on the basis of the future demands on the health system – i.e. from the point of view of the patients. The most important future demands result from demographic factors (ageing of society), the disease spectrum (multimorbidity), innovation (faster introduction of new methods) and the integration of health care provision (abolition of the sectoral structure). The prerequisite for any sustainable change in the distribution of tasks between the health care professions is a willingness of the individual service providers to re-think, accept a change of paradigm and thus abolish traditional, but now outdated methods for allocating resources and regulatory autonomy. The hearing of the professional associations showed that many occupational groups themselves already consider the existing fragmentation of health care provision to be an unsatisfactory situation. In view of the explosive nature of the idea of changing the distribution of tasks, it is advis-

2 The "Physician-Relieving, Community-Oriented, E-Health-Assisted, Systemic Intervention" (AGnES) pilot project in Mecklenburg-Western Pomerania and Brandenburg employs specially trained nursing professionals to relieve the workload of family doctors (country doctors).

able to start with small steps. In the first step, physicians' tasks can be handed over to non-physician health care professions by way of delegation. In the second step, regional pilot projects relating to changing the mix of professions and greater independence of non-physician health care professions should be implemented and evaluated. If these pilot projects demonstrate their practicability, the innovation should be introduced on a wider scale in the third step. The Council recommends a clause regulating pilot projects to increasingly involve non-physician health care professions in health care provision.

24. Changes will only come about through a mix of different forms of occupational role changes: activities can be transferred from one occupational group to another (delegation or substitution), specialisation in specific tasks can emerge, and new spheres of work have to be integrated, either by being assigned to existing occupational groups or by being covered by new occupational groups (diversification or enhancement). Once a transfer of activities by the delegation method has been practised sufficiently long and proven to be appropriate to the goals, permanent transfer to the previous substitutes should be open to discussion. In this context, the legal prerequisites need to be clarified (e.g. the sharing of liability between the professions) and legal changes made, where appropriate. The frequent transfer of activities previously performed by physicians to nursing or other health care professions presupposes either an increase in manpower in the receiving occupational group or, in turn, transfer of its activities to others. For example, tasks of specialist nursing could be passed on to nursing care. As regards activities that are so far inadequately covered in the provision of health care services, e.g. in the field of prevention, or for new tasks, e.g. technology-assisted tasks, it would be advisable to assign the work in question to the corresponding occupational groups from the outset and to increasingly involve non-physician health care professions. All three forms of occupational role change will have to be exploited and coordinated with each other, depending on the health care provision situation. By way of example, this will be illustrated on the basis of the three modern forms of cooperation mentioned earlier.

25. The multiprofessional outpatient team: Ageing and multimorbidity are confronting health care with major problems. Concepts in the field of primary care that have already been implemented internationally illustrate corresponding possible solutions and are in some cases currently also being tested in Germany, such as the Chronic Care model. It supports patient self-management – e.g. by means of patient training, which can certainly also be given by non-physician health care professions – structures the procedures for providing health care services by more efficiently distributing the tasks in the health care team, works on the basis of guidelines and uses clinical information systems. The

Council recommends adoption of the principles of the Chronic Care model to improve outpatient care in Germany, as well as the increased utilisation of non-physician health care professions for counselling, educational, organisational and preventive tasks.

The transfer of tasks, particularly to the nursing sector, and greater independence of action in that sector are inevitable if the provision of health care services is to be maintained and improved. The adoption of international, sometimes very far-reaching models, such as (e.g.) must be examined. The assignment of responsibility to the nursing sector should be more extensively tested in pilot trials. In future, the nursing sector should firstly itself assess the nursing requirement, secondly bear responsibility for performing nursing, and thirdly assume the task of checking the results of nursing care. The nursing sector should be given the right to prescribe aids and articles needed for nursing care. The nursing sector today does not have the possibility of itself ensuring follow-up supplies of nursing aids and articles, or of initiating the provision of initial supplies. Supplies of nursing aids and articles are totally dependent on prescription by a physician. This leads to interruptions in supplies, especially in rural areas with a low physician density, but also in long-term inpatient care. In addition, more extensive transfers of activities should be examined, such as the possibility of prescribing specific medication groups for a limited period of time.

26. Transsectoral case management: Better case management across sectoral borders (e.g. outpatient, inpatient, rehabilitation) is one of the most urgent demands for the future and is currently already being applied and improved. In conjunction with reduction of the length of stay in hospital, this results in far greater process orientation of health care provision, especially when moving from one sector to another. Case management can be seen as a new task, meaning that, in the spirit of diversification/enhancement, either a new occupation of 'case manager' should be created, or existing occupational groups would have to assume this task. Generally speaking, case management means a reduction of the workload on physicians. It can only achieve its goal if the occupational group of physicians accepts control of the process by non-physician case managers as being authoritative and binding (adherence to deadlines, times of visits, etc.). The Council recommends further strengthening of transsectoral case management, the expansion of corresponding qualification structures and, in this process, particularly exploiting the competencies of the nursing professions. However, in keeping with the concept of pool competence, other appropriately qualified occupational groups can also be involved in the work.

27. The highly specialised treatment team in a hospital: Even in the past, this innovation-oriented sector was open to new structures of the spheres of work of the occupational groups (e.g. intensive-care medicine, transplantation medicine). The reason for this was that innovations can be implemented more effectively in team structures than in rigid, hierarchical structures, where responsibilities first always have to be negotiated anew before innovative methods are approved. The experience gained here should serve as a model for demonstrating the link between organisational structure and capacity for innovation to other sectors.

Both specialisation, the transfer of activities and the integration of new tasks are to be found in highly specialised teams. Examples include the employment of surgical assistants (transfer of physicians' activities, simultaneous specialisation of nursing staff, for example) and the assumption of documentation tasks in the DRG system by medical documentation assistants (new tasks are integrated). Increasing academicism of the health care professions is of great importance in highly specialised teams, because the implementation of innovation can be accurately examined and taken forwards by a multiprofessional concept of (health services) research.

28. The introduction of tasks reserved for individual non-physician health care professions is not a suitable means for redistributing tasks, since it would again create inflexible structures. Instead, pool competencies would appear to be more sensible, enabling a group of appropriate health care professions to perform activities. In this context, the qualification necessary for carrying out a specific activity is defined and can be acquired by various health care professions. In this way, health care provision can react more flexibly to special regional features, e.g. as regards the personnel composition of a support team or the personnel competencies. At the same time, this would create clearly defined responsibilities for the activities involved in health care provision. However, vocational training and specialist training must cater to these pool competencies. Reserved tasks are only suitable for increasing patient safety in connection with particularly risky interventions.

29. To achieve better interaction between all health care professions and for early acquisition of competencies in the field of cooperation and collaboration, it is advisable to gear training in all health care professions to action on a common object. This is made necessary by medicine, which is becoming increasingly diverse and complex, as well as by evidence-based decision-making and the pressure to improve efficiency. The Medical Faculties of the universities should draw conclusions from this and assume respon-

sibility for education and training for all occupational branches that belong to medicine, including new ones. If the health care professions are to cooperate better in future, this cooperation must already be practised during training. Partial overlapping of training contents and stages holds the promise of better mutual understanding.

30. The Medical Faculties should assume the task of continuous further development of health care professions, which is ultimately based on the historical development of health care provision. On the one hand, the almost exclusive purpose of hospitals up to modern times – in addition to salvation – was the provision of nursing care. Only in the early 19th century did medicine find its way into hospitals as places of experimentation and teaching. On the other hand, the surgical disciplines, originating from the occupation of barber-surgeon, already merged with medicine in the 18th century. The same applied to many natural sciences some decades later. Only in the last decades of the 20th century did more and more natural scientists take up independent professorships within the Medical Faculties. From the end of the 19th century onwards, the psychosocial disciplines broadened the horizon of medicine, and independent faculties were established.

31. The Council advises the Medical Faculties to examine whether and to what extent they can expand the range of their professorships, specifically by integrating, for example, nursing sciences and practice, physiotherapy, logopaedics and other health care professions. As part of medicine, non-physician health care professions, such as nursing, can be defined with their own research requirement (cf. 2005 Report, II-6). If cooperation between numerous professions is required when caring for most illnesses, it is only logical to also strive for the necessary degree of community as regards basic training, specialist training and continuing education, and not least research. Multiprofessional research is a central task of universities, meaning that the Medical Faculties are called upon to assume responsibility for cooperation-promoting and interprofessional teaching and research in the field of all health care professions.

32. The process of increasing academicism in various health care professions can in principle be rated positively. However, the hitherto highly heterogeneous study courses should be harmonised in this context. Since this does not come under the responsibility of the Federal Government, it is the responsibility of the Länder and the universities in collaboration with expert representatives.

33. In addition to the further development of academic training for health care professions, there is a need to coordinate the different levels of training within the individual groups of non-physician health care professions. A division of labour between the vari-

ous levels, e.g. in nursing or in physiotherapy, would be an obvious step in this context. Not every activity need be performed by a specialist with academic training. Moreover, multi-level, coordinated vocational training programmes offer occupational prospects for the future and new career options for employees within an occupational group. This leads to graduated responsibilities within an occupational group, and also between occupational groups. These then also need unequivocal liability regulations.

34. To guarantee the quality of professional practice, the Council recommends the introduction of professional identity cards for non-physician health care professions. An identity card of this kind could be used to indicate the authorisation to perform certain activities and store information regarding material and formal qualifications. This would be possible in connection with the introduction of identity cards for health professionals in Germany. At the same time, the identity card for health professionals authorises the health care professions to access electronic patient data, this being relevant to all health care professions involved in patient care. The identity card for health care professionals thus offers a modern form of licensing, registration and information access, and is a step towards establishing nursing and other health care professions as autonomous service occupations with recognised competencies and regulated self-control.

35. Guidelines can contribute to counteracting legal uncertainty regarding any redistribution of tasks between the health care professions, because the medical standard determines the standard under liability law. With the help of guidelines, the parts of the work performed by non-physician health care professions can be described and possibilities for the assumption of activities presented. Guidelines should be elaborated on an interprofessional basis, involving all the affected health care professions.

36. Since the determination, healing and alleviation of diseases, i.e. the practice of medicine, can only be effective and efficient if all health care professions interact, the Council recommends that the definition of the concept of medicine be modernised, since it is currently still based on the Alternative Medical Practitioners Act of 1939. On the one hand, the new definition should make it clear that the population can only be provided with health care services if all health care professions cooperate. On the other hand, the definition should also include tasks of prevention, i.e. the avoidance of diseases. Also to be examined is the question of to what extent there is a need to amend the obligation of physicians to render services personally, as defined in various legal norms.

37. Good cooperation of the numerous health care professions in interprofessional teams and across the different sectors of health care provision requires a target-oriented

division of labour among different occupations that accept each other and respect the specific competencies of the others. Part of this is that the occupational titles take into account the division of labour in teams. In the spirit of cooperation based on partnership, the titles selected when re-categorising the health care professions should avoid misleading connotations, such as subdivisions into health professions and assistant health professions or medical professions and assistant medical professions.

3. Integrated health care in SHI: development, status and prospects

38. In its Report for 2003 (Paras. 647ff.), the Council already made several proposals regarding target-oriented further development of health care structures, and the legislature has in the meantime implemented a major proportion of these recommendations. The laws passed in recent years, primarily the SHI Modernisation Act (GMG) of 14.11.2003, the Panel Doctors' Rights Amendment Act (VÄndG) of 22.12.2006 and the Act to Strengthen Competition in the SHI System (GKV-WSG) of 26.03.2007, created a greatly improved legal framework for integrated health care, and thus at the same time for efficiency and effectiveness-boosting competition at the interfaces between outpatient and inpatient care. As potential contract partners, the health insurance funds and service providers now at least find adequate regulatory prerequisites for implementing innovative health care concepts or launching corresponding projects.

39. Although some 3,500 applications relating solely to integrated forms of health care according to Section 140a-d SGB V have been submitted up to now (end of the 1st quarter of 2007), and although a number of "lighthouse projects" in this field are showing certain signs of success, an interim assessment of what has so far been achieved from a health-related and economic point of view cannot yet be regarded as satisfactory. Since integrated forms of health care are part of standard care, the law makes no provision for obligatory evaluation of the programmes or networks in the corresponding projects – in contrast to the pilot projects according to Sections 63-65 and the structured treatment programmes according to Section 137f-g. Where this is done voluntarily, even the published results show no indication of the targeted breakthrough towards more efficient or effective patient care. At the interfaces between the different service sectors, there still exists a substantial rationalisation potential that has not yet been exploited and whose realisation could be facilitated by more intensive competition, among other things. In this context, there are still deficits as regards the transparency that insureds and patients have in relation to any health care options and service qualities, regarding the competition parameters of the health insurance funds, the remuneration systems of the service providers, quality assurance, drugs distribution, the relationship between the individual varieties of integrated health care and target-oriented cooperation among the various players.

40. Like competition, integrated health care in all its different forms is not an end in itself, but a means for realising health-related and economic goals. This means that projects on integrated health care do not in themselves satisfy the target criteria, but can –

and, from the normative point of view, must – demonstrate their efficiency and effectiveness only through their ratio of health-related outcomes to the input of resources. Like almost the entire German health sector, most projects on integrated health care still display a noticeable lack of outcome and target orientation. In this context, outcome indicators express – in the most quantitative form possible – the health-related benefit or the corresponding welfare accruing to patients and insureds from health care or certain health care services. Compared to outcome indicators, which reflect the life expectancy and quality of life of patients and insureds, management indicators, which also encompass the specific forms of health care and health strategies, are of only instrumental importance from the target-related point of view.

41. Integrated health care projects make use of certain elements of managed care, in different forms and to different degrees. In addition to a wide range of action parameters of the health insurance funds in the field of contract and service structures, they primarily include intersectoral coordination and cooperation between all players involved in the treatment procedure, patient control, selective contracting of the health insurance funds with selected service providers, advance flat-rate payments in the form of capitation or complex fees for defined service packages, and intensive quality assurance. As defined here, managed care encompasses not only inter-indication, population-related health care networks, but also disease management and case management, among other things. In this context, disease management refers to patient groups with certain similar, usually chronic diseases, whereas case management concentrates on individual complicated and usually expensive cases of illness.

42. Table 1 provides a synoptic overview of the managed care elements in the 'special forms of health care'. Although all these health care forms, except the pilot projects, are part of standard care, several of them have an interdisciplinary and intersectoral orientation and permit selective contracting, as well as, explicitly or implicitly, payment of the service providers by capitation or complex fees. However, only the limited-term pilot projects and structured treatment programmes prescribe obligatory evaluation of the respective programmes by independent experts. The possibility of selective contracting only fundamentally precludes collective agreements or the involvement of the Regional Associations of SHI-Accredited Physicians (KVs) in the case of integrated forms of health care. In contrast, the service guarantee of the KVs can be restricted in connection with three forms of health care.

43. Compared to the existing allocation processes in SHI, the projects on integrated health care also aim at improving the efficiency and effectiveness of the German health sector by intensifying competition between health insurance funds and service providers. This necessitates both an increase in the competition parameters of health insurance funds and service providers, and also a tendency to shift allocation decisions from the macro level to the meso level and ultimately to the micro level. Joint and uniform action, or corporative control, is then increasingly replaced by decentralised negotiations and thus by competition for contracts and health care provision with selective contracting. In this context, it is not a question of replacing collective agreements by selective contracting, and of abolishing the Regional Associations of SHI-Accredited Physicians (KVs) as a result. Rather, selective contract negotiations can, as indicated in the Report for 2005 (Paras. 38ff.), also be held within a collective contractual framework and likewise complete with corporative coordination.

44. Integrated health care encompasses both the integrated forms of health care according to Section 140a-d SGB V and the structural contracts according to Section 73a SGB V, as well as the pilot projects and the structured treatment programmes. The interest of the contract partners currently focuses more on the integrated forms of health care and the structured treatment programmes according to Section 137f-g, owing to their pronounced incentive structures. The structured treatment programmes target integrated health care for the chronically ill and are a variety of disease management programme. However, the contract partners can also implement indication-specific treatment programmes of this kind with the help of integrated forms of health care or pilot projects. Structured treatment programmes are thus only a subset of disease management programmes (DMPs), specifically the variety that is linked to risk structure compensation.

Table 1: Managed care elements in the special forms of health care

Health care forms Elements	Conventional health care	Structural contracts	Pilot projects	Family doctor- based health care	Special outpatient care	Integrated forms of health care	Structured treatment programmes
Legal basis	SGB V	Section 73a	Sections 63-65	Section 73b	Section 73c	Section 140a-d	Section 137f-g
Voluntary nature of the offer		X	X		X	X	X
Interdisciplinary design		X	X		X	X	X
Intersectoral orientation			X			X	X
Selective contracting possible			X	X	X	X	
Collective agreements possible	X	X	X	(X) ^{a)}	X		X
Restricted service guarantee of the KVs				X	X	X	
Special financial incentives						X	X
Obligatory evaluation			X				X
Limited duration			X				X
Capitation possible		X	X	(X) ^{b)}	(X) ^{b)}	X	

a) If groups of SHI-accredited service providers authorise the KVs accordingly.

b) Not unequivocally regulated in the law.

Source: Own data

45. Above and beyond the specific organisational forms of integrated health care, the legislature has in recent years offered hospitals diverse options for participating in outpatient care. This particularly applies to the provision of outpatient surgery, the rendering of highly specialised services on an outpatient basis, and the Medical Service Centres (MSCs) according to Section 95 Para. 1. Of the current (end of 2006) 666 licensed MSCs, 29 % are operated purely by hospitals, although only 7 % of all hospitals have so far established an MSC. Through a modified Regulation on the Licensing of Doctors, the VÄndG enables SHI physicians in private practice to form efficient treatment networks without having to avail themselves of the services of an MSC. In this context, 'special outpatient physician care' deserves special attention in the GKV-WSG. In its framework, the health insurance funds can, alone or in cooperation with other funds, conclude contracts covering both the entire sphere of outpatient physician care on a population-related basis and individual areas thereof on an indication-related basis. The KVs can likewise act as contract partners of the health insurance funds in the framework of special outpatient physician care, whereas the integrated forms of health care preclude such collective agreements (see Table 1).

46. For successful implementation of integrated forms of health care, the GMG not only eliminated the previously existing weaknesses in the framework regulations, but also contributed to additionally improving the incentive structures with its one-percent start-up financing. The VÄndG prolonged this start-up financing up to the end of 2008, and the GKV-WSG enables health insurance funds to offer greatly expanded selectable tariffs, which can primarily be applied in the context of integrated health care. The regulation that health insurance funds must finance every single selectable tariff from specific savings, is the legislature's attempt to prevent the risk selection that would otherwise obviously occur. The corresponding reports and evaluations promise a broader base of information regarding the hitherto disputed suitability of this type of tariff in SHI.

47. As a result of the attractive start-up financing, the number of contracts relating to integrated forms of health care registered by the German National Institute for Quality Measurement in Health Care (BQS) rose from 613 in the first quarter of 2005 to 3,498 in the first quarter of 2007. Almost 99 % of these contracts are indication-specific and mainly relate to surgical interventions, e.g. hip and knee joint endoprosthetics. In contrast, the directory provision in the GKV-WSG calls for "population-related, ubiquitous health care" in this context. Of the approx. 4.07 million registered insureds (figures for the first quarter of 2007), however, more than half are covered by contracts for family-

doctor and interdisciplinary health care, although these contracts only account for a good 1 % of the total. There is controversy as regards whether and to what extent family doctor-based models meet the criteria of integrated forms of health care in individual cases. Purely family doctor-centred health care according to Section 73b SGB V, which covered approx. 1.3 million insureds in mid-2007, can definitely not be classified as integrated health care. Family doctor-based models can, however, be expanded to include modules of the other special forms of health care, and thus transformed into integrated health care. Since approx. 2.69 million insureds were taking part in structured treatment programmes at the end of 2006, the total number of insureds in the special forms of health care now amounts to over 8 million.

48. In contrast to indication-related projects, population-related projects, which target all insureds of the respectively contracting health insurance fund in the region, have the advantage of being able to comprehensively determine and optimise the service quality. The health-related development of non-registered insureds in the same or other regions can serve as a benchmark or assessment criterion. A population-related network of this kind can also purchase any materials, drugs and therapeutic appliances, as well as medical equipment and products, at favourable prices.

49. Complex population-related health care networks generally make provision for a constant (medical) contact selected by the insured, this usually, but not necessarily, being a family doctor. This physician is then compelled to assume diverse new functions and expand his or her knowledge regarding multimorbidity, this benefiting older patients, in particular. Successful performance of such a gatekeeper function requires not only commitment, but also extensive knowledge of differential diagnosis, psychosocial skills and, beyond this, knowledge of regional assistance and support organisations.

50. From the medical and economic point of view, the structured treatment or disease management programmes are a variety of integrated health care. There are currently six such DMPs, i.e. for the indications Type 1 and Type 2 diabetes mellitus, breast cancer, coronary heart disease, asthma and chronic-obstructive pulmonary disease (COPD). They differ from other approaches to integrated health care mainly in that they are linked to the risk structure compensation system. The registration of chronic patients in a DMP for Type 2 diabetes, coronary heart disease or breast cancer increases the specific contribution requirement of a health insurance fund by an average of 250 %, 252 % or 376 %, respectively. The health insurance funds thus have a great financial incentive to implement DMPs ubiquitously with the help of the KVs and to encourage all chronic

patients to register. The link between DMPs and risk structure compensation thus leads to a registration competition between the health insurance funds, rather than the targeted quality competition. Moreover, restriction to just six chronic diseases threatens to jeopardise the treatment of others, this possibly being a disadvantage not only for certain patients, but also for specific service providers and health insurance funds. Finally, the uniform structuring of the DMPs prevents promising, decentralised search processes, thus leaving potential for competition unused.

51. Although the results of international empirical studies on the effects of DMPs differ, these findings nevertheless permit the conclusion that DMPs are fundamentally also capable of improving efficiency and effectiveness in the German health sector. However, this requires suitable incentive structures and target-oriented cooperation between all the players involved. Seen from this angle, not DMPs as such are up for debate, but their current structure and, above all, their link to risk structure compensation, which is accompanied by uniform programmes and a lack of risk stratification. The external evaluations by independent experts, to which the health insurance funds are committed by law in connection with DMPs, will probably not be available until mid-2007. The first publications by health insurance funds suggest that DMPs lead to greater patient satisfaction and a number of improved surrogate parameters, but not to a generally convincing cost-benefit ratio. In view of the substantial administrative effort involved, not the renunciation of DMPs is the adequate benchmark here, but other forms of health care, such as pilot projects, forms of integrated health care and, in that context, case management. If risk structure compensation experiences the differentiation envisaged in the GKV-WSG, the linking of DMPs to risk structure compensation will expire at the end of 2008.

52. Since Switzerland and the USA already have longer and more extensive experience with managed care approaches, it would make sense to examine the development of integrated health care models in these countries and look for findings that can be put into practice in the provision of health care services in Germany. Contrary to the originally far more optimistic forecasts, the market share of managed care models in Switzerland in 2005 was just 12.1 %. With 6.7 %, family doctor-based models are dominant among these managed care approaches, while the classical health maintenance organisations (HMOs) achieve only 1.4 %. Regardless of their low prevalence, studies agree that HMOs have greater cost-cutting potential than family doctor-based models. Experience in Switzerland shows that selectable tariffs are perfectly capable of surviving in regulated competition with other forms of insurance. In this context, it is generally apparent

that the health insurance funds should base their advertising on the quality of treatment, rather than on premium payments. managed care models become more attractive for insureds if they allow them to also consult a service provider outside the network in individual cases in return for co-payment. The Swiss legislation refrained from compelling the health insurance funds to offer certain managed care models. Competition in the form of a search process led to the health insurance funds taking models off the market again if they failed to live up to expectations.

53. In the USA, the establishment and spread of managed care organisations (MCOs) was a reaction to rapidly increasing health expenditure and quality deficits in the 1980s. In contrast to Switzerland, MCOs in the USA have in the meantime succeeded in capturing a 93 % share of the market, thus virtually ousting conventional health insurance. Among the MCOs, the proportion of health maintenance organisations (HMOs) dropped from 31 % to 20 % between 1996 and 2006. In the same period, on the other hand, there was an increase from 28 % to 60 % in the share of Preferred Provider Organisations (PPOs), which grant insureds greater freedom in choosing the service providers. Since the employers pay the greater part of the insurance premiums in the USA, the applicable benefits catalogue and the terms for utilising it also reflect developments on the labour market. The targeted increase in the efficiency of health care provision was often frustrated by a lack of qualified networks on the provider side, insufficient competition between the health insurers and the market power of the providers. Among other things, it was found that the pure integration of hospitals and outpatient physicians does not generate efficiency gains if there is no competition between the network providers. This situation exists, for example, if all health insurance funds conclude contracts with the same provider networks – much as in the case of the structured treatment programmes in Germany. As a result of the high market share of MCOs in the USA, aspects of competition policy and law play a major role on the supply and the demand side. Independently of the question as to the commercially oriented nature of health insurance funds or the validity of the functional business concept, the experience in the USA suggests a need for accompanying measures in the law on competition and cartel law in the case of competitive markets. To prevent undesirable developments and the resultant harm, the move towards a more competition-based system requires an appropriate regulatory framework.

3.1 Recommendations on integrated health care

54. Intersectoral optimisation that overcomes sectorally oriented calculation calls for uniform service definitions and identical (minimum) quality standards at the interfaces between the service sectors, as well as identical remuneration for identical services. In the interests of functioning and fair competition, not only quality assurance needs to be given a uniform, intersectoral structure, but also the approval of new treatment methods and the financing system. Relatively large outpatient units and MSCs can implement modern procedures in much the same qualified manner as hospitals. As regards remuneration, intersectoral financing agreements with complex fees would be an obvious possibility. Identical competitive opportunities among hospitals, and between hospitals and SHI-accredited physicians, imply monistic financing, which also holds the promise of better resource allocation. Otherwise, competition aspects would suggest remuneration reductions for inpatient institutions compared to outpatient facilities.

55. With the exception of the obligatory offer of family doctor-centred health care, all special forms of health care are based on contracts, and thus on agreements between health insurance funds and service providers. Even in the past, i.e. since the beginning of structural contracts and pilot projects, the initiative for the corresponding negotiation processes came from both sides. In this context, involvement of the SHI-accredited physicians at an early stage particularly leads to greater acceptance. This, alongside patient compliance, is one of the key prerequisites for exhausting the potential for improvement when introducing new health care concepts. As a rule, for example, the SHI-accredited physicians only accept network-internal drug positive lists that they themselves have helped to compile and update. In the interests of dynamic, continuing development of health care processes, it is also necessary in this context to avoid strict definition of the respective competencies in the contract. The contracts should remain open to adaptation in line with medical and technical progress, and learning effects from evaluation results.

56. The activity of the service providers in outpatient and inpatient health care is based on once-only registration acts in the context of collective contracts, but on individual contracts in the case of selective contracting. In this context, the registration of physicians in private practice and of hospitals for the provision of health care services in SHI is primarily based not on quality criteria, but on regional capacity calculations. The service providers or *beati possedentes* registered at a given time are thus not necessarily characterised by higher quality than those who are so far (still) excluded from participation in the provision of health care. For this reason, and also to promote quality-based

competition, those physicians in private practice and those hospitals who are currently not registered, but meet the specific quality requirements, should also be able to contract selectively with the health insurance funds (see also Report for 2005, Para. 109). The exclusion from health care provision in SHI of service providers who demonstrably meet the qualitative demands better than others, is irreconcilable with target-oriented competition.

57. Since the structured treatment programmes are a variety of integrated health care, there are no convincing grounds for separating DMPs from the remainder of integrated health care and applying different financial incentive mechanisms to them. Given risk structure compensation that is thoroughly differentiated as regards the morbidity indicators, there is no need to link DMPs to risk structure compensation anyway, although the corresponding regulation in the GKV-WSG still leaves many questions unanswered. With the currently valid system of risk structure compensation, which essentially only equalises age and gender as regards the morbidity structure, there is a need for additional incentives in order to persuade health insurance funds to provide high-quality health care for the chronically ill. Given these conditions, it is logical to incorporate DMPs in the forms of integrated health care and increase their start-up financing for a limited period, as envisaged here.

58. The regulation in Section 73b SGB V, according to which the health insurance funds must offer their insureds special family-doctor or family doctor-centred health care, contradicts both regulatory notions of functioning competition and the idea of integration. From the point of view of competition, it is fully sufficient if the health insurance funds have the possibility of making such an offer. If, compared to alternative forms of health care provision, family doctor-centred health care has comparative advantages in the eyes of the insureds or patients, and leads to greater efficiency and effectiveness, the health insurance funds themselves have a major interest in this form of health care anyway. Like its alternatives, family doctor-centred health care should be given a fair chance in the competition process, but not enjoy any privileges. For health insurance funds that would not offer family doctor-centred health care if not compelled by law to do so, the corresponding expenditure is sometimes tantamount to a waste of resources. The experience acquired in Switzerland and the USA likewise speaks against compelling the health insurance funds to offer a specific form of health care, rather than leaving the choice of models to competition as a search process. While, based on the current health care structures, a number of cost aspects may at first glance speak in favour of an obligation to offer family doctor-centred health care, this would ultimately

more resemble a fragmented health care model than an integrated one. In the latter model, family doctor-centred health care plays a central role – not as an isolated and segmented institution, however, but enriched by numerous modules in an integrated network. If no intersectoral financing agreements are reached, complex fees that cover treatment, support and consulting services should be applied, at least to the fee for the family doctor.

59. Since the statutory regulations regarding integrated forms of health care, and particularly DMPs, provide strong financial incentives, there was, understandably, a major decline in the interest of the contracting parties in the pilot projects, which are most likely to aim at decentralised search processes and additionally require accompanying research. However, accompanying research by independent experts also appears to be necessary in connection with the integrated forms of health care, at least in the case of disputed or complex and expensive projects, insofar as they can also constitute innovations in organisational terms. Otherwise, it also remains unclear whether and to what extent the individual models improve the efficiency and effectiveness of health care provision, i.e. demonstrate advantages compared to conventional health care. Finally, the call for evaluation also arises from the financing methods of the integrated forms of health care. Since the financing comes not from a specific budget, but from the general outpatient and inpatient coffers, the co-financers who are not parties to the contracts have a legitimate interest in information and protection when it comes to efficient and effective appropriation of the funds taken from the general budgets.

Considering the fact that projects relating to integrated health care initially cause investment costs that are only reflected in lower expenditure or quality improvements after an occasionally considerable time, start-up financing in the form of global sectoral budgeting for a certain period of time would appear to be a justifiable measure that has so far proven successful, also as regards its incentive structure. In terms of the utilisation of the resources set apart, however, it does not constitute a just solution in terms of causation. From the allocation point of view, it does not guarantee that any efficiency gains occur at the contract partners who generate these positive effects. This requires specific adjustment of the overall remunerations by the amount that the provision of care for the respective network insureds would have cost in conventional health care in the framework of the collective system. The alternative conventional health care in the outpatient and inpatient sector is the benchmark for assessing the efficiency and effectiveness of the integrated networks. All in all, the existing start-up financing and (with the current risk structure compensation system) the possible inclusion of DMPs – the fi-

nancing then being increased to 2 % – can even be justified up to the year 2010. After that, however, the overall remunerations should be adjusted on a specific, morbidity-oriented basis.

60. Target-oriented competition for contracts also presupposes a number of additional structural changes within the types of treatment. It means, for example, that the DRGs in the inpatient sector cannot be fixed prices (see Chapter 4). While the health insurance funds can already conclude discount agreements with pharmaceutical companies in the current system according to Section 130 Para. 8 SGB V, they have difficulty guaranteeing the companies additional sales in the event of price cuts without incurring an unreasonable administrative effort or without the help of the KVs. Apart from the associated problems in terms of the law on competition, the current discount agreements that market-dominating types of health insurance fund conclude with (generics) producers and attempt to implement with the help of KVs, are not in keeping with the principles of competition for contracts with selective contracting between health insurance funds and service providers at the micro level. Finally, if the Price Margin Ordinance is not suspended, German (mail-order) pharmacies will continue to be disadvantaged compared to foreign mail-order pharmacies.

61. Extended options for selective contracting tend to favour concentration processes, both among the service providers and among the health insurance funds. Depending on the specific situation, these processes can trigger negative allocative effects, but also positive ones (see also Report for 2005, Para. 70ff.). The ubiquitous provision of high-quality health care certainly does not need some 240 health insurance funds, about 21,500 pharmacies or roughly 2,100 hospitals. This finding applies regardless of the fact that there is no optimum business size a priori in this respect, but that it must develop in the course of the competition processes and, moreover, changes constantly over time. To safeguard the functional capacity of the competition for contracts and health care provision, intensification of selective contracting in the health sector necessitates the existence of legal norms relating to competition, such as the Non-Restraint of Trade Act (GWB) and the Unfair Competition Act (UWG). The market-dominating position often held by (types of) health insurance funds in a region leaves hardly any possibility for avoiding entering into a contract, particularly for individual SHI-accredited physicians and hospitals.

According to the juristic opinion prevailing to date, Section 69 SGB V totally excluded application of these laws, which is contradictory to strengthening target-oriented com-

petition. Experience with managed care systems in the USA indicates the medium to long-term risks of uncontrolled competition processes. The GKV-WSG catered to these aspects in that it in principle included the applicability of Sections 19-21 of the Non-Restraint of Trade Act in Section 69. Consequently, the bans on abuse of a market-dominating position, discrimination, inequitable obstruction, boycotts and other forms of conduct restricting competition are applicable here. A critical eye likewise needs to be kept on whether these regulations under the law on competition, for which the social courts have jurisdiction, will be sufficient for ensuring functioning competition in the future, or need to be expanded.

Excursion: A way to optimum allocation of health care services

62. With the aim of improving the efficiency and effectiveness of health care, the legislature has, as illustrated in this chapter, created numerous possibilities and incentives in the last 10 years for overcoming the hitherto excessive fragmentation of the service sectors in the framework of medical treatment. Particularly given the diverging interests of the service providers, however, intersectoral health care is not capable per se of guaranteeing the effectiveness and efficiency of the rendering of services. From the allocation point of view, optimum integration of health care services in relation to the incentive systems presupposes that the respective, individual rationales of the service providers correspond to the system rationale of efficient and effective patient care. Under ideal regulatory conditions, this means, in terms of remuneration for example, that physicians who neglect preventive offers or refer patients to specialised units too late, and hospitals that engage in patient selection or discharge them too soon, would end up harming themselves financially and, in view of such expectations, act in compliance with the system in their own interests. These considerations in no way preclude system-compliant health care for ethical reasons, but these motives are – as in all other countries and occupations – no substitute for a regulatory framework with financial incentives for acting in compliance with the system rationale.

63. In the context of rendering health care services, the conditions for harmonising individual and system rationale are most likely to be found in a health care unit offering a comprehensive range of preventive and therapeutic health care services. If a health care unit of this kind receives a flat rate or an intersectoral complex fee from a health insurance fund for specific services, business considerations make the efficient rendering of services only logical. However, external control would remain indispensable for safeguarding the quality of services. If the health insurance fund pays such a comprehensive health care unit an annual lump sum (capitation) for each insured with discharging effect, the service providers also have an interest – insofar as the insureds do not change their health care network, or only rarely – in preventive service offers and no motives for a non-indicated increase in the number of cases and, after registering the insureds, no possibilities for risk selection. The annual lump sum can tend to be morbidity-oriented, but this should not impair the incentive to offer preventive services.

This kind of comprehensive health care unit combines the following, among other things, under one 'economic roof':

- To optimise clinical processes in the spirit of the flow principle, the four levels of hospitalisation – Intensive Care, Intermediate Care, Normal Care and Low Care – including semi-inpatient care and possibly external hospital doctors and a teleportal clinic,
- An affiliated MSC with salaried or self-employed physicians, as well as decentralised family doctors and specialists in private practice,

- The full range of nursing activities,
- All service providers in the field of remedies, such as physiotherapy,
- Specialists for preventive measures,
- Connections with institutions for social work and self-help, as well as
- A network pharmacy with branches that contracts directly with pharmaceutical companies on the basis of indication-specific drug lists.

64. The initiative for such a comprehensive health care unit can come from a hospital operator, which would initially appear sensible from the logistical point of view, but also from a relatively large network of physicians in private practice. In this context, it would be logical for these health care units to concentrate their sphere of activity on specific regions. From the economic point of view, however, it would also be conceivable to centrally pool such health care units from different regions. In economic terms, this supraregionally operating health care enterprise could advertise with a brand name and binding internal quality standards, and exploit the advantages of a network of several teleportal clinics with a specialist clinic. The distribution of the income and profits within the (supra)regional health care units is then left to the discretion of the enterprises or the service providers involved. They have an interest in structuring the forms of remuneration in such a way that the associated incentives harmonise as closely as possible with the objectives of the health care unit. The same applies as regards the distribution of tasks among the health care professions. In the framework of Gatekeeping and case management, tasks and functions can be assumed by physicians and specialised nursing professionals with corresponding qualifications, depending on the requirements profile. Concomitant medical and economic controlling permits any necessary learning processes and swift adaptation.

65. On the service provider side – and indirectly possibly also among the health insurance funds – the emergence and expansion of health care units offering the full range of outpatient and therapeutic services is accompanied by marked intensification of the concentration processes currently already taking place. Several such health care units can still compete with each other in conurbations, whereas the necessary capacities on the supply side are lacking in less densely populated areas. However, if transparency regarding service quality increases in conjunction with outcome management on the part of the health care units, even service providers in different regions are at least indirectly in performance-based competition with each other. The more transparency insureds and patients have regarding the quality of services, the more likely they are, in the event of non-urgent interventions, to give preference to the competence of specialised service providers, rather than the convenience of treatment close to home. The publication and dissemination of quality data with the help of corresponding indicators is a key prerequisite for triggering and intensifying quality-based competition – including at the supraregional level. In areas close to the border, qualified service providers outside Germany can additionally contribute to stimulating competition. Despite the elements of competition still remaining with regionally comprehensive health care units compared to the status quo, the problem of economically unfavourable concentration processes nevertheless becomes greater. As a result, the control function of the agencies responsible for supervising competition acquires far greater importance.

4. Hospital sector: planning and financing

66. The principle of the social state, rooted in Art. 20 of the Basic Law, is the basis of the unchanging responsibility of the state for providing the population with hospital services. The Coalition Agreement stipulates that the regulatory framework for the provision of hospital services is to be reorganised upon expiry of the convergence phase of the G-DRG system (German Diagnosis-Related Groups) at the end of 2008. The Advisory Council takes this as an occasion to address the topic once more.

67. For many years, a discussion has been in progress regarding whether hospital services are rendered in a needs-based and economical manner. Despite a reduction in the number of beds, an international comparison shows that Germany is still well above the European average in terms of bed density and length of stay. The utilisation of bed capacities has continued to decline in recent years, amounting to just 75.6 % in 2005. These figures indicate that excess capacities exist. At the same time, the Länder are increasingly withdrawing from the public funding of investment costs. The adjusted costs of the hospitals have risen by roughly 52 % (nominal) since 1991, while the Länder have cut public investment funding according to Section 9 Hospital Financing Act (KHG) by more than 25 % (status: 2006). The public sector is apparently hardly capable of providing the existing hospital structure with sufficient investment funds.

The fact that there are simultaneously complaints about excess capacities and investment deficits suggests that target-oriented control of the hospital sector has so far succeeded only inadequately. The end of the principle of cost coverage, which began with entry into force of the Health Structure Act in 1993, was a step in the right direction. However, the Federal Government and the Länder have not yet succeeded in also reforming the other central elements of the regulatory framework for the provision of hospital services – namely hospital planning and public funding of investment costs by the Länder.

Hospitals in the context of the fee-per-case system

68. There has been a radical change in the financing of the regular operating and treatment costs of Germany's hospitals in the last two decades. With the aim of arriving at performance-oriented distribution of the financial resources, the system of financing via fixed daily rates for patient care, which had been customary since 1972, was replaced in

several reform steps by a case-related, cost-homogeneous financing system based on flat rates. Introduction of the fee-per-case system was intended to improve not only transparency in the hospital sector, but also the allocation of funds within the hospital, and also between hospitals. Moreover, the introduction of fees per case aimed to eliminate the undesirable incentive, inherent in the system of fixed daily rates for patient care, to unnecessarily prolong the length of stay, and thus to increase efficiency in the hospital sector.

The G-DRG system was designed as a learning system. Its introduction is based on the budget-neutral transitional years 2003 and 2004 and the subsequent convergence phase, which runs from 2005 to 2008 and aims to generally remunerate all hospital services in a Federal Land at a uniform basic case rate from 2009 onwards, ultimately meaning that identical prices are paid for comparable hospital services.

69. The introduction of a new, comprehensive remuneration system posed major challenges for the responsible players. Now that initial difficulties in implementing and further developing the system have been overcome, roughly 1,770 acute-care hospitals in Germany now charge on the basis of DRG fees per case. The interaction between the players in implementing the G-DRG system has also increasingly acquired routine in the past few years. Thanks to a major effort on the part of the self-governing bodies and the Ministry, as well as the individual hospitals and their employees, in the few years since its launch, the system has, all in all, developed from an adapted version of the Australian DRG system into a fee-per-case system in its own right that is tailored to the health care situation in Germany and demonstrates an unparalleled breadth and depth by international comparison.

In the framework of the learning system, the German fee-per-case system has in recent years achieved an ever more accurate picture of the services provided and service-orientation of remuneration. Among other things, this is attributable to the fact that the number of DRGs has risen by almost 40 % since introduction of the catalogue, while a far more differentiated range of valuations has been achieved at the same time. This, too, is an indicator that the compression effect in the G-DRG system, which was repeatedly criticised at the start of the launch phase, has become far less pronounced, having originally put higher-value services at a disadvantage in accounting terms. The fact that the current G-DRG system permits more distinct representation of treatment services than at the time of its introduction in 2003 is also illustrated by the extent of variance

reduction (R^2) that measures the statistical spread of costs: here – excluding the outliers – the system today achieves a remarkable degree of explanation of more than 80 %.

However, in addition to the positive aspects, the further development of the German fee-per-case system also gives rise to problematic tendencies. These particularly include the major increase in the number of supplementary payments, which reduce the system's coverage rate, open the door to fee-for-service payment and cost coverage in the flat-rate system and thus give substantial incentives for increasing volumes.

70. Five years after the launch of the new remuneration system, it is still not possible to make a concluding statement regarding the impact of the G-DRG system. This is partly due to the fact that the self-governing bodies have not yet satisfactorily implemented the mandate to conduct concomitant research. It can nevertheless be stated that the target parameters of the reform – shorter length of stay, greater transparency and improved efficiency in rendering services – have developed positively. For lack of evidence so far, it remains to be seen whether this also applies to the quality of the services rendered and the realisation of health-related outcomes.

As regards transparency, the documentation and encoding requirements of the G-DRG system have led to a situation where the cost and service structures of inpatient health care facilities have become more transparent, and where, with the data according to Section 21 Hospital Remuneration Act (KHEntgG), information on the provision of inpatient services is available that not only enables hospitals to determine their position on a comparative basis, but also offers a valuable starting point for quality assurance if used critically.

As regards lengths of stay, a further decline can be seen on the whole in the context of the G-DRG system, but no acceleration of the reduction of the length of stay. It is probably of central importance in this respect that the mean length of stay in the first few years after introduction of the G-DRG system was comparatively high, meaning that those hospitals that had already succeeded in reducing the length of stay had little incentive to further reduce the length of stay because of the high lower threshold lengths of stay based on the calculation sample. In addition, as a result of the increasing transfer of less severe inpatient cases to the outpatient sector, many cases with a below-average length of stay were no longer included in the length-of-stay statistics. Beyond the general trend, however, there have recently also been signs of an above-average reduction in the length of stay of fee-per-case patients where there is a high proportion of transfers to the rehabilitation or nursing sector – particularly in the fields of orthopaedics and car-

diology. A further decrease in the lengths of stay can be expected in future, also on the basis of international evidence.

Owing to the competition for patients among hospitals, which has become more intensive in the context of the G-DRG system, the inpatient institutions have in recent years made great efforts to improve their efficiency. Apart from optimising cost structures – for instance, by means of horizontal cooperation (e.g. in the framework of purchasing networks or inter-hospital laboratory facilities) – attention also focused on optimising the rendering of services. This was achieved by, among other things, greater standardisation of workflows, the upgrading of admissions management or a new mix of professions in the hospital. In addition to cutting costs and optimising in-house procedures, many hospitals have, in the context of the G-DRG system, also improved their efficiency by changing their range of services. Three trends, in particular, are to be seen here: first, the reorganisation of treatment workflows (e.g. clinical pathways), second, the increasing specialisation of the range of services, primarily by concentrating on the key competencies of the respective hospital and, third, a trend towards increasing emphasis on quality-related aspects. However, the project entitled "Changes in Medicine and Nursing in the DRG System" (WAMP), in which physicians, nursing staff and patients are interviewed regarding the introduction of fees per case, also documents massive fears concerning the impact of the G-DRGs on the work situation in hospitals and the quality of care.

Investment cost financing

71. To safeguard the economic basis of the hospitals, their investment costs have, since 1972, been financed via public funds of the Länder, the operating costs being financed by the health insurance funds (dual financing). This system is based on the idea that the public sector is responsible for building and modernising hospitals and that only their utilisation by patients should be paid for by their health insurance. With the help of public financing of the investment costs of hospitals, it has repeatedly proven possible to overcome investment backlogs and upgrade hospitals in keeping with the latest medical and technical possibilities.

72. On the other hand, the dual financing system has the following faults: the principal causes of excess capacities and the suspected inefficiency were, first and foremost, bed-oriented hospital planning in conjunction with the principle of cost coverage, and fi-

nancing via fixed daily rates. Even in the convergence phase, the transition to performance-oriented fees per case has already led to a marked change in the incentives that induce more efficient rendering of services. However, public investment cost financing, and particularly individual financing, brings about external bureaucratisation of the investment decisions of hospital owners. In an increasingly competition-oriented environment, it is important to hospital owners to be able to decide quickly and on their own when it comes to necessary restructuring measures. In conjunction with the hospital planning of the Länder, public investment cost financing has also contributed to the much-bemoaned isolation of the sectors in the German health sector, since outpatient care and inpatient care are controlled by different institutions. Moreover, the decisions regarding allocation between outpatient and inpatient treatment are influenced: while the investments of the service providers must be financed completely from the remuneration of the health insurance funds in outpatient care, the health insurance funds bear only the operating costs in inpatient care. The relative prices between outpatient and inpatient care thus tend to be distorted. In connection with public investment financing, there are also complaints regarding the exertion of outside influence on the approval of investments by the hospitals: it is said that not only the condition of the buildings or the mandate to provide care decides on the amount of investment financing, but also the negotiating skills of the hospital owners and good contacts with political decision-makers. Moreover, the Länder are increasingly withdrawing from public investment cost financing, as a result of which hospital financing is practically developing into a monistic system.

Privatisation tendencies and competition

73. In addition to the closure and merging of hospitals, there have in recent years also been signs of a trend towards increasing material privatisation of hospitals in Germany's hospital landscape. Since the early 1990s, the proportion of privately-owned general hospitals has risen from 14.8 % to 26 %, while the proportion of public hospitals has declined from 46.0 % to 35.1 %, and that of non-profit private hospitals from 39.1 % to 38.6 %. Although this picture is put into perspective by the fact that more than half of all beds were still publicly owned in 2005, and only roughly 11 % privately, the shift in the owner mix is also clearly visible in the bed sector. In this context, the trend towards material privatisation, which most recently also began to affect university hospitals, is accompanied by a trend towards formal privatisation. As a result, the number of legally

dependent public hospitals (e.g. municipal or publicly owned) has declined steadily in recent years, while the number of public hospitals having a private legal form (e.g. private limited company/non-profit company) has increased at the same time.

74. The described trend towards privatisation of inpatient institutions is accompanied by a growing number of hospital mergers. This development is by no means restricted to private institutions, but can equally be observed among public and non-profit private hospitals. Nonetheless, the trend towards forming chains, i.e. towards uniting several hospitals under a common umbrella, is currently most apparent in the private sector.

75. In addition to privatisation and the establishment of chains, one key feature of the recent changes in Germany's hospital landscape is the increasing competition between the institutions. Against the backdrop of excess capacities, decreasing lengths of stay and remuneration on a fee-per-case basis, they are increasingly competing for patients. Together with the trends described above, this intensification of competition is leading to, among other things, cartel law and the law on competition acquiring greater importance in the German hospital sector. This is particularly true since the first prohibitions of hospital mergers by the Federal Cartel Office, which has in the course of the last two years prohibited the acquisition of the district hospitals in Neustadt and Mellrichstadt or Eisenhüttenstadt by the Rhön-Kliniken AG company, as well as the acquisition of Wolgast District Hospital by Greifswald University Hospital. It can be assumed that privatisation, the establishment of chains and competition in the hospital sector will continue or become more intensive towards the end of the convergence phase and beyond – even though the forecasts concerning the number of hospital closures, the concrete changes in the owner structure and the continuing concentration process arrive at widely different results. However, based on the intensified reform efforts and endeavours on the part of the public and non-profit private hospital owners, it is not to be expected that the observed increase in the number of private hospital owners will lead to complete privatisation of Germany's hospital landscape. Similarly, developments in the USA also make it appear likely that non-profit private and public hospitals will continue to play a central role in the provision of inpatient care.

4.1 Recommendations on the hospital sector

From detail planning to framework planning

76. The hospital planning of the Länder is more and more being overtaken by developments in the hospital landscape. While the Länder are increasingly withdrawing from investment cost financing, the possible surpluses arising from the G-DRG system and the continuing trend towards privatisation enable hospitals to realise independent investment projects. At the same time, selective contracting in the framework of integrated health care is contributing to increasing micro-level negotiations between funding agencies and service providers regarding the provision and financing of hospital services. This trend towards decentralised coordination between the service providers, the health insurance funds and patient demand is politically intended and an expression of the change in the way the state sees its role: the state is now less responsible for fulfilment and instead responsible for providing a guarantee. Detailed supply planning and financing in the framework of individual and global funding by the Länder is being replaced by framework hospital planning that grants the hospitals extensive autonomy, but at the same time creates a regulatory framework that guarantees the provision of the population with inpatient services. The data necessary for monitoring health care provision must be available for future hospital planning.

77. Hospital planning is the task of the Federal Länder. The details are regulated in the hospital laws of the individual Länder, leaving the Länder considerable latitude. According to their own statements, a number of Länder have in the meantime switched to framework planning. The hospital planning of the Länder will also tend to develop only gradually in the future. The Council's recommendations should thus be seen as a prospect that the Länder can take as a guide. The recommendations are based on the following premises:

- At the end of the convergence phase, the G-DRG system will be continued as a fixed-price or maximum-price system with a uniform basic case value in each Land. This will implement a performance-oriented remuneration system in inpatient care that allows hospitals to generate surpluses in accordance with their own cost structure. (See Para. 94 ff.)
- The dual financing of investment costs will gradually be abandoned in favour of monistic financing, thus putting hospitals in a position to take autonomous decisions regarding their investments. (See Para. 91 ff.)

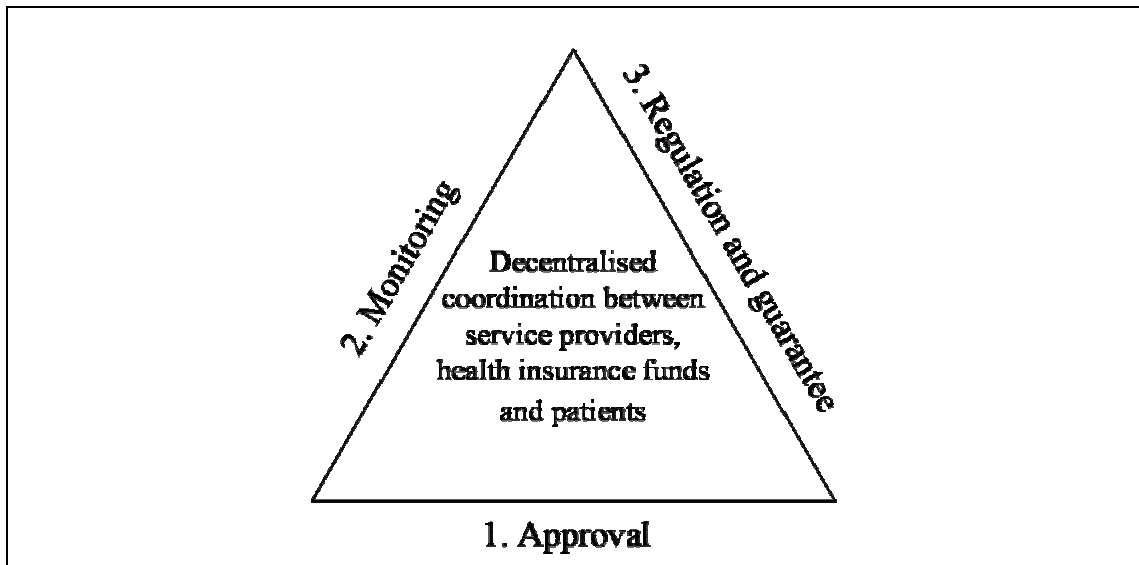
- Integrated health care – and thus also selective contracting between service providers and health insurance funds – will develop into an essential element of standard care. (See Chapter 3)

78. The guarantee responsibility of the state should in future no longer be expressed in the form of supply planning, but in supply monitoring. The primary goal of supply monitoring by the Federal Länder must be to avoid underuse of hospital services. In contrast, oversupply can generally be tolerated because, in the framework of a uniform, performance-oriented fee-per-case system, in which the investment cost elements are also included, the community of insureds is not additionally burdened by double provision if the "price" for rendering the services is identical everywhere, as in a fixed-price system. In this context, it is the task of health insurance funds and the chambers of physicians to counteract any expansion of the number of cases that is possibly not medically indicated.

79. Framework hospital planning should encompass three central elements (Fig. 1):

1. The Approval of hospitals for providing health care for insureds of the statutory health insurance funds,
2. Monitoring of the health care structures in terms of capacities, access and the quality of the services rendered, and
3. Regulation and guarantee of the provision of hospital services in the event that undersupply is determined or impending.

Figure 1: Elements of framework planning by the Federal Länder



Source: Own data

80. Approval: In a performance-oriented fee-per-case system, in which the investment costs are included, hospital planning no longer requires any examination of efficiency and need-orientation, since the risk of insufficient demand passes to the service providers. Therefore, the approval procedure for hospitals wishing to take part in the provision of health care for persons with statutory health insurance should also be changed. It would then only be necessary to ensure that the hospital is in a position to render inpatient services to sufficiently high standards of quality and, particularly, safety. At the same time, approval can be linked to requirements that contribute to the Länder also being able to exert an influence on health care structures in the future – e.g. by means of disclosure obligations.

81. Monitoring: Following abandonment of the principle of cost coverage and the transition to remuneration based on diagnosis-related flat rates for inpatient services, there has been a radical change in the economic incentives for hospitals. In future, a hospital must be interested in covering the largest possible catchment area in order to be able to work efficiently. At the same time, the minimum-quantity regulation encourages specialisation among the hospitals. Centralisation of the hospital structure must be expected owing to these incentives. While this can enhance the quality of the services rendered, it simultaneously tends to make access more difficult for the insureds. Undersupply of inpatient services can consequently be expressed in three dimensions: excessively tight

capacities, unreasonable distances to the service (access) and insufficient quality of the services rendered.

82. *Monitoring of capacities:* A first, general sign of a bed shortage is to be seen when newly admitted patients are provisionally accommodated in beds or on couches in the corridors of a hospital for one or more days. Circumstances of this kind could be controlled with the help of patient surveys. The waiting periods for optional treatments and the rates of readmission with the same diagnosis are further indications of underuse. Since the capacities for rendering inpatient services cannot be changed at short notice, there is a need to draw up advance forecasts regarding the development of the population density and morbidity. The Council furthermore recommends function-related and regionalised demand analyses. The methods for such forecasts are constantly being improved and are already being used to different extents in the hospital planning of the Länder. The economic pressure to which hospitals are subject is accompanied by the risk of hospital operators having to close some of their sites. For this reason, it will be important for the monitoring of the Länder to make a detailed assessment of the consequences of hospital closures for health care provision. The Council thus recommends the development of concepts for comparing the target and actual hospital supply that take into account the data on hospital supply, the population distribution, the geographic conditions and the framework conditions, such as minimum-quantity requirements and guidelines for emergency medicine. The Council recommends careful observation of these data in future, using the methods of health services research. The right time for counteraction must not be missed, since there is a risk of the number of beds in Germany possibly declining too rapidly or too far in some regions.

83. *Monitoring of access:* The formulation of a special indicator relating to 'access to health care services' could in future be used by the Länder and by regional hospital conferences, together with the minimum-quantity indicator, as an element of framework hospital planning. Access indicators are already being used internationally. The indicator should do justice to the following demands:

- It is primarily used in its geographic dimension, where the distance from the place of residence to the place of treatment corresponds to a travelling time that must pay attention to local traffic and transport conditions.
- A distinction is made between emergency and optional indications, and between acute (e.g. myocardial infarction) and chronic (e.g. chronic heart failure) illnesses.

- The 'access' indicator is presented as an example for individual illnesses and interventions (tracer):
 - Emergency medicine (intensive-care unit),
 - Obstetrics (normal-risk births),
 - Visceral surgery (basic care),
 - Community acquired pneumonia,
 - Chronic heart failure,
 - Round-the-clock availability of a stand-by catheterisation team for treatment of acute myocardial infarction,
 - Oncology centre (without radiotherapy),
 - Bone marrow transplantation.
- The indicator should give consideration to structural policy conditions – e.g. regional centres for pooling competencies,
- And permit competition, e.g. in that the distance to a second treatment location is taken into account, so that no monopolies can emerge.

84. Monitoring of quality: In order to guarantee not only capacities and access, but also the quality of care, the Council recommends that, in addition to the institutional indicators geared to the service providers, area indicators also be taken into account that describe the overall supply in a region. A transsectoral viewpoint should be adopted in this context. The area indicators can be divided into three groups, relating to the utilisation of services, the rate of hospital admissions and patient safety indicators (PSIs). Particularly suitable are indicators that give a good description of the quality of cooperation between the outpatient and the inpatient sector, such as the admission rate of asthma patients or the admission of patients with bacterial pneumococcal pneumonia in the absence of ubiquitous vaccination. The 'professionally independent institution' pursuant to Section 137a SGB V should identify indicators that can be surveyed reliably for Germany and yield valid statements.

85. *Regulation and guarantee:* The Länder have a choice of tools for guaranteeing inpatient care in the event of existing or impending underuse. The Länder can use the Land Health Conferences as a platform for discussing the goals of framework hospital planning with the players in the hospital sector. To maintain necessary inpatient services in a number of regions where they cannot be offered in a cost-covering manner, service guarantee incentives must be granted by the health insurance funds, or financing of deficits by local authorities, with appropriate speed. The Council recommends that service guarantee incentives be granted only on the basis of nationally uniform specifications, while deficit financing can be left to the discretion of the Länder.

86. Beyond the changes in ownership in Germany's hospital landscape, which have particularly accelerated in the last few years, owner plurality is sociopolitically desirable and should thus be preserved. Against the backdrop of the results of research in the USA on the effects of ownership on the quality and efficiency of patient care in hospital, the Advisory Council considers accompanying research on this subject to be urgently necessary in Germany, as well.

87. What happens if the owner of a hospital fails to fulfil, or no longer fulfils, its patient care obligations in economic or qualitative terms? In such cases, the Länder should have sufficient sanctions at their disposal to be able to enforce central elements of the framework hospital plan, particularly as regards emergency care. The sanctions could range from simple fines, all the way to revocation of the approval or exercise of the right of reversion, if fundamental quality and safety specifications are repeatedly disregarded.

88. Against the backdrop of increasing competition between hospitals and the efforts to also arrive at a more competition-oriented structure in the hospital sector, it is of central importance to ensure even today that no market-controlling positions develop on the side of the service providers. As evidenced in the US context, for example, positions of this kind could impede the efforts of the legislature to improve efficiency in the hospital sector in the medium and long term. For this reason, the Council recommends consistent application of merger control in the hospital sector.

Excursion: Demands on the rescue service and emergency care

89. The rescue service and emergency care will have to continue to be coordinated centrally in the future. The Advisory Council made a detailed statement on the subject of the rescue service in its Report for 2003 (Vol. II, Chapter 6.4), describing the provision of emergency care, in organisational coordination with the provision of rescue services in the framework of the 'rescue chain', as one of the central functions of hospitals, which it considered to be capable of structuring in modular fashion. There have been several positive changes since then. All in all, however, the Council's recommendations have only been followed in isolated instances.

There continues to be a need for emergency-care practices, which could relieve the burden on the stand-by service of SHI-accredited physicians, particularly during the day. Integrated control centres have hardly been set up to date, and a single emergency number '112' as a central contact point for all medical emergencies has still not been introduced throughout the country.

90. To define the demands on the spatial distribution of the locations for providing emergency care, the concept of the 'time to assistance' or the 'therapy-free period' has been further developed into the concept of the 'golden hour'. The main objective in this context is to standardise structures, processes and outcome quality in emergency care:

A rescue assistant is expected to be at the scene after a two or twelve-minute 'time to assistance' period (lay helpers) at the latest. Care by the emergency physician must start after 20 minutes at the latest; after an hour at most, the 'golden hour', the patient should have arrived at a hospital that is at least capable of continuing to stabilise his/her condition and, if necessary, referring him/her for further, more specific treatment, preferably with a preliminary diagnosis. In view of today's transport technology, hardly any increase in risk results from transporting adequately stabilised emergency patients over relatively long distances for secondary treatment of emergencies in specialist hospitals.

Transition to monistic hospital financing

91. The danger of creeping monistic financing without a corresponding statutory framework lies in the fact that the health insurance funds do not feel responsible and the Länder are no longer willing or able to supply the existing hospital landscape with sufficient capital for investments. Much as in the period before 1972, hospital owners would partly have to finance their investment costs themselves, something of which probably only few are capable. The result could be further deterioration of the condition of the buildings of individual hospitals. The Council thus again advocates a transition to monistic hospital financing, thereby ensuring a system for financing investment costs that also develops target-oriented incentives at the same time.

92. The Council recommends that the award of investment funds in the framework of monistic financing be directly linked to DRGs. In this context, the self-governing bodies should examine whether a functional allowance, based on the investment requirement in the respective case group, can be determined without unreasonable complexity. Otherwise, a percentage allowance should be chosen and, in individual instances, supplemented by additional allowances that help cover a special investment requirement. The

volume of the investment cost allowances should be determined in a structured dialogue between representatives of the hospitals, the health insurance funds, the Länder and the Federal Government.

The hospitals should very largely be able to dispose freely of the investment cost allowances. In the framework of their service guarantee, however, the Länder should be able to compel hospitals to offer specific services, such as emergency care. Moreover, the investment cost allowances should be earmarked for investments and not granted for the purpose of covering deficits. In this context, the term "investment" is defined much as already in the Hospital Financing Act (KHG), and the maintenance costs already financed by the health insurance funds are included. In contrast, the acquisition of other hospitals should not be eligible for funding through investment cost financing.

Excursion: Possible scenario for the transition to a monistic system

93. The additional burdens on statutory and private health insurance resulting from the allowances on the DRGs, are co-financed by the Länder, the Federal Government, the health insurance funds and the hospitals, in order to avoid an increase in the contribution rates, if possible: The previous global funding will be paid into the planned Health Fund by the Länder on the basis of their population figures as a permanent tax subsidy.

In a transitional phase lasting several years, the Länder will continue to pursue their investment programmes for individual funding, fully financing them, with the aim of putting hospitals whose structural condition means that they must fear a serious competitive disadvantage on the same footing as other hospitals. Following the transitional phase, the Länder will use an appropriate portion of their previous individual financing to guarantee emergency care and avert underuse.

To clear the backlog of reforms regarding investment cost financing, the Federal Government participated in the financing of the investment costs, as in the case of introduction of the dual system and in the new Federal Länder following German Unification. Part of the investment costs is borne by the health insurance funds, since the anticipated higher efficiency in the hospital sector will reduce operating costs in the medium term.

In return for greater security of investments, autonomy and flexibility, the hospitals refrain from demanding that the investment backlog be completely financed in retrospect.

Further development of the German fee-per-case system

94. After the end of the convergence phase, the future framework for the G-DRG system must be redefined. Based on the current structure of the fee-per-case system, the Council advocates that the G-DRG system initially be further developed as a fixed-price system. Since, in a remuneration system based on fixed prices, hospitals that are efficiently organised and whose cost level is below the respective fixed price have little mo-

tivation to mobilise further efficiency reserves, meaning that fixed prices can thus result in inefficient overpayment, the G-DRG system should, however, also be partially opened to price-based competition. The Council therefore proposes a partial maximum-price solution to supplement the fixed-price system.

95. Against the backdrop of these considerations, a fixed-price system based on the Land basic case value should initially be retained for the greater part of the range of services of hospitals, as should the negotiation structure based on collective contracts, and the obligation to contract. A maximum-price system, based on selective contracts between the funding agencies and the hospitals, should initially only be implemented for areas of optional hospital services. For the field of integrated health care, the current approach should be retained, being based on selective contracts and already permitting discounts. A first starting point for the range of optional services to be negotiated at the individual level can be found in the optional services in the fee-per-case catalogue contained in the Federal Ordinance on Hospital and Nursing Charges of 1995. The Council bases its recommendation to select this segment of the range of services for a maximum-price system on the fact that the longest and most extensive experience regarding the assessment of desirable and undesirable incentive effects in quality assurance exists in connection with the former per-case fees.

If the accompanying research to be targeted shows that the maximum-price system proves successful for optional services from the point of view of cost and quality aspects, as well as from the point of view of the transaction cost problem, the outlined system should be extended to further service areas. Owing to the specific nature of emergency services, it must be assumed in this context that these services will not be able to be handled sensibly in the framework of selective contracts, even in the medium term, meaning that a collective-contract framework will be retained in this respect.

In the course of this partial relaxation of the fixed-price system, the health insurance funds will be granted the right, based on correspondingly designed selectable tariffs, to direct their insureds to the hospitals with which they have agreed on discounts for the optional services in question. In addition, the health insurance funds can use selectable tariffs as a framework for passing on to their insureds the savings achieved by selecting certain hospitals.

96. Given that a maximum-price system can also have far-reaching negative effects on guaranteeing ubiquitous health care provision, and also on the quality of the rendering of services, the Council recommends that the gradual introduction of a maximum-price

system be accompanied by the strengthening of quality assurance measures and service guarantee incentives. Moreover, accompanying research should also analyse the impact of the partially introduced maximum-price system on the efficiency and quality of health care provision. This would leave open the possibility of countermeasures in the event of identifiable quality and/or access problems.

97. Beyond the future structuring of the German fee-per-case system as of 2009, the current fee-per-case system also requires immanent further development. Since, despite being rooted in law in Section 17b Para. 8 KHG, the commission to engage in accompanying research has so far not been satisfactorily implemented by the responsible players in self-government, the Council in this respect initially recommends the immediate issue of invitations for tenders for the research contracts pursuant to Section 17b Para. 8, second sentence, KHG – alternatively by the Ministry, if necessary. Independent accompanying research is the only way of establishing whether the mandate to provide care is fulfilled and the necessary quality assured. In this context, the content of the mandated accompanying research may not be limited to evaluation of the routine data to be submitted pursuant to Section 21 KHEntgG because, for example, these data are not capable of adequately describing interface problems. Moreover, restriction to quantitative research would also be insufficient because supplementary qualitative studies are the only way of adequately determining the complexity of the changes in health care structures and quality initiated by the remuneration system.

98. The development of patient transfers from outpatient to inpatient care, as well as from inpatient care to rehabilitation or nursing, should also be analysed in the framework of health services research. Among the questions to be clarified in this context is that as to the impact on the quality and the overall cost of health care of the premature transfer from inpatient care to rehabilitation or nursing, which is repeatedly described in connection with the G-DRG system. Owing to the growing importance of pre-hospital and post-hospital diagnosis and care, as well as the general tendency towards fragmented treatment or treatment workflows, there is additionally an urgent need for research regarding the impact of this development on the quality of patient care and the efficiency of the rendering of services.

99. Furthermore, the Council advocates examination of what competitive disadvantage is incurred by hospitals from the fact that they participate to an above-average extent in the specialist training of physicians. In the event that competitive disadvantages exist,

appropriate allowances are to be considered, e.g. in the context of a compensatory fund solution, similar to the training fund.

100. Finally, when further developing the DRG catalogue, attention should be paid to ensuring that the flat-rate nature of the G-DRG system is preserved and the incentives of individual-service remuneration thus remain limited. Among other things, this presupposes special care when introducing further supplementary payments. Moreover, the balance should be maintained between the further improvement of economic homogeneity and the steadily growing complexity of the catalogue of per-case fees.

101. As in all payment systems where money follows the service, there is also an incentive to expand volumes in the framework of a maximum-price system. The Advisory Council is of the opinion that the instrument of the second opinion must be applied to diagnostic and therapeutic measures that may be particularly affected by induced extensions of indications. Second opinions of this kind may neither be biased in favour of the health insurance funds, nor may they be exposed to the bias of all-too-close colleagues. It will not be possible to ubiquitously obtain a second opinion on all cases and indications open to consideration. Therefore, a small number of particularly critical examples should first be taken as a basis for testing whether commissions of mixed composition, similar to the Arbitration Boards of the Chambers of Physicians and including retired professionals and emeriti, could not satisfactorily handle such a task.

5. Quality and safety: appropriateness and responsibility in health care provision

102. There is increasing discussion of benefit aspects that, beyond demonstrating absolute efficacy, address patient and societal preferences and have so far not yet been applied to transparent discussions and decisions. As an element of the objective requirement, these aspects are grouped under the concept of appropriateness. In particular, patient safety and its representation are of primary importance for the net benefit of processes and in the perception of patients. Patient Safety Indicators (PSIs) must be integrated in quality indicator sets. The GKV-WSG gave the 'professionally independent institution' pursuant to Section 137a SGB V the commission to develop indicators with a transsectoral focus, meaning that the role of Patient Safety Indicators must be specified. Particularly in connection with patient safety, responsibility is increasingly being demanded of the service providers, such that it appears indicated to take up the discussion surrounding the concept of accountability. To improve the quality of health care provision, there is increasing discussion of external incentives, ranging from ranking lists all the way to additional, performance-related remuneration elements. International studies relating to the publication of quality data (public disclosure), and more so in connection with quality-based remuneration (pay for performance, P4P), indicate a tendency towards quality improvements and must be reviewed critically as regards their applicability in the German health system.

Appropriateness as an element of the benefit of health services

103. The Council defines the term 'appropriateness' under the concept of need and benefit, which was described in detail in previous Reports (Report for 2000/2001, Para. 21ff.). The objective need calls for demonstration of the positive health-related and economic net benefit, given individual and/or societal acceptance. The latter, however, could not be sufficiently operationalised to date, meaning that allocation decisions resulted in mixing of the decision-making levels. The concept of appropriateness describes benefit aspects beyond absolute efficacy, from cost-effectiveness and societal acceptance (e.g. legitimacy, fundamental ethical and cultural attitudes) all the way to patient preferences and patient-related end-points (patient-reported outcomes, PROs), thus making clear the determinants of relative effectiveness. Absolute efficacy and appropriateness are both considered to be necessary conditions for the benefit of a process,

but cannot be mutually substituted; in particular, given appropriateness cannot replace lacking proof of absolute efficacy.

104. The concept of appropriateness has important implications for understanding health services research. Health services research describes the conditions for implementation in reality, from absolute efficacy to relative effectiveness, and thus focuses on appropriateness as a central subject of research. In the coming years, the task of health services research will be to devise method standards for interdisciplinary and multidisciplinary issues that form the concept of appropriateness, similarly to the role of evidence-based medicine in clinical evaluation research with controlled clinical studies.

105. Below, the Report gives a proposal regarding how appropriateness can be represented at the different system levels (e.g. the health system, institutions, patients), and provides an overview of the decision-making situations in which the appropriateness of services and processes play a role. Parameters and indicators for appropriateness are often geared to the social sciences or economics (e.g. surveys) and use data from registers, company reports and court proceedings. To support allocation decisions, data on the appropriateness of processes can – assuming the validity of the methods – be used, e.g. by the Joint Federal Committee (GBA), to evaluate processes above and beyond efficacy issues and to assess factors impeding or promoting implementation. Equally, however, funding agencies, service providers and manufacturers of pharmaceutical or medical products can judge the market opportunities of their products far better if they can reliably foresee not only the absolute efficacy, but also the chances of implementation in reality. More extensive addressing of the concept of appropriateness is also necessary to update the innovation cycle in the biomedical sector, above and beyond basic research, transnational and clinical evaluation research, into the description of and research into the conditions for implementation.

Patient Safety Indicators are quality indicators of central importance

106. One key aspect of the benefit concept lies in the topic of patient safety. With reference to the Report for 2003, the nomenclature focuses on the concept of the 'adverse event' (AE), which denotes treatment-related, negative outcomes. Accordingly, 'preventable adverse events' (PAEs) are those AEs that are attributable to an error and can be equated with the epidemiological concept of 'damage'.

107. Regarding the incidence of adverse events, preventable adverse events and negligent adverse events (treatment errors), as well as mortality, reference is made to the papers of the German Coalition for Patient Safety. A systematic review that, based on more than 25,000 studies, identified 184 studies providing incidence figures (including 51 studies also reporting on mortality) yielded an incidence of between 5 and 10 % of all hospital patients for AEs, between 2 and 4 % for PAEs, 1 % for negligent adverse events, and PAE-related mortality in hospital of 0.1 %. According to a special analysis relating to gender as an influencing factor, the risk would appear to be higher in female patients. Bearing in mind that nosocomial infections already occur in 3-4 % of all hospital patients in Germany, and taking into account the variance of the studies included, it can be stated that these data on incidence certainly do not overestimate the scope of the problem. There are indirect indications that the validity of the studies is sufficient; after all, the variance of the results decreases with increasing sample size. The possibility was ruled out of this decrease in variance being exclusively attributable to the application of different survey methods when using large sample sizes.

With a total of 17 million hospital patients, a mortality rate of 0.1 % corresponds to roughly 17,000 deaths attributable to preventable adverse events in Germany. This figure, which indicates an order of magnitude, is more than three times higher than the current number of road deaths and shows the importance of continuing, concentrated and concerted work on prevention programmes. While there is no need for alarm, all the players involved must remain aware of the magnitude of the problem, so that its urgency is not underestimated.

108. The German Coalition for Patient Safety generally reflects the call of the Advisory Council for a "national process for consensus and cooperation involving all relevant actors in the German health care system" (Report for 2003, Para. 497). Way at the top of the Coalition's list of priorities is the development of concrete prevention programmes. It is also important to establish and continuously develop adequate access to the problem of patient safety, in order to give service providers and occupational groups options for taking action. PSIs are an important tool in this context. This Report thus presents a comprehensive analysis of international experience and examples of PSIs, also offering a synopsis of indicators open to consideration as PSIs.

On the one hand, the focus in this context is on the consideration that the indicator concept can be applied very effectively and appropriately to the field of patient safety because 'near misses', the basic element of every chain of errors, display the fundamental

characteristics of indicators in that they predict damage (with a certain degree of accuracy). On the other hand, particular demands must be imposed on PSIs, especially in terms of high sensitivity (because of the importance of the damage events to be predicted), low response times (because of the urgency of the events) and a rule-based nature (because of the special demands on process analysis in the event of treatment errors). The Council therefore supports the use of indicators developed specifically for recording and improving aspects of patient safety. The Council recommends the integration of PSIs in general quality indicator sets and not the introduction of selective PSI sets that 'measure' patient safety in the manner of a score.

109. The Council's proposal, which refers to the above-mentioned synopsis of PSIs open to consideration, ultimately encompasses 30 Patient Safety Indicators which, in turn, are to be taken as a pool from which a choice can be made for Germany (Table 2). The proposed indicators are divided into five groups, comprising global, interdisciplinary, diagnosis-specific, speciality-specific and organisational indicators. By way of example, the Council lists the evidence of five PSIs from the group of global and interdisciplinary indicators. Study of the available literature on reliability and validity shows that the reliability of the indicators still needs to be improved as a whole. On the other hand, PSIs are already included in numerous indicator sets developed and used internationally (e.g. PATH indicators of the WHO). Three large PSI sets have been devised internationally specifically for the needs of patient safety, namely by the AHRQ, the OECD and the European Commission (SimPatIE project). These concepts each include extensive studies of feasibility, reliability and validity. The last two mentioned are largely based on the AHRQ indicators.

Table 2: Council proposal for a PSI pool³

Areas	Indicators
1. Global indicators	
	1. Mortality of DRGs with low mortality rates
	2. Decubitus
	3. In-hospital hip fracture
2. Interdisciplinary indicators	
2.1 General indicators	4. Perioperative mortality
	5. Nosocomial myocardial infarction
2.2. (Re-)admission	6. Unplanned inpatient readmission within 30 days
	7. Unplanned admission or return to the intensive-care unit
2.3. Intraoperative	8. Anaesthesia complication
	9. Mix-up of interventions and left/right sides
	10. Leaving-in of a foreign body during the intervention
2.4. Postoperative	11. Unplanned re-operation
	12. Postoperative pulmonary embolism or deep vein thrombosis
	13. Postoperative sepsis
	14. Postoperative haemorrhage or haematoma
2.5. Selected nosocomial infections	15. Wound infection
	16. Ventilation-induced pneumonia
	17. Infections of intravascular and urinary tract catheters and drains
2.6. Technical devices	18. Adverse events in connection with medical products (AMDE: adverse medical device events)
2.7. Drug-related	19. Inappropriate medication in elderly patients
	20. Contrast medium-associated nephropathy
2.8. Individual events (sentinel events)	21. Iatrogenic pneumothorax
	22. Transfusion reaction
	23. Unsuccessful resuscitation
3. Diagnosis-related indicators	
	24. Stroke following heart surgery
	25. Amputation in diabetes patients
	26. Amputation following vascular surgery

³ This proposal is not to be taken as a 'PSI set' and is not suitable for forming scores.

4. Speciality-specific indicators – Example: obstetrics	
	27. Obstetric trauma – vaginal delivery with instrument
	28. Obstetric trauma – vaginal delivery without instrument
5. Organisational indicators	
5.1. Incidents	29. Physical restraint measures (duration, time, reason, injuries)
5.2 Personnel and equipment resources	30. Working time

Source: Own data

The proposed PSIs can be regarded as a pool for selecting Patient Safety Indicators that should be developed, validated and applied in Germany. The development and validation of PSIs should be integrated in the sphere of responsibility of the 'professionally independent institution' pursuant to Section 137a SGB V. International experience concerning the development, specification and validation of general quality indicators and PSIs should be utilised. The group of BQS indicators must be examined as regards the extent to which these parameters can be used as PSIs. Attention must be paid to the transsectoral aspect in this context (see Section 137 Para. 2 SGB V).

110. Typical discussions occur time and again when developing indicators. A combination of outcome and process indicators should be used. Exclusive use of routine data (e.g. ICD, OPS, DRG, Section 21 KHentgG) must be viewed critically, particularly as the validity of routine data is limited because they are developed and optimised for accounting purposes, and medically homogeneous groups are unknown to the G-DRG system. Epidemiological studies on adverse events make exclusive use of clinical data, routine data serving only as a trigger. Data of relevance for quality assurance are insufficiently documented in the framework of routine data. It nonetheless makes sense to use data available in the form of routine data in the framework of PSIs in order to minimise the data collection effort and, in the interests of adequate understanding of the indicator concept, to take them as starting points for areas in which further studies are necessary. The future will lie in a coordinated mix of clinical and routine data.

Drug therapy safety

111. In recent decades, drug therapy has opened up new treatment options that benefit patients in many indications (e.g. in the field of oncology with Herceptin or Avastin, in the treatment of hepatitis C with interferons, or of rheumatoid arthritis with TNF antagonists, such as adalimumab, etanercept or infliximab). Each year sees the arrival on the market of a number of new drugs that are either therapeutically or technologically innovative and permit better care for patients. They also increasingly include drugs that intervene highly selectively in metabolic processes and body functions. Information on correct use and the consideration of possible risks are of growing relevance for all drugs, especially new ones. The effectiveness and efficiency of drug therapy always require appropriate weighing-up of the benefits and risks. Consequently, pointers to potential risks, emerging in relatively small patient populations in the framework of clinical trials, are becoming an increasingly important element of the decision relating to drug safety in the context of the marketing authorisation of a drug.

112. In Germany, the most important tool for documenting adverse drug reactions (ADRs) is the spontaneous reporting system, the success and effectiveness of which is primarily dependent on the cooperation of physicians, who report their experience and insights when using authorised drugs if they suggest the suspicion of an ADR. However, systems of this kind are fundamentally subject to under-reporting, because physicians often lack information regarding the cases to be reported. The spontaneous reporting system is embedded in the strategy of pharmacovigilance, the objective of which is to monitor the clinical development of a drug and its use in terms of drug safety.

113. ADRs are a subset of adverse drug events (ADEs). An ADE is thus any unfavourable medical event that occurs in conjunction with the prescription, use, distribution, administration, etc. of a drug, but is not necessarily causally related to this treatment. In a terminological hierarchy, the most comprehensive category is thus the adverse drug event, while adverse drug reactions and medication errors rank equally on the second level. This hierarchical structure means that the customary, product-related pharmacovigilance information (ADRs) hitherto defined according to the German Drugs Act (AMG) and use-related treatment pharmacovigilance (ADEs) must complement each other with the aim of improving patient safety. Product safety is regulated by the AMG (drug safety law (public law); AMG), while safety in use is subject to liability law (civil law; German Civil Code (BGB)).

114. It is currently assumed that ADRs occur in approx. 5 % of patients receiving drug therapy and that an ADR is the cause of admission of roughly 3-6 % of all patients admitted to an internal medicine ward on an inpatient basis (an estimated 150,000-300,000). 2.3 % of the patients died as a direct effect of the ADR. Adverse drug reactions were thus responsible for the death of 0.15 % of hospitalised patients (0.1-0.2 %). 49.6 % of the fatal ADRs were rated as being due to incorrect use of the drugs involved. Apart from the burden on the patients caused by ADRs, the economic burden on the health care system is also substantial. Estimates are available from a 700-bed teaching hospital in the USA, where the annual treatment costs for ADRs were estimated at \$ 5.6 million, of which \$ 2.8 million were attributable to preventable ADRs. A further study states the cost of treating ADRs in a hospital as being 5-9 % of the total hospital costs. For Germany, the annual cost of ADR-induced treatment in hospital was estimated at €350-400 million.

115. The international literature points out that roughly 13 % of outpatients suffer serious adverse drug events (ADEs) and that roughly 0.1 % of inpatients die of ADEs. Definitely preventable medication errors are stated as being the cause in at least 18 % of cases. In Germany, medication errors mostly tend to be investigated in hospitals and, based on the first studies in Germany, there can be no doubt that the internationally discussed medication errors also occur in this country. A study presented in November 2004 revealed an error rate of between 0.2 % and 5.1 % for oral drug therapy in German hospitals. According to an international study, the error rate when preparing and intravenously administering drugs was even as high as 48 %, although this did not necessarily result in the patients being harmed.

116. Hospital pharmacists in particular have turned their attention to this 'error problem' in recent years. To identify and examine medication errors, Rostock University Clinic has, like many another hospital, implemented a clinic-wide system for the anonymous documentation of near-miss incidents CIRS (Critical Incident Reporting System), the goal of which is to learn from mistakes, rather than to identify 'guilty parties'. To reduce the incidence of medication errors, clinical pharmacologists and clinical pharmacists should be involved in pharmacotherapeutic decisions, or computer-aided prescription systems used for assistance. The 'unusual occurrences' and medication errors include, for example, administration problems, pharmacokinetic problems, interaction problems, production problems, information problems, prescription problems and unclear prescriptions.

117. The Council recommends the establishment of large-scale pharmacoepidemiological databases to permit continuous, systematic research into adverse effects. Marketing authorisation studies with up to 3,000 patients are not an adequate basis for determining ADR risks. Statistically speaking, when exposing 5,000 patients, the probability of observing an ADR with a true incidence of 1 in 10,000 at least once is less than 40 %, and even less than 5 % for an ADR with an incidence of 1 in 100,000. Spontaneous reporting systems are characterised by under-reporting – this system lacks data on the order of magnitude of the exposed patients (numerator/denominator problem). Outside Germany, pharmacoepidemiological databases of this kind are today rated as indispensable. In addition to the pharmacoepidemiological databases, regionally organised pharmacovigilance centres must also survey the risk situation in drug therapy (e.g. in the framework of studies on hospital admissions).

118. There is a need for computer-aided systems, both at the drug prescription level (physician) and the drug issue level (pharmacist), that sensitively, promptly and rapidly draw attention to problems with interactions, dosage (age and gender-adjusted) and handling. Implementation should be encouraged by means of incentives (e.g. integral element of integrated-care contracts). Publicly funded action programmes for reducing severe medication errors raise awareness of this problem, and the electronic support of prevention strategies for avoiding ADRs and ADEs is promising. The electronic health card with a memory chip is intended to make it possible, at the point of sale in the pharmacy, to document prescribed drugs and self-medication drugs and establish any interactions.

119. Adverse drug events (ADEs) resulting from medication errors are primarily discovered in connection with drug provision in hospitals. The systematic analysis of such medication errors can lead to optimisation of the process of using drugs. PSIs should be agreed on, implemented and evaluated in this context (e.g. prophylactic antibiotics in hysterectomy patients, which, according to the BQS data, were given in 85.8 % of cases with a spread of 0 (!) to 100 % in 2005 – the reference value is 90 % – or, as a further indicator, the percentage of ADR-related hospital admissions).

The Council explicitly proposes the following two PSIs:

- The incidence of X-ray contrast medium-induced acute kidney failure, i.e. contrast-medium nephropathy, which is considered to be the most common cause of kidney failure acquired in hospital and occurs in up to 5 % of cases. This figure should be halved by means of suitable prophylactic measures.

- The second PSI relates to the percentage of 'inappropriate' drug therapy for elderly persons over the age of 65, according to a list compiled for Germany on the basis of the 'Beers List'. Here, the reference value is set at 10 % of the drugs prescribed for elderly persons, whereas it is currently roughly 20 % - 25 %. Reduction of the percentage of such drugs that are problematic for elderly persons would mean an important improvement in drug therapy, tolerability and safety for elderly persons.

Accountability as a overriding concept

120. Patient safety and Patient Safety Indicators are directly linked to the subject of accountability. Accountability has not only become a key topic in the business sciences in recent years, but also has a long, international tradition in quality management and health policy. Accountability ranks among the strategic and role model-oriented values and, beyond responsibility towards owners and creditors, equally encompasses responsibility towards patients, staff and partners in social life. Alongside basing on science and evidence, patient orientation, the commitment to continuous quality improvement and patient safety, guideline and efficiency orientation, accountability in the health sector is one of the central elements of an understanding of management that could be referred to as clinical governance. The more the health system moves away from its paternalistic tradition and external incentives like public disclosure and pay for performance play a role, the more accountability becomes the focus for all partners.

121. Accountability must be discussed at the system level, the institutional level, the individual level of the members of the occupational groups in the health sector, and the patient level. At the system level, accountability primarily exists in relation to the appropriate provision of care for patients. The example of the system orientation of the patient safety debate, which must not detract from the individual accountability of physicians and other occupational groups, is a good illustration of the tensions existing in the public discussion in which the subject of accountability unfolds. At the institutional level, there is, on the one hand, the accountability of the parts of the organisation towards the institution as a whole, across the boundaries of specialist and occupational group, and, on the other hand, the 'responsible' integration of the institution in the surrounding environment.

122. The discussion of the concept of accountability in reference to the self-image of occupational groups is of substantial importance. The occupational groups in the health

sector traditionally have a high degree of accountability towards their patients, although this tends to be more of an implicit nature, and attempts of the public to give this accountability an explicit nature must almost inevitably lead to misunderstandings and disappointment. From the point of view of the occupational groups, the impression even predominates in this situation that the public wants to weaken the confidence existing between therapist and patient, although it has already been burdened by structural change. The call for accountability of institutions and individual physicians, carers and members of other occupational groups for their services will, however, not die down and constitutes an important, fundamental decision to stabilise the relationship between therapist and patient by means of explicit accountability, based on a non-paternalistic view of the patient, characterised by equality. On the patient side, however, a change in the role image is likewise coming to bear, because the active patient is now called for, a patient who demands accountability on the therapeutic side. One unsolved problem in this respect is that not all patients are willing and able to do this. However, the patient should also contribute to the success of the rendering of therapeutic services by behaving appropriately. After all, what is involved here is a 'joint product' of service providers and patients.

Publication of quality data and quality-based competition

123. An analysis of the international literature regarding the publication of quality data shows the great difficulty of the empirical data situation concerning the subject of accountability in the health sector. The public disclosure concept is based on the idea that, particularly if prices are fixed, patients, referrers and funding agencies specifically turn to service providers who demonstrate the better quality of their services by means of published, non-anonymous indicators. The sum of these developments leads to a shift in market shares and, at the system level, to a lasting improvement in the provision of health care services. This positive trend is promoted by increasing accountability of the stakeholders in the health sector and the members of the occupational groups, who accept this competition in the long term and incorporate it into their decisions. A distinction must be made between public disclosure and private disclosure, where quality data are reported back within the institutions (see BQS method). Public disclosure can contain data on hospitals or physicians, and concrete incidents can additionally be explicitly described.

124. The international literature on this subject is very extensive and, at first glance, arrives at very different results, which have in many reviews already led to the conclusion that the publication of quality data has no positive effects and that 'quality-based competition' does not work. In the present Report, the Council therefore performs the analysis on the basis of certain criteria, specifically according to

- The nature of the end-points investigated (e.g. mortality),
- The respective addressees (e.g. patients, hospital, market occurrences), and
- The study design used (e.g. historical control).

A representation based on these three criteria yields a much clearer picture. Regarding the object of the study, for example, it can be stated that

- Hospitals react most strongly, namely as regards outcome-relevant end-points and as regards the initiation of in-house quality measures – as negative as the surveys regarding the attitude of hospital managements may be,
- Patients are in principle very interested in quality information, but do not acquire it and do not use it if the information is only prepared and disseminated in the conventional manner. However, if the information is efficiently prepared and patients actually do take note of it, they can understand it and use it to assist decision-making processes,
- Referring physicians make little use of published quality data and are sceptical,
- Funding agencies are interested, but ultimately do not act in accordance with the information,
- The health system as a whole benefits at least from the fact that the variance of the quality indicators is disclosed and made accessible to public debate, although proof of a sustainable improvement at the system level, or a widespread shift in market shares, could so far not be furnished, or only in individual studies.

As regards end-points, a clear distinction must be made between studies on outcome and process quality, on the one hand, and surveys regarding attitudes and approaches, on the other. The surveys tend to yield a more negative picture, both among hospital managements and among hospital physicians and physicians in private practice. The better the information is prepared, the greater the benefit that patients derive from it. In

contrast, hard end-points relating to outcome quality (mortality) and process quality (e.g. investment in quality management) show an effect in favour of the publication of quality data in a larger number of studies.

Because of the small number of studies open to consideration, it is not possible to perform a regular sensitivity analysis in the sense of a meta-analysis in order to interpret the methodological quality of the studies. However, there are qualitative indications that methodologically better studies also demonstrate a stronger effect, meaning that, for example,

- Studies based on better preparation of the information for the patients can also show better utilisation of this information in decision-making processes, and
- Studies based on higher-quality methods and using a quasi-experimental design in the hospital sector show a greater improvement in the outcome parameters and process quality.

125. Discussed exhaustively in the literature is the need to have in place measures to act against so-called gaming, i.e. the wilful manipulation of data and the development of avoidance strategies (e.g. rejection of high-risk patients). One tool for this purpose is appropriate risk adjustment, another being strictly transsectoral quality assurance and the development of transsectoral public disclosure, although this is only promising in integrated health care networks and in population-based health care systems, because responsibility for quality is not perceived at a transsectoral level in sectorised systems.

Since 2001, the German health system has had a private disclosure system through the German National Institute for Quality Measurement in Health Care (BQS). Only the overall statistics and the variance values are made known to the public, and an individual institution can only access its own data in non-anonymous form. To improve reliability, random checks are performed in the event of unusual data, an audit procedure being activated in the event of unusual findings. Although Germany currently has no legal procedure for lifting data anonymity similar to the Freedom of Information Act, which enforced the publication of cardiac surgery data in New York, a debate on public disclosure is also on the agenda in this country. The Joint Federal Committee (GBA) has already taken a decision regarding a list of 26 indicators that hospitals will be required to publish, starting with the 2007 Quality Report.

126. The Council is aware of the above-described limitations and methodological demands (e.g. risk adjustment) and, based on the situation portrayed, recommends the following regulation for hospitals in the coming years:

1. Comparative quality assurance pursuant to Section 137 Para. 1 SGB V by the BQS, or the 'professionally independent institution' pursuant to Section 137a, is expanded swiftly, particularly paying attention to the statutory call for inclusion of transsectoral workflows (Section 137 Para. 2), taking into account Patient Safety Indicators (Table 2), and with priority inclusion of the conservative specialities.
2. The 'independent institution' elaborates a list of indicators that are suitable for publication. These indicators envisaged for public disclosure should, on the one hand, include Patient Safety Indicators and, on the other hand, expand the latest catalogue presented by the BQS to include indicators of a global and interdisciplinary nature that relate to the conservative specialities. Registered hospitals are obliged to publish the results of the indicators in the Quality Reports pursuant to Section 137 SGB V. In the framework of the audit procedure of the current BQS, the independent institution also checks the reliability of these indicators. Preference should be given to annual publication.
3. The institution pursuant to Section 137a furthermore offers interested hospitals an in-house benchmarking procedure that involves disclosure of the data among the participating hospitals.
4. The institution pursuant to Section 137a additionally offers hospitals the possibility of making the results of their in-house CIRS systems accessible in anonymous form, so that registered incidents can improve the possibilities for internal learning across the boundaries of the institutions.

The Council recommends that data publication be regarded as a development process in which the health care professions are involved in their entirety. The development of risk adjustment models and the improvement of the indicators deserve particular mention in this context. The reports according to No. 4 should moreover be addressed to a trained team of patient representatives, which could act as a kind of call centre to effectively handle enquiries from patients who, for a variety of reasons, do not or cannot make use of the available data. The Independent Patient Advice Centre Germany (UPD) pursuant to Section 65b SGB V and other qualified patient representatives should be involved.

Cooperation with a (telephone) interpreter centre would be advisable, so that citizens with language-related communication problems can also benefit.

Quality-based remuneration (pay for performance)

127. Pay for performance (P4P) is one of the concepts that aims to improve quality in health care provision by means of external incentives. In contrast to the publication of quality data (public disclosure), this concept involves directly financial incentives, not non-material incentives, although both forms can support each other and are often used together. The development of P4P programmes has primarily been advanced in the USA and the UK in recent years, although the discussion has now also reached Germany.

The definition of pay for performance is roughly based on the assumption that it is a financing concept where not only quantity aspects are taken into account, but where the quality of care is the focus of attention. The concept of the 'value of care' is also used in the international debate to describe the fact that the value of the treatment, and thus efficiency aspects, also play a role. A corresponding definition is "any type of performance-based provider payment arrangements, including those that target on cost measures," meaning that, in German, the term 'Ziel-bezogene Vergütung' ('target-based remuneration') could be discussed as an alternative to the term 'Qualitäts-bezogene Vergütung' ('quality-based remuneration') used here, if the latter definition were found to be acceptable.

128. The concept of quality-based remuneration has its origins in evidence-based medicine, on the one hand, and in organisational theory and the behavioural sciences, on the other. Access via evidence-based medicine is established via scientifically derived treatment guidelines, addresses the high variability of health care and refers to the goal of reducing this variability. Access via organisational theory and the behavioural sciences is attributable, inter alia, to the concept of motivation, which has received great attention in the context of health care provision over the last 15 years. Particularly in the field of the health system, this concept is said to be highly complex: incentives such as quality reporting and quality-based remuneration are geared to external motivation, and this should not come into conflict with the elements of internal motivation, such as professionalism, ethical attitudes and altruism.

129. The internationally common models of quality-based remuneration are extraordinarily diverse in terms of their structures and incentives. On the one hand, individual physicians or organisations may be addressed, in which case implementation is based on widely differing mechanisms. On the other hand, the level of the additional remuneration, the inclusion of efficiency indicators, the choice of indicators (outcome vs. process indicators, routine vs. clinical data) and combination with the publication of quality data must be clarified, and particularly also the exact specification of the incentives. This is a question of whether the best ('top') service providers are to receive additional remuneration, or those that improve most, and whether surcharges, discounts or special payments are to be used, or a combination of these forms of remuneration. The choice of indicators must not give rise to a 'blind spot', i.e. areas that are not covered by the indicators and are thus excluded from the postulated improvement in quality.

130. The present analysis, based on 28 studies, initially shows a mixed picture, much as in the other reviews. The majority of the studies (21/28) show a positive effect, regardless of whether simple (15/19) or complex (6/9) end-points were chosen, regardless of whether only P4P (14/18) or complex (7/10) procedures were used as interventions, and largely regardless of the study design. The only striking feature is that all historically controlled studies (12/12) show a positive impact of quality-based remuneration, as opposed to only 9/16 studies with a higher-quality design (6/9 randomised studies, 2/4 studies with a quasi-experimental design and 1/3 case control studies). Of the seven studies showing no positive result, three reveal a mixed result and four a negative result. Although conclusions can only be drawn with caution owing to the small number of studies, the possibility cannot be ruled out that the historically controlled studies overestimate the effect of P4P. But even with this limitation, it can still be stated that the majority of the studies showed a positive effect, both in relation to the studies in their entirety and in relation to the studies with a higher-quality study design.

131. Undesirable effects can be caused by inaccurate validation and risk adjustment of the indicators used, on the one hand, and by misplaced incentives, on the other, which in turn lead to a deterioration in health care provision. For example, the quality data of small hospitals are more susceptible to isolated cases ('outliers') and may therefore tend to be at a disadvantage. Moreover, the exclusion of patients by manipulation or exception rules plays a role, since it falsifies the reference in the denominator of the indicators.

However, the discussion centres on effects that are to be observed in a remuneration system that works in principle and is partly based on quality indicators. This discussion concentrates on the motivation of the physicians, the danger of misplaced incentives and the intensification of inequality. The weakening of internal motivation by external motivation can basically not be ruled out, particularly if bureaucratisation and responsibility problems are feared; however, such an effect cannot be demonstrated empirically. Quality-based remuneration is, for example, rated far more positively than the compulsory publication of quality data. Misplaced incentives can always occur in indicator-based incentive systems, especially in the case of small hospitals and if there is a lack of risk adjustment. Risk selection can only be demonstrated empirically in exceptional cases. However, there are findings that point towards a risk of vulnerable patient groups being disadvantaged, especially low-income patients, ethnic minorities and patients with multiple and chronic illnesses. The last group, in particular, deserves attention, since incentive systems could lead to a situation where every single illness is formally treated in accordance with the guidelines, in order to achieve the additional remuneration, but the required adjustment of the treatment necessitated by multimorbidity is not undertaken.

132. Considering the scientific results regarding the effectiveness of quality-based remuneration, and the potential negative impacts, the Council recommends the gradual introduction of elements of this form of remuneration in pilot projects with intensive evaluation. The term 'quality-based remuneration' should be given preference in order to make it clear that the quality of care is the prime concern. The following aspects must be taken into account:

1. The professions in the health sector, particularly the physicians, are to be involved in the development, implementation and evaluation of concepts for quality-based remuneration. Any contradiction with professionalism and other elements of internal motivation must be avoided.
2. Health care provision is organised on a regional basis. It is therefore sensible and important to embed quality-based remuneration concepts in regional health care structures. Projects should initially be small and manageable, in order to permit rapid demonstration of successes and correction of mistakes.
3. Owing to the great importance of system factors, remuneration-related incentives should be targeted primarily at organisations, not individual physicians. While it may be indicated to also address individual physicians in the field of outpatient care,

preference should be given to involving physician networks, associations and other organisational structures.

4. Remuneration-related incentives should regularly be combined with other incentives and methods, primarily the publication of quality data (public disclosure), and also feedback processes, 'academic detailing', etc. Suitable options are combination with the service guarantee as an element of hospital planning, involvement in certification concepts and the development of the 'new forms of health care'.
5. The indicators used should include a combination of process and outcome indicators with individual structural indicators and a sensible combination of routine and clinical data. The addition of efficiency criteria is fundamentally possible and useful. The indicators must be adapted and regularly changed (rotation). The latter serves to avoid manipulation. It must be ensured that no 'blind spots' occur that would be excluded from the improvement potentials due to a lack of indicators. The indicators must be precisely specified and feasible, and 'exception reporting' that excludes 'complicated cases' is not advisable, since comparability would be severely restricted as a result.
6. In addition to service provider-related targets, the concepts for quality-based remuneration should also always include population-related targets (e.g. transsectoral coordination).
7. Special attention must be paid to the danger of risk selection and the disadvantaging of vulnerable groups, and particularly to deterioration of the health care provided for multimorbid, chronically ill patients. The projects must include recognisable approaches for counteracting these undesirable effects.
8. The level of the remuneration apparently plays no decisive role, but it must compensate for investment and opportunity costs. Owing to the broader incentive for improvement, the Council considers it sensible to base the incentive system on evidence of a relative improvement referred to the individual starting point of the service provider. The 'top' service providers are upgraded by the parallel system of public disclosure.
9. Organisational realisation, data access and computer equipment are critical factors from the outset and must be given appropriate consideration in financial planning.

Concepts and projects relating to quality-based remuneration must be evaluated effectively, promptly and critically. Not only is there a need to adapt international experience to the situation in Germany, but the concept must also be further developed as regards a whole number of open questions. This development requirement ranges from the identification and specification of appropriate indicators and the clarification of questions relating to implementation (level of the financial incentive, duration of the intervention, interaction with other incentives, addressee of the incentive, relative improvement vs. absolute position), all the way to the establishment of tools for avoiding undesirable side-effects. The Council sees this as being one of the priority tasks for health services research.

6. Primary prevention in vulnerable groups

133. In previous Reports (Report 2005, I-4; Report 2003, II-5; Report 2000/2001, I-2; Special Report 1996, I-4.4; Annual Report 1988), the Council repeatedly described that primary prevention is a central field of action for safeguarding health and, at the same time, severely affected by underuse. Quantitative and qualitative expansion, orientation on target groups and settings, suitable consideration of socially induced inequality of health-related opportunities and improvements in quality assurance and evaluation were repeatedly called for. The Council reinforces the recommendations formulated in previous Reports.

134. Despite a pleasing increase in public and political interest in primary prevention, the Council can still see substantial, avoidable deficits. While, on the one hand, many theoretical, methodological and practical questions regarding the methods and success of prevention certainly remain unanswered, it can, on the other hand, in no way be said that existing knowledge about proven and promising interventions is even fractionally implemented. With this Report, the Council would like to support the ongoing process of development of a public and political will in this respect, because not much will change without such a will.

135. Primary prevention denotes measures and strategies for reducing (partial) causes of certain illnesses or of illness in general. In keeping with the contribution of different factors to the causation of morbidity and mortality and its influenceability, the fields of intervention for primary prevention lie predominantly outside the medical services system and thus follow different logics of action than individual medicine. But cooperation with medicine remains indispensable on two levels: on the one hand, all prevention policy goals and activities ultimately also relate to medicine's knowledge of what is good and bad for people's health. On the other hand, we live in a medical culture in which the curative physician is regarded as the first contact for all health-related matters. The primary prevention potentials to be found in the physician-patient relationship are still far from being exhausted. Moreover, even outside the health care system, the success of many a primary prevention intervention is based on the social diagnostic skills of medical people and their ability to show persons seeking advice health-promoting ways of coping by referring them to non-medical projects.

136. A – generally latent – need for such support is to be found in all population strata. However, it grows with declining social status. Consequently, the formulation to be found in Section 20 Para. 1 SGB V for prevention funded by the health insurance funds

can serve as a model for prevention policy as a whole: primary prevention is intended to "improve the general state of health and, in particular, contribute to reducing socially induced inequality of health-related opportunities". Accordingly, success is gauged by two criteria: 1. Improvement in all social strata and groups. 2. Closing of the gaps between these groups. Under the existing conditions, this necessarily implies the concentration of attention and resources on 'vulnerable groups', in order to give socially disadvantaged groups and strata better access to the development of the compression of morbidity. In this context, particular attention must also be paid to the different problems and needs of men and women, as well as to different reachability. In the sense of elevated morbidity, disability and mortality probabilities, 'vulnerability' is to be encountered particularly often where membership of a group whose full participation in society is at risk or impaired (e.g. the unemployed, the aged) coincides with constrained or poor material conditions.

137. By way of example, this Report presents the problematic health situation, and the approaches of primary prevention, encountered in the groups of unemployed persons, socially disadvantaged elderly people, the homeless and in relation to HIV/AIDS. In this way, the Council would like to clearly point out the implications associated with the target of 'primary prevention for reducing socially induced inequality of health-related opportunities': systematic primary prevention in vulnerable groups is a necessary, new focus of health policy. The contours of the expedient and necessary forms and fields of intervention for this purpose are only slowly emerging. This development cannot be restricted to the application of established rules; rather, experiments must be allowed. Only if they – as part of health services research – are expediently documented and evaluated can the necessary learning effects be achieved.

Primary prevention for unemployed persons

138. Unemployed persons are generally more often and more seriously ill than employed persons and the population as a whole. Moreover, they display a higher mortality rate than the reference groups.

Despite major problems in designing and organising primary prevention measures for unemployed persons, a number of sponsors have recently initiated or implemented pilot projects. For instance, the Federal Association of Company Sickness Funds (BKK-Bundesverband) has initiated several projects on the subject of '(un)employment and

health' in the framework of its 'More Health for All' initiative. They include motivating health talks, the BEAM (Occupational Integration and Employment Measure) project and the Job Fit Regional project. The Amiga (Health-Oriented Labour Promotion) project, initiated by the Brandenburg Ministry of Labour and Health and combining health promotion with job placement, can be mentioned as an example, as can the project coordinated by Dortmund University under the title Network for Labour Market-Integrating Health Promotion (N.A.G.) or the projects to be found under the heading 'Unemployed' in the project database of the Federal Centre for Health Education (BZgA – www.gesundheitliche-chancengleichheit.de).

139. The Council recommends that the group of the unemployed, and especially the sub-groups particularly affected by health problems, be increasingly offered primary prevention, including diagnostic, therapeutic and rehabilitation measures of secondary and tertiary prevention, where appropriate. Meeting-places for the unemployed and municipal neighbourhood centres are suitable for this purpose, for example. The basis of participation is always a voluntary decision of the person seeking employment. A fair balance between the 'demands' imposed and the 'promotion' provided must be maintained at all times. A further integral element of social strategies for primary prevention in the field of unemployment is, in the opinion of the Council, the de-stigmatisation of the subject of unemployment, the goal of which is that unemployment is – both in self-assessment and external assessment – not perceived, addressed and dealt with as though it were a question of personal fault. While prejudices in this respect have decreased in recent years as a result of unemployment becoming a mass phenomenon, they are still very much alive.

140. Prevention and health promotion among persons seeking employment constitutes an interface between labour market policy and health policy. Since the potential benefit of prevention among unemployed persons, i.e. less utilisation of outpatient or inpatient services, and also improved reintegration opportunities on the labour market, would benefit not only the affected persons, but also the unemployment and health insurance systems, it would appear sensible to also extend the responsibility for financing this sector to the Federal Employment Agency, e.g. in the planned Prevention Act.

This should be supplemented by explicitly anchoring the concept of prevention in Books II and III of the Social Security Code (SGB II and SGB III). This would make it possible to simplify complex project structures and guarantee sustainable and ubiquitous financing of projects.

141. Potential for primary prevention is also to be found in the sphere of the Medical Advisory Service of the Federal Employment Agency and in the field of the public health service. In the framework of multi-stage prevention strategies for the target group of the unemployed, consideration could particularly be given in this respect to active involvement of the Medical Advisory Service in determining prevention requirements, as well as in the concrete structuring and coordination of secondary and tertiary prevention measures at the individual level.

142. The reorganised system of labour promotion improves the starting position for health promotion and prevention measures among unemployed persons. The anchoring of the subject of prevention in the framework of the new system could, for example, additionally be strengthened by all unemployed persons with serious, i.e. placement-relevant, health problems being directly included in case management and thus given better access to health-related measures. However, this also presupposes that the case managers or the respective teams are skilled in social medicine. Moreover, health-related prevention in labour promotion can also be strengthened by the Agencies paying greater attention to health aspects when allocating the funds available to them for discretionary benefits according to Section 10 SGB III. Similar potential is offered by Section 16 Para. 2 SGB II, which makes provision for social integration assistance (debt counselling, psychosocial support or drug counselling) that can be made available to recipients of unemployment benefit II.

Both the health situation of persons seeking employment and the effectiveness of different prevention approaches require further research.

Primary prevention for socially disadvantaged old people

143. The target groups of socioeconomically disadvantaged elderly people are of great importance for sustainable prevention policy that looks for an answer to demographic challenges and thus aims to contribute to the quality of life, the preservation of independence and autonomy and, of course, the health of these groups. Promising approaches are setting-oriented and thus essentially geared to city districts for these target groups. Up to now, only little systematic and knowledge-based development is to be seen in this sector – apart from individual Good Practice models, this field can be said to be generally underdeveloped in terms of concept development, implementation, evaluation and quality assurance.

144. There are a number of municipalities and projects that take innovative approaches, reach different target groups of elderly disadvantaged persons and thus achieve great effectiveness in terms of reaching, activating and socially integrating their target groups, and presumably also as regards their health and their quality of life. Examples worthy of mention in this context include the 'Bürgerbeteiligung Lindau-Zech' project on Lake Constance, the 'Kölner Seniorennetzwerke' in Cologne or 'Miteinander Wohnen e.V.' in Berlin-Lichtenberg. These and other initiatives usually combine offers of intergenerational or cross-cultural communication and entertainment (neighbourhood meeting-places, etc.) with voluntary duties in the residential environment and assistance in obtaining access to social and health care services. In successful cases (which are still far too seldom), such networks become independent of their original initiators.

145. The Council recommends supporting the development of target group-specific, multimodal and transsectoral strategies that are suitable for improving the health-related resources of disadvantaged elderly people and reducing their health-related burdens. The city district (municipality, quarter, village) should be the central setting here.

146. Support should be given to the development of suitable evaluation and quality development strategies that are adapted to the strategies described and contribute to better evidence-basing. Knowledge already available, which is reflected in the Good Practice criteria for primary prevention among the socially disadvantaged, for example, should be specified for the target group of elderly disadvantaged people.

147. Primary, secondary and tertiary prevention overlap in old age. Primary prevention strategies must thus also include the needs of elderly people who are already chronically ill or disabled. Conversely, the players in health care should increasingly be encouraged to also motivate socially disadvantaged elderly people to participate in primary prevention and health promotion measures.

'Outreach activation' (preventive house calls) can play an important role in this context, especially if this essentially diagnostic measure is linked to target group-specifically effective interventions – also in the social environment – and to offerings.

148. Promotion programmes should make it possible to develop decentralised and exploratory projects, whose learning processes are based on local conditions, on the one hand, and that can make a contribution towards coordinated competence development, on the other.

The Council welcomes the fact that the Federal Ministry of Education and Research (BMBF) is actively tackling the growing need for knowledge in this field by issuing several invitations for tenders for health services and prevention research for the target groups of the elderly and the old.

Primary prevention for homeless people

149. Homeless people are affected by physical or psychological impairments, including addiction, far more frequently than the general population. The mortality rate among the homeless is also higher than the population average.

150. The setting approach, being an implementation strategy for health promotion that focuses on defined social environments and is thus based on the everyday life of the affected persons, runs up against certain obstacles in the case of the homeless, since the target group is not to be found in one of the 'classic' settings, such as school, workplace, etc. As the setting of this target group, 'the street' displays a rate of fluctuation of the affected persons that is a problem for this type of intervention. Good Practice models that link primary prevention to the creation or facilitation of access to health and social services, and sometimes to the labour market, are to be found in pilot projects for 'outreach social work' in various Federal Länder and big cities, as well as, for example, in the 'Die KuRve' and 'Mecki' projects set up by the Diakonisches Werk in the vicinity of a flat for sick homeless persons and a contact centre in Hanover. Valuable ideas for the concept, structure and management of health-related projects for and with homeless people are also to be found in non-governmental projects in the USA. The common feature of all these models is that they go beyond the charitable support required by social ethics and attempt to pave ways to reintegration by activating the affected persons.

151. The Council recommends that the target group of homeless people, and especially the sub-groups of homeless people particularly affected by health problems, be increasingly made prevention offers. This applies equally to those who live rough due to distressed circumstances and those who choose to do so of their own free will. Such measures should have a sufficiently low threshold and proceed according to a multi-stage concept, major segments of which are based on outreach work and that addresses different levels of health care provision.

152. Stronger networking of health-related offerings with social offerings of help for the homeless and other institutions could facilitate access and increase effectiveness. The different situations and needs of homeless men and women should be taken into account in this context. Adequate networking of different, target group-specific measures will probably also be necessary in order to counteract service deficits in relation to the high rate of alcohol abuse and dependence among the homeless. Closer cooperation between drug counselling and help for the homeless would appear to be suitable and necessary.

153. Particular attention should be paid to health care services for homeless young people. For this purpose, outreach offerings should also be available in the field of child and youth medicine and psychiatry. Moreover, the demand for target group-specific offers of withdrawal programmes is also not covered in the youth sector.

154. Initiatives for providing medical care for the homeless should have a secure, sustainable financial basis. The need for this will even continue to exist following successful implementation of compulsory insurance pursuant to the GKV-WSG, at least for persons of unclear residence status. Stable financing is necessary to guarantee projects the planning security they need for continuous work with the affected persons.

155. To integrate homeless people into the standard medical system sooner or later, the Council recommends the elimination of structural barriers to the utilisation of 'regular' medical services. This means that homeless people affected by poverty should be exempted from the medical consultation fee and compulsory co-payment for medication and therapeutic treatment.

156. Health care offerings should be supplemented by employment and accommodation-related measures, such as mentioned in the 'National Action Plan to Combat Poverty and Social Exclusion', for example. As regards strategies for avoiding homelessness, the Council refers to the example of France, where there has been a legal right to housing since February 2007. To counteract the social isolation of affected persons and to give them psychological and social stability, realistic opportunities should be available or created to enable homeless persons to enter the third, second and first labour market.

157. To enable action-oriented analysis of the health care service requirements of the target group of homeless persons, who are hard to reach for the standard medical system, the Council recommends corresponding health reporting, studies regarding the

quality and effectiveness of promoted measures, and health services research geared to this target group.

Improvement of HIV/AIDS prevention

158. The rise in the number of newly diagnosed HIV infections in Germany in recent years has occurred both in the group of what the WHO refers to as men who have sex with men (MSM) and among heterosexuals. However, the Council does not consider this to be a sign of failure of the prevention model of the multi-modal, multi-level 'Don't give AIDS a chance' campaign established in the 1980s. This model is based on the coordinated division of labour between government agencies and non-governmental organisations, involvement of the affected groups, voluntary participation and the concerted interaction of messages communicated through mass media, numerous decentralised activities in the settings of the target groups, and personal counselling. As regards AIDS prevention, the Council still considers this strategy to be viable and exemplary, and recommends its further development and adaptation to the changes that have taken place.

159. As a result of the ground-breaking success of pharmacological therapy of the consequences of an HIV infection, there has been a dramatic improvement in the life expectancy and quality of life of most people with HIV and AIDS in Germany. The prevention messages must take this fact into account: the motive for preventive behaviour (safe sex and safe use) is no longer just that of averting impending death, but of maintaining personal health and that of the respective partner. However, the disease AIDS should on no account be played down in this connection.

160. Prevention messages, media and locations must do justice to the changes taking place. Where the messages are concerned, it is a question of differentiating and partly individualising risk minimisation strategies. Greater attention must be paid to the inherent dangers (miscalculation of risks, misunderstandings in risk communication). As regards the media, the Internet is becoming increasingly important. Recent developments in the field of leisure activities demand that prevention work be geared more to social environments, all the way to outreach counselling. It should be remembered in this context that, particularly in population groups with a migration background and generally among people with a low socioeconomic status, prevention was less successful in the past and thus needs to be improved.

161. Promising results are also shown by approaches that support the local and regional Aids-Hilfe organisations, which continue to be highly motivated, in developing and assuring the quality of their prevention work. In view of the great differences in the conditions encountered 'on the spot', there can be no standard solutions in this field. Quality criteria and local features of prevention can only be found and developed in a dialogue between evaluation experts and prevention practitioners as equal partners.

162. From the point of view of the Council, the quality of prevention would also be enhanced if – as recommended by UNAIDS with Germany's support – Germany also set up a body responsible for all AIDS issues to coordinate and monitor the AIDS-related activities of the various spheres of politics. The deficits in prevention that have become apparent also call for social science research relating to the reasons for, and the social and regional distribution of, the increase in HIV-risky behaviour, as well as for testing the effectiveness of new forms of intervention.

Challenges for politics, practice and science

163. Health vulnerability has many origins and takes on many forms. If health policy addresses the resultant challenges, it finds itself confronted with what initially appears to be an overwhelming variety of different target groups and problem situations. Designing and implementing promising prevention first of all presupposes identification and analysis of the conditions under which threats to health develop, and also of the current living situations of the target groups in their respective settings. In this context, different accesses, forms of intervention and quality assurance methods prove to be suitable for prevention in each case. To be able to utilise the possibilities of modern forms of primary prevention, specific networks or player constellations have to be motivated and activated each time. This also includes the health care system and, in particular, medical professionals working on an outpatient basis – not only as players in the overcoming of illnesses that have already occurred, but also as initiators, stimulators and mediators of primary prevention. However, not only professional players in the respective field of action are regularly involved, but also people from the target groups and other players in civil society. Establishing health-promoting and illness-avoiding behaviour in such constellations calls for diverse material and intangible incentives and changes in the behaviour-shaping environment. In addition, the impact of such interventions on health can often not be measured directly, and the effects determined with the help of the indicators used as an alternative can frequently not be related directly to the

intervention – meaning that the effectiveness of many of these interventions may appear to be plausible and observable, but cannot be regarded as scientifically proven. All in all, this means that primary prevention in vulnerable groups cannot restrict itself to the application of established rules, but that experiments must be permissible, provided that they are expediently documented and independently assessed, thereby enabling learning effects.

164. The brief descriptions of successful prevention approaches for the target groups examined in this Report show that interventions should, as a general rule, fulfil five requirements:

- The interventions aim not only at reducing health-related burdens (arising from the physical and social environment, as well as from behaviour), but also at increasing health-related and health-conducive resources.
- Interventions should influence not only disease-specific, but also non-specific burdens and resources, i.e. they should set in as far upstream as possible.
- According to available experience, interventions are all the more successful, the more they succeed in changing the respective settings of the target groups, i.e. the contexts of relevance to health and behaviour, in a health-promoting direction.
- Of extreme importance for the design, implementation and quality assurance of target-oriented interventions is the greatest possible involvement of the respective target groups; participation is the key factor in successful prevention.
- Setting-based primary prevention is a development task. Development presupposes learning. People can only learn from experience – be it of success or of failure – if it is appropriately documented. Therefore, quality assurance and serviceable documentation are essential for gradually expanding the knowledge base and improving the quality of interventions. Based on current knowledge, the criterion for support or funding, especially of complex prevention projects in settings, cannot always be the demonstration of effectiveness ('proven interventions'). Interventions that are plausible from the social and health-related point of view should also be promoted if both a theoretically sound model of their effectiveness and empirical evidence supporting at least part of this model are available ('promising interventions').

The examples, outlined or cited in the respective sections of this Report, of primary prevention interventions in individual vulnerable groups all fulfil the criterion 'promising' and thus constitute challenges both for quality enhancement and for research.

European strategies for fighting health inequalities

165. Compared to other countries of the European Union facing similar challenges in the field of prevention policy, Germany proves to be way behind in important sub-areas. Target formulation and the associated prioritisation must be mentioned first and foremost in this context. However, without scientifically founded targets and priorities on which political consensus exists, neither the pooling of efforts and experience, nor the rational and legitimate allocation of resources would appear to be possible. The lead of other countries can be explained, on the one hand, by many historical, cultural and institutional specifics that are not readily transferable. On the other hand, the national examples outlined also illustrate factors in the development of health goals that can be transferred and whose application could give prevention policy in Germany an additional boost. A striking feature in the United Kingdom is the extensive involvement of the general public in the identification and formulation of targets through events, mass media and the Internet. This made it possible to involve significant parts of the population and of the priority target groups, as well as important state and non-governmental players, in the debate on the 'Our healthier nation' programme and motivate them to participate in this way. The background to this process was a clearly formulated political will of the British government. The same applies, with phase-related differences, to the Netherlands, where support in the form of government-funded research programmes to accompany the target formulation process played an important role. These related both to the magnitude and forms of the problem of socially induced health inequalities and to interventions, and ultimately also to intervention effects. In Sweden, in turn, orientation on a national Prevention Act was an important stimulus for this process. In contrast to the situation in Germany, all these approaches led to target systems that claim to cover the entire breadth of the problem by defining fields of intervention or target groups or social health determinants. Although these programmes and systems are still very fuzzy as regards the target groups and settings, as well as their prioritisation, they represent a major step forwards compared to orientation on individual target diseases, behavioural targets or groups. In the United Kingdom, in particular, the few, initially abstract-sounding targets were specified in the form of concrete proposals for action for players

at all levels of government, the National Health Service (NHS) and society. In Sweden, the formulation of sub-targets of this kind is part of the regulations and the calls upon state, commercial and civil society players contained in the – ultimately adopted – Act. Implementation in the Netherlands is partly on an experimental basis, through primarily local pilot trials.

It can ultimately be stated that, in contrast to the situation in Germany, the prevention policy of these countries has a scientifically sound framework justified by transparent procedures. It is less clear whether, in practice, this 'superstructure' also equates with more sound prevention in vulnerable groups in the respective countries: no truly informative evaluation is yet available regarding any of the programmes generated from these target systems. Further information on the subject is expected from, among other things, the EU project Closing the Gap – Strategies for Action to Tackle Health Inequalities in Europe, which examines practical projects for vulnerable groups in an international comparison and, in this context, identifies models of good practice, develops corresponding criteria and controls an international benchmarking process.

Practical approaches in Germany

166. The testing and development of suitable accesses and intervention methods for primary prevention in vulnerable groups can be described as a search process involving experiments (and, consequently, also successes and failures). As Germany so far lacks an action-guiding, national prevention strategy – and thus also criteria for prioritisation, as well as incentives and mechanisms for pooling experience, qualifications and resources – the prevention players in Germany are reliant on themselves creating such mechanisms, as well as possibilities for coordinated documentation and quality assurance, at least in their own fields of action. Two different roads to this goal are presented in the Report.

167. In the 'gesund leben lernen' (learning to live healthily) project of the head associations of the SHI system, 63 educational institutions with above-average numbers of pupils from socially disadvantaged circumstances were identified in three Federal Länder (Lower Saxony, Rhineland-Palatinate, Saxony-Anhalt) and recruited to participate in primary prevention interventions. The project started in mid-2003. This criteria-driven, coordinated and quality-assured approach of the head associations of the SHI system reflects the spirit of Section 20 SGB V and, by choosing 'school' as the setting,

also offers possibilities for synergistic effects, benchmarking and the accumulation of experience. Careful documentation and publication of the – positive and negative – project experience gained is necessary, because only in this way can an impact be expected on the quality of primary prevention in schools and in settings as a whole. It appears promising and desirable to compare experiences regarding access, project planning, participation, project implementation and quality assurance in this pilot project with available findings relating to company-based health promotion, in order to broaden the knowledge base concerning interventions in settings as a whole in this way. It is to be hoped that, at the end of the current pilot trial, the head associations or the Central Federal Association of Health Insurance Funds (Bund der Krankenkassen) head association will utilise the experience and knowledge gained to initiate, finance and assure the quality of further pilot trials in settings. The transformation of successful models into standard practice remains an important task.

168. While the schools participating in the 'gesund leben lernen' pilot project of the head associations of the SHI system were selected on a criteria-driven basis, i.e. more or less deductively, the nationwide Cooperation Network 'Health Promotion for the Socially Disadvantaged' of the Federal Centre for Health Education (BZgA) takes the other, more inductive approach: the starting point is not settings that lend themselves to interventions according to social and thus also health-related criteria, but existing social and health projects of different sponsors for different groups in different settings. Operating on a voluntary and free basis, these projects are offered networking, qualification and quality assurance services, and these are well received. This, too, is an approach that can not only improve the quality and sustainability of the individual projects, but also helps to pool and systematise experience and knowledge by means of networking, dialogue and benchmarking. The establishment and expansion of the Cooperation Network 'Health Promotion for the Socially Disadvantaged' is a promising step towards strengthening the networking of players and practice in the field of social situation-based health promotion. The creation and maintenance of an interactive information and communication platform can help consolidate this process. The establishment of the regional node coordinated by the Berlin Land Association for Health (Landesvereinigung Gesundheit Berlin e.V.) represents an important step towards uniform structures for strengthening social situation-based health promotion at the Länder level. These structures should be strengthened and expanded. The continuity of financing should be secured. Equal financing by the Länder ministries and the SHI system is already practised in a number of Federal Länder and should serve as a guideline for the creation of comparable financing structures in the other Länder. Special emphasis should be placed on

the contribution to low-threshold and low-cost quality development made in the framework of the Cooperation Network by selecting and communicating examples of Good Practice. The approach of participatory quality development in social situation-based health promotion thus selected should be continued and, in particular, also utilised in the implementation of measures according to Section 20 (1) SGB V.

Prevention research

169. Progress regarding accesses, methods, impacts and impact assessment in relation to primary prevention in vulnerable groups cannot be expected without scientific support on this difficult terrain that is new to health policy. Albeit somewhat later than in other European countries, government research promotion in Germany has now also taken up the problem of reducing socially induced inequalities in health. The most important provider of funds for research into non-medical primary prevention is the Federal Government with its health research programme and, in the sphere of responsibility of the Federal Ministry of Health, the BZgA. With a total of 28 out of 38, this sponsor accounts for almost three-quarters of the funded projects on non-medical primary prevention in vulnerable groups.

The research activities focus on impact research, i.e. on the search for effective intervention methods. The researchers are constantly identifying new target groups. Evaluation research is becoming established. Health impact assessment is underdeveloped as yet. So, the critical assessment of political decisions is hardly funded. Research centres on the target groups 'poor children' and 'young adults'. Research reproduces the dominance of behavioural prevention over setting-based prevention, as familiar from the practice of prevention. This means that the further development of setting-based prevention receives hardly any scientific support, although setting-based prevention measures impose greater conceptual demands, meaning that there is a great need for research precisely in this quarter. Major gaps in research still exist, specifically as regards the application, quality assurance and impact measurement of the setting approach.

170. An increase in financial promotion would be desirable. Compared to research expenditure on medical technologies, including pharmaceuticals, the sum spent on non-medical prevention is in the range of a few thousandths. Additional funds would make it possible to analyse interventions that have so far been neglected. It would appear insufficient to deal with consideration of the socially disadvantaged in prevention research as

though it were a cross-sectional task. Specific research is necessary. Therefore, an adequately large portion of research funding in the field of non-medical primary prevention should be reserved for projects relating to the socially disadvantaged.

As regards current departmental research, it is recommended that the use of funds be made more efficient by explicitly defining key areas and priorities. The overriding goal of all funded projects must be to make a useful contribution to method development. The Council additionally proposes that priority be given to projects with a link to setting-based prevention and in the spirit of a participatory setting approach. Greater support should be given to the secondary analysis of projects, methods and findings.

171. The lack of transparency in research is also currently an obstacle to development. Only few of the research projects publish a summary project report. Frequently, neither the methods nor the results are made accessible to a wider professional audience. To enable further development of research, the documentation of the results should be substantially improved. The Council sees this as being a task for the funding agencies. They are in a position to demand and publish detailed final reports from their contractors.

172. Research results from outside Germany should be incorporated to a greater extent than has so far been the case. It is not enough for the introduction to simply classify the respective project in the context of the international literature. The minimum requirement for funded projects must be that they justify their procedures against the empirical backdrop of international method development. Up to now, many research projects consist in intervention projects with scientific accompaniment. However, it basically appears necessary to separate intervention and research. The mixing of personnel between intervention and analysis can lead to conflicts of interests. Researchers who develop falsifiable theses and test new methods can easily come into conflict with the goals of the agencies that finance interventions. The latter want effective promotion of the target group. However, it should also become possible for researchers to test new intervention methods that involve a substantial risk of failure. Consequently, there should also be room for projects in which promotion of the target group is not emphasised as the success criterion, but where the improvement of scientific knowledge is rated as being at least equally important.

Legislation

173. The Council expressly welcomes the intention of the Federal Government, also set out in the Coalition Agreement, according to which "prevention is to be expanded to become an independent pillar of health care provision". The reduction of avoidable health burdens and the promotion of health-promoting resources for the entire population, with the secondary condition of reducing socially induced inequalities in health, is a lasting challenge in virtually all spheres of society and for virtually all players in society. However, the magnitude and the simultaneously unclear definition of this cross-sectional task, which can probably never be completely resolved, must not serve as an excuse for not trying the obvious and the feasible.

174. For this reason, the Council supports the fundamental idea of the Federal Government, set out in the Coalition Agreement, of passing a law on non-medical primary prevention before the end of this legislative term with the aim of top-level and un-bureaucratic improvement of the cooperation and coordination, as well as the quality of the measures, of the providers and branches of social insurance. The incorporation of health, long-term care, pension, accident and unemployment insurance is intended not only to secure and expand the framework of resources. Rather, this can also be seen as the first step in a development that will gradually bring the insurance providers (including private health insurers) to realise that their task does not consist solely in funding and steering the provision of health care, but also includes the prevention of insurance claims.

175. Above and beyond this, the law planned for the current legislative term should also regulate the cooperative and financial relationships between the insurance providers and the public sector. It should above all be ensured that the activities of the Länder or the public health service, for example, are coordinated with those of the insurance providers in terms of targets and programmes. On the other hand, the situation must also be avoided where public funding agencies at the municipal, Länder and Federal level withdraw from the financing and organisation of primary prevention at the expense of the insurance providers.

176. The Council supports the intention of the Federal Government, likewise set out in the Coalition Agreement, to also stipulate in a Prevention Act that actions must be geared to prevention targets. The solution found in the failed draft of a Prevention Act in 2005, according to which publicly funded prevention is particularly required to make a contribution to reducing socially induced or gender-related health inequalities, should

be retained. It should at the same time be specified whether and, if so, how this general orientation could be supported by concrete prevention targets or target systems, as in the United Kingdom, Sweden or the Netherlands.

177. The Act should stipulate that prevention can only be financed from taxes or contributions if its quality is assured in accordance with the state of the art. Apart from forms of intervention whose effectiveness has been demonstrated ('proven interventions'), it should also be possible to finance plausible interventions if they are based on a theoretically conclusive effect model, for at least parts of which there is empirical evidence ('promising interventions'). A central agency should be commissioned with the accumulation, pooling and analysis of information on the quality and effectiveness of primary prevention. Given its sphere of activity and competence, the BZgA would be particularly suitable for this purpose.

178. The planned Act should include regulations and incentives to ensure that publicly funded prevention satisfies the quality criteria developed in recent decades. Accordingly, primary prevention should relate equally to the reduction of health-threatening burdens and to the improvement of health-promoting resources, and thus deal both with disease-specific factors and with non-specific burdens and resources. It should, as far as possible, be based on settings or the respective behavioural contexts and further develop them in the spirit of health promotion. In this context, participation of the target groups at every stage of addressing the problem is a key variable for effective and sustainable prevention.

179. The regulations of the planned Prevention Act should envisage and enable interventions both at the individual level and in settings, as well as for the entire population (health campaigns). Experience shows that, in the practice of prevention policy, preference is regularly and inexpediently given to interventions that are easy to organise and less complex (e.g. counselling and information regarding health-related behaviour, instead of participatory changing of the behavioural context; intervention at the individual level, rather than projects in the respective settings; mere information and PR campaigns, instead of multi-modal, multi-level campaigns). To counteract this tendency, the planned Act should revive and further develop the regulations contained in the failed draft of 2005, according to which 40 % of the available resources are to be reserved for setting-based projects. The competences of the BZgA should be used for the concept development and quality assurance of health campaigns.

180. With regard to supporting primary prevention with public funds, the planned Act should not fall short of the failed draft, which envisaged an annual volume of approx. €250 million. This is roughly one-thousandth of total health expenditure in Germany and approx. 1.6% of the expenditure of the SHI system. In view of the poorly developed infrastructure for modern prevention in Germany, this relatively small sum would appear to be just about sufficient for a start. However, the Act should indicate mechanisms and sources by means of or from which this future-oriented branch of health protection can be financed.

Appendix

Legal basis for the activity of the Advisory Council on the Assessment of Developments in the Health Care System (since 1 January 2004)

Social Security Code, Book Five

Chapter Five

Advisory Council on the Assessment of Developments in the Health Care System

Section 142

(1) The Federal Ministry of Health shall appoint an Advisory Council on the Assessment of Developments in the Health Care System. The Federal Ministry of Health shall establish an office to support the work of the Advisory Council.

(2) The Advisory Council shall have the task of preparing expert reports on the development of health care services, including the medical and economic effects. In the framework of the expert reports, the Advisory Council shall, giving consideration to the financial framework conditions and existing efficiency reserves, develop priorities for the reduction of medical services deficits and existing overuse, and indicate ways and means of further developing the health care system; it may include developments in other branches of social security in its reports. The Federal Ministry of Health may define the subject of the reports in detail and also commission the Advisory Council with the preparation of special reports.

(3) The Advisory Council shall prepare the report at intervals of two years and submit it to the Federal Ministry of Health, generally on 15 April and starting in 2005. The Federal Ministry of Health shall present the report to the legislative bodies of the Federal Government without delay.

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Annual Report 1987:

Medizinische und ökonomische Orientierung (Medical and Economic Orientation)
Baden-Baden 1987

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(The Health Sector in United Germany)
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Lung Disease

Vol. III.3: Selected Diseases: Back Pain, Oncological Diseases, Depressive Disorders

Vol. III.4: Oral, Dental and Orthodontic Health

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Health; Primary Prevention Strategies

Vol. II: Interfaces Between Health Insurance and Long-Term Care Insurance; Thera-
peutic Appliances and Remedies in SHI; Factors Influencing the Prescription
of Drugs

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